Document 1

Form Date: 24/08/2009
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 138438

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
20011		146628	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
21/08/2009	24/08/2009		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
06/05/2010			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Asymptomatic proximal loosening reported in post-op x-ray.
Visual, dimensional, functional and material inspections were not performed as the items currently remain implanted and hence were not available for examination.
Stryker Orthopaedics conducted an investigation to evaluate other reports of shell loosening. The number of reported cases has a low incidence rate over the number of sales. Over 500,000 Trident Acetabular Shells have been implanted worldwide to date, with an incidence rate of 0.020% reported for shell loosening. In addition, these incidents have been reported by a small fraction of the number of institutions currently implanting these shells. Specifically, analysis of the event data reported between August 2002 and December 31, 2008 indicated almost 43% of the reported events were reported by 15 user groups, which represent approximately 0.5% of the total number of USA domestic user groups. The fact that 43% of the Product Experience Reports are among a small number of users suggests the underlying root cause is related to surgical technique, in this user group, rather than the device itself. In these cases loosening was most likely caused by the failure to achieve initial biological fixation due to inadequate execution of the recommended surgical technique. Specifically, surgeons were not adequately executing the correct reaming technique required for the preparation of the acetabulum. The techniques differ between the Trident PSL and Hemispherical Shells.
It is also noted that the event description does mention patient trauma, i.e. "Patient had a fall at the 6-7 week post op mark - heavy bruising". If additional information becomes available then this investigation will be reopened for further analysis.

Similar events: 0.02%

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

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Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	First Name:	Surname:	
Mr	s22	s22	
Position:		Company/Institution:	
Regulatory Affairs Officer		Stryker Australia	
Address 1:	Address 2:	Town/Suburb:	State:
8 Herbert Street		St Leonards	NSW
Country:	Postcode:	Phone:	Fax:
Australia	2065	s22	(02) 9467 1010
Mobile:	Email:		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*	Initial Reporter Confidential:

Search Reporter By Surname:	Initial Reporter #:		
Title:	First Name:	Surname:	
Position:		Company/Institution:	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Phone:	Fax:	Mobile:

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Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		152396	152396

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
Medical Device	Included	Class III	35661

GMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, acetabular component	

Initial Device Description:

Trident (Mfr 146628)

Usage of Device:	Software Version:

Model #:	Serial #:	Batch #:	Lot #:
	21693201		

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

Email:	Manufacturer Informed:	Date Aware of Adverse Event:
	No	

Contact Title:	Contact First Name:	Contact Surname:

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Supplier Information Section

Supplier Name:	Address 1:	Address 2:	
Town/Suburb:	**State:**	**Postcode:**	**Phone:**
Fax:	**Email:**		**Supplier Informed:**
Date of Supplier Contact:	**Contact Title:**	**Contact First Name:**	**Contact Surname:**
Contact Phone:	**Contact Fax:**		

Statistics Checklist Section

Date:	Assessed By:			
Sample Received:	**Sterile:**	**Reusable:**	**Single Use:**	
No	No	No		
Potential Effect:	**Actual Effect:**	**Injured Party:**		
Serious Injury	Serious Injury	Patient		
Risk Frequency:	**Risk Severity:**	**Risk Detectability:**	**Classification:**	**Exclude report from DIRE:**
			Routine	

Sponsor Information Section

Search Sponsors:	Name:		Client #:
St	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	02 94671010
Email:			
s22 [redacted] @stryker.com			

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Investigation Information Section

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent		Date Received	Sponsor's Response	Investigator's Notes

Document 1

		Date Response Expected			

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Other	Other	Orthopaedic implant loosening/early revision

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Unable to confirm complaint		

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

Implant loosening follwed by revision of the implant is a known complication associated with the use of this type of device.

The Trident acetabular cup is a popular device in Australia - and the National Joint Replacement Registry has not identified the implant as one that is experiencing higher than expected revision rates.

It appears that the incidence of this type of problem when this device is used is too low to warrant further investigation. The TGA will continue to monitor the performance of the device in the Australian market.

Flow Details : DIR-REQ - Device Incident Request : 28419

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
28419	DIR-REQ		Closed	theta	IRIS Coordinator	06/05/2010	Normal	0

Signature Details

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Role	IRIS Investigator	
User	theta - Theta Technologies	
Signed At	06/05/2010 00:00:00	
Comment	Automatically signed off closed DIR forms as part of data migration	

Created By Theta Technologies - 24/08/2009

Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

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Form Date: 01/09/2009
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 138473

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
20046	2008/009779	146634	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
26/08/2009	01/09/2009		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
16/09/2009			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Implant Date: s22

Post op x-ray showed signs of proximal loosening.

Visual, dimensional, functional and material inspection was not performed as no items were returned as they remain implanted.

The device manufacturing history records were reviewed and no reported discrepancies were noted.

It is very difficult to ascertain the exact root cause of the loose stem. A review of Stryker's records reveals the devices were manufactured and accepted into finished goods with no reported discrepancies. It is noted that the patient here has a BMI of 45, and the packaging insert contains the following warning: "An overweight or obese patient can produce higher loads on the prosthesis which can lead to failure of the device. The effect of these loads will be accentuated when a small sized prosthesis must be used because of bone size in such patients."

At this time, no corrective action is planned due to the difficulty in ascertaining the exact root cause of the loose stem. Product Surveillance will continue to monitor for trends.

Patient outcome: N/K.

Similar events: 10.

Report sourced from sponsor.

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

Patient Information

Sex:	Weight:	Age:

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Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Regulatory Affairs Officer		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	(02) 9467 1010
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*	Initial Reporter Confidential:	
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Phone:**	**Fax:**	**Mobile:**

Document 2

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	**Product Licence Category:**	**Device Class:**	**GMDN Code:**
Medical Device	Included	Class III	35666

GMDN Text: Prosthesis, internal, joint, hip, femoral component

Brand Name:

Initial Device Description: Accolade - (mfr ref: 146634)

Usage of Device:	Software Version:		
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
	16408602		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Reported Device Location:	**Access Contact Title:**	**Access Contact First Name:**	**Access Contact Surname:**
Access Contact Phone:	**Access Contact Fax:**		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	
Email:		**Manufacturer Informed:**	**Date Aware of Adverse Event:**
		Yes	
Contact Title:	**Contact First Name:**	**Contact Surname:**	

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Supplier Information Section

Supplier Name:	Address 1:	Address 2:	
Town/Suburb:	**State:**	**Postcode:**	**Phone:**
Fax:	**Email:**		**Supplier Informed:**
Date of Supplier Contact:	**Contact Title:**	**Contact First Name:**	**Contact Surname:**
Contact Phone:	**Contact Fax:**		

Statistics Checklist Section

Date:	Assessed By:		
Sample Received:	**Sterile:**	**Reusable:**	**Single Use:**
No	No	No	
Potential Effect:	**Actual Effect:**	**Injured Party:**	
Serious Injury	Temporary Injury	Patient	
Risk Frequency:	**Risk Severity:**	**Risk Detectability:**	**Classification:**
			Routine

Exclude report from DIRE:

Sponsor Information Section

Search Sponsors:	Name:		Client #:
St	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	(02) 9467 1010

Email:

s22 [redacted] @stryker.com

Investigation Information Section

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Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion Notification	16/09/2009				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC20046.DOC

Document 2

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Mechanical		

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Unable to confirm complaint		

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

Available frequency and severity data do not indicate further investigation is appropriate at this time. The TGA will continue to monitor for similar incidents and may re-open the file if appropriate.

Flow Details : DIR-REQ - Device Incident Request : 28454

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
28454	DIR-REQ		Closed	theta	IRIS Coordinator	13/10/2009	Normal	0

Signature Details

Role	IRIS Investigator
User	theta - Theta Technologies
Signed At	13/10/2009 00:00:00
Comment	Automatically signed off closed DIR forms as part of data migration

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Documet 3

Form Date: 09/09/2009
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Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 138522

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
20097	2008/009779	146633	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22 [redacted]	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
07/09/2009	09/09/2009		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
28/09/2009			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Implant Date: s22 [redacted]
Explant Date: N/A.

One year post op x-rays s22 [redacted] presented with asymptomatic proximal loosening of stem.

The investigation team found it difficult to determine the exact root cause for the event reported here, as the item in question remains in situ. A review of the provided x-rays by a clinician concluded that the asymptomatic x-ray finding suggests the possible failure of biologic fixation in Gruen Zones I and VII, but the absence of stem subsidence or a distal bony pedestal suggests a stable construct. The non progressive nature of these findings may be due to the initial reaction to micro motion, which did not progress after biologic fixation subsequently occurred. In the absence of symptoms no treatment or increased follow-up should be required in this case. There is no evidence of prosthetic design, manufacturer, or materials being associated with these findings.

Patient outcome: N/K.

Similar events: None.

Report sourced from sponsor.

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

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Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Regulatory Affairs Officer		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	(02) 9467 1010
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*	Initial Reporter Confidential:	
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Phone:**	**Fax:**	**Mobile:**
Email:			

Documet 3

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
Medical Device	Included	Class III	35666

GMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, femoral component	

Initial Device Description:

Accolade - (mfr ref: 146633)

Usage of Device:	Software Version:

Model #:	Serial #:	Batch #:	Lot #:
	17095403		

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

Email:	Manufacturer Informed:	Date Aware of Adverse Event:
	Yes	

Contact Title:	Contact First Name:	Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

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Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:			
Sample Received:	Sterile:	Reusable:	Single Use:	
No	No	No		
Potential Effect:	Actual Effect:	Injured Party:		
Temporary Injury	Temporary Injury	Patient		
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
			Routine	

Sponsor Information Section

Search Sponsors:	Name:		Client #:
St	Stryker Australia Pty Ltd		1251
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 970		ARTARMON
State:	Postcode:	Phone:	Fax:
NSW	1570	s22 [redacted]	(02) 9467 1010
Email:			
s22 [redacted] @stryker.com			

Investigation Information Section

Device Analysis Results:
Corrective/Preventative Actions:

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Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion Notification	28/09/2009				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC20097.DOC

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Documet 3

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Mechanical			

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint			

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
Not investigated		

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 28503

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
28503	DIR-REQ		Closed	theta	IRIS Coordinator	17/11/2009	Normal	0

Signature Details

Role	IRIS Investigator	
User	theta - Theta Technologies	
Signed At	17/11/2009 00:00:00	
Comment	Automatically signed off closed DIR forms as part of data migration	

Created By Theta Technologies - 09/09/2009

Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

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Form Date: 09/09/2009
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 138521

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
20096	2008/009779	146637	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22 [redacted]	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
07/09/2009	09/09/2009		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
28/09/2009			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Implant Date: s22 [redacted]
Explant Date: N/K.

Loose Stem. Patient had stem revised due to infection.

No analysis of device was performed as it was not returned to the manufacturer for investigation.

A review of the provided x-rays by a clinician concluded "The stem has a 3 to 5 millimetre radiolucency in Gruen Zone I, II, VI and VII with a distal bony pedestal suggestive of end bearing. There is also a suggestion of subsidence consistent with loosening.

If, as stated, the revision was for "septic loosening" of the stem no prosthetic manufacture, design or material factors are involved in this clinical complication.

Similar events: None.

Report sourced from sponsor.

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

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Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Regulatory Affairs Officer		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	(02) 9467 1010
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*	Initial Reporter Confidential:	
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Phone:**	**Fax:**	**Mobile:**
Email:			

Document 4

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
Medical Device	Included	Class III	35666

GMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, femoral component	

Initial Device Description:

Accolade - (mfr ref: 146637)

Usage of Device:	Software Version:

Model #:	Serial #:	Batch #:	Lot #:
	18006102		

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

Email:	Manufacturer Informed:	Date Aware of Adverse Event:
	Yes	

Contact Title:	Contact First Name:	Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

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Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:			
Sample Received:	Sterile:	Reusable:	Single Use:	
No	No	No		
Potential Effect:	Actual Effect:	Injured Party:		
Temporary Injury	Temporary Injury	Patient		
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
			Routine	

Sponsor Information Section

Search Sponsors:	Name:		Client #:
St	Stryker Australia Pty Ltd		1251
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 970		ARTARMON
State:	Postcode:	Phone:	Fax:
NSW	1570	s22 [redacted]	(02) 9467 1010
Email:			
s22 [redacted] @stryker.com			

Investigation Information Section

Device Analysis Results:
Corrective/Preventative Actions:

Document 4

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion Notification	28/09/2009				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC20096.DOC

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Document 4

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Mechanical			

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Not product related			

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
Not investigated		

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 28502

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
28502	DIR-REQ		Closed	theta	IRIS Coordinator	17/11/2009	Normal	0

Signature Details

Role	IRIS Investigator	
User	theta - Theta Technologies	
Signed At	17/11/2009 00:00:00	
Comment	Automatically signed off closed DIR forms as part of data migration	

Created By Theta Technologies - 09/09/2009

Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

Document 5

Form Date: 05/11/2009
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 138794

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
20370	2010/006922	155914	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22 [redacted]	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
30/10/2009	05/11/2009		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
25/11/2009			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Implant Date: s22 [redacted]
Explant Date: N/A.

Surgeon reported that X rays demonstrate stem loosening and a lack of bone in-growth. No revision at this stage.

Visual, dimensional, functional and material inspection was not performed as no items were returned as they remain implanted.
The review of the device manufacturing history records for the reported lot numbers did not indicate any discrepancies.
A review of the provided x-rays by a clinical consultant was conducted. The clinician's report concluded the following "The serial x-rays seem to be more consistent with stress shielding rather than loosening of this stem whose distal two-third demonstrate maintained excellent fit, fill and fixation. There is no evidence of subsidence or migration. In the absence of symptoms I would not be concerned with these x-rays."

No corrective action is planned at this time, as the clinicians review does not indicate any issue with the stem. Product Surveillance will continue to monitor for trends, and should further information become available this investigation will be re-opened.

Patient outcome: N/A.

Similar events: There have been [redacted] similar events reported worldwide.

Report sourced from sponsor.

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

Patient Information

Sex:	Weight:	Age:

Document 5

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Regulatory Affairs Officer		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	(02) 9467 1010
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Phone:**	**Fax:**	**Mobile:**

Document 5

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	**Product Licence Category:**	**Device Class:**	**GMDN Code:**
Medical Device	Included	Class III	35666
GMDN Text:		**Brand Name:**	
Prosthesis, internal, joint, hip, femoral component			
Initial Device Description:			
Accolade			
Usage of Device:	**Software Version:**		
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
	9356501		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Reported Device Location:	**Access Contact Title:**	**Access Contact First Name:**	**Access Contact Surname:**
Access Contact Phone:	**Access Contact Fax:**		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	
Email:		**Manufacturer Informed:**	**Date Aware of Adverse Event:**
		Yes	
Contact Title:	**Contact First Name:**	**Contact Surname:**	

Supplier Information Section

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Supplier Name:		Address 1:	Address 2:

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:

Sample Received:	Sterile:	Reusable:	Single Use:
No	No	No	

Potential Effect:	Actual Effect:	Injured Party:
Temporary Injury	Temporary Injury	Patient

Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
			Routine	

Sponsor Information Section

Search Sponsors:	Name:	Client #:
St	Stryker Australia Pty Ltd	1251

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 970		ARTARMON

State:	Postcode:	Phone:	Fax:
NSW	1570	s22	(02) 9467 1010

Email:
s22 @stryker.com

Investigation Information Section

Device Analysis Results:

Document 5

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion Notification	25/11/2009				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC20370.DOC

List of Problem Type Codes - Click **New** to begin entering information.

Document 5

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Mechanical		

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Not product related		

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 28775

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
28775	DIR-REQ		Closed	theta	IRIS Coordinator	28/05/2010	Normal	0

Signature Details

Role	IRIS Investigator
User	theta - Theta Technologies
Signed At	28/05/2010 00:00:00
Comment	Automatically signed off closed DIR forms as part of data migration

Created By Theta Technologies - 05/11/2009

Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

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Form Date: 10/03/2010
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 139326

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
20919	2010/008178	168759	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22 [redacted]	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
09/03/2010	10/03/2010		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
20/04/2010			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Implant Date: s22 [redacted]
Explant Date: s22 [redacted]

Revision of loose femoral stem.

A review of the provided x-ray by a clinical consultant indicated that the implanted Accolade stem was too small for this patient, and he also suggested that under sizing of the stem in this case was likely a contributing factor to failure of the prosthesis. The clinician also noted that here is no evidence of prosthesis design, manufacturing, or material factors contributing to this clinical situation. The patient is obese, with a BMI of 38.3. The packaging insert states that an overweight or obese patient can produce higher loads on the prosthesis which can lead to failure of the device.

A review of Stryker's records indicates that the reported device was manufactured and accepted into final stock with no reported discrepancies. There have been no other reported events for this lot.

There have been other reported events regarding loosening for this product family, but no trends are noted. A trend analysis performed in September 2009 showed the incidence rate for Accolade stems loosening was 0.018%. As a result, no further action is planned at this time, though Product Surveillance will continue to monitor for trends.

Similar events: 0.018%.

Report sourced from sponsor.

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

Patient Information

Sex:	Weight:	Age:

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Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Regulatory Affairs Officer		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	(02) 9467 1010
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*	Initial Reporter Confidential:	
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Phone:**	**Fax:**	**Mobile:**

Document 6

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
Medical Device	Included	Class III	35666

GMDN Text: Prosthesis, internal, joint, hip, femoral component

Brand Name:

Initial Device Description: Accolade - (mfr ref: 168759)

Usage of Device:	Software Version:

Model #:	Serial #:	Batch #:	Lot #:

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

Email:	Manufacturer Informed:	Date Aware of Adverse Event:
	Yes	

Contact Title:	Contact First Name:	Contact Surname:

Document 6

Supplier Information Section

Supplier Name:	Address 1:	Address 2:	
Town/Suburb:	**State:**	**Postcode:**	**Phone:**
Fax:	**Email:**		**Supplier Informed:**
Date of Supplier Contact:	**Contact Title:**	**Contact First Name:**	**Contact Surname:**
Contact Phone:	**Contact Fax:**		

Statistics Checklist Section

Date:	Assessed By:			
Sample Received:	**Sterile:**	**Reusable:**	**Single Use:**	
No	No	No		
Potential Effect:	**Actual Effect:**	**Injured Party:**		
Serious Injury	Serious Injury	Patient		
Risk Frequency:	**Risk Severity:**	**Risk Detectability:**	**Classification:**	**Exclude report from DIRE:**
			Routine	

Sponsor Information Section

Search Sponsors:	Name:		Client #:
St	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	(02) 9467 1010
Email:			
s22 [redacted] @stryker.com			

Investigation Information Section

Document 6

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion Notification	20/04/2010				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC20919.DOC

Document 6

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Mechanical		

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Mechanical problem		

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 29307

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
29307	DIR-REQ		Closed	theta	IRIS Coordinator	28/05/2010	Normal	0

Signature Details

Role	IRIS Investigator
User	theta - Theta Technologies
Signed At	28/05/2010 00:00:00
Comment	Automatically signed off closed DIR forms as part of data migration

Document 6

Created By Theta Technologies - 10/03/2010 Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

Document 7

Form Date: 10/12/2010
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 140849

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
22483	2010/020028	210384	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22 [redacted]	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
02/12/2010	10/12/2010		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
20/12/2010			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Implant Date: s22 [redacted]
Explant Date: N/A.

Post-operative follow up of the patient revealed loosening of the femoral stem.

Visual, dimensional, functional and material inspection was not performed as no items were returned. It is reported the device remains implanted. It is difficult to determine the exact root cause for the loose stem reported here. Additional information including x-rays, the operative report from the primary surgery, follow-up notes, the return of the reported device for analysis and the patient's medical and clinical history would be useful in completing a full investigation of this event.

A review of Strykers manufacturing records for the reported device indicates that the device was manufactured and inspected as per procedure and accepted into final stock with no reported discrepancies that impacted the form, fit or function of the device.

The packaging insert for these devices contains the following applicable warnings:
The correct selection of the implant is extremely important. The potential for success in total joint replacement is increased by selection of the proper size, shape, and design of the implant. Total joint prostheses require careful seating and adequate bone support.

Warnings: Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent reduction in service life of the prosthetic implant. The surgeon should be thoroughly familiar with the surgical procedure, instruments, and implant characteristics, prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and condition of the prosthetic components, as well as the condition of the adjoining bone.

(see diary)

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

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Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Regulatory Affairs Officer		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	(02) 9467 1010
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*	Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**	
Title:	**First Name:**	**Surname:**
Position:		**Company/Institution:**

Document 7

Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Phone:	Fax:	Mobile:
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
Medical Device	Included	Class III	35666
GMDN Text:		Brand Name:	
Prosthesis, internal, joint, hip, femoral component			

Initial Device Description:

Accolade Plus - (mfr ref: 210384)

Usage of Device:	Software Version:		
Model #:	Serial #:	Batch #:	Lot #:
TMZP Hip Stem #3			
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	

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Contact Title:	Contact First Name:	Contact Surname:

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Postcode:**	**Phone:**
Fax:	**Email:**		**Supplier Informed:**
Date of Supplier Contact:	**Contact Title:**	**Contact First Name:**	**Contact Surname:**
Contact Phone:	**Contact Fax:**		

Statistics Checklist Section

Date:	Assessed By:			
Sample Received:	**Sterile:**	**Reusable:**	**Single Use:**	
No	No	No		
Potential Effect:	**Actual Effect:**	**Injured Party:**		
Serious Injury	Temporary Injury	Patient		
Risk Frequency:	**Risk Severity:**	**Risk Detectability:**	**Classification:**	**Exclude report from DIRE:**
			Routine	

Sponsor Information Section

Search Sponsors:	Name:		Client #:
St	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	(02) 9467 1010
Email:			
s22 [redacted] @stryker.com			

Document 7

Investigation Information Section

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Diary Entry: s22 - Adverse Effects: Implants can loosen or migrate due to trauma or loss of fixation.

As there is no indication available at this time to suggest any manufacturing related issues, no action is required at this time.

Patient outcome: N/K.

Similar events: 0.028%.

Report sourced from sponsor.

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

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Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion Notification	20/12/2010				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC22483.DOC

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Mechanical		

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Mechanical problem		

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

Revision rate 0.9 revisions per 100 years - Accolade is generally performing slightly higher than or in line with similar device on the registery.

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 30830

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
30830	DIR-REQ		Closed	s22	OPR Administration User	28/09/2012	Normal	0

Signature Details

Role	IRIS Investigator

Document 7

User	theta - Theta Technologies	
Signed At	20/12/2010 00:00:00	
Comment	Automatically signed off closed DIR forms as part of data migration	

Created By Theta Technologies - 10/12/2010

Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

Document 8

Form Date: 22/06/2011
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 142091

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
23755			Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22	21/06/2011
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
21/06/2011	22/06/2011		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
02/12/2011			Yes
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Specialist		For IRIS Meeting	

Clinical Event Information:

Explant Date: s22

The device was implanted in New Zealand in s22 While in Australia on holiday, the previously painless hip replacement spontaneously fractured at the neck of the prosthesis. There were no identified traumatic incidents. Since being put in s22 the initial Ceramic on ceramic bearing surface was revised to a polyethylene cup due to creaking of the bearing surface.

The patient underwent a revision hip replacement on the s22 . The neck of the prosthesis was found to be broken. The acetabulum and the polyethylene liner were intact. The femoral side, only, of the prosthesis was revised. The patient recovered well.

Report sourced from Specialist.

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

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Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	First Name:	Surname:	
s22	s22	s22	
Position:		Company/Institution:	
Consultant Surgeon		s22	
Address 1:	Address 2:	Town/Suburb:	State:
s22		s22	VIC
Country:	Postcode:	Phone:	Fax:
Australia	s22	s22	
Mobile:	Email:		
	s22		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*	Initial Reporter Confidential:

Search Reporter By Surname:	Initial Reporter #:		
Title:	First Name:	Surname:	
Position:		Company/Institution:	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Phone:	Fax:	Mobile:
Email:			

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Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
Medical Device	Included	Class III	35666

GMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, femoral component	

Initial Device Description:

Hip Prosthesis

Usage of Device:	Software Version:

Model #:	Serial #:	Batch #:	Lot #:
Accolade TMZF	6021-0335		

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Stryker Australia Pty Ltd	1251	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

Email:	Manufacturer Informed:	Date Aware of Adverse Event:
	No	

Contact Title:	Contact First Name:	Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Document 8

Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:			
Sample Received:	Sterile:	Reusable:	Single Use:	
No	No	No		
Potential Effect:	Actual Effect:	Injured Party:		
Serious Injury	Serious Injury	Patient		
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
			Routine	

Sponsor Information Section

Search Sponsors:	Name:		Client #:
St	Stryker Australia Pty Ltd		1251
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 970		ARTARMON
State:	Postcode:	Phone:	Fax:
NSW	1570		
Email:			
s22 [redacted] @stryker.com			

Investigation Information Section

Device Analysis Results:

Document 8

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Letter		28/07/2011			Overdue Sponsor Response - > 10 Days
Letter		17/10/2011			Overdue Sponsor Response - > 70 Days

Document 8

Receipt Acknowledgement	01/07/2011				D:\TEMP\DIR\RN23755.DOC	
Sponsor Notification	01/07/2011				D:\TEMP\DIR\SN23755.DOC	
SC23755	02/12/2011				R11/531482	
RC23755	02/12/2011				R11/531491	

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Mechanical			

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Device not returned		

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
No further action		

Recall Number:

Investigation Summary:

The TGA has reviewed this incident. It was confirmed by the sponsor that the explanted device was discarded by the hospital. The sponsor investigation was limited due to the device, x-rays and medical records being unavailable for examination. No root cause can be attributed to the fractured device. The sponsor confirmed that one other similar report has been received for this model.

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 32072

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
32072	DIR-REQ		Closed	s22	OPR Administration User	02/12/2011	Normal	0

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Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	02/10/2015 14:46:35	
Comment		

Created By Theta Technologies - 22/06/2011

Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

Document 9

Form Date: 25/07/2011
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 142365

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
24039	2011/011260	199598	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22	25/07/2011
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
25/07/2011	25/07/2011		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
29/08/2011			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Implant Date: s22 Explant Date: s22

Explant and replacement of implant pursuant to loosening.

No visual, dimensional or functional test was performed as no item was returned for investigation. A review of the manufacturing records for the Accolade stem reported shows it was manufactured according to specification and inspected as per procedure with no reported discrepancies.

The result of the investigation suggests the implantation of a potentially undersized uncemented stem in an elderly post menopausal female may have led to the failure of biologic fixation. A reviewing clinician stated the event is unlikely to be related to device design, manufacturing or material factors. The IFU state that improper selection, placement, positioning, and fixation of the implant components may result in usual stress conditions and subsequent reduction in service of the prosthetic implant.

As manufacturer determines there is no indication the event was device related, no action is required at this time. However, product surveillance will continue to monitor for trends.

Other Devices: 32mm + 8 V40 Taper Vit Head - 62605332
Trident PSL HA Solid Back 52mm - 5401152E
Trident 10¿ Crossfire Insert 32mm ID - 6211032E

Similar Events: Globally, there have been s22 reported events for the product family due to loosening.

Report sourced from Sponsor

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

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Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert St		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	02 9467 1042
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*	Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**	
Title:	**First Name:**	**Surname:**
Position:		**Company/Institution:**

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Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Phone:	Fax:	Mobile:
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
Medical Device	Included	Class III	35666
GMDN Text:		Brand Name:	
Prosthesis, internal, joint, hip, femoral component			
Initial Device Description:			
Hip Prosthesis (Mfr# 199598)			
Usage of Device:	Software Version:		
Model #:	Serial #:	Batch #:	Lot #:
Accolade Plus TMZF H	18029702		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	

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Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		No	

Contact Title:	Contact First Name:	Contact Surname:

Supplier Information Section

Supplier Name:		Address 1:	Address 2:

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:

Sample Received:	Sterile:	Reusable:	Single Use:
No	No	No	

Potential Effect:	Actual Effect:	Injured Party:
Serious Injury	Serious Injury	Patient

Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
			Routine	

Sponsor Information Section

Search Sponsors:	Name:	Client #:
St	Stryker Australia Pty Ltd	1251

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 970		ARTARMON

State:	Postcode:	Phone:	Fax:

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NSW	1570	s22 [redacted]	02 9467 1042

Email:

s22 [redacted] @stryker.com

Investigation Information Section

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

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Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion Notification	29/08/2011				D:\TEMP\DIR\SC24039.DOC

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Mechanical		

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Not product related		

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 32346

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
32346	DIR-REQ		Closed	s22	OPR Administration User	17/08/2015	Normal	0

Signature Details

Role	IRIS Investigator

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User	s22 [redacted]	
Signed At	17/08/2015 09:17:03	
Comment	Automatically signed off closed DIR forms as part of data migration	

Created By Theta Technologies - 25/07/2011

Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

Document 10

Form Date: 18/11/2011
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 144319

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
24907	2011/017510	199598	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Death / Serious Injury	s22	17/11/2011
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
17/11/2011	18/11/2011		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
30/11/2011	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Explant and replacement of implant pursuant to loosening.

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

N/K.

Patient History:

N/K.

Patient Outcome/Consequences:

N/K.

Other Devices Involved:

32mmn + 8 V40 Taper Vit Head - 62605332. Trident PSL HA Solid Back 52mm - 5401152E. Trident 10 degrees Crossfire Insert 32mm ID - 6211032E.

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Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5181		
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	New South Wales
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	02 9467 1042
Mobile:	**Email:**		
	s22 @stryker		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
		s22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
s22		s22	s22
Postcode:	**Phone:**	**Fax:**	**Mobile:**
s22	s22	s22	
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	**Product Licence Category:**	**Device Class:**	**GMDN Code:**

Document 10

Medical Device	Included	Class III	35666

GMDN Text:
Prosthesis, internal, joint, hip, femoral component

Brand Name:
Accolade Plus

Initial Device Description:
Accolade Plus

Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
TMZF Hip STem #1	18029702		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	325 Corporate Drive
Address 2:	Town/Suburb:	State/Province:	Country:
	Mahwah	NJ	United States
Postcode:	Phone:	Fax:	
07430			
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:

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Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:
18/11/2011	s22 [redacted]

Sample Received:	Sterile:	Reusable:	Single Use:
No	Yes	No	Yes

Potential Effect:	Actual Effect:	Injured Party:
Serious Injury	Serious Injury	Patient

Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
Unlikely	Serious	Likely	Routine	☐

Sponsor Information Section

Search Sponsors:	Name:	Client #:
stryker	Stryker Australia Pty Ltd	1251

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 970		ARTARMON

State:	Postcode:	Phone:	Fax:
NSW	1570	s22 [redacted]	(02) 9467 1042

Email:

s22 [redacted] @stryker.com

Investigation Information Section

Device Analysis Results:

No visual, dimensional or functional test was performed as no item was returned for investigation. A review of the manufacturing records for the Accolade stem reported shows it was manufactured according to specification and inspected as per procedure with no reported discrepancies.
The result of the investigation suggests the implantation of a potentially undersized uncemented stem in an elderly post menopausal female may have led to the failure of biologic fixation. A reviewing clinician stated the event is unlikely to be related to device design, manufacturing or material factors. The IFU state that improper selection, placement, positioning, and fixation of the implant components may result in usual stress conditions and subsequent reduction in service of the prosthetic implant.

Corrective/Preventative Actions:

As manufacturer determines there is no indication the event was device related, no action is required at this time. Product surveillance will continue to monitor for trends.

Document 10

Details of Similar Events:

From April 2004 to September 2010 there have been s22 reported events for the product family due to loosening, resulting in a compliant rate of 284 CPM.

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Australia, Austria, New Zealand, United States.

Additional Comments:

None.

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion letter	30/11/2011				

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected

Document 10

Mechanical	Unintended Movement	

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Unable to confirm complaint	Device not returned	

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 33261

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
33261	DIR-REQ		Closed	s22	s22	30/11/2011	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	09/03/2012 14:45:19
Comment	

Created By s22 - 18/11/2011 10:54:39

Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

Document 11

Form Date: 19/03/2012
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 6 - ID : 152359

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
26031	2012/008184	297221	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22	21/12/2011
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
07/03/2012	19/03/2012	27/03/2012	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
28/03/2012	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Patient experienced anterior thigh pain.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
		s22

Patient Focused Corrective Action Taken:

Patient was revised.

Patient History:

N/K

Patient Outcome/Consequences:

Patient returned for revision 18 months following implantation of Accolade stem. Patient experienced anterior thigh pain. Stem was difficult to remove with bone fixation proximally. Osteotomy performed to aid removal. Restoration Modular stem inserted. No delay in surgery as a result.

Other Devices Involved:

N/A

Document 11

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5418		
Reporter Title:	First Name:	Surname:	
	s22	s22	
Position:		Company/Institution:	
		Stryker Australia	
Address 1:	Address 2:	Town/Suburb:	State:
8 Herbert Street		St Leonards	New South Wales
Country:	Postcode:	Phone:	Fax:
Australia	2065	s22	02 9467 1042
Mobile:	Email:		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			
Search Reporter By Surname:	Initial Reporter #:		
Title:	First Name:	Surname:	
Mr		s22	
Position:		Company/Institution:	
		s22	
Address 1:	Address 2:	Town/Suburb:	State:
s22		s22	s22
Postcode:	Phone:	Fax:	Mobile:
s22	s22		
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:

Document 11

Medical Device	Included	Class III	35666

GMDN Text:

Prosthesis, internal, joint, hip, femoral component

Brand Name:

Accolade Plus TMZF Hip Stem #5

Initial Device Description:

Accolade Plus TMZF Hip Stem #5

Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
6021-0537	32773602		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
With Supplier			
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:

Document 11

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:
22/03/2012	s22 [redacted]

Sample Received:	Sterile:	Reusable:	Single Use:
No	Yes	No	Yes

Potential Effect:	Actual Effect:	Injured Party:
Serious Injury	Serious Injury	Patient

Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
Unlikely	Serious	Likely	Routine	☐

DIRE Meeting Notes:

The device has not been highlighted as an implant of concern through the NJRR - Monitor

Sponsor Information Section

Search Sponsors:	Name:	Client #:
stryker	Stryker Australia Pty Ltd	1251

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 970		ARTARMON

State:	Postcode:	Phone:	Fax:
NSW	1570	s22 [redacted]	

Email:

s22 [redacted] @stryker.com

Investigation Information Section

Device Analysis Results:

The event was not confirmed.
The exact cause of the event could not be determined due to the lack of information provided to Stryker. No information was provided to indicate a manufacturing related root cause. A review of the manufacturing records for the reported Lot ID's indicates all devices were manufactured to specification. A review of the complaints database showed that no other events have been received for the reported lot ID's. A dimensional inspection of the returned Accolade stem showed it conformed to specification on its profile dimensions and an osteotomy of the femur was required to be performed in order to remove the Accolade stem indicating a well fixated device.

Document 11

Corrective/Preventative Actions:

No further investigation for this event is possible at this time. If additional information becomes available, this investigation will be reopened.
No action is required at this time as there was no indication of a product non-conformance or adverse trend. Product Surveillance will monitor for trends.

Details of Similar Events:

No related Lot or Catalogue numbers have been assosicated with any adverse events. No commonalities for region/surgeon/facility/patient factors were observed.

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

None.

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion letter	28/03/2012				

Document 11

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Other	Other	Patient factors

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Unable to confirm complaint	Investigation did not reveal a root cause	

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 34835

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
34835	DIR-REQ		Closed	s22	OPR Administration User	27/04/2012	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	27/04/2012 13:58:38
Comment	

Document 11

Created By s22 - 19/03/2012 14:42:46

Template Revision Released by Theta Technologies on 01/03/2012 12:04:11

Document 12

Form Date: 24/04/2012
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 6 - ID : 155071

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
26467	2012/010941	285602	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22	19/10/2011
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
20/04/2012	24/04/2012	01/05/2012	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
04/05/2012	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Hip Stem revised due to loosening.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22	N/K	s22

Patient Focused Corrective Action Taken:

s22 a revision of the right total hip was performed.

Patient History:

No patient demographics, no clinical or past medical history, and no operative reports are available for review.

Patient Outcome/Consequences:

s22 a revision of the right total hip was performed

Other Devices Involved:

NA

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Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5418		
Reporter Title:	**First Name:**	**Surname:**	
	s22	s22	
Position:		**Company/Institution:**	
		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	New South Wales
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	(02) 9467 1010
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			No
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
	s22	s22	
Position:		**Company/Institution:**	
		s22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
s22		s22	s22
Postcode:	**Phone:**	**Fax:**	**Mobile:**
s22	s22		
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	**Product Licence Category:**	**Device Class:**	**GMDN Code:**

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Medical Device	Included	Class III	35666

GMDN Text:
Prosthesis, internal, joint, hip, femoral component

Brand Name:
Accolade 127◦ Hip Stem # 2.5

Initial Device Description:
Accolade 127◦ Hip Stem # 2.5

Usage of Device:	Software Version:		
Single Use	NA		
Model #:	Serial #:	Batch #:	Lot #:
6021-2530	34246905		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22 [redacted]	s22 [redacted]
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
With Supplier			
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	
	s22 [redacted]	(02) 9467 1010	
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
s22 [redacted] @stryker.com		Yes	s22 [redacted]
Contact Title:	Contact First Name:	Contact Surname:	
	s22 [redacted]	s22 [redacted]	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:

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Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:
26/04/2012	s22 [redacted]

Sample Received:	Sterile:	Reusable:	Single Use:
No	Yes	No	Yes

Potential Effect:	Actual Effect:	Injured Party:
Serious Injury	Serious Injury	Patient

Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
Unlikely	Minor	Unlikely	Routine	☐

DIRE Meeting Notes:

Log

Sponsor Information Section

Search Sponsors:	Name:	Client #:
Stryker Australia	Stryker Australia Pty Ltd	1251

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 970		ARTARMON

State:	Postcode:	Phone:	Fax:
NSW	1570	s22 [redacted]	(02) 9467 1010

Email:

s22 [redacted] @stryker.com

Investigation Information Section

Device Analysis Results:

An event regarding Accolade loosening was reported.

The reported event of loosening could not be confirmed from the information provided. A review of the provided x-rays by a clinician indicated that there is no evidence of subsidence or migration of the femoral component. The clinician goes on to say that there is no clinical, radiographic, or surgical description confirming a loose femoral component requiring revision and that there is no evidence that factors of faulty prosthetic design, manufacturing, or materials were responsible for this clinical situation.

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As the reported event of apparent loosening was not confirmed, a root cause could not be established. A review of the manufacturing records indicates all devices were manufactured to specification. Should additional information become available the investigation will be reopened.

Corrective/Preventative Actions:

No action is required at this time as there is no indication of a product non conformance or adverse trend. Product Surveillance will continue to monitor for trends.

Details of Similar Events:

Trending file # 0000139548 determined the overall complaint rate estimation to be 295 CPM.

Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

NK

Additional Comments:

None

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion letter	04/05/2012				

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List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Mechanical	Unintended Movement	

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Unable to confirm complaint	Investigation did not reveal a root cause	

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 35460

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
35460	DIR-REQ		Closed	s22	OPR Administration User	04/05/2012	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	04/05/2012 13:58:44
Comment	

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Created By s22 - 24/04/2012 16:03:52

Template Revision Released by Theta Technologies on 01/03/2012 12:04:11

Document 13

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

Form Date: 03/08/2012
SIGNED

DIR : 20 ID : 162336

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
27722	2012/017182	271863	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22	08/08/2011
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
01/08/2012	03/08/2012		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
06/08/2012	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Revision hip surgery performed subsequent to loosening.

Clinical Event Information:

Revision hip surgery performed subsequent to loosening.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22		s22

Patient Focused Corrective Action Taken:

Revision hip surgery performed.

Patient History:

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NK

Patient Outcome/Consequences:

Revision hip surgery performed.

Other Devices Involved:

Mitch TRH Md Hd Sz50+4 - Cat # 60210435

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5418		
Reporter Title:	**First Name:**	**Surname:**	
	s22	s22	
Position:		**Company/Institution:**	
		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	New South Wales
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	02 9467 1042
Mobile:	**Email:**		**Last External Submission By:**
	s22 @stryker.com		

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			No
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
s22	s22	s22	
Position:		**Company/Institution:**	
		s22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
s22		s22	s22

Postcode:	Phone:	Fax:	Mobile:
s22	s22		

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35666

GMDN / UMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, femoral component	Accolade Plus TMZF Hip Stem #4

Initial Device Description:

Accolade

Usage of Device:	Software Version:
Single Use	

Model #:	Serial #:	Batch #:	Lot #:
	26795203		

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

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Email:		Manufacturer Informed:	Date Aware of Adverse Event:
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
03/08/2012	s22	Yes	Yes	☐
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	Yes	No	Yes	Serious Injury
Actual Effect:	Injured Party:			Risk Frequency:
Serious Injury	Patient			Unlikely
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Serious	Likely	Routine		
DIRE Meeting Notes:				

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Sponsor Information Section

Search Sponsors:	Name:		Client #:
stryker	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22	(02) 9467 1042
Email:			
s22 @stryker.com			

Investigation Information Section

Device Analysis Results:

An event regarding an Accolade stem loosening was reported. The event was confirmed.
The profile of the returned Accolade stem was dimensionally inspected and was found to conform to specification.The mating taper surface between the Accolade Stem and Mitch Head was analysed by the Materials Analysis group. Their report indicated that the taper interface between the internal female taper of the Mitch head and male taper of the Accolde trunnion showed dark discolorations, indicative of corrosion mechanisms taking place.
All returned material was reviewed by a clinical professional who noted the following; X-ray copies, all undated, include an AP of the pelvis and a lateral of the left hip demonstrating bilateral uncemented reduced total hip arthroplasties with no screws. The right is in nominal position and the left has a stem subsided approximately 1.5cm into the femur. Another undated AP of the pelvis and AP and lateral of the left hip shows no change on the right. The left has the same acetabular component but a Restoration Modular stem is now in place. It is reduced and in nominal position.
No operative reports, no past medical history, and no serial x-rays are available for review.
The exact root cause of this specific event could not be determined with the provided information. There is no indication or likelihood that the minimal corrosion described at the trunnion was responsible for the stem loosening and subsidence described in this case. Other patient factors such as medication, disease state, infection, and surgical fit and fill should be ruled out as causative factors.

Corrective/Preventative Actions:

No further actions required. Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

Details of Similar Events:

0.03% incident rate.

Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

n/k

Additional Comments:

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Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text
	Finsbury Orthopaedics Ltd		Mitch TRH Md Hd Sz50+4		60210435	

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion letter		06/08/2012				

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List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Implantable Device Failure	Osseodisintegration		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Investigation did not reveal a root cause		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Not investigated		

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 37064

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
37064	DIR-REQ		Closed	s22	OPR Administration User	06/08/2012	Normal	0

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Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	06/08/2012 09:47:43	
Comment		

Created By s22 [redacted] - 03/08/2012 14:51:39

Template Revision Released by s22 [redacted] on 25/06/2015 15:11:06

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 20 ID : 166519

Form Date: 27/09/2012
SIGNED

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
28746	2012/021113	308856	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Death / Serious Injury	s22	27/02/2012
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
25/09/2012	27/09/2012	09/10/2012	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
12/10/2012	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

Femoral hip stem revised, loose.

Clinical Event Information:

Femoral hip stem revised, loose.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22	s22	s22

Patient Focused Corrective Action Taken:

Revision surgery.

Patient History:

The patients BMI is calculated as 41.6 which is considered obese.

Patient Outcome/Consequences:

Revision surgery.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
	5418 - s22 - - Stryker Australia		
Reporter Title:	First Name:	Surname:	
	s22	s22	
Position:		Company/Institution:	
		Stryker Australia	
Address 1:	Address 2:	Town/Suburb:	State:
8 Herbert Street		St Leonards	New South Wales
Country:	Postcode:	Phone:	Fax:
Australia	2065	s22	02 9467 1042
Mobile:	Email:		Last External Submission By:
	s22 @stryker.com		

Initial Reporter Section

As Above?:		Initial Reporter Confidential:
No	*If No, fill out the following:*	No
Search Reporter By Surname:	Initial Reporter #:	
Title:	First Name:	Surname:
	s22	s22
Position:		Company/Institution:
		s22
Address 1:	Address 2:	Town/Suburb:	State:
s22		s22	s22

Postcode:	Phone:	Fax:	Mobile:
s22	s22	s22	

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35666

GMDN / UMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, femoral component	ACCOLADE (127 DEG) SIZE 4.5

Initial Device Description:

ACCOLADE (127 DEG) SIZE 4.5

Usage of Device:	Software Version:
Single Use	

Model #:	Serial #:	Batch #:	Lot #:
6021-4535	21792702		

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Place of use			

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
28/09/2012	s22	Yes	Yes	☐
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	Yes	No	Yes	Serious Injury
Actual Effect:	Injured Party:			Risk Frequency:
Temporary Injury	Patient			Sometimes
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Serious	Likely	Routine		
DIRE Meeting Notes:				
Not investigated				

Sponsor Information Section

Search Sponsors:	Name:		Client #:
stryker	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	02 9467 1042
Email:			
s22 [redacted] @stryker.com			

Investigation Information Section

Device Analysis Results:

An event regarding Accolade Stem Loosening was reported. The event was confirmed.
The returned Accolade stem showed deformation around the drive-hole with discolouration on the device taper and neck, heavy scratching was noted on the anterior plasma coated surface. There was little evidence of bony or fibrous on-growth and some hydroxyapatite coating was present on the stem. On the posterior face of the stem there was some small evidence of bony on-growth, which was identifiable as a white colour mid way on the plasma coated portion.
A dimensional inspection of the returned stem indicated the stem profile conformed to specification.
A review by a clinical consultant concluded that the root cause of this PER case was procedure-related through inadequate positioning of all components involved. Excessive force applied to seat the implants caused the damage as listed. It was possible that the patient-related factor of morbid obesity has played an aggravating role to complicate adequate exposure of the hip during primary arthroplasty. There was no evidence for device-related factors playing a role in this case.
The root cause is most likely patient / user related due to inadequate positioning of all components & the patient-related factor of morbid obesity.

Corrective/Preventative Actions:

There is no indication that the device contributed to the event. Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

Details of Similar Events:

0.0039 similar events per sales (AUS).

Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

Australia, United Kingdom, United States

Additional Comments:

Narrow femoral canal with thick cortices.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion letter sent		12/10/2012				

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Implantable Device Failure	Osseodisintegration		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Not product related	Event related to patient condition or anatomy		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Inital IRIS 308856 - ACCOLADE (127 DEG) 1	160	Form	
FILE		Final IRIS 308856 - ACCOLADE (127 DEG) 1	161	Form	

Flow Details : DIR-REQ - Device Incident Request : 38310

Request Details

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ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
38310	DIR-REQ		Closed	s22	OPR Administration User	12/10/2012	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	12/10/2012 09:14:44	
Comment		

Created By s22 - 27/09/2012 13:46:00

Template Revision Released by s22 on 25/06/2015 15:11:06

Document 15

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

Form Date: 05/11/2012
SIGNED

DIR : 20 ID : 169038

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
29142	2012/022854	296223	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22 [redacted]	12/12/2011
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
07/11/2012	05/11/2012		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
15/11/2012	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Hip stem loosening requiring revision surgery.

Clinical Event Information:

Hip stem loosening requiring revision surgery.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Revision surgery was performed on s22 [redacted].

Patient History:

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s22 patient underwent a primary left total hip arthroplasty due to osteoarthritis.

Patient Outcome/Consequences:

Revision surgery was performed on s22 .

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5691 - s22 - Regulatory Affairs Officer - Stryker Australia		
Reporter Title:	First Name:	Surname:	
Mr	s22	s22	
Position:		Company/Institution:	
Regulatory Affairs Officer		Stryker Australia	
Address 1:	Address 2:	Town/Suburb:	State:
8 Herbert Street		St Leonards	New South Wales
Country:	Postcode:	Phone:	Fax:
Australia	2065	s22	(02) 9467 1042
Mobile:	Email:		Last External Submission By:
	s22 @stryker.com		

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			No
Search Reporter By Surname:	Initial Reporter #:		
Title:	First Name:	Surname:	
Position:		Company/Institution:	
		s22	
Address 1:	Address 2:	Town/Suburb:	State:
s22		s22	s22

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Postcode:	Phone:	Fax:	Mobile:
s22	s22	s22	

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35666

GMDN / UMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, femoral component	Accolade Plus TMZF Hip Stem #5

Initial Device Description:

Accolade Plus TMZF Hip Stem

Usage of Device:	Software Version:
Single Use	

Model #:	Serial #:	Batch #:	Lot #:
6021-0537	28650201		

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
With Supplier			

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

Document 15

Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
09/11/2012	s22	Yes	Yes	☑
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
Yes	Yes	No	Yes	Serious Injury
Actual Effect:	Injured Party:			Risk Frequency:
Temporary Injury	Patient			Sometimes
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Minor	Likely	Not Investigated		

DIRE Meeting Notes:

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Sponsor Information Section

Search Sponsors:	Name:		Client #:
stryker	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	(02) 9467 1042
Email:			
s22 [redacted] @stryker.com			

Investigation Information Section

Device Analysis Results:

A visual inspection of the returned stem shows no evidence of bony ongrowth and sparse areas of fibrous ongrowth. The HA surface of stem shows shiny wear marks consistent with loosening of the device. The stem profile was dimensionally inspected as per the in-process inspection and was found to conform to specification.
The exact root cause of the stem loosening cannot be determined with the information provided, however there is no information available to suggest it is device related. A review of the provided x-rays by a clinical professional confirmed that the stem was loose proximally around the anterior and posterior surfaces, however, he did indicate that there was no evidence to suggest the event was device related and stated that patient factors such as infection, medication, disease states or metabolic conditions have not been ruled out.
A review of the instructions for use (IFU), noted the following applicable warnings;
Press-Fit Application. Secure fixation at the time of surgery is critical to the success of the procedure. The femoral component stem must press fit into the femur, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture of the femur can occur during seating of the prosthesis. Bone stock must be adequate to support the device. Implants can loosen or migrate due to trauma or loss of fixation. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants.
There is no evidence that factors of faulty prosthetic design, manufacturing, or materials were responsible for this clinical situation.

Corrective/Preventative Actions:

Based on the results of the IFU review, component loosening is a well known potential adverse consequence. Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.
Further investigation is not required at this time, as there is no indication to suggest a product non-conformance.

Details of Similar Events:

0.03%

Number of Similar Events:	Rate of Similar Events:
	0.03%

Countries Similar Events Also Occurred:

Additional Comments:

Document 15

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion Letter		15/11/2012				

Document 15

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Implantable Device Failure	Osseodisintegration		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Investigation did not reveal a root cause		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		...tial IRIS - PER 296223 Accolade Plus TMZF Hip Stem	252	Form	
FILE		...inal IRIS - PER 296223 Accolade Plus TMZF Hip Stem	161	Form	

Document 15

Flow Details : DIR-REQ - Device Incident Request : 38897

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
38897	DIR-REQ		Closed	s22	OPR Administration User	15/11/2012	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	05/12/2012 12:30:25	
Comment		

Created By s22 - 05/11/2012 14:00:50

Template Revision Released by s22 on 25/06/2015 15:11:06

Document 16

Form Date: 05/11/2012
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 20 ID : 169008

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
29132	2012/022806	261775	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Death / Serious Injury	s22 [redacted]	20/06/2011
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
07/11/2012	05/11/2012	27/11/2012	06/12/2012
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
18/12/2012	N/A		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

The Accolade Stem fractured 7 years post operatively.

Clinical Event Information:

The Accolade Stem fractured 7 years post operatively.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22 [redacted]		s22 [redacted]

Patient Focused Corrective Action Taken:

N/K.

Patient History:

Document 16

N/K.

Patient Outcome/Consequences:

N/K.

Other Devices Involved:

Alumina V40 - Femoral Head 32mm, +0MM NK
Trident Alumina Insert

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5076 - s22 - - Stryker Australia		
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert St		St Leonards	New South Wales
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	02 9467 1042
Mobile:	**Email:**		**Last External Submission By:**
	s22 @stryker.com		

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			No
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
		s22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**

s22		s22	s22
Postcode:	Phone:	Fax:	Mobile:
s22	s22	s22	
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35666
GMDN / UMDN Text:		Brand Name:	
Prosthesis, internal, joint, hip, femoral component		Accolade Plus TMZF Hip Stem #3	
Initial Device Description:			
Accolade Plus TMZF Hip Stem #3			
Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
	9429501		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Discarded			
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	
Address 2:	Town/Suburb:	State/Province:	Country:

Document 16

Postcode:	Phone:	Fax:	
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
09/11/2012	s22	Yes	Yes	☐
Sample Received:	**Sterile:**	**Reusable:**	**Single Use:**	**Potential Effect:**
No	Yes	No	Yes	Serious Injury
Actual Effect:	**Injured Party:**			**Risk Frequency:**
Serious Injury	Patient			Sometimes
Risk Severity:	**Risk Detectability:**	**Classification:**	**Investigated:**	**Date of DIRE Meeting:**
Serious	Likely	Routine		

DIRE Meeting Notes:

Document 16

Obtain actual rates - investigate

Sponsor Information Section

Search Sponsors:	Name:		Client #:
stryker	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22	(02) 9467
Email:			
s22 @stryker.com			

Investigation Information Section

Device Analysis Results:

No device associated with the event was returned to Stryker Orthopaedics. It is not possible to determine the exact root cause of the reported event with the limited information provided. A review of the provided x-rays and medical information by a clinical professional could not make any determination about the root cause of the stem fracture. A review of Stryker's records indicates that the reported device was manufactured and accepted into final stock with no reported discrepancies.

Corrective/Preventative Actions:

No further investigation is possible at this time. Further information such as return of the device for analysis and X-rays from before the reported fracture would be helpful in conducting a full investigation into the reported event. If additional information becomes available, this investigation will be reopened. No action is required at this time. Product Surveillance will continue to monitor for trends.

Details of Similar Events:

The complaint rate for the reported failure mode is 6 complaints per million (CPM).

Number of Similar Events:	Rate of Similar Events:
6 complaints per million	

Countries Similar Events Also Occurred:

USA, Australia

Additional Comments:

Device Lookup

Document 16

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text	
128024	Howmedica Osteonics Corporation		Alumina V40 - Femoral Head 32mm, +0MM				
	Howmedica Osteonics Corporation		Trident Alumina Insert				

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution	

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing	

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes	

Request for information		30/11/2012	13/12/2012	06/12/2012		See TRIM R12/1154026.	Document 16
SC19132		18/12/2012	29/12/2012			R12/1169074	

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Material	Crack		

Investigation Problem Causes

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Device not returned		

Investigation Outcomes

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, No Further Action Required		

Recall Number:

Investigation Summary:

The sponsor was asked to provide the rates for this type of occurrence both in Australia and worldwide. they have stated the rates as follows based on sales: Australia 0.0004% and worldwide 0.00002%. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To

Document 16

FILE		Initial IRIS - PER 261775 200611	132	Form
FILE		Final IRIS - PER 261775	134	Form
FILE		SC29132	260	Form

Flow Details : DIR-REQ - Device Incident Request : 38882

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
38882	DIR-REQ		Closed	s22	OPR Administration User	18/12/2012	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	18/12/2012 15:40:40	
Comment		

Created By s22 - 05/11/2012 11:53:16

Template Revision Released by s22 on 25/06/2015 15:11:06

Document 17

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

Form Date: 23/10/2012
SIGNED

DIR : 20 ID : 168051

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
28963	2012/022102	346663	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Death / Serious Injury	s22 [redacted]	24/09/2012
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
08/11/2012	23/10/2012		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
30/11/2012	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

Revision surgery following corrosion and fretting at the head taper junction.

Clinical Event Information:

Revision surgery following corrosion and fretting at the head taper junction.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22 [redacted]		s22 [redacted]

Patient Focused Corrective Action Taken:

Revision surgery.

Patient History:

Document 17

N/K.

Patient Outcome/Consequences:

Revision surgery.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5418 - s22 - - Stryker Australia		
Reporter Title:	First Name:	Surname:	
	s22	s22	
Position:		Company/Institution:	
		Stryker Australia	
Address 1:	Address 2:	Town/Suburb:	State:
8 Herbert Street		St Leonards	New South Wales
Country:	Postcode:	Phone:	Fax:
Australia	2065	s22	02 9467 1042
Mobile:	Email:		Last External Submission By:
	s22 @stryker.com		

Initial Reporter Section

As Above?:		Initial Reporter Confidential:
No	*If No, fill out the following:*	No
Search Reporter By Surname:	Initial Reporter #:	
Title:	First Name:	Surname:
Mr	s22	s22
Position:		Company/Institution:
		s22
Address 1:	Address 2:	Town/Suburb:	State:
s22		s22	s22

Postcode:	Phone:	Fax:	Mobile:
s22	s22		

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35666

GMDN / UMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, femoral component	Accolade Plus TMZF Hip Stem #5

Initial Device Description:

Accolade Plus TMZF Hip Stem #5

Usage of Device:	Software Version:
Single Use	

Model #:	Serial #:	Batch #:	Lot #:
6021-0537	25807003		

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Place of use			

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

Document 17

Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
21/11/2012	s22	Yes	Yes	☑
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	Yes	No	Yes	Temporary Injury
Actual Effect:	Injured Party:			Risk Frequency:
Temporary Injury	Patient			Rarely
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Serious	Likely	Not Investigated		

DIRE Meeting Notes:

Document 17

Sponsor Information Section

Search Sponsors:	Name:		Client #:
stryker	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	(02) 9467 1042
Email:			
s22 [redacted] @stryker.com			

Investigation Information Section

Device Analysis Results:

No items were made available for identification or evaluation.

A review of Stryker's records indicates that the reported devices were manufactured and accepted into final stock with no relevant reported discrepancies.

A review of the packaging insert noted the following:
"PRECAUTIONS - The surgeon must caution/warn the patient of surgical risks, and made aware of possible adverse effects. The surgeon must caution/warn the patient that the device does not replicate a normal healthy joint, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device has a finite service life and may need to be replaced in the future."

The root cause cannot be determined.

Corrective/Preventative Actions:

No action is required at this time. Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

Details of Similar Events:

0.005% rate of similar events per sales (AUS), 0.002% (WW).

Number of Similar Events:	Rate of Similar Events:
	0.005% (Aus) 0.002% (WW)

Countries Similar Events Also Occurred:

Australia, Canada, United States.

Additional Comments:

The cup was left in-situ, however the liner was changed.

Device Lookup

Document 17

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text	
152396	Howmedica Osteonics Corporation		Trident PSL HA Solid Back Acetabular Shell				
128024	Howmedica Osteonics Corporation		Prosthesis, hip, internal, femoral head component				
128021	Howmedica Osteonics Corporation		Prosthesis, internal, joint, hip, acetabular component				

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution	

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing	

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Document 17

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes	
Completion letter sent		30/11/2012	13/12/2012				

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Material	Degrade		

Investigation Problem Causes

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Device not returned		

Investigation Outcomes

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To

FILE		Inital IRIS 346663 - Accolade Plus TMZF	161	Form	Document 17
FILE		Final IRIS 346663 - Accolade Plus TMZF	161	Form	

Flow Details : DIR-REQ - Device Incident Request : 38652

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
38652	DIR-REQ		Closed	s22	OPR Administration User	30/11/2012	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	06/06/2013 08:42:40	
Comment		

Created By s22 - 23/10/2012 09:26:21

Template Revision Released by s22 on 25/06/2015 15:11:06

Document 18

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

Form Date: 09/01/2013
SIGNED

DIR : 20 ID : 232587

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
29811	2013/000575	332142	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22	19/12/2012
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
08/03/2013	09/01/2013		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
20/03/2013	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Revision surgery planned for pain and reported inflammation in hip.

Clinical Event Information:

Revision surgery planned for pain and reported inflammation in hip.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22		s22

Patient Focused Corrective Action Taken:

Revision surgery.

Patient History:

Document 18

N/K.

Patient Outcome/Consequences:

Patient revised.

Other Devices Involved:

Std MITCH TRH Cp Sz 54/60, MAC-9988-5460, 144011.
MITCH TRH Md Hd Sz 54+4, MMH-9988-1454, 138942.

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5418 - s22 - - Stryker Australia		
Reporter Title:	**First Name:**	**Surname:**	
	s22	s22	
Position:		**Company/Institution:**	
		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	New South Wales
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	02 9467 1042
Mobile:	**Email:**		**Last External Submission By:**
	s22 @stryker.com		

Initial Reporter Section

As Above?:			Initial Reporter Confidential:
No	*If No, fill out the following:*		No
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
		s22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**

s22		s22	s22
Postcode:	Phone:	Fax:	Mobile:
s22	s22		
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35666
GMDN / UMDN Text:		Brand Name:	
Prosthesis, internal, joint, hip, femoral component		Accolade TMZF Hip Stem	

Initial Device Description:

Accolade TMZF Stem

Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
6021-5537	26115905		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	
Address 2:	Town/Suburb:	State/Province:	Country:

Document 18

Postcode:	Phone:	Fax:	
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
18/03/2013	s22	Yes	Yes	☑
Sample Received:	**Sterile:**	**Reusable:**	**Single Use:**	**Potential Effect:**
No	Yes	No	Yes	Temporary Injury
Actual Effect:	**Injured Party:**			**Risk Frequency:**
Temporary Injury	Patient			Unlikely
Risk Severity:	**Risk Detectability:**	**Classification:**	**Investigated:**	**Date of DIRE Meeting:**
Minor	Likely	Not Investigated		

DIRE Meeting Notes:

Document 18

Sponsor Information Section

Search Sponsors:	Name:		Client #:
stryk	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22	02 9467 1042
Email:			
s22 @stryker.com			

Investigation Information Section

Device Analysis Results:

An event regarding an Accolade stem loosening was reported. The event was not confirmed.
No devices were returned.

Device history review indicated that all reported devices were manufactured and accepted into final stock with no reported discrepancies.
A review of the instructions for use (IFU) packaged with the Accolade stem, noted the following applicable warnings;
Press-Fit Application. Secure fixation at the time of surgery is critical to the success of the procedure. The femoral component stem must press fit into the femur, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture of the femur can occur during seating of the prosthesis. Bone stock must be adequate to support the device.

Implants can loosen or migrate due to trauma or loss of fixation.

The root cause of this specific event could not be determined with the limited information provided.

Corrective/Preventative Actions:

No action is required at this time.
Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

Details of Similar Events:

0.0114 similar events per sales (AUS).
0.0005 similar events per sales (WW).

Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

Australia, United States.

Document 18

Additional Comments:

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text	
144011	Finsbury Orthopaedics Ltd		Std MITCH TRH Cp Sz 54/60		MAC-9988-5460		
138942	Finsbury Orthopaedics Ltd		MITCH TRH Md Hd Sz 54+4		MMH-9988-1454		

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution	

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing	

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Document 18

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes	
Completion Letter		20/03/2013					

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Other	Other	Patient Factors	

Investigation Problem Causes

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Investigation did not reveal a root cause		

Investigation Outcomes

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

National Joint Replacement Register (NJRR) was reviewed, no further action at this stage , the TGA will continue to monitor.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To

FILE		DIR 29811 NJRR data Accolade	153	Form	Document 18

Flow Details : DIR-REQ - Device Incident Request : 39889

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
39889	DIR-REQ		Closed	s22	OPR Administration User	20/03/2013	Normal	1

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	20/03/2013 12:10:29	
Comment		

Created By s22 - 09/01/2013 17:16:28

Template Revision Released by s22 on 25/06/2015 15:11:06

Document 19

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

Form Date: 17/01/2013
SIGNED

DIR : 20 ID : 233056

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
29864	2013/000944	365179	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Death / Serious Injury	s22	31/12/2012
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
15/04/2013	17/01/2013		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
23/04/2013	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Revision surgery for signs of loosening.

Clinical Event Information:

Revision surgery for signs of loosening.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22		s22

Patient Focused Corrective Action Taken:

Revision surgery.

Patient History:

Document 19

Osteoarthitis.

Patient Outcome/Consequences:

Revision surgery.

Other Devices Involved:

Tritanium acetabular cup, Model NK, ARTG 128021.

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5418 - s22 - - Stryker Australia		
Reporter Title:	First Name:	Surname:	
	s22	s22	
Position:		Company/Institution:	
		Stryker Australia	
Address 1:	Address 2:	Town/Suburb:	State:
8 Herbert Street		St Leonards	New South Wales
Country:	Postcode:	Phone:	Fax:
Australia	2065	s22	02 9467 1042
Mobile:	Email:		Last External Submission By:
	s22 @stryker.com		

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			No
Search Reporter By Surname:	Initial Reporter #:		
Title:	First Name:	Surname:	
Mr	s22	s22	
Position:		Company/Institution:	
		s22	
Address 1:	Address 2:	Town/Suburb:	State:
s22		s22	s22

Document 19

Postcode:	Phone:	Fax:	Mobile:
s22	s22		

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35666

GMDN / UMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, femoral component	Accolade Plus TMZF Hip Stem #6

Initial Device Description:

Accolade Plus TMZF Hip Stem #6

Usage of Device:	Software Version:
Single Use	

Model #:	Serial #:	Batch #:	Lot #:
6021-0637	24002201		

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Place of use			

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

Document 19

Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
16/04/2013	s22	Yes	Yes	☑
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	Yes	No	Yes	Serious Injury
Actual Effect:	Injured Party:			Risk Frequency:
Serious Injury	Patient			Unlikely
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Minor	Likely	Not Investigated		

DIRE Meeting Notes:

Document 19

Sponsor Information Section

Search Sponsors:	Name:		Client #:
stryker	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	(02) 9467 1042
Email:			
s22 [redacted] @stryker.com			

Investigation Information Section

Device Analysis Results:

A Visual and Dimensional inspection were not possible as the explanted products were not returned. A review of Strykers records indicates that the reported device was manufactured and accepted into final stock with no reported discrepancies.

A review of the provided surgical records, product photographs and x-rays by a clinical consultant confirmed that the stem was loose. It was also concluded that the cup had a position with zero degrees of anteversion, rendering the arthroplasty very vulnerable to impingement although type and quality of picture do not show enough detail to allow for detection of possible impingement signs in the stem neck area. Therefore the root cause of this issue is potentially procedure related, but this cannot be confirmed.

A review of Strykers Technical Report noted the following:
Long term survivorship of cementless femoral stems requires initial stable fixation and achievement of biological fixation to bone. Fixation may be compromised where the host bone is weak or osteoporotic.

Based on the results of the evaluation, insufficient information was received and a root cause could not be determined. Return of the explanted devices would be helpful in investigating this event further.

Corrective/Preventative Actions:

No action is required at this time; there is no evidence to suggest that the event involved a product problem indicating a non-conformity or unanticipated hazard.

Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

Details of Similar Events:

1 of 184 units sold, 0.543% similar event rate (AUS).
2 of 6433 units sold, 0.031% similar event rate (WW).

Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

Australia, United States.

Document 19

Additional Comments:

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text
128021	Howmedica Osteonics Corporation		Prosthesis, internal, joint, hip, acetabular component, Tritanium			

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Document 19

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes	
Completion Letter		23/04/2013					

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Implantable Device Failure	Osseodisintegration		

Investigation Problem Causes

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Investigation did not reveal a root cause		

Investigation Outcomes

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

National Joint Replacement Register (NJRR) was reviewed, no further action at this stage , the TGA will continue to monitor.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To

FILE		Initial IRIS - PER 365179 - Accolade TMZF Stem	160	Form	Document 19
FILE		Final IRIS - PER 365179 - Accolade II Femoral Stem	168	Form	
FILE		DIR 29864 NJRR info	158	Form	
FILE		... 365179 - Accolade II Femoral Stem - Amended stats	168	Form	

Flow Details : DIR-REQ - Device Incident Request : 39960

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
39960	DIR-REQ		Closed	s22	OPR Administration User	23/04/2013	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	12/06/2013 08:32:45	
Comment		

Created By s22 - 17/01/2013 08:48:07

Template Revision Released by s22 on 25/06/2015 15:11:06

Document 20

Form Date: 23/04/2013
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 20 ID : 240854

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
30705	2014/045796	107881	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22 [redacted]	23/04/2013
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
16/10/2014	23/04/2013		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
28/10/2014	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Patient developed Mantle Cell Carcinoma and requires revision surgery.

Clinical Event Information:

Patient developed Mantle Cell Carcinoma and requires revision surgery.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22 [redacted]	s22 [redacted]	s22 [redacted]

Patient Focused Corrective Action Taken:

Revision surgery planned for the s22 [redacted].

Patient History:

Document 20

Patient Outcome/Consequences:

Revision surgery yet to occur.

Other Devices Involved:

MAC-9988-5056 Std MITCH TRH Cp Sz 50/56 FM063019 MITCH TRH SYSTEM
MMH-9988-0050 MITCH TRH Md Hd Sz50+0 FM061493 MITCH TRH SYSTEM

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Regulatory Affairs Manager		Stryker	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	02 9467 1042
Mobile:	**Email:**		**Last External Submission By:**
	s22 @stryker.com		

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**		
s22			
Title:	**First Name:**	**Surname:**	
	s22	s22	
Position:		**Company/Institution:**	
s22		s22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**

s22		s22	s22
Postcode:	Phone:	Fax:	Mobile:
s22	s22		
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35666
GMDN / UMDN Text:		Brand Name:	
Prosthesis, internal, joint, hip, femoral component		ACCOLADE femoral component	

Initial Device Description:

ACCOLADE femoral component

Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
6021-0537			24082301/10298483CF
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
With Patient			
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	325 Corporate Drive
Address 2:	Town/Suburb:	State/Province:	Country:
	Mahwah	NJ	United States

Document 20

Postcode:	Phone:	Fax:	
07430	02 9467 1218	02 9467 1042	
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
s22 @stryker.com		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	
Mr	s22	s22	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
16/10/2014	s22	Yes	Yes	☑
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	Yes	No	Yes	Serious Injury
Actual Effect:	Injured Party:			Risk Frequency:
Serious Injury	Patient			Unlikely
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Serious	Unlikely	Not Investigated		

DIRE Meeting Notes:

Document 20

This report has been reassessed due to age of the report, as the final report was not submitted by the sponsor. National Joint Replacement Register (NJRR) was reviewed, no further action at this stage, the TGA will continue to monitor.

Sponsor Information Section

Search Sponsors:	Name:		Client #:
stryker	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	02 9467 1042
Email:			
s22 [redacted] @stryker.com			

Investigation Information Section

Device Analysis Results:

Pending Manufacturer's investigation

Corrective/Preventative Actions:

Pending Manufacturer's investigation

Details of Similar Events:

NK

Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

NK

Additional Comments:

NA

Device Lookup

Document 20

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
completion letter		28/10/2014				

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Document 20

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Other	Other	patient factors	

Investigation Problem Causes

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Not product related	Event related to patient condition or anatomy		

Investigation Outcomes

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

National Joint Replacement Register (NJRR) was reviewed, no further action at this stage, the TGA will continue to monitor.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 30705 NJRR Info	130	Form	

Flow Details : DIR-REQ - Device Incident Request : 41101

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
41101	DIR-REQ		Closed	s22	OPR Administration User	28/10/2014	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	18/11/2014 09:23:45	
Comment		

Created By Theta Technologies - 23/04/2013 14:51:01

Template Revision Released by s22 [redacted] on 25/06/2015 15:11:06

Document 21

Form Date: 13/11/2012
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 20 ID : 169695

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
29257	2012/023261	308279	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Death / Serious Injury	s22 [redacted]	27/02/2012
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
22/08/2013	13/11/2012		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
03/01/2014	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor			

Event Description for Website Publication:

The acetabular cup had came away from the cement mantel and slipped down out of Acetabulum. The patient required unanticipated revision surgery due to pain and difficulty walking.

Clinical Event Information:

The acetabular cup had came away from the cement mantel and slipped down out of Acetabulum. The patient required unanticipated revision surgery due to pain and difficulty walking.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22 [redacted]	s22 [redacted]	s22 [redacted]

Patient Focused Corrective Action Taken:

Revision surgery.

Document 21

Patient History:

NK.

Patient Outcome/Consequences:

Patient successfully revised.

Other Devices Involved:

TRIDENT 10º X3 INSERT 32mm ID, 623-10-32F, ARTG # 128021

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5801 - s22 - - Stryker Australia Pty Ltd		
Reporter Title:	**First Name:**	**Surname:**	
	s22	s22	
Position:		**Company/Institution:**	
		Stryker Australia Pty Ltd	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	New South Wales
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	02 9467 1042
Mobile:	**Email:**		**Last External Submission By:**
	s22 @stryker.com		

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			No
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Ms	s22	s22	
Position:		**Company/Institution:**	
		s22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**

s22		s22	s22
Postcode:	Phone:	Fax:	Mobile:
s22	s22	s22	
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		152396	152396
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35661
GMDN / UMDN Text:		Brand Name:	
Prosthesis, internal, joint, hip, acetabular component		Trident PSL HA Solid Back 54MM	
Initial Device Description:			
Trident PSL HA Solid Back 54MM			
Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
540-11-54F	34877201		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
With Reporter			
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	
Address 2:	Town/Suburb:	State/Province:	Country:

Document 21

Postcode:	Phone:	Fax:	
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
23/08/2013	s22	Yes	Yes	☐
Sample Received:	**Sterile:**	**Reusable:**	**Single Use:**	**Potential Effect:**
No	Yes	No	Yes	Serious Injury
Actual Effect:	**Injured Party:**			**Risk Frequency:**
Serious Injury	Patient			Unlikely
Risk Severity:	**Risk Detectability:**	**Classification:**	**Investigated:**	**Date of DIRE Meeting:**
Minor	Likely	Not Investigated		

DIRE Meeting Notes:

Document 21

Document 21

Sponsor Information Section

Search Sponsors:	Name:		Client #:
stryker	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22	(02) 9467 1042
Email:			
s22 @stryker.com			

Investigation Information Section

Device Analysis Results:

An event regarding loosening of a cemented Trident shell was reported. The event was confirmed.
Visual Inspection: The returned Trident Shell has a 40mm x 15mm area of cement on its peripheral rim on one side of the device. There are sporadic areas of fibrous bone ongrowth on the back-side of the shell. There are also many shiny wear marks on the back-side, indicating micro-motion during in-vivo use. The returned head and liner are unremarkable apart scratching which was most likely caused during explantation.
Based on the results of the packaging insert and surgical protocol review, cementing a Trident shell is not an indication for use, therefore further investigation is not required. Stryker Orthopaedics can only address approved indications for use.
A review of Stryker's records indicates that the reported devices were manufactured and accepted into final stock with no reported discrepancies

Corrective/Preventative Actions:

No action is required t this time. The event did not involve a product problem indicating a non-conformity, adverse trend or unanticipated hazard.
Product surveillance will continue to monitor for trends.
Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

Details of Similar Events:

0.00008 similar events per sales (WW), 0.0006 (AUS).

Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

Australia.

Additional Comments:

During primary surgery the surgeon had difficulty inserting the PSL cup.

Device Lookup

Document 21

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text
128021	Howmedica Osteonics Corporation		Trident x3 insert 32mm - Prosthesis, internal, joint, hip, acetabular component		623-10-23F	

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion letter		14/01/2014				

Document 21

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Mechanical	Unintended Movement		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Not product related	Off-label, unapproved or contra-indicated use		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

This report describes the use of an uncemented prosthesis being used with cement. Subsequently the cement mantle has failed causing the implant to move. The use of this implant in this manner is user error.

The TGA monitors use as well as safety and performance of medical devices. This type of problem is known to occur occasionally.

No further investigation will occur at this time.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Initial IRIS 308279 - Trident Cemented PSL Cup	161	Form	

FILE		DIR 29257 NJRR Info	730	Form	Document 21

Flow Details : DIR-REQ - Device Incident Request : 39047

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
39047	DIR-REQ		Closed	s22	OPR Administration User	14/01/2014	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	14/01/2014 09:05:26	
Comment		

Created By s22 - 13/11/2012 14:04:45

Template Revision Released by s22 on 25/06/2015 15:11:06

Document 22

Form Date: 26/03/2012
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 6 - ID : 152887

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
26109	2012/008562	267217	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Death / Serious Injury	s22 [redacted]	18/07/2011
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
14/03/2012	26/03/2012	03/04/2012	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
04/04/2012	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Following patient fall, cup had moved which subsequently resulted in sublaxation. The ceramic liner was replaced and a Biolox ceramic femoral head with a longer neck was implanted.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22 [redacted]	s22 [redacted]	s22 [redacted]

Patient Focused Corrective Action Taken:

Removal and replacement of right acetabular components.

Patient History:

Clinically obese with a B.M.I. of 32.4. She had bilateral hip arthroplasties and these were both revised, possibly on s22 [redacted].

Patient Outcome/Consequences:

Revision surgery it was noted that the Trident cup was solid and unable to be moved, indicating that the cup was placed in a vertical position at the patients primary surgery.

Other Devices Involved:

N/A

Document 22

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	5418		
Reporter Title:	**First Name:**	**Surname:**	
	s22	s22	
Position:		**Company/Institution:**	
		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	New South Wales
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	02 9467 1042
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
	s22	s22	
Position:		**Company/Institution:**	
		s22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
s22		s22	s22
Postcode:	**Phone:**	**Fax:**	**Mobile:**
s22			
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		152396	152396
Therapeutic Licence Type:	**Product Licence Category:**	**Device Class:**	**GMDN Code:**

Document 22

Medical Device	Included	Class III	35661

GMDN Text:
Prosthesis, internal, joint, hip, acetabular component

Brand Name:
Ceramic Liner

Initial Device Description:
Ceramic Liner

Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
	N/K	N/K	N/K
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
			s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:

Document 22

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:
26/03/2012	s22 [redacted]

Sample Received:	Sterile:	Reusable:	Single Use:
No	Yes	No	Yes

Potential Effect:	Actual Effect:	Injured Party:
Serious Injury	Serious Injury	Patient

Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
Unlikely	Minor	Likely	Routine	☐

DIRE Meeting Notes:

The device has not been highlighted as an implant of concern through the NJRR
Procedural and patient factors - no investigation

Sponsor Information Section

Search Sponsors:	Name:	Client #:
stryker	Stryker Australia Pty Ltd	1251

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 970		ARTARMON

State:	Postcode:	Phone:	Fax:
NSW	1570	s22 [redacted]	

Email:

s22 [redacted] @stryker.com

Investigation Information Section

Device Analysis Results:

An event regarding dislocation of a Trident hip was reported on s22 [redacted]. The event was not confirmed.
The exact cause of the event could not be determined however the reported dislocation in this obese patient may be due to the vertical positioning of the shell, as noted in Strykers technical report for dislocation. It is noted in the review of the provided x-rays by a clinical professional that the shell on the right hand side is vertically placed. It is not possible to determine if the shell was placed in this position at the primary surgery or if it was displaced after the reported trauma the patient suffered. No further investigation for this event is possible at this time because no devices and insufficient information was received by Stryker Orthopaedics. If devices and / or additional information become available, this investigation will be reopened.

Document 22

Corrective/Preventative Actions:

No action is required at this time as there was no indication of a product non-conformance or adverse trend. Product Surveillance will monitor for trends.

Details of Similar Events:

Unable to calculate, no Lot or Catalogue # provided.

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion letter	04/04/2012				

List of Problem Type Codes - Click **New** to begin entering information.

Document 22

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Mechanical	Unintended Movement		

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Not product related	Event related to patient condition or anatomy		
Not product related	User error caused or contributed to event		

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Not investigated		

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 34966

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
34966	DIR-REQ		Closed	s22	OPR Administration User	08/01/2015	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	04/04/2012 11:41:53	
Comment		

Document 22

Created By s22 - 26/03/2012 11:07:33

Template Revision Released by Theta Technologies on 01/03/2012 12:04:11

Document 23

Form Date: 17/09/2010
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 140353

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
21961		206372	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
08/09/2010	17/09/2010		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
29/09/2010			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Implant date: Not known
Explant date: s22

Cup was implanted s22 in Canada, patient reported feeling pain for last 1.5 years. A bone scan confirmed that the cup was loose, and the surgeon decided to revise. Upon removal of the cup, there was no appearance of ongrowth.

It is not possible to confirm the reported event nor to determine a root cause with the limited information provided. No items associated with the event were returned to Stryker Orthopaedics, and the device details, such as catalog and lot numbers, were not available. No further investigation is possible at this time. Further information such as return of the explanted devices, device details, pre- and post-operative reports and X-rays from both primary and revision surgeries as well as patient history and follow-up notes would be helpful in conducting a full investigation into the reported event. If additional information becomes available, this investigation will be reopened.

Investigations have previously been conducted on individual product complaints which reported loosening, or poor fixation of Trident Hemispherical and Peripheral Self Locking (PSL) shells. Stryker Orthopaedics conducted an investigation to evaluate reports of shell loosening involving Trident Hemispherical and PSL acetabular shells. The analysis conducted as part of this investigation determined the root cause of reports of Trident Shell loosening was failure to achieve initial biological fixation due to inadequate execution of the recommended surgical technique. Specifically, some surgeons were not adequately executing the correct reaming technique required for the preparation of the acetabulum.

(see diary).

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

Patient Information

Sex:	Weight:	Age:

Document 23

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Regulatory Affairs Officer		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	(02) 9467 1010
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Phone:**	**Fax:**	**Mobile:**

Document 23

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		152396	152396

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
Medical Device	Included	Class III	35661

GMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, acetabular component	

Initial Device Description:

Trident - (mfr ref: 206372)

Usage of Device:	Software Version:

Model #:	Serial #:	Batch #:	Lot #:
Not known	Not known	Not known	

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:

Email:	Manufacturer Informed:	Date Aware of Adverse Event:
	Yes	

Contact Title:	Contact First Name:	Contact Surname:

Supplier Information Section

Document 23

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Postcode:**	**Phone:**
Fax:	**Email:**		**Supplier Informed:**
Date of Supplier Contact:	**Contact Title:**	**Contact First Name:**	**Contact Surname:**
Contact Phone:	**Contact Fax:**		

Statistics Checklist Section

Date:	Assessed By:		
Sample Received:	**Sterile:**	**Reusable:**	**Single Use:**
No	No	No	
Potential Effect:	**Actual Effect:**	**Injured Party:**	
Serious Injury	Serious Injury	Patient	
Risk Frequency:	**Risk Severity:**	**Risk Detectability:**	**Classification:**	**Exclude report from DIRE:**
			Routine	

Sponsor Information Section

Search Sponsors:	Name:		Client #:
St	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22	02 9467 1010
Email:			
s22 @stryker.com			

Investigation Information Section

Device Analysis Results:

Document 23

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Diary Entry: s22 - Stryker Orthopaedics has implemented preventative actions to reduce the likelihood of Trident Shell Loosening. Stryker Orthopaedics created and released separate and distinct surgical techniques, one for the Trident PSL Shell and one for the Trident Hemispherical Shell in order to further clarify the different reaming techniques recommended to achieve initial fixation. As the root cause of this particular event could not be determined based on the limited information provided, no further corrective/ preventative action is planned at this time. Product surveillance will continue to monitor for trends.

Similar events: 0.018%.

Report sourced from sponsor.

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent		Date Received	Sponsor's Response	Investigator's Notes

Document 23

		Date Response Expected			
Completion Notification	29/09/2010				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC21961.DOC

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Mechanical		

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Not product related		

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 30334

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
30334	DIR-REQ		Closed	theta	IRIS Coordinator	29/09/2010	Normal	0

Signature Details

Role	IRIS Investigator
User	theta - Theta Technologies
Signed At	29/09/2010 00:00:00

Document 23

Comment	Automatically signed off closed DIR forms as part of data migration	

Created By Theta Technologies - 17/09/2010

Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

Document 24

Form Date: 06/11/2009
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 2 - ID : 138802

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
20378	2010/006922	146812	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		s22 [redacted]	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
04/11/2009	06/11/2009		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
27/11/2009			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Implant Date: s22 [redacted]
Explant Date: s22 [redacted]

Patient experienced a sense of impingement in groin s22 [redacted] post op. but he returned to vigorous exercise. s22 [redacted] post op x-ray showed signs of loosening. No revision surgery at this time.

The items were not returned to the manufacturer for investigation as they remain implanted at this stage. Investigations have been conducted on individual product complaints which reported loosening, or poor fixation of Trident Hemispherical and Peripheral Self Locking (PSL) shells. Stryker has received some reports of shell loosening involving Trident Hemispherical and PSL acetabular shells. The number of reported cases has a low incidence rate over the number of sales. Over 500,000 Trident Acetabular Shells have been implanted worldwide to date, with an incidence rate of 0.020% reported for shell loosening. In addition, these incidents have been reported by a small fraction of the number of institutions currently implanting these shells. The fact that a large number of the PERs are among a very small number of users demonstrates the underlying root cause is related to surgical technique rather than the device itself.

Patient outcome: N/K.

Similar events: 0.02%.

Report sourced from sponsor.

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	**Alternative Person Fax:**		

Patient Information

Sex:	Weight:	Age:

Document 24

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Regulatory Affairs Officer		Stryker Australia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	(02) 9467 1010
Mobile:	**Email:**		
	s22 @stryker.com		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Phone:**	**Fax:**	**Mobile:**

Document 24

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		152396	152396
Therapeutic Licence Type:	**Product Licence Category:**	**Device Class:**	**GMDN Code:**
Medical Device	Included	Class III	35661
GMDN Text:		**Brand Name:**	
Prosthesis, internal, joint, hip, acetabular component			
Initial Device Description:			
Trident - (mfr ref: 146812)			
Usage of Device:	**Software Version:**		
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
PSL HA Solid Back	22481201		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Reported Device Location:	**Access Contact Title:**	**Access Contact First Name:**	**Access Contact Surname:**
Access Contact Phone:	**Access Contact Fax:**		

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	
Email:	**Manufacturer Informed:**	**Date Aware of Adverse Event:**
	Yes	
Contact Title:	**Contact First Name:**	**Contact Surname:**	

Supplier Information Section

Document 24

Supplier Name:		Address 1:	Address 2:

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:

Sample Received:	Sterile:	Reusable:	Single Use:
No	No	No	

Potential Effect:	Actual Effect:	Injured Party:
Serious Injury	Temporary Injury	Patient

Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
			Routine	

Sponsor Information Section

Search Sponsors:	Name:	Client #:
St	Stryker Australia Pty Ltd	1251

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 970		ARTARMON

State:	Postcode:	Phone:	Fax:
NSW	1570	s22	(02) 9467 1010

Email:
s22 @stryker.com

Investigation Information Section

Device Analysis Results:

Document 24

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **New** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion Notification	27/11/2009				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC20378.DOC

List of Problem Type Codes - Click **New** to begin entering information.

Document 24

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Mechanical		

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Not product related		

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 28783

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
28783	DIR-REQ		Closed	theta	IRIS Coordinator	28/05/2010	Normal	0

Signature Details

Role	IRIS Investigator
User	theta - Theta Technologies
Signed At	28/05/2010 00:00:00
Comment	Automatically signed off closed DIR forms as part of data migration

Created By Theta Technologies - 06/11/2009

Template Revision Released by Theta Technologies on 26/06/1985 21:02:22

Document 25

In – Confidence

RECALL
File Barcode Only
F5500025295966

Commercial In Confidence	TGA File	2008/009779
Therapeutic Goods Administration		
Previous Part	*Next Part*	

THERAPEUTIC ADMINISTRATION - POST MARKET MONITORING - Complaint Investigation - Accolade Prosthesis Internal - Stryker Australia Pty Ltd - ODBT

22-7-2009 R 62397
28-01-2009 D120 D2130

Information relating to this file may have been saved to the Departmental Electronic Document Management System using the file number appearing on the label.

- This file contains information concerning the private affairs of individuals, companies, organisations or other information obtained under assurance of confidentiality. When not in use, this file is to be stored in a locked cabinet or secured room.

Previous Parts

Each officer must enter their own initials when clearing the folio.

Folio No. (1)	Referred to (2)	Date (3)	Date Cleared (4)	Initials
	s22 [redacted]	27.10.08		s22 [redacted]
		10/12/08		
		9/2/09		
		25.9.09	11/6/10	

Please do not hold this file when delays in action may exceed seven (7) days.

Later Parts

Each officer must enter their own initials when clearing the folio.

Folio No. (1)	Referred to (2)	Date (3)	Date Cleared (4)	Initials

Archival Action	
AFDA/RDA Number	
Retain/Destroy Review Date	

2008/009779

In – Confidence

537 (0801)

s22

Document 25

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Document 25

Therapeutic Goods Administration
Device Incident Reports
Full Details Report

DIR /20096 — **Accolade TMZF 127? HA Hip Stem - Prosthesis, internal, joint, hip, femoral component/Howmedica Osteonics Corporation**

Exempt/Not on Artg: N

Syst/Artg No ARTG / 145594

Ecri Code: 35666 Prosthesis, internal, joint, hip, femoral component

Device: Accolade - (mfr ref: 146637)

Model No: **Batch No:** **Serial No:** 18006102

Manufacturer: Howmedica Osteonics Corporation 9211
USA

Sponsor: Stryker Australia Pty Ltd 1251
PO Box 970
ARTARMON NSW 1570 AU

Contact: s22 **Phone:** s22 **Fax:** (02) 9467 1010

Reporter Details: Confidential: No
s22

Position: Regulatory Affairs Officer

Institution: Stryker Australia
8 Herbert Street
St Leonards NSW 2065 AUST

Phone: s22

Incident Description: Implant Date: s22 .
Explant Date: N/K.

Loose Stem. Patient had stem revised due to infection.

No analysis of device was performed as it was not returned to the manufacturer for investigation.

A review of the provided x-rays by a clinician concluded "The stem has a 3 to 5 millimetre radiolucency in Gruen Zone I, II, VI and VII with a distal bony pedestal suggestive of end bearing. There is also a suggestion of subsidence consistent with loosening.

If, as stated, the revision was for "septic loosening" of the stem no prosthetic manufacture, design or material factors are involved in this clinical complication.

Similar events: None.

Report sourced from sponsor.

Date Received: 07/09/2009

Date Entered: 09/09/2009

Date Completed: 28/09/2009

Therapeutic Goods Administration
Device Incident Reports
Full Details Report

DIR /20096 — **Accolade TMZF 127? HA Hip Stem - Prosthesis, internal, joint, hip, femoral component/Howmedica Osteonics Corporation**

Date Closed: 28/09/2009

Associated Files: S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC20096.DOC

Device Type - Sterile: N
- Reusable: N
Sample Received: N
Classification: Routine
Potential Outcome: Temporary Injury
Actual Outcome: Temporary Injury
Injured Party: Patient
Reporter Category: Other - Sponsor
Type of Incident: Mechanical
Cause of Incident: Not Device Related
Investigation Result: Not Investigated
Recommendation: No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.
Investigator Name: s22 09/09/2009

***** End Of DIR / 20096 *****

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22
Stryker Australia Pty Ltd
PO Box 970
ARTARMON NSW 1570

Dear s22,

DEVICE INCIDENT REPORT DIR 20096 - Accolade TMZF 127? HA Hip Stem - Prosthesis, internal, joint, hip, femoral component/Howmedica Osteonics Corporation

We have now completed our evaluation of the incident reported to the Therapeutic Goods Administration concerning the above device.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, complete with closing recommendations is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please do not hesitate to contact me here in Canberra on s22.

Yours sincerely

s22

Incident Report and Investigation Scheme
Market Vigilance and Monitoring Section
Therapeutic Goods Administration

28/09/2009

E-MAILED 28/9/09

IRIS Program DIRE Committee Results

Document 25

DIR #: 20096 **File No:**

Device Name: Accolade **File Location:**

Classification: Urgent: ☐ Expedite: ☐ Routine: ☐ Not Investigated: ☑

Resolution: Investigate ☐ Referral to……..

Information Only ☑ Await sponsor response and review ☐

Attendees: AECS ☐ MDAS ☑ LABS ☑ CLINICAL ☑ MVMS ☑

Investigator: **Competitor report** (do not send letters) ☐

Letters: Yes ☐ No ☐

Is the sample going to be tested by Lab staff? Yes ☐ No ☐

Name of person testing the sample: _____

Special Instructions on Letters: (to be completed by / /)

(Please provide any additional questions for letters and tick in the brackets if you require any of the information below)

- Sample of product ( ) – if requesting samples please tick above if they will be tested by Lab staff or not.
- Product Specifications ( )
- Descriptive product promotional documentation ( )
- Instructions for use, as supplied with the device ( )
- Device Packaging with printed instructions ( )
- Operator's manual ( )
- Technical Service Manual ( )
- Clinical training manual in printed or video form ( )
- In-house training documentation ( )
- Evidence of compliance with the Essential Principles ( )
- A summary of risk management activities performed by the manufacturer for the device, e.g. Risk Management Report required by Clause 8 of ISO 14971:2000 ( )

DIRE Committee comments for the investigator or rationale for not investigating:

- patient anatomy.

IRIS Program DIRE Committee Results

Document 25

Cause of Incident	Result of Investigation
☐ Biocompatibility	☐ Bulletin Article
☐ Component Failure	☐ Company Warned
☐ Contamination	☐ Compliance Testing
☐ Design	☐ No Further Action
☐ Diagnostic Inaccuracy	☑ Not Investigated
☐ Electrical	☐ Other
☐ Inadequate Instructions	☐ Problem Not Confirmed
☐ Labelling	☐ Product Improvement
☐ Maintenance	☐ Recall / Hazard Alert
☐ Manufacture	☐ Refer to ADRAC
☐ Material / Formulation Deficiency	☐ Refer to GMP
☐ Mechanical	☐ Refer to Surveillance
☐ Not Applicable - ADR	☐ Safety Alert
☑ Not Device Related	☐ User Education
☐ Other	
☐ Packaging / Sterility	
☐ Quality Assurance	
☐ Unknown	
☐ Wear / Deterioration	

Recommendation (please circle the appropriate recommendation):

1. The cause of this problem has not been conclusively determined; however the low level of occurrence is not currently cause for concern.
2. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.
3. Available frequency and severity data do not indicate further investigation is appropriate at this time. The TGA will continue to monitor for similar incidents and may re-open the file if appropriate.
4. This product is not a therapeutic device within the meaning of the Therapeutic Goods Act 1989. This report will not be investigated.
5. The framework for the regulation of disinfectants and sterilants is not fully implemented. Sponsors have until October 1998 to fully comply with labelling requirement.
6. This report is entered for the record, and is not investigated at this time. The incidence of failure with this device is reviewed regularly for changes in trending or significant failure modes.
7. The information is entered for the record. This report is not being investigated at this time.

Other recommendations:

Form completed by: s22 [redacted]

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *	146637 Document 25
TGA DIR #	

Medical Device Incident Report Investigation Scheme

I- Administrative Information * Mandatory

Report Type (select one)

Initial ☐ Follow-Up ☐ Final ☒ Trend ☐

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☐ Other ☒

A) Date of this report (dd-mm-yyyy)	07/09/2009
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	s22
D) Date of next report (max 30 days from A)	n/a

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert St
	St. Leonards, NSW, 2065
Tel.	s22 Fax 02 9467 1010
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

none

II- Clinical Event Information * Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 **Explant Date:** n/k

Loose Stem. Patient had stem revised due to infection.

RECEIVED
-7 SEP 2009

III- Healthcare Facility Information * Mandatory

Name	s22
Address	s22
	s22
Tel	s22 Fax n/a
E-mail	n/a
Contact name at site of event	s22

IV- Device Information Primary Device * Mandatory

Generic Device Information

Device ARTG # *	145594
GMDN Code	35666
GMDN Code Text (eg catheters, central venous, peripherally inserted)	
Prosthesis, internal, joint, hip, femoral component	

Specific Device Information

Brand Name *	Accolade
Model # *	ACCOLADE (127 DEG)
Catalogue #	6021-0335
Ser. or Lot #'s	18006102
Mfr. Name*	Howmedica Osteonics Corporation
Contact Name *	s22
Address *	8 Herbert St.
	St. Leonards, NSW, 2065
Tel *	s22 Fax 02 9467 1010
E-mail *	s22 @stryker.com
ARTG Mfr. # *	9208

Operator of Device at Time of Event (select one)

HC Prof'nal ☒ Other Caregiver ☐ Patient ☐ N/A ☐

Usage of Device*

Single Use ☒ Reuse of Single Use ☐

Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location *

Implanted

V- Results of Mfr's Investigation *Mandatory

...nufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

No analysis of device was performed as it was not returned to the manufacturer for investigation.
A review of the provided x-rays by a clinician concluded "The stem has a 3 to 5 millimetre radiolucency in Gruen Zone I, II, VI and VII with a distal bony pedestal suggestive of end bearing. There is also a suggestion of subsidence consistent with loosening.

If, as stated, the revision was for "septic loosening" of the stem no prosthetic manufacture, design or material factors are involved in this clinical complication.

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

No corrective action is planned at this time. Product Surveillance will continue to monitor for trends

VI- Patient Information *Mandatory as marked below

Document 25

Age (yrs, mths)		M/F		Wt. (kg)	97

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

N/A

Patient history (co-morbidities & medication):

N/A

* Patient outcome:

n/k

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

621-10-32E TRIDENT 10? CROSSFIRE INSERT 32 mm ID

540-11-52E TRIDENT PSL HA SOLID BACK 52mm

6565-0-232 ALUMINA V40-FEMORAL HEAD 32MM, +4MM NK

VII- Other Reporting Information *Mandatory

Mfr/Sponsor aware of other similar events? (*number or *rate)

None

Countries where these similar adverse events occurred:

None

Additional Comments

N/A

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

s22 s22 @stryker.com>
Sent by: s22 s22 @stryker.com>

07/09/2009 12:41 PM

To <iris@tga.gov.au>
cc s22 @stryker.com>, s22
bcc
Subject IRIS Final Reports PER#s 146633, 146637

FULL HEADER

DOCUMENT NOT YET CLASSIFIED

To Whom It May Concern:

Please find attached final IRIS reports for incidents reported at s22 and s22

Kind Regards,

s22
RA/QA Coordinator
Stryker South Pacific-Head Office
8 Herbert Street
St. Leonards NSW Australia
Ph: s22
Fax: +61 02 94671010
Email: s22 @stryker.com


IRIS Final Report PER 146637 07 09 2009.doc


IRIS Final Report PER 146633 07 09 2009.doc

DOCUMENT NOT YET CLASSIFIED

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *	146637
TGA DIR #	

Re: Medical Device Incident Report Investigation Scheme

I- Administrative Information *Mandatory

Report Type (select one)

Initial ☐ Follow-Up ☒ Final ☐ Trend ☐

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☐ Other ☒

A) Date of this report (dd-mm-yyyy)	03/09/2009
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	
D) Date of next report (max 30 days from A)	01/10/2009

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert St
	St. Leonards, NSW, 2065
Tel.	s22
Fax	02 9467 1010
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

none

II- Clinical Event Information *Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 **Explant Date:**

Loose Stem. Patient had stem revised due to infection.

III- Healthcare Facility Information *Mandatory

Name	s22
Address	s22
	s22
Tel	s22
Fax	n/a
E-mail	n/a
Contact name at site of event	s22

IV- Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	152396
GMDN Code	35661
GMDN Code Text (eg catheters, central venous, peripherally inserted)	
Prosthesis, internal, joint, hip, acetabular component	

Specific Device Information

Brand Name *	TRIDENT
Model # *	TRIDENT PSL HA SOLID BACK 52mm
Catalogue #	540-11-52E
Ser. or Lot #'s	18310301
Mfr. Name*	Stryker Orthopaedics (Cork)
Contact Name *	s22
Address *	8 Herbert St.
	St. Leonards, NSW, 2065
Tel *	s22
Fax	02 9467 1010
E-mail *	s22 @stryker.com
ARTG Mfr. # *	40670

Operator of Device at Time of Event (select one)

HC Prof'nal ☒ Other Caregiver ☐ Patient ☐ N/A ☐

Usage of Device*

Single Use ☒ Reuse of Single Use ☐

Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location *

Implanted

V- Results of Mfr's Investigation *Mandatory

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's Invesitgation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Manufacturer was notified and awaiting investigation to be finalised before any further action is planned.

VI- Patient Information *Mandatory as marked below

Age (yrs, mths)		M/F		Wt. (kg)	

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

N/A

Patient history (co-morbidities & medication):

N/A

* Patient outcome:

Further details to be confirmed

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

621-10-32E TRIDENT 10? CROSSFIRE INSERT 32 mm ID

6021-0335 ACCOLADE (127 DEG)

6565-0-232 ALUMINA V40-FEMORAL HEAD 32MM, +4MM NK

VII- Other Reporting Information *Mandatory

Mfr/Sponsor aware of other similar events? (*number or *rate)

To be confirmed

Countries where these similar adverse events occurred:

To be confirmed

Additional Comments

N/A

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

s22 s22 @stryker.com>
Sent by: s22 s22 @stryker .com>

03/09/2009 10:29 AM

To <iris@tga.gov.au>
cc s22 @stryker.com>, 's22
bcc
Subject IRIS Follow-up Reports PER#s 146633, 146637, 146812

FULL HEADER

DOCUMENT NOT YET CLASSIFIED

To Whom It May Concern:

Please find attached follow up IRIS reports for incidents reported at s22 , s22 , and s22 . Please note there has not been any change to the status of these reports as we are awaiting the results of the manufacturer's investigations.

Kind Regards,

s22
RA/QA Coordinator
Stryker South Pacific-Head Office
8 Herbert Street
St. Leonards NSW Australia
Ph: s22
Fax: +61 02 94671010
Email: s22 @stryker.com

IRIS Follow Up Report PER 146633 03 09 2009.doc
IRIS Follow Up Report PER 146637 03 09 2009.doc
IRIS Follow Up Report PER 146812 03 09 2009.doc

DOCUMENT NOT YET CLASSIFIED

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *	146637 Document 25
TGA DIR #	

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information *Mandatory

Report Type (select one)

Initial ☐ Follow-Up ☒ Final ☐ Trend ☐

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☐ Other ☒

A) Date of this report (dd-mm-yyyy)	07/08/2009
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	
D) Date of next report (max 30 days from A)	05/09/2009

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert St
	St. Leonards, NSW, 2065
Tel.	s22
Fax	02 9467 1010
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

none

II- Clinical Event Information *Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 **Explant Date:**

Loose Stem. Patient had stem revised due to infection.

RECEIVED
7 AUG 2009

III- Healthcare Facility Information *Mandatory

Name	s22
Address	s22
	s22
Tel	s22
Fax	n/a
E-mail	n/a
Contact name at site of event	s22

IV- Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	152396
GMDN Code	35661
GMDN Code Text (eg catheters, central venous, peripherally inserted)	
Prosthesis, internal, joint, hip, acetabular component	

Specific Device Information

Brand Name *	TRIDENT
Model # *	TRIDENT PSL HA SOLID BACK 52mm
Catalogue #	540-11-52E
Ser. or Lot #'s	18310301
Mfr. Name*	Stryker Orthopaedics (Cork)
Contact Name *	s22
Address *	8 Herbert St.
	St. Leonards, NSW, 2065
Tel *	02 9467 1219
Fax	02 9467 1010
E-mail *	s22 @stryker.com
ARTG Mfr. # *	40670

Operator of Device at Time of Event (select one)

HC Prof'nal ☒ Other Caregiver ☐ Patient ☐ N/A ☐

Usage of Device*

Single Use ☒ Reuse of Single Use ☐

Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location *

Implanted

V- Results of Mfr's Investigation * *Mandatory*

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's Invesitgation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Manufacturer was notified and awaiting investigation to be finalised before any further action is planned.

VI- Patient Information * *Mandatory as marked below*

Age (yrs, mths)		M/F		Wt. (kg)	

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

N/A

Patient history (co-morbidities & medication):

N/A

* Patient outcome:

Further details to be confirmed

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

621-10-32E TRIDENT 10? CROSSFIRE INSERT 32 mm ID

6021-0335 ACCOLADE (127 DEG)

6565-0-232 ALUMINA V40-FEMORAL HEAD 32MM, +4MM NK

VII- Other Reporting Information * *Mandatory*

Mfr/Sponsor aware of other similar events? (*number or *rate)

To be confirmed

Countries where these similar adverse events occurred:

To be confirmed

Additional Comments

N/A

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

s22 "
s22 @stryker.com>
Sent by: s22
s22 @stryker.com>

07/08/2009 10:00 AM

To <iris@tga.gov.au>
cc s22 @stryker.com>, 's22
bcc
Subject IRIS Follow-up Reports PER#s 146628, 146633, 146634, 146637, 1

FULL HEADER

DOCUMENT NOT YET CLASSIFIED

To Whom It May Concern:

Please find attached follow up IRIS reports for incidents reported at s22 , s22 and s22 . Please note there has not been any change to the status of these reports as we are awaiting the results of the manufacturer's investigations.

Kind Regards,

s22
RA/QA Coordinator
Stryker South Pacific-Head Office
8 Herbert Street
St. Leonards NSW Australia
Ph: s22
Fax: +61 02 94671010
Email: s22 @stryker.com

IRIS Follow Up Report PER 146812 07082009.doc
IRIS Follow Up Report PER 146628 07082009.doc
IRIS Follow Up Report PER 146633 07082009.doc
IRIS Follow Up Report PER 146634 07082009.doc
IRIS Follow Up Report PER 146637 07082009.doc

DOCUMENT NOT YET CLASSIFIED

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *	146637 Document 25
TGA DIR #	

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information *Mandatory

Report Type (select one)

Initial ☐ Follow-Up ☒ Final ☐ Trend ☐

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☐ Other ☒

A) Date of this report (dd-mm-yyyy)	10/07/2009
B) Date of adverse event (dd-mm-yyyy)	s22 [redacted]
C) Date mfr aware (dd-mm-yyyy)	
D) Date of next report (max 30 days from A)	08/08/2009

Person (authorised representative) Submitting This Report

Name	s22 [redacted]
Company	Stryker Australia
Address	8 Herbert St
	St. Leonards, NSW, 2065
Tel.	s22 [redacted] Fax 02 9467 1010
E-mail	s22 [redacted] @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

none

II- Clinical Event Information *Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 [redacted] **Explant Date:**

Loose Stem. Patient had stem revised due to infection.

III- Healthcare Facility Information *Mandatory

Name	s22 [redacted]
Address	s22 [redacted]
	s22 [redacted]
Tel	s22 [redacted] Fax n/a
E-mail	n/a
Contact name at site of event	s22 [redacted]

IV- Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	152396
GMDN Code	35661
GMDN Code Text (eg catheters, central venous, peripherally inserted)	
Prosthesis, internal, joint, hip, acetabular component	

Specific Device Information

Brand Name *	TRIDENT
Model # *	TRIDENT PSL HA SOLID BACK 52mm
Catalogue #	540-11-52E
Ser. or Lot #'s	18310301
Mfr. Name*	Stryker Orthopaedics (Cork)
Contact Name *	s22 [redacted]
Address *	8 Herbert St.
	St. Leonards, NSW, 2065
Tel *	s22 [redacted] Fax 02 9467 1010
E-mail *	s22 [redacted] @stryker.com
ARTG Mfr. # *	40670

Operator of Device at Time of Event (select one)

HC Prof'nal ☒ Other Caregiver ☐ Patient ☐ N/A ☐

Usage of Device*

Single Use ☒ Reuse of Single Use ☐

Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location *

Implanted

V- Results of Mfr's Investigation *Mandatory

...ufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's Invesitgation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Manufacturer was notified and awaiting investigation to be finalised before any further action is planned.

VI- Patient Information *Mandatory as marked below

Age (yrs, mths)		M/F		Wt. (kg)	

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

N/A

Patient history (co-morbidities & medication):

N/A

* Patient outcome:

Further details to be confirmed

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

621-10-32E TRIDENT 10? CROSSFIRE INSERT 32 mm ID

6021-0335 ACCOLADE (127 DEG)

6565-0-232 ALUMINA V40-FEMORAL HEAD 32MM, +4MM NK

VII- Other Reporting Information *Mandatory

Mfr/Sponsor aware of other similar events? (*number or *rate)

To be confirmed

Countries where these similar adverse events occurred:

To be confirmed

Additional Comments

N/A

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

s22 s22 @stryker.com>
Sent by: 's22 s22 @stryker.com>

09/07/2009 04:13 PM

To <iris@tga.gov.au>
cc s22 @stryker.com>, 's22 " <(
bcc
Subject IRIS Follow-up Reports PER#s 146628, 146633, 146634, 146637, 146812

FULL HEADER

DOCUMENT NOT YET CLASSIFIED

To Whom It May Concern:

Please find attached follow up IRIS reports for incidents reported at s22 , s22 , and s22 . Please note there has not been any change to the status of these reports as we are awaiting the results of the manufacturer's investigations.

Kind Regards,

s22
RA/QA Coordinator
Stryker South Pacific-Head Office
8 Herbert Street
St. Leonards NSW Australia
Ph: s22
Fax: +61 02 94671010
Email: s22 @stryker.com

IRIS Follow Up Report 3 PER 146634.doc IRIS Follow Up Report 3 PER 146628.doc IRIS Follow Up Report 3 PER 146633.doc
IRIS Follow Up Report 3 PER 146637.doc IRIS Follow Up Report 3 PER 146812.doc

DOCUMENT NOT YET CLASSIFIED

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *	146637 Document 25
TGA DIR #	

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information * Mandatory

Report Type (select one)

Initial ☐ Follow-Up ☒ Final ☐ Trend ☐

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☐ Other ☒

A) Date of this report (dd-mm-yyyy)	11/06/2009
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	
D) Date of next report (max 30 days from A)	10/07/2009

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert St
	St. Leonards, NSW, 2065
Tel.	s22 Fax 02 9467 1010
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

none

II- Clinical Event Information * Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 **Explant Date:**

Loose Stem. Patient had stem revised due to infection.

RECEIVED
12 JUN 2009

III- Healthcare Facility Information * Mandatory

Name	s22
Address	s22
	s22
Tel	s22 Fax n/a
E-mail	n/a
Contact name at site of event	s22

IV- Device Information Primary Device * Mandatory

Generic Device Information

Device ARTG # *	152396
GMDN Code	35661
GMDN Code Text (eg catheters, central venous, peripherally inserted)	
Prosthesis, internal, joint, hip, acetabular component	

Specific Device Information

Brand Name *	TRIDENT
Model # *	TRIDENT PSL HA SOLID BACK 52mm
Catalogue #	540-11-52E
Ser. or Lot #'s	18310301
Mfr. Name*	Stryker Orthopaedics (Cork)
Contact Name *	s22
Address *	8 Herbert St.
	St. Leonards, NSW, 2065
Tel *	s22 Fax 02 9467 1010
E-mail *	s22 @stryker.com
ARTG Mfr. # *	40670

Operator of Device at Time of Event (select one)

HC Prof'nal ☒ Other Caregiver ☐ Patient ☐ N/A ☐

Usage of Device*

Single Use ☒ Reuse of Single Use ☐
Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location *

Implanted

V- Results of Mfr's Investigation * *Mandatory*

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's Invesitgation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Manufacturer was notified and awaiting investigation to be finalised before any further action is planned.

VI- Patient Information * *Mandatory as marked below*

Age (yrs, mths)		M/F		Wt. (kg)	

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

N/A

Patient history (co-morbidities & medication):

N/A

* Patient outcome:

Further details to be confirmed

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

621-10-32E TRIDENT 10? CROSSFIRE INSERT 32 mm ID

6021-0335 ACCOLADE (127 DEG)

6565-0-232 ALUMINA V40-FEMORAL HEAD 32MM, +4MM NK

VII- Other Reporting Information * *Mandatory*

Mfr/Sponsor aware of other similar events? (*number or *rate)

To be confirmed

Countries where these similar adverse events occurred:

To be confirmed

Additional Comments

N/A

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *	146637
TGA DIR #	

Document 25

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information * Mandatory

Report Type (select one)

Initial ☐ Follow-Up ☒ Final ☐ Trend ☐

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☐ Other ☒

A) Date of this report (dd-mm-yyyy)	14/05/2009
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	
D) Date of next report (max 30 days from A)	13/06/2009

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert St
	St. Leonards, NSW, 2065
Tel.	s22
Fax	02 9467 1010
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

none

II- Clinical Event Information * Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 **Explant Date:**

Loose Stem. Patient had stem revised due to infection.

RECEIVED
15 MAY 2009

III- Healthcare Facility Information * Mandatory

Name	s22
Address	s22
	s22
Tel	s22
Fax	n/a
E-mail	n/a
Contact name at site of event	s22

IV- Device Information Primary Device * Mandatory

Generic Device Information

Device ARTG # *	152396
GMDN Code	35661
GMDN Code Text (eg catheters, central venous, peripherally inserted)	
Prosthesis, internal, joint, hip, acetabular component	

Specific Device Information

Brand Name *	TRIDENT
Model # *	TRIDENT PSL HA SOLID BACK 52mm
Catalogue #	540-11-52E
Ser. or Lot #'s	18310301
Mfr. Name*	Stryker Orthopaedics (Cork)
Contact Name *	s22
Address *	8 Herbert St.
	St. Leonards, NSW, 2065
Tel *	s22
Fax	02 9467 1010
E-mail *	s22 @stryker.com
ARTG Mfr. # *	40670

Operator of Device at Time of Event (select one)

HC Prof'nal ☒ Other Caregiver ☐ Patient ☐ N/A ☐

Usage of Device*

Single Use ☒ Reuse of Single Use ☐

Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location *

Implanted

V- Results of Mfr's Investigation * Mandatory

...ufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's Invesitgation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Manufacturer was notified and awaiting investigation to be finalised before any further action is planned.

VI- Patient Information * Mandatory as marked below

Age (yrs, mths)		M/F		Wt. (kg)	

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

N/A

Patient history (co-morbidities & medication):

N/A

* Patient outcome:

Further details to be confirmed

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

621-10-32E TRIDENT 10? CROSSFIRE INSERT 32 mm ID

6021-0335 ACCOLADE (127 DEG)

6565-0-232 ALUMINA V40-FEMORAL HEAD 32MM, +4MM NK

VII- Other Reporting Information * Mandatory

Mfr/Sponsor aware of other similar events? (*number or *rate)

To be confirmed

Countries where these similar adverse events occurred:

To be confirmed

Additional Comments

N/A

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *	146637
TGA DIR #	

Document 25

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information * Mandatory

Report Type (select one)

Initial ☒ Follow-Up ☐ Final ☐ Trend ☐

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☐ Other ☒

A) Date of this report (dd-mm-yyyy)	14/04/2009
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	
D) Date of next report (max 30 days from A)	14/05/2009

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert St
	St. Leonards, NSW, 2065
Tel.	s22
Fax	02 9467 1010
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

none

II- Clinical Event Information * Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 **Explant Date:**

Loose Stem. Patient had stem revised due to infection.

RECEIVED
15 APR 2009

III- Healthcare Facility Information * Mandatory

Name	s22
Address	s22
	s22
Tel	s22
Fax	n/a
E-mail	n/a
Contact name at site of event	s22

IV- Device Information Primary Device * Mandatory

Generic Device Information

Device ARTG # *	152396
GMDN Code	35661

GMDN Code Text (eg catheters, central venous, peripherally inserted)

Prosthesis, internal, joint, hip, acetabular component

Specific Device Information

Brand Name *	TRIDENT
Model # *	TRIDENT PSL HA SOLID BACK 52mm
Catalogue #	540-11-52E
Ser. or Lot #'s	18310301
Mfr. Name*	Stryker Orthopaedics (Cork)
Contact Name *	s22
Address *	8 Herbert St.
	St. Leonards, NSW, 2065
Tel *	s22
Fax	02 9467 1010
E-mail *	s22 @stryker.com
ARTG Mfr. # *	40670

Operator of Device at Time of Event (select one)

HC Prof'nal ☒ Other Caregiver ☐ Patient ☐ N/A ☐

Usage of Device*

Single Use ☒ Reuse of Single Use ☐

Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location *

Implanted

V- Results of Mfr's Investigation * Mandatory

..ufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's Invesitgation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Manufacturer was notified and awaiting investigation to be finalised before any further action is planned.

VI- Patient Information * Mandatory as marked below

Age (yrs, mths)		M/F		Wt. (kg)	

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

N/A

Patient history (co-morbidities & medication):

N/A

* Patient outcome:

Further details to be confirmed

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

621-10-32E TRIDENT 10? CROSSFIRE INSERT 32 mm ID

6021-0335 ACCOLADE (127 DEG)

6565-0-232 ALUMINA V40-FEMORAL HEAD 32MM, +4MM NK

VII- Other Reporting Information * Mandatory

Mfr/Sponsor aware of other similar events? (*number or *rate)

To be confirmed

Countries where these similar adverse events occurred:

To be confirmed

Additional Comments

N/A

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

IRIS – Initial Risk Assessment & Data Entry Checklist

Document 25

Device Description:	Accolade Prosthesis						
Date Assessed:	8 Sept 2009	Assessed By:	s22 [redacted]				
Sample Requested:	☐ YES ☐ NO	Sample Received:	☐ YES ☐ NO	Received From:	☐ Reporter ☐ Other	Device Type:	☐ Sterile ☐ Reusable ☑ Single Use
Classification:	☐ Urgent *(48hrs)*	☐ Expedite *(5days)*	☑ Routine *(10days)*	☐ Not Investigated			
If **Not** Investigated:	Cause:	Result:	Recommendation:				
Initial Recommendation:	☑ Investigate *(to IRIS Meeting)*	☐ Information Only	☐ Refer to Surveillance				

Type of Incident

(tick more than one if necessary)

☐ Advertising	☐ Fails TGO / Standard	☐ Product Mix Up
☐ Biocompatibility	☐ Labelling/Product Info	☐ Software
☐ Contamination	☐ Material / Formulation	☐ Supply of Unlisted Device
☐ Diagnostic Inaccuracy	☑ Mechanical	☐ Other .....
☐ Electrical	☐ Packaging	

Outcome of Incident

(tick one only for each criteria)

Potential Outcome	Actual Outcome	Injured Party
☐ Death	☐ Death	☑ Patient
☐ Serious Injury	☐ Serious Injury	☐ Operator
☑ Temporary Injury	☑ Temporary / Minor	☐ Not Applicable
☐ No Injury	☐ No Injury	

Reporter Type

(Source Category)

Administrator	Clinician	Nurse
☐ Medical	☐ General Practitioner	☐ Community
☐ Lay	☐ Specialist	☐ Hospital
		☐ Private

Government Agency	Paramedical	Technical
☐ Consumer Affairs	☐ Ambulance	☐ Biomed Engineer
☐ Coroner	☐ Dentist	☐ Biomed Technician
☐ TGA - Recalls	☐ Pharmacist	☐ Clinical Technician
☐ TGA – Labs	☐ Physiotherapist	☐ Hospital Engineer
☐ TGA – GMP	☐ Radiographer	☐ Medical Physicist
☐ TGA – CAB	☐ Rehabilitation	
☐ TGA - Surveillance	☐ Other	

Other	Overseas Advice
☐ Blood Bank	☐ ECRI
☐ Competitor	☐ EU Vigilance
☐ Hospital Supply Service	☐ FDA (USA)
☐ Patient / User	☐ MDA (UK)
☑ Sponsor	☐ MDB (Canada)
☐ Other	☐ Other .....

Risk Analysis

(tick one only for each criteria)

Frequency	Severity	Detectable
☐ Frequently	☐ Life Threatening	☑ Likely
☐ Sometimes	☐ Serious	☐ Occasionally
☐ Rarely	☑ Minor	☐ Rarely
☑ Unlikely	☐ Nil	☐ Unlikely

Therapeutic Goods Administration
Device Incident Reports

Report to Sponsor

DIR /20096 — **Accolade TMZF 127? HA Hip Stem - Prosthesis, internal, joint, hip, femoral component/Howmedica Osteonics Corporation**

Exempt/Not on Artg: N

Syst/Artg No ARTG / 145594

Ecri Code: 35666 Prosthesis, internal, joint, hip, femoral component

Device: Accolade - (mfr ref: 146637)

Model No: **Batch No:** **Serial No:** 18006102

Manufacturer: Howmedica Osteonics Corporation 9211
USA

Sponsor: Stryker Australia Pty Ltd 1251
PO Box 970
ARTARMON NSW 1570 AU

Contact: s22 **Phone:** s22 **Fax:** (02) 9467 1010

Reporter Details: Confidential: No
s22

Position: Regulatory Affairs Officer

Institution: Stryker Australia
8 Herbert Street
St Leonards NSW 2065 AUST

Phone: s22

Incident Description: Implant Date: s22 .
Explant Date: N/K.

Loose Stem. Patient had stem revised due to infection.

No analysis of device was performed as it was not returned to the manufacturer for investigation.

A review of the provided x-rays by a clinician concluded "The stem has a 3 to 5 millimetre radiolucency in Gruen Zone I, II, VI and VII with a distal bony pedestal suggestive of end bearing. There is also a suggestion of subsidence consistent with loosening.

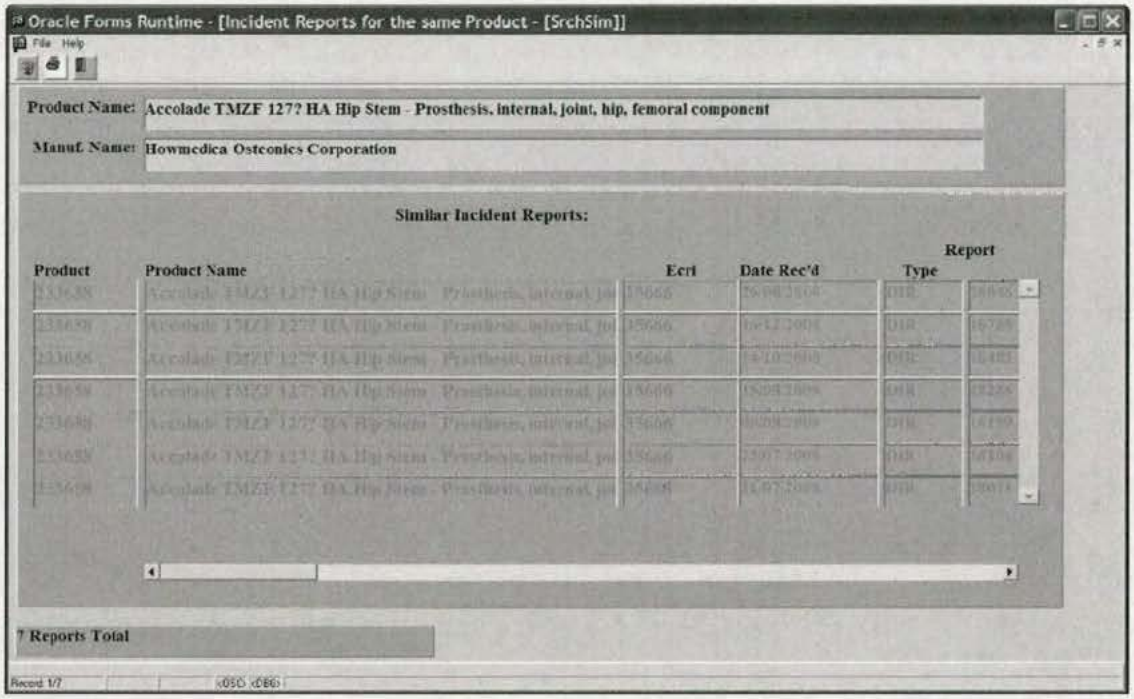
If, as stated, the revision was for "septic loosening" of the stem no prosthetic manufacture, design or material factors are involved in this clinical complication.

Similar events: None.

Report sourced from sponsor.

Date Received: 07/09/2009

***** End Of DIR / 20096 *****


Oracle Forms Runtime - [Incident Reports for the same Product - [SrchSim]]
File Help
Product Name: Accolade TMZF 127? HA Hip Stem - Prosthesis, internal, joint, hip, femoral component
Manuf. Name: Howmedica Osteonics Corporation
Similar Incident Reports:
Product
Product Name
Ecri
Date Rec'd
Report Type
7 Reports Total
Record 1/7

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Last revised: November 2008

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *	346663 Document 26
TGA DIR #	

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information * Mandatory

Report Type (select one)

Initial ☐ Follow-Up ☐ Final ☒ Trend ☐

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☒ Other ☐

A) Date of this report (dd-mm-yyyy)	08/11/2012
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	s22

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert Street St Leonards NSW 2065
Tel.	s22 Fax 02 9467 1042
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

NA

II- Clinical Event Information * Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 **Explant Date:** s22

Revsion surgery following corrosion and fretting at the head taper junction.

III- Healthcare Facility Information * Mandatory

Name	s22
Address	s22
	s22
Tel	s22 Fax NK
E-mail	NK
Contact name at site of event	s22

IV- Device Information Primary Device * Mandatory

Generic Device Information

Device ARTG # *	145594
GMDN Code	35666

GMDN Code Text (eg catheters, central venous, peripherally inserted)

Prosthesis, internal, joint, hip, femoral component

Specific Device Information

Brand Name *	ACCOLADE PLUS TMZF HIP STEM #5
Model # *	6021-0537
Software Version	NA
Ser. or Lot #'s	25807003
Mfr. Name*	Stryker Orthopaedics
Contact Name *	s22
Address *	325 Corporate Drive Mahwah NJ 07430 USA
Tel *	s22 Fax 02 9467 1042
E-mail *	s22 @stryker.com
ARTG Mfr. # *	9211

Operator of Device at Time of Event (select one)

HC Prof'nal ☐ Other Caregiver ☐ Patient ☒ N/A ☐

Usage of Device*

Single Use ☒ Reuse of Single Use ☐

Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location *

Surgeon

V- Results of Mfr's Investigation * *Mandatory*

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

No items were made available for identification or evaluation.

A review of Stryker's records indicates that the reported devices were manufactured and accepted into final stock with no relevant reported discrepancies.

A review of the packaging insert noted the following:

"PRECAUTIONS

The surgeon must caution/warn the patient of surgical risks, and made aware of possible adverse effects. The surgeon must caution/warn the patient that the device does not replicate a normal healthy joint, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device has a finite service life and may need to be replaced in the future."

The root cause cannot be determined.

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

No action is required at this time.

Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

VI- Patient Information * *Mandatory as marked below*

Age (yrs, mths)	s22	M/F	s22	Wt. (kg)	s22

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

Revision surgery.

Patient history (co-morbidities & medication):

NK

* Patient outcome:

Revision surgery.

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

Trident PSL HA Solid Back 56MM, 540-11-56F, 152396

V40 COCR LFIT HEAD 40MM/+4, 6260-9-240, 128024

TRIDENT 0 DEG INSERT 40MM, 623-00-40F, 128021

VII- Other Reporting Information * *Mandatory*

Mfr/Sponsor aware of other similar events? (*number or *rate)

0.005% rate of similar events per sales (AUS), 0.002% (WW)

Countries where these similar adverse events occurred:

Australia, Canada, United States

Additional Comments

The cup was left in-situ, however the liner was changed.

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (02) 6203 1713

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Guidance on how to complete this form

NB: Sections or fields marked with an ✱ are mandatory minimum requirements for a complete report

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time)

If some of the applicable information required in this form is not available by the time the deadline (2, 10, or 30 days) for the particular category of report has expired, a report should be submitted containing all the available information. Such a report should be marked "initial" in Section I.

The form may be filled long-hand or electronically using Word® - simply <tab> to the appropriate field and type the required information. The form can then be submitted by fax or mail or saved and attached to an email and sent to the email address provided. *This instructions page should not be included in the submission (This section is not protected and may be deleted).*

The following provides some guidance on what information is required in some parts of the form. It is envisaged that the fields not mentioned in this explanatory note are self-explanatory.

Section I – Administrative Information

Report Type, Initial: The first report that the reporter (sponsor, manufacturer) is submitting about an event. The reporter expects to have to submit further information about the event at a later date.

Report Type, Follow-up: Additional information to a previous (initial, follow-up or final) report.

Report Type, Final: The last report that the reporter expects to submit about an event. It is possible for the final report to also be the initial report about an event. If so, please indicate by crossing both boxes.

Report Type, Trend: Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called "trend" reports.

Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

Report Category, Death/Serious Injury: Choose this category where the event subject of the report resulted in the death or serious injury of a patient, user or other person.

Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

Section II – Clinical Event Information

Provide as much detail about the event as possible, including what happened and what lead up to the vent (eg the type of surgery or treatment) If the device is implantable, provide date of implant & explant.

Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event: Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

Section VII - Other Reporting Information

Mfr/Sponsor aware of other similar events? (# or rate): If there have been other similar events reported to either the sponsor or the manufacturer enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold for example12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none, write "0" or "nil".

When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.

A final report is considered to be a complete report and therefore all fields marked with an ✱ must be completed.

Last revised: November 2008

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *	Document 27 346663
TGA DIR #	

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information * Mandatory

Report Type (select one)

Initial ☒ Follow-Up ☐ Final ☐ Trend ☐

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☒ Other ☐

A) Date of this report (dd-mm-yyyy)	24/09/2012
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	s22

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert Street St Leonards NSW 2065
Tel.	s22
Fax	02 9467 1042
E-mail	s22@stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

NA

II- Clinical Event Information * Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 **Explant Date:** s22

Revsion surgery following corrosion and fretting at the head taper junction.

III- Healthcare Facility Information * Mandatory

Name	s22
Address	s22
	s22
Tel	s22
Fax	NK
E-mail	NK
Contact name at site of event	s22

IV- Device Information Primary Device * Mandatory

Generic Device Information

Device ARTG # *	145594
GMDN Code	35666

GMDN Code Text (eg catheters, central venous, peripherally inserted)

Prosthesis, internal, joint, hip, femoral component

Specific Device Information

Brand Name *	ACCOLADE PLUS TMZF HIP STEM #5
Model # *	6021-0537
Software Version	NA
Ser. or Lot #'s	25807003
Mfr. Name*	Stryker Orthopaedics
Contact Name *	s22
Address *	325 Corporate Drive Mahwah NJ 07430 USA
Tel *	s22
Fax	02 9467 1042
E-mail *	s22@stryker.com
ARTG Mfr. # *	9211

Operator of Device at Time of Event (select one)

HC Prof'nal ☐ Other Caregiver ☐ Patient ☒ N/A ☐

Usage of Device*

Single Use ☒ Reuse of Single Use ☐

Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location *

Surgeon

V- Results of Mfr's Investigation * *Mandatory*

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's investigation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Pending Manufacturer's investigation

VI- Patient Information * *Mandatory as marked below*

Age (yrs, mths)	s22	M/F	s22	Wt. (kg)	s22

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

NK

Patient history (co-morbidities & medication):

NK

* Patient outcome:

NK

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

Trident PSL HA Solid Back 56MM, 540-11-56F, 152396

V40 COCR LFIT HEAD 40MM/+4, 6260-9-240, 128024

TRIDENT 0 DEG INSERT 40MM, 623-00-40F, 128021

VII- Other Reporting Information * *Mandatory*

Mfr/Sponsor aware of other similar events? (*number or *rate)

NK

Countries where these similar adverse events occurred:

NK

Additional Comments

The cup was left in-situ, however the liner was changed.

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (02) 6203 1713

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Guidance on how to complete this form

NB: Sections or fields marked with an ✱ are mandatory minimum requirements for a complete report

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time)

If some of the applicable information required in this form is not available by the time the deadline (2, 10, or 30 days) for the particular category of report has expired, a report should be submitted containing all the available information. Such a report should be marked "initial" in Section I.

The form may be filled long-hand or electronically using Word® - simply <tab> to the appropriate field and type the required information. The form can then be submitted by fax or mail or saved and attached to an email and sent to the email address provided. *This instructions page should not be included in the submission (This section is not protected and may be deleted).*

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Report Type, Trend: Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called "trend" reports.

Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

Report Category, Death/Serious Injury: Choose this category where the event subject of the report resulted in the death or serious injury of a patient, user or other person.

Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

Section II – Clinical Event Information

Provide as much detail about the event as possible, including what happened and what lead up to the vent (eg the type of surgery or treatment) If the device is implantable, provide date of implant & explant.

Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event: Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

Section VII - Other Reporting Information

Mfr/Sponsor aware of other similar events? (# or rate): If there have been other similar events reported to either the sponsor or the manufacturer enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold for example12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none, write "0" or "nil".

When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.

A final report is considered to be a complete report and therefore all fields marked with an ✱ must be completed.

Document 28

Email Message

From:	s22 @stryker.com]
To:	IRIS [SMTP:IRIS@tga.gov.au]
Cc:	
Sent:	24/09/2012 at 12:21 PM
Received:	24/09/2012 at 1:00 PM
Subject:	Initial IRIS
Attachments:	Inital IRIS 348019- UNITRAX HEAD.docx Inital IRIS 346663 - Accolade Plus TMZF.docx

To whom it may concern,

Please see attached IRIS for your approval.

Thank you,

s22

Regulatory Affairs Co-ordinator

Stryker South Pacific

St Leonards, NSW 2065, Australia

t: s22

f: +61 (0)2 9467 1042

s22 @stryker.com

- Inital IRIS 348019- UNITRAX HEAD.docx - Inital IRIS 346663 - Accolade Plus TMZF.docx

IRIS: Medical Device Incident Report Investigation Scheme

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Last revised: November 2008

Mfr report # *	348019
TGA DIR #	

I– Administrative Information *Mandatory

Report Type (select one)

Initial [X] Follow-Up [ ] Final [ ] Trend [ ]

Report Category

S Pblc Hlth Threat [ ] Death/Serious Injury [X] Other [ ]

A) Date of this report (dd-mm-yyyy)	24/09/2012
B) Date of adverse event (dd-mm-yyyy)	21/09/2012
C) Date mfr aware (dd-mm-yyyy)	21/09/2012

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert Street St Leonards NSW 2065
Tel.	s22
Fax	02 9467 1042
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

NA

II– Clinical Event Information *Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: NK Explant Date: s22

Revision surgery.

III– Healthcare Facility Information *Mandatory

Name	s22
Address	s22
	s22

Tel	s22	Fax	s22
E-mail	NK		
Contact name at site of event	s22		

IV– Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	128024
GMDN Code	44855
GMDN Code Text (eg catheters, central venous, peripherally inserted)	

Prosthesis, hip, internal, femoral head component

Specific Device Information

Brand Name *	UNITRAX Head
Model # *	NK
Software Version	NA
Ser. or Lot #'s	NK
Mfr. Name*	Stryker Orthopaedics
Contact Name *	s22
Address *	325 Corporate Drive
	Mahwah NJ 07430 USA

Tel *	s22	Fax	02 9467 1042
E-mail *	s22@stryker.com		
ARTG Mfr. # *	9211		

Operator of Device at Time of Event (select one)

HC Prof'nal [ ] Other Caregiver [ ] Patient [X] N/A [ ]

Usage of Device*

Single Use [X] Reuse of Single Use [ ]

Reuse of Reusable [ ] Reserviced/Refurbished [ ]

Device Disposition/Current Location *

In situ.

V– Results of Mfr's Investigation *Mandatory

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's investigation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Pending Manufacturer's investigation

VI– Patient Information *Mandatory as marked below

Age (yrs, mths)	NK	M/F	NK	Wt. (kg)	NK

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

NK

Patient history (co-morbidities & medication):

NK

* Patient outcome:

NK

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

32MM +12 LFIT V40 HEAD, 6260-9-432, 128024

VII– Other Reporting Information *Mandatory

Mfr/Sponsor aware of other similar events? (*number or *rate)

NK

Countries where these similar adverse events occurred:

NK

Additional Comments

32mm +12 size head implanted & left insitu.

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (02) 6203 1713

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Guidance on how to complete this form

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Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

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Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

Section II – Clinical Event Information

Provide as much detail about the event as possible, including what happened and what lead up to the vent (eg the type of surgery or treatment) If the device is implantable, provide date of implant & explant.

Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

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IRIS: Medical Device Incident Report Investigation Scheme

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Last revised: November 2008

Mfr report # *	346663
TGA DIR #	

I– Administrative Information *Mandatory

Report Type (select one)

Initial [X] Follow-Up [ ] Final [ ] Trend [ ]

Report Category

S Pblc Hlth Threat [ ] Death/Serious Injury [X] Other [ ]

A) Date of this report (dd-mm-yyyy)	24/09/2012
B) Date of adverse event (dd-mm-yyyy)	17/09/2012
C) Date mfr aware (dd-mm-yyyy)	17/09/2012

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert Street St Leonards NSW 2065
Tel.	s22
Fax	02 9467 1042
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

NA

II– Clinical Event Information *Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: [s22] Explant Date: [s22]

Revsion surgery following corrosion and fretting at the head taper junction.

III– Healthcare Facility Information *Mandatory

Name	s22
Address	s22

	s22		
Tel	s22	Fax	
E-mail	NK		
Contact name at site of event		s22	

IV- Device Information Primary Device * *Mandatory*

Generic Device Information

Device ARTG # *	145594
GMDN Code	35666
GMDN Code Text (eg catheters, central venous, peripherally inserted)	Prosthesis, internal, joint, hip, femoral component

Specific Device Information

Brand Name *	ACCOLADE PLUS TMZF HIP STEM #5
Model # *	6021-0537
Software Version	NA
Ser. or Lot #'s	25807003
Mfr. Name*	Stryker Orthopaedics
Contact Name *	s22
Address *	325 Corporate Drive Mahwah NJ 07430 USA
Tel *	s22
Fax	9467 1042
E-mail *	s22@stryker.com
ARTG Mfr. # *	9211

Operator of Device at Time of Event (select one)

HC Prof'nal [ ] Other Caregiver [ ] Patient [X] N/A [ ]

Usage of Device*

Single Use [X] Reuse of Single Use [ ]

Reuse of Reusable [ ] Reserviced/Refurbished [ ]

Device Disposition/Current Location *

Surgeon

V- Results of Mfr's Investigation * *Mandatory*

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's investigation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Pending Manufacturer's investigation

VI- Patient Information * *Mandatory as marked below*

Age (yrs, mths)	s22	M/F	s22	Wt. (kg)	s22

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

NK

Patient history (co-morbidities & medication):

NK

* Patient outcome:

NK

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

Trident PSL HA Solid Back 56MM, 540-11-56F, 152396

V40 COCR LFIT HEAD 40MM/+4, 6260-9-240, 128024

TRIDENT 0 DEG INSERT 40MM, 623-00-40F, 128021

VII– Other Reporting Information *Mandatory*

Mfr/Sponsor aware of other similar events? (*number or *rate)

NK

Countries where these similar adverse events occurred:

NK

Additional Comments

The cup was left in-situ, however the liner was changed.

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (02) 6203 1713

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Report Type, Final: The last report that the reporter expects to submit about an event. It is possible for the final report to also be the initial report about an event. If so, please indicate by crossing both boxes.

Report Type, Trend: Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called "trend" reports.

Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

Report Category, Death/Serious Injury: Choose this category where the event subject of the report resulted in the death or serious injury of a patient, user or other person.

Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

Section II – Clinical Event Information

Provide as much detail about the event as possible, including what happened and what lead up to the vent (eg the type of surgery or treatment) If the device is implantable, provide date of implant & explant.

Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event: Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

Section VII - Other Reporting Information

Mfr/Sponsor aware of other similar events? (# or rate): If there have been other similar events reported to either the sponsor or the manufacturer enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold for example12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none, write "0" or "nil".

When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.

A final report is considered to be a complete report and therefore **all fields marked with an ✱ must be completed**.

Document 29

Email Message

From:	
To:	
Cc:	
Sent:	19/11/2012 at 4:19 PM
Received:	19/11/2012 at 4:19 PM
Subject:	Final IRISes
Attachments:	Final IRIS PER 342960 - Trident Cup & Liner.docx Final IRIS PER 343253 - LFIT V40 Head.docx Final IRIS 349206 - DELTA V-40 CERAMIC HEAD.docx Final IRIS 348022 - Mitch Cup.docx Final IRIS 345950 - Mitch Cup v1.1.docx Final IRIS 346663 - Accolade Plus TMZF.docx

To whom it may concern,

Please see attached final IRIS reports for your review.

Thank you,

s22

RAQA Co-ordinator

Stryker South Pacific

St Leonards, NSW, Australia

t: s22

f: +61 (0)2 9467 1042

s22 @stryker.com

- Final IRIS PER 342960 - Trident Cup & Liner.docx - Final IRIS PER 343253 - LFIT V40 Head.docx - Final IRIS 349206 - DELTA V-40 CERAMIC HEAD.docx - Final IRIS 348022 - Mitch Cup.docx - Final IRIS 345950 - Mitch Cup v1.1.docx - Final IRIS 346663 - Accolade Plus TMZF.docx

IRIS: Medical Device Incident Report Investigation Scheme

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Last revised: November 2008

Mfr report # *	346663
TGA DIR #	

I– Administrative Information *Mandatory

Report Type (select one)

Initial [ ] Follow-Up [ ] Final [X] Trend [ ]

Report Category

S Pblc Hlth Threat [ ] Death/Serious Injury [X] Other [ ]

A) Date of this report (dd-mm-yyyy)	08/11/2012
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	s22

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert Street St Leonards NSW 2065
Tel.	s22
Fax	02 9467 1042
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

NA

II– Clinical Event Information *Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: [s22] Explant Date: [s22]

Revsion surgery following corrosion and fretting at the head taper junction.

III– Healthcare Facility Information *Mandatory

Name	s22
Address	s22

	s22		
Tel	s22	Fax	
E-mail	NK		
Contact name at site of event		s22	

IV- Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	145594
GMDN Code	35666
GMDN Code Text (eg catheters, central venous, peripherally inserted)	Prosthesis, internal, joint, hip, femoral component

Specific Device Information

Brand Name *	ACCOLADE PLUS TMZF HIP STEM #5
Model # *	6021-0537
Software Version	NA
Ser. or Lot #'s	25807003
Mfr. Name*	Stryker Orthopaedics
Contact Name *	s22
Address *	325 Corporate Drive Mahwah NJ 07430 USA
Tel *	s22
Fax	9467 1042
E-mail *	s22@stryker.com
ARTG Mfr. # *	9211

Operator of Device at Time of Event (select one)

HC Prof'nal [ ] Other Caregiver [ ] Patient [X] N/A [ ]

Usage of Device*

Single Use [X] Reuse of Single Use [ ]

Reuse of Reusable [ ] Re-serviced/Refurbished [ ]

Device Disposition/Current Location *

Surgeon

V- Results of Mfr's Investigation *Mandatory

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

No items were made available for identification or evaluation.

A review of Stryker's records indicates that the reported devices were manufactured and accepted into final stock with no relevant reported discrepancies.

A review of the packaging insert noted the following:

"PRECAUTIONS

The surgeon must caution/warn the patient of surgical risks, and made aware of possible adverse effects. The surgeon must caution/warn the patient that the device does not replicate a normal healthy joint, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device has a finite service life and may need to be replaced

in the future."

The root cause cannot be determined.

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

No action is required at this time.

Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

VI- Patient Information *Mandatory as marked below

Age (yrs, mths)	M/F	Wt. (kg)
s22	s22	s22

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

Revision surgery.

Patient history (co-morbidities & medication):

NK

* Patient outcome:

Revision surgery.

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

Trident PSL HA Solid Back 56MM, 540-11-56F, 152396

V40 COCR LFIT HEAD 40MM/+4, 6260-9-240, 128024

TRIDENT 0 DEG INSERT 40MM, 623-00-40F, 128021

VII- Other Reporting Information *Mandatory

Mfr/Sponsor aware of other similar events? (*number or *rate)

0.005% rate of similar events per sales (AUS), 0.002% (WW)

Countries where these similar adverse events occurred:

Australia, Canada, United States

Additional Comments

The cup was left in-situ, however the liner was changed.

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (02) 6203 1713

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Guidance on how to complete this form

NB: Sections or fields marked with an ✱ are mandatory minimum requirements for a complete report

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time)

If some of the applicable information required in this form is not available by the time the deadline (2, 10, or 30 days) for the particular category of report has expired, a report should be submitted containing all the available information. Such a report should be marked "initial" in Section I.

The form may be filled long-hand or electronically using Word® - simply <tab> to the appropriate field and type the required information. The form can then be submitted by fax or mail or saved and attached to an email and sent to the email address provided. *This instructions page should not be included in the submission (This section is not protected and may be deleted).*

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Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

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GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

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Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with

manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event: Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

Section VII - Other Reporting Information

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When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.

A final report is considered to be a complete report and therefore all fields marked with an * must be completed.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22

File Reference: 2012/022102

Stryker Australia Pty Ltd
PO Box 970
ARTARMON NSW 1570

Attention: s22

DEVICE INCIDENT REPORT DIR 28963 - ARTG # 145594 - Prosthesis, internal, joint, hip, femoral component

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact me on s22 .

Yours sincerely

s22

Incident Report and Investigation Scheme
Device Vigilance and Monitoring
Office of Product Review
Therapeutic Goods Administration

30/11/2012

DIR 28963 - ARTG # 145594 - Prosthesis, internal, joint, hip, femoral component

Reporter Reference #: 346663

Date of Adverse Event:
s22

Date of Initial Report:
24/09/2012

ARTG #:
145594

Brand Name:
Accolade Plus TMZF Hip Stem

Device Class:
Class III

Model #:
6021-0537

Serial #:
25807003

Software Version:

Batch #:

Lot #:

Manufacturer:
Howmedica Osteonics Corporation [9211]

Sponsor:
Stryker Australia Pty Ltd [1251]
PO Box 970

ARTARMON NSW 1570

Fax:
(02) 9467 1042

Contact Name:
s22

Phone:
s22

Email:
s22 @stryker.com

Reporter:
s22

Stryker Australia
8 Herbert Street
St Leonards New South Wales 2065

Email:
s22 @stryker.com

Confidential: No

Phone: s22
Fax: 02 9467 1042

Date of Implant:
s22

Date of Explant:
s22

Clinical Event Information:
Revision surgery following corrosion and fretting at the head taper junction.

Patient Outcome/Consequences:
Revision surgery.

Device Analysis Results:
No items were made available for identification or evaluation.

A review of Stryker's records indicates that the reported devices were manufactured and accepted into final stock with no relevant reported discrepancies.

A review of the packaging insert noted the following:
"PRECAUTIONS - The surgeon must caution/warn the patient of surgical risks, and made aware of possible adverse effects. The surgeon must caution/warn the patient that the device does not replicate a normal healthy joint, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device has a finite service life and may need to be replaced in the future."

The root cause cannot be determined.

Corrective/Preventative Actions:
No action is required at this time. Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

Details of Similar Events:
0.005% rate of similar events per sales (AUS), 0.002% (WW).

Number of Similar Events:

Rate of Similar Events:
0.005% (Aus) 0.002% (WW)

Countries Similar Events Also Occurred:
Australia, Canada, United States.

Type of Problem (Level 1)	Type of Problem (Level 2)
Material	Degrade

Cause of Problem (Level 1)	Cause of Problem (Level 2)
Unable to confirm complaint	Device not returned

Outcome of Investigation

Reviewed, for Trending Purposes Only

Summary of Investigation:
No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Date Completed:
30/11/2012

***** End of DIR 28963 *****

TOTAL	10818	291925	1216742	0.89 (0.87, 0.91)

Please note this is not a survivorship analysis. If further analysis is required please contact Ann Tomkins

Type of Revision of Primary Hip Replacement using the Accolade Stem for the Entire Time Period

Type of Revision	N	%
Femoral Component	136	34.3
Acetabular Component	93	23.4
Head/Insert	61	15.4
THR (Femoral/Acetabular)	60	15.1
Cement Spacer	20	5.0
Head Only	14	3.5
Minor Components	5	1.3
Insert Only	3	0.8
Removal of Prostheses	2	0.5
Bipolar Head and Femoral	2	0.5
Bipolar Only	1	0.3
TOTAL	397	100.0

Reason for Revision of Primary Hip Replacement using the Accolade Stem for the Entire Time Period

	Accolade		
Revision Diagnosis	N	% Revision	% Primary
Loosening/Lysis	147	37.0	1.5
Infection	69	17.4	0.7
Fracture	62	15.6	0.6
Prosthesis Dislocation	48	12.1	0.5
Pain	15	3.8	0.1
Metal Sensitivity	11	2.8	0.1
Leg Length Discrepancy	6	1.5	0.1
Malposition	6	1.5	0.1
Instability	5	1.3	0.0
Heterotopic Bone	3	0.8	0.0
Chondrolysis/Acetab. Erosion	2	0.5	0.0
Wear Acetabular Insert	2	0.5	0.0
Incorrect Sizing	1	0.3	0.0
Osteonecrosis	1	0.3	0.0
Tumour	1	0.3	0.0
Wear Head	1	0.3	0.0
Other	17	4.3	0.2
N Revision	397	100.0	4.0
N Primary	10016		

AUSTRALIAN ORTHOPAEDIC ASSOCIATION
NATIONAL JOINT REPLACEMENT REGISTRY

Regulatory Bodies

Tree View | Catalogue Number Search

60215537 Search

Please enter at least 3 characters

Stryker Australia: 60215537
Accolade TMZF Plus Hip Stem #5.5

Stryker Australia: 60215537
TMZF Plus neck Angle V40 Hip Stem #5.5 NK LNTH 37mm STM LNTH 133mm

Organisation: Stryker Australia
Model: Accolade
Prosthesis Type: Stem

60200030	*60215537*	*Howmedica*	*Accolade TMZF Plus Hip Stem*
60200030	*60215537*	*Howmedica/Osteonics*	*Accolade TMZF Plus Hip Stem*
60200030	*60215537*	*Stryker Orthopaedics*	*TMZF Plus neck Angle V40 Hip Stem*
60570230	60580740	How medica/Osteonics	Accolade C Cemeted Hip Stem
60570335	60580435	How medica	Accolade Cemeted Hip Stem
60770130	60770840	Stryker Orthopaedics	Fracture Hip Stem CoCr Plasma not HA
67210330	67210737	Stryker Orthopaedics	127° Neck Angle V40 Hip Stem

Contract

From: January 2001
To: December 2013
Filter

Primary Procedures: Includes all primary procedures entered up to close of business **last working day** or for the period selected using the year/month filter.

Revisions of Primary: Includes all initial revisions of primary procedures currently identified by the NJRR up to close of business **last working day**.

Please note the revisions listed include only initial revisions of the identified primary procedures. These initial revisions may have occurred at any time since the primary procedure up to the current time.

Number of Primary Hip Procedures per Year using the Accolade Stem and Number of Subsequent Revisions

Year	Primary Procedures	Revisions of Primary
2001	45	3
2002	117	6
2003	343	28
2004	589	37
2005	961	44
2006	1388	60
2007	1617	83
2008	1219	52
2009	1171	36
2010	949	22
2011	849	18
2012	704	8
2013	64	.
TOTAL	**10016**	**397**

Revision Rates of Primary Hip Replacement using the Accolade Stem for the Entire Time Period

Model	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95%CI)
Accolade	397	10016	46804	0.85 (0.77, 0.94)
TOTAL	**397**	**10016**	**46804**	**0.85 (0.77, 0.94)**

National - Revision Rates of Primary Hip Replacement (1 Sept 1999 to 31 Dec 2011)

Hip Class	N Revised	N Total	Obs. Years	Revisions/100 Obs. Years (95% CI)
Unipolar Monoblock	855	22929	55623	1.54 (1.44, 1.64)
Unipolar Modular	597	19157	44317	1.35 (1.24, 1.46)
Bipolar	381	11599	40791	0.93 (0.84, 1.03)
Total Resurfacing	880	14901	82314	1.07 (1.00, 1.14)
Total Conventional	8105	223339	993697	0.82 (0.80, 0.83)

Document 32

Email Message

From:	s22 @tga.gov.au]
To:	IRIS [SMTP:IRIS@TTRA]
Cc:	
Sent:	09/01/2013 at 4:58 PM
Received:	09/01/2013 at 4:58 PM
Subject:	Emailing: Initial IRIS 332142 - Accolade TMZF Stem.docx [SEC=UNCLASSIFIED]
Attachments:	Initial IRIS 332142 - Accolade TMZF Stem.docx.docx

Your message is ready to be sent with the following file or link attachments:
Initial IRIS 332142 - Accolade TMZF Stem.docx

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

s22
Departmental Officer
Signal Investigation Unit - Devices
Office of Product Review

Phone: s22
Fax: 02 6203 1713
Email: s22 @tga.gov.au

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
www.tga.gov.au

- Initial IRIS 332142 - Accolade TMZF Stem.docx.docx

IRIS: Medical Device Incident Report Investigation Scheme

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Last revised: November 2008

Mfr report # *	332142
TGA DIR #	

I– Administrative Information *Mandatory

Report Type (select one)

Initial [X] Follow-Up [ ] Final [ ] Trend [ ]

Report Category

S Pblc Hlth Threat [ ] Death/Serious Injury [ ] Other [X]

A) Date of this report (dd-mm-yyyy)	19/12/2012
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	s22

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert Street St Leonards NSW 2065
Tel.	s22
Fax	02 9467 1042
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

NA

II– Clinical Event Information *Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: [s22] Explant Date: [s22]

Revision surgery planned for pain and reported inflammation in hip.

III– Healthcare Facility Information *Mandatory

Name	s22
Address	s22
	s22

Tel	s22	Fax	s22
E-mail	NK		
Contact name at site of event	s22		

IV- Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	145594
GMDN Code	35666
GMDN Code Text (eg catheters, central venous, peripherally inserted)	

Prosthesis, internal, joint, hip, femoral component

Specific Device Information

Brand Name *	Accolade TMZF Stem
Model # *	6021-5537
Software Version	NA
Ser. or Lot #'s	26115905
Mfr. Name*	Stryker Orthopaedics
Contact Name *	s22
Address *	325 Corporate Drive Mahwah NJ 07430 USA

Tel *	s22	Fax	201 831-6283
E-mail *	s22@stryker.com		
ARTG Mfr. # *	9211		

Operator of Device at Time of Event (select one)

HC Prof'nal [X] Other Caregiver [ ] Patient [ ] N/A [ ]

Usage of Device*

Single Use [X] Reuse of Single Use [ ]

Reuse of Reusable [ ] Reserviced/Refurbished [ ]

Device Disposition/Current Location *

Discarded.

V- Results of Mfr's Investigation *Mandatory

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

An event regarding an Accolade stem loosening was reported. The event was not confirmed.

No devices were returned.

Device history review indicated that all reported devices were manufactured and accepted into final stock with no reported discrepancies.

A review of the instructions for use (IFU) packaged with the Accolade stem, noted the following applicable warnings;

Press-Fit Application. Secure fixation at the time of surgery is critical to the success of the procedure. The femoral component stem must press fit into the femur, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture of the femur can occur during seating of the prosthesis. Bone stock must be adequate to support the

device.

Implants can loosen or migrate due to trauma or loss of fixation.

The root cause of this specific event could not be determined with the limited information provided.

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

No action is required at this time.

Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

VI- Patient Information *Mandatory as marked below

Age (yrs, mths)	s22	M/F	s22	Wt. (kg)	s22

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

Revision surgery.

Patient history (co-morbidities & medication):

NK

* Patient outcome:

Patient revised.

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

Std MITCH TRH Cp Sz 54/60, MAC-9988-5460, 144011

MITCH TRH Md Hd Sz 54+4, MMH-9988-1454, 138942

VII- Other Reporting Information *Mandatory

Mfr/Sponsor aware of other similar events? (*number or *rate)

0.012 similar events per sales (AUS)

Countries where these similar adverse events occurred:

Australia

Additional Comments

NA

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (02) 6203 1713

By e-mail: iris@tga.gov.au

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Report Type, Final: The last report that the reporter expects to submit about an event. It is possible for the final report to also be the initial report about an event. If so, please indicate by crossing both boxes.

Report Type, Trend: Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called "trend" reports.

Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

Report Category, Death/Serious Injury: Choose this category where the event subject of the report resulted in the death or serious injury of a patient, user or other person.

Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

Section II – Clinical Event Information

Provide as much detail about the event as possible, including what happened and what lead up to the vent (eg the type of surgery or treatment) If the device is implantable, provide date of implant & explant.

Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event: Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

Section VII - Other Reporting Information

Mfr/Sponsor aware of other similar events? (# or rate): If there have been other similar events reported to either the sponsor or the manufacturer enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold for example12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none, write "0" or "nil".

When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.

A final report is considered to be a complete report and therefore all fields marked with an * must be completed.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6232 8605 Email: info@tga.gov.au **www.tga.gov.au**

Document 33

Email Message

From:	
To:	
Cc:	
Sent:	08/03/2013 at 2:44 PM
Received:	08/03/2013 at 2:45 PM
Subject:	Final IRIS
Attachments:	Final IRIS - PER 334029 Tibial Comp Hinge Knee.docx Final IRIS - PER 335198 MISC. INSTRUMENTS - UPPER TRAY.docx Final IRIS - PER 336014 Exeter Stem.docx Final IRIS 309530 - M-1 Cot.docx Final IRIS 314063 - ABG Modular stem.docx Final IRIS 332142 - Accolade TMZF Stem.docx Final IRIS 343460 - Trident Cup and X3 Liner.docx Final IRIS 353860 - Duracon Baseplate.docx Final IRIS 354635- Tritanium Cluster Cup.docx Final IRIS 355332- TRIATHLON KNEE.docx

To Whom it May Concern,

Â

Please find attached a number of Final IRIS.

Â

Kind regards,

Â

s22 [redacted]

RA Intern

Stryker South Pacific

St Leonards, NSW, Australia

t: s22 [redacted]

f: +61 (0)2 9467 1042

s22 [redacted]@stryker.com

Â - Final IRIS - PER 334029 Tibial Comp Hinge Knee.docx - Final IRIS - PER 335198 MISC. INSTRUMENTS - UPPER TRAY.docx - Final IRIS - PER 336014 Exeter Stem.docx - Final IRIS 309530 - M-1 Cot.docx - Final IRIS 314063 - ABG Modular stem.docx - Final IRIS 332142 - Accolade TMZF Stem.docx - Final IRIS 343460 - Trident Cup and X3 Liner.docx - Final IRIS 353860 - Duracon Baseplate.docx - Final IRIS 354635- Tritanium Cluster Cup.docx - Final IRIS 355332- TRIATHLON KNEE.docx

IRIS: Medical Device Incident Report Investigation Scheme

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Last revised: November 2008

Mfr report # *	332142
TGA DIR #	

I– Administrative Information *Mandatory

Report Type (select one)

Initial [ ] Follow-Up [ ] Final [X] Trend [ ]

Report Category

S Pblc Hlth Threat [ ] Death/Serious Injury [ ] Other [X]

A) Date of this report (dd-mm-yyyy)	08/03/2013
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	s22

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert Street St Leonards NSW 2065

Tel. s22 Fax

E-mail s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

NA

II– Clinical Event Information *Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 Explant Date: s22

Revision surgery planned for pain and reported inflammation in hip.

III– Healthcare Facility Information *Mandatory

Name	s22
Address	s22
	s22

Tel	s22	Fax	s22
E-mail	NK		
Contact name at site of event	s22		

IV- Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	145594
GMDN Code	35666
GMDN Code Text (eg catheters, central venous, peripherally inserted)	

Prosthesis, internal, joint, hip, femoral component

Specific Device Information

Brand Name *	Accolade TMZF Stem
Model # *	6021-5537
Software Version	NA
Ser. or Lot #'s	26115905
Mfr. Name*	Stryker Orthopaedics
Contact Name *	s22
Address *	325 Corporate Drive Mahwah NJ 07430 USA

Tel *	s22	Fax	201 831-6283
E-mail *	s22@stryker.com		
ARTG Mfr. # *	9211		

Operator of Device at Time of Event (select one)

HC Prof'nal [X] Other Caregiver [ ] Patient [ ] N/A [ ]

Usage of Device*

Single Use	[X]	Reuse of Single Use	[ ]
Reuse of Reusable	[ ]	Re-serviced/Refurbished	[ ]

Device Disposition/Current Location *

Discarded.

V- Results of Mfr's Investigation *Mandatory

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

An event regarding an Accolade stem loosening was reported. The event was not confirmed.

No devices were returned.

Device history review indicated that all reported devices were manufactured and accepted into final stock with no reported discrepancies.

A review of the instructions for use (IFU) packaged with the Accolade stem, noted the following applicable warnings;

Press-Fit Application. Secure fixation at the time of surgery is critical to the success of the procedure. The femoral component stem must press fit into the femur, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture of the femur can occur during seating of the prosthesis. Bone stock must be adequate to support the

device.

Implants can loosen or migrate due to trauma or loss of fixation.

The root cause of this specific event could not be determined with the limited information provided.

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

No action is required at this time. The event did not involve a product problem indicating a non-conformity, trend or unanticipated hazard. Product Surveillance will continue to monitor complaints of this type for adverse trends.

Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

VI- Patient Information * *Mandatory as marked below*

Age (yrs, mths)	M/F	Wt. (kg)
s22	s22	s22

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

Revision surgery.

Patient history (co-morbidities & medication):

NK

* Patient outcome:

Patient revised.

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

Std MITCH TRH Cp Sz 54/60, MAC-9988-5460, 144011

MITCH TRH Md Hd Sz 54+4, MMH-9988-1454, 138942

VII- Other Reporting Information * *Mandatory*

Mfr/Sponsor aware of other similar events? (*number or *rate)

0.0114 similar events per sales (AUS)

0.0005 similar events per sales (WW)

Countries where these similar adverse events occurred:

Australia, United States

Additional Comments

NA

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (02) 6203 1713

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Guidance on how to complete this form

NB: Sections or fields marked with an ✱ are mandatory minimum requirements for a complete report

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time)

If some of the applicable information required in this form is not available by the time the deadline (2, 10, or 30 days) for the particular category of report has expired, a report should be submitted containing all the available information. Such a report should be marked "initial" in Section I.

The form may be filled long-hand or electronically using Word® - simply <tab> to the appropriate field and type the required information. The form can then be submitted by fax or mail or saved and attached to an email and sent to the email address provided. *This instructions page should not be included in the submission (This section is not protected and may be deleted).*

The following provides some guidance on what information is required in some parts of the form. It is envisaged that the fields not mentioned in this explanatory note are self-explanatory.

Section I – Administrative Information

Report Type, Initial: The first report that the reporter (sponsor, manufacturer) is submitting about an event. The reporter expects to have to submit further information about the event at a later date.

Report Type, Follow-up: Additional information to a previous (initial, follow-up or final) report.

Report Type, Final: The last report that the reporter expects to submit about an event. It is possible for the final report to also be the initial report about an event. If so, please indicate by crossing both boxes.

Report Type, Trend: Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called "trend" reports.

Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

Report Category, Death/Serious Injury: Choose this category where the event subject of the report resulted in the death or serious injury of a patient, user or other person.

Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

Section II – Clinical Event Information

Provide as much detail about the event as possible, including what happened and what lead up to the vent (eg the type of surgery or treatment) If the device is implantable, provide date of implant & explant.

Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event: Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

Section VII - Other Reporting Information

Mfr/Sponsor aware of other similar events? (# or rate): If there have been other similar events reported to either the sponsor or the manufacturer enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold for example12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none, write "0" or "nil".

When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.

A final report is considered to be a complete report and therefore **all fields marked with an ✱ must be completed**.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22

File Reference: 2013/000575

Stryker Australia Pty Ltd
PO Box 970
ARTARMON NSW 1570

Attention: s22

DEVICE INCIDENT REPORT DIR 29811 - ARTG # 145594 - Prosthesis, internal, joint, hip, femoral component

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact me on s22

Yours sincerely

s22

Incident Report and Investigation Scheme
Device Vigilance and Monitoring
Office of Product Review
Therapeutic Goods Administration

20/03/2013

DIR 29811 - ARTG # 145594 - Prosthesis, internal, joint, hip, femoral component

Reporter Reference #: 332142

Date of Adverse Event:
s22

Date of Initial Report:
19/12/2012

ARTG #:
145594

Brand Name:
Accolade TMZF Stem

Device Class:
Class III

Model #:
6021-5537

Serial #:
26115905

Software Version:

Batch #:

Lot #:

Manufacturer:
Howmedica Osteonics Corporation [9211]

Sponsor:
Stryker Australia Pty Ltd [1251]
PO Box 970

ARTARMON NSW 1570

Fax:
02 9467 1042

Contact Name:
s22

Phone:
s22

Email:
s22 @stryker.com

Reporter:
s22

Stryker Australia
8 Herbert Street
St Leonards New South Wales 2065

Email:
s22 @stryker.com

Confidential: No

Phone: s22
Fax: 02 9467 1042

Date of Implant:
s22

Date of Explant:
s22

Other Devices Involved:
Std MITCH TRH Cp Sz 54/60, MAC-9988-5460, 144011.
MITCH TRH Md Hd Sz 54+4, MMH-9988-1454, 138942.

Clinical Event Information:
Revision surgery planned for pain and reported inflammation in hip.

Patient Outcome/Consequences:
Patient revised.

Device Analysis Results:
An event regarding an Accolade stem loosening was reported. The event was not confirmed.
No devices were returned.

Device history review indicated that all reported devices were manufactured and accepted into final stock with no reported discrepancies.
A review of the instructions for use (IFU) packaged with the Accolade stem, noted the following applicable warnings;
Press-Fit Application. Secure fixation at the time of surgery is critical to the success of the procedure. The femoral component stem must press fit into the femur, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture of the femur can occur during seating of the prosthesis. Bone stock must be adequate to support the device.

Implants can loosen or migrate due to trauma or loss of fixation.

The root cause of this specific event could not be determined with the limited information provided.

Corrective/Preventative Actions:
No action is required at this time.
Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

Details of Similar Events:
0.0114 similar events per sales (AUS).
0.0005 similar events per sales (WW).

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:
Australia, United States.

Type of Problem (Level 1)	Type of Problem (Level 2)
Other	Other
Patient Factors	

Cause of Problem (Level 1)	Cause of Problem (Level 2)
Unable to confirm complaint	Investigation did not reveal a root cause

Outcome of Investigation

Reviewed, for Trending Purposes Only

Summary of Investigation:
National Joint Replacement Register (NJRR) was reviewed, no further action at this stage , the TGA will continue to monitor.

Date Completed:
20/03/2013

***** End of DIR 29811 *****

AUSTRALIAN ORTHOPAEDIC ASSOCIATION
NATIONAL JOINT REPLACEMENT REGISTRY

Regulatory Bodies

Tree View | Catalogue Number Search

5401154 Search

Please enter at least 4 characters

Stryker Australia: 5401154F
Trident PSL Acetabular Shell

Stryker Australia: 5401154K
Trident PSL Acetabular Shell

Stryker Australia: 5401154F
Trident AD With PureFix HA Acetabular Shell

Stryker Australia: 5401154F
PSL HA Solid Back Acetabular Shell 54mm F

Organisation: Stryker Australia
Model: Trident (Shell)
Prosthesis Type: Shell

10168915CL	10168915CL	Stryker Orthopaedics	Hemispherical Shell
5000142A	5000174J	How medica/Osteonics	Hemispherical Solid Shell
5000142A	5000174J	Stryker Orthopaedics	Hemispherical Solid Shell
5000344A	5000366H	Stryker Orthopaedics	Tritanium Hemispherical Solid Shell
5001142A	5001174J	How medica/Osteonics	Hemispherical HA Solid Shell
5001142A	5001174J	Stryker Orthopaedics	Hemispherical HA Solid Shell
5020142A	5020174J	How medica/Osteonics	Hemispherical Cluster Hole Shell
5020344A	5020366H	Stryker Orthopaedics	Tritanium Hemispherical Cluster Hole Shell
5021142A	5021174J	How medica/Osteonics	Hemispherical HA Cluster Hole Shell
5021142A	5021174J	Stryker Orthopaedics	Hemispherical HA Cluster Hole Shell
5081142A	5081174J	How medica/Osteonics	Titanium HA Multi-Hole Cup
5081142A	5081174J	Stryker Orthopaedics	Titanium HA Multi-Hole Cup
5090254E	5090280J	How medica/Osteonics	Titanium Revision Hemispherical Cluster Hole Shell
5090254E	5090280J	Stryker Orthopaedics	Titanium Revision Hemispherical Cluster Hole Shell
5401140A	*5401174K*	*Howmedica*	*PSL Titanium HA No Hole Cup*
5401140A	*5401174K*	*Howmedica/Osteonics*	*PSL Titanium HA No Hole Cup*
5401140A	*5401174K*	*Osteonics*	*PSL Titanium HA No Hole Cup*
5401140A	*5401174K*	*Stryker Orthopaedics*	*PSL Titanium HA No Hole Cup*
5421140A	5421172J	How medica	PSL Titanium HA Cluster Hole Cup
5421140A	5421172J	How medica/Osteonics	PSL Titanium HA Cluster Hole Cup
5421140A	5421172J	Osteonics	PSL Titanium HA Cluster Hole Cup
5421140A	5421172J	Stryker Orthopaedics	PSL Titanium HA Cluster Hole Cup

Contract

From: January 2000
To: December 2013
Filter

Primary Procedures: Includes all primary procedures entered up to close of business **last working day** or for the period selected using the year/month filter.

Revisions of Primary: Includes all initial revisions of primary procedures currently identified by the NJRR up to close of business **last working day.**

Please note the revisions listed include only initial revisions of the identified primary procedures. These initial revisions may have occurred at any time since the primary procedure up to the current time.

Number of Primary Hip Procedures per Year using the Trident (Shell) Shell and Number of Subsequent Revisions

Year	Primary Procedures	Revisions of Primary
2000	11	.
2001	472	20
2002	1011	48
2003	1425	72
2004	1524	60
2005	1671	38
2006	1706	59
2007	1821	65
2008	1447	43
2009	1607	31
2010	1385	26
2011	1384	20
2012	1454	22
2013	876	4
TOTAL	**17794**	**508**

Revision Rates of Primary Hip Replacement using the Trident (Shell) Shell for the Entire Time Period

Model	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Trident (Shell)	508	17794	96451	0.53 (0.48, 0.57)
TOTAL	**508**	**17794**	**96451**	**0.53 (0.48, 0.57)**

National - Revision Rates of Primary Hip Replacement (1 Sept 1999 to 31 Dec 2011)

Hip Class	N Revised	N Total	Obs. Years	Revisions/100 Obs. Years (95% CI)
Unipolar Monoblock	855	22929	55623	1.54 (1.44, 1.64)
Unipolar Modular	597	19157	44317	1.35 (1.24, 1.46)
Bipolar	381	11599	40791	0.93 (0.84, 1.03)
Total Resurfacing	880	14901	82314	1.07 (1.00, 1.14)
Total Conventional	8105	223339	993697	0.82 (0.80, 0.83)
TOTAL	**10818**	**291925**	**1216742**	**0.89 (0.87, 0.91)**

Please note this is not a survivorship analysis. If further analysis is required please contact the AOA National Joint Replacement Registry

Type of Revision of Primary Hip Replacement using the Trident (Shell) Shell for the Entire Time Period

Type of Revision	N	%
Femoral Component	183	36.0
Head/Insert	123	24.2
Acetabular Component	84	16.5
THR (Femoral/Acetabular)	55	10.8
Cement Spacer	30	5.9
Head Only	20	3.9
Minor Components	6	1.2
Insert Only	5	1.0
Removal of Prostheses	2	0.4
TOTAL	**508**	**100.0**

Reason for Revision of Primary Hip Replacement using the Trident (Shell) Shell for the Entire Time Period

	Trident (Shell)		
Revision Diagnosis	**N**	**% Revision**	**% Primary**
Loosening/Lysis	117	23.0	0.7
Infection	116	22.8	0.7
Prosthesis Dislocation	111	21.9	0.6
Fracture	99	19.5	0.6
Pain	13	2.6	0.1
Leg Length Discrepancy	8	1.6	0.0
Instability	7	1.4	0.0
Malposition	6	1.2	0.0
Implant Breakage Acetabular Insert	4	0.8	0.0
Implant Breakage Stem	4	0.8	0.0
Incorrect Sizing	2	0.4	0.0
Wear Acetabular Insert	2	0.4	0.0
Implant Breakage Acetabular	1	0.2	0.0
Implant Breakage Head	1	0.2	0.0
Metal Sensitivity	1	0.2	0.0
Other	16	3.1	0.1
N Revision	**508**	**100.0**	**2.9**
N Primary	**17794**		

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *	308279
TGA DIR #	

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information * *Mandatory*

Report Type (select one)

Initial ☒ Follow-Up ☐ Final ☐ Trend ☒

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☒ Other ☐

A) Date of this report (dd-mm-yyyy)	27/02/2012
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	s22

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert Street St Leonards NSW 2065

Tel.	s22	Fax	02 9467 1042
E-mail	s22@stryker.com		

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

NA

II- Clinical Event Information * *Mandatory*

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: s22 **Explant Date:** s22

The acetabular cup had came away from the cement mantel and slipped down out of Acetabulum. The patient required unanticipated revision surgery due to pain and difficulty walking.

III- Healthcare Facility Information * *Mandatory*

Name	s22		
Address	s22		
Tel	s22	Fax	08 9346 8470
E-mail	NK		
Contact name at site of event	s22		

IV- Device Information Primary Device * *Mandatory*

Generic Device Information

Device ARTG # *	152396
GMDN Code	35661

GMDN Code Text (eg catheters, central venous, peripherally inserted)

Prosthesis, internal, joint, hip, acetabular component

Specific Device Information

Brand Name *	Trident PSL HA Solid Back 54MM
Model # *	540-11-54F
Software Version	NA
Ser. or Lot #'s	34877201
Mfr. Name*	Howmedica Osteonics Corporation (USA)
Contact Name *	s22
Address *	325 Corporate Drive Mahwah NJ 07430 USA

Tel *	s22	Fax	+ 201 831-6283
E-mail *	s22@Stryker.com		
ARTG Mfr. # *	9211		

Operator of Device at Time of Event (select one)

HC Prof'nal ☐ Other Caregiver ☐ Patient ☒ N/A ☐

Usage of Device*

Single Use ☒ Reuse of Single Use ☐

Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location *

Surgeon

V- Results of Mfr's Investigation * *Mandatory*

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's investigation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Pending Manufacturer's investigation

VI- Patient Information * *Mandatory as marked below*

Age (yrs, mths)	s22	M/F	s22	Wt. (kg)	s22

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

NK

Patient history (co-morbidities & medication):

NK

* Patient outcome:

NK

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

TRIDENT 10° X3 INSERT 32mm ID, 623-10-32F, ARTG # 128021

VII- Other Reporting Information * *Mandatory*

Mfr/Sponsor aware of other similar events? (*number or *rate)

NK

Countries where these similar adverse events occurred:

NK

Additional Comments

During primary surgery the surgeon had difficulty inserting the PSL cup.

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (02) 6203 1713

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Guidance on how to complete this form

NB: Sections or fields marked with an ✱ are mandatory minimum requirements for a complete report

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time)

If some of the applicable information required in this form is not available by the time the deadline (2, 10, or 30 days) for the particular category of report has expired, a report should be submitted containing all the available information. Such a report should be marked "initial" in Section I.

The form may be filled long-hand or electronically using Word® - simply <tab> to the appropriate field and type the required information. The form can then be submitted by fax or mail or saved and attached to an email and sent to the email address provided. *This instructions page should not be included in the submission (This section is not protected and may be deleted).*

The following provides some guidance on what information is required in some parts of the form. It is envisaged that the fields not mentioned in this explanatory note are self-explanatory.

Section I – Administrative Information

Report Type, Initial: The first report that the reporter (sponsor, manufacturer) is submitting about an event. The reporter expects to have to submit further information about the event at a later date.

Report Type, Follow-up: Additional information to a previous (initial, follow-up or final) report.

Report Type, Final: The last report that the reporter expects to submit about an event. It is possible for the final report to also be the initial report about an event. If so, please indicate by crossing both boxes.

Report Type, Trend: Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called "trend" reports.

Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

Report Category, Death/Serious Injury: Choose this category where the event subject of the report resulted in the death or serious injury of a patient, user or other person.

Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

Section II – Clinical Event Information

Provide as much detail about the event as possible, including what happened and what lead up to the vent (eg the type of surgery or treatment) If the device is implantable, provide date of implant & explant.

Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event: Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

Section VII - Other Reporting Information

Mfr/Sponsor aware of other similar events? (# or rate): If there have been other similar events reported to either the sponsor or the manufacturer enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold for example12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none, write "0" or "nil".

When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.

A final report is considered to be a complete report and therefore all fields marked with an ✱ must be completed.

Document 37

Email Message

From:	
To:	
Cc:	
Sent:	27/02/2012 at 5:05 PM
Received:	27/02/2012 at 5:05 PM
Subject:	IRIS Reports: PER 308281, 308856 & 308279
Attachments:	Initial IRIS 308279 - Trident Cemented PSL Cup.docx Initial IRIS 308281 - Core Mirco Drill.docx Inital IRIS 308856 - ACCOLADE (127 DEG) 1.1.docx

To whom it may concern,

Please see attached IRIS reports for PER 308281, 308856 & 308279.

Kind regards,

s22

Regulatory Affairs Co-ordinator

Stryker South Pacific

8 Herbert Street

St Leonards, NSW 2065

Australia

t: s22

f: +61 (0)2 9467 1042

s22 @stryker.com

- Initial IRIS 308279 - Trident Cemented PSL Cup.docx - Initial IRIS 308281 - Core Mirco Drill.docx - Inital IRIS 308856 - ACCOLADE (127 DEG) 1.1.docx

IRIS: Medical Device Incident Report Investigation Scheme

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Last revised: November 2008

Mfr report # *	308279
TGA DIR #	

I– Administrative Information *Mandatory

Report Type (select one)

Initial [X] Follow-Up [ ] Final [ ] Trend [X]

Report Category

S Pblc Hlth Threat [ ] Death/Serious Injury [X] Other [ ]

A) Date of this report (dd-mm-yyyy)	27/02/2012
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	s22

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert Street St Leonards NSW 2065
Tel.	s22
Fax	02 9467 1042
E-mail	s22 @stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

NA

II– Clinical Event Information *Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: [s22] Explant Date: [s22]

The acetabular cup had came away from the cement mantel and slipped down out of Acetabulum. The patient required unanticipated revision surgery due to pain and difficulty walking.

III– Healthcare Facility Information *Mandatory

Name	s22
Address	s22

Tel	s22	Fax	02 9346 8470
E-mail	NK		
Contact name at site of event	s22		

IV– Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	152396
GMDN Code	35661
GMDN Code Text (eg catheters, central venous, peripherally inserted)	Prosthesis, internal, joint, hip, acetabular component

Specific Device Information

Brand Name *	Trident PSL HA Solid Back 54MM
Model # *	540-11-54F
Software Version	NA
Ser. or Lot #'s	34877201
Mfr. Name*	Howmedica Osteonics Corporation (USA)
Contact Name *	s22
Address *	325 Corporate Drive Mahwah NJ 07430 USA

Tel *	+s22	Fax	201 831-6283
E-mail *	s22 @Stryker.com		
ARTG Mfr. # *	9211		

Operator of Device at Time of Event (select one)

HC Prof'nal [ ] Other Caregiver [ ] Patient [X] N/A [ ]

Usage of Device*

Single Use [X] Reuse of Single Use [ ]

Reuse of Reusable [ ] Re-serviced/Refurbished [ ]

Device Disposition/Current Location *

Surgeon

V– Results of Mfr's Investigation *Mandatory

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending Manufacturer's investigation

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Pending Manufacturer's investigation

VI– Patient Information *Mandatory as marked below

Age (yrs, mths)	s22	M/F	s22	Wt. (kg)	s22

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient: NK
Patient history (co-morbidities & medication): NK
* Patient outcome: NK
* List of other devices involved in the event: *if other implants involved – list brand, model & ARTG #* TRIDENT 10° X3 INSERT 32mm ID, 623-10-32F, ARTG # 128021
VII– Other Reporting Information *Mandatory
Mfr/Sponsor aware of other similar events? (*number or *rate) NK
Countries where these similar adverse events occurred: NK
Additional Comments
During primary surgery the surgeon had difficulty inserting the PSL cup.

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (02) 6203 1713

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Guidance on how to complete this form

NB: Sections or fields marked with an ✱ are mandatory minimum requirements for a complete report

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time)

If some of the applicable information required in this form is not available by the time the deadline (2, 10, or 30 days) for the particular category of report has expired, a report should be submitted containing all the available information. Such a report should be marked "initial" in Section I.

The form may be filled long-hand or electronically using Word® - simply <tab> to the appropriate field and type the required information. The form can then be submitted by fax or mail or saved and attached to an email and sent to the email address provided. *This instructions page should not be included in the submission (This section is not protected and may be deleted).*

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Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

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Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

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Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event: Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

Section VII - Other Reporting Information

Mfr/Sponsor aware of other similar events? (# or rate): If there have been other similar events reported to either the sponsor or the manufacturer enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold for example12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none, write "0" or "nil".

When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.

A final report is considered to be a complete report and therefore **all fields marked with an ✱ must be completed**.

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22

File Reference: 2012/023261

Stryker Australia Pty Ltd
PO Box 970
ARTARMON NSW 1570

Attention: s22

DEVICE INCIDENT REPORT DIR 29257 - ARTG # 152396 - Prosthesis, internal, joint, hip, acetabular component

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact me on s22 .

Yours sincerely

s22

Incident Report and Investigation Scheme
Device Vigilance and Monitoring
Office of Product Review
Therapeutic Goods Administration

14/01/2014

DIR 29257 - ARTG # 152396 - Prosthesis, internal, joint, hip, acetabular component

Reporter Reference #: 308279

Date of Adverse Event:
s22

Date of Initial Report:
27/02/2012

ARTG #:
152396

Brand Name:
Trident PSL HA Solid Back

Device Class:
Class III

Model #:
540-11-54F

Serial #:
34877201

Software Version:

Batch #:

Lot #:

Manufacturer:
Howmedica Osteonics Corporation [9211]

Sponsor:
Stryker Australia Pty Ltd [1251]
PO Box 970

ARTARMON NSW 1570

Fax:
(02) 9467 1042

Contact Name:
s22

Phone:
s22

Email:
s22 @stryker.com

Reporter:
s22

Stryker Australia Pty Ltd
8 Herbert Street
St Leonards New South Wales 2065

Email:
s22 @stryker.com

Confidential: No

Phone: s22
Fax: 02 9467 1042

Date of Implant:
s22

Date of Explant:
s22

Other Devices Involved:
TRIDENT 10° X3 INSERT 32mm ID, 623-10-32F, ARTG # 128021

Clinical Event Information:
The acetabular cup had came away from the cement mantel and slipped down out of Acetabulum. The patient required unanticipated revision surgery due to pain and difficulty walking.

Patient Outcome/Consequences:
Patient successfully revised.

Device Analysis Results:
An event regarding loosening of a cemented Trident shell was reported. The event was confirmed.
Visual Inspection: The returned Trident Shell has a 40mm x 15mm area of cement on its peripheral rim on one side of the device. There are sporadic areas of fibrous bone ongrowth on the back-side of the shell. There are also many shiny wear marks on the back-side, indicating micro-motion during in-vivo use. The returned head and liner are unremarkable apart scratching which was most likely caused during explantation.
Based on the results of the packaging insert and surgical protocol review, cementing a Trident shell is not an indication for use, therefore further investigation is not required. Stryker Orthopaedics can only address approved indications for use.
A review of Stryker's records indicates that the reported devices were manufactured and accepted into final stock with no reported discrepancies.

Corrective/Preventative Actions:
No action is required t this time. The event did not involve a product problem indicating a non-conformity, adverse trend or unanticipated hazard.
Product surveillance will continue to monitor for trends.
Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

Details of Similar Events:
0.00008 similar events per sales (WW), 0.0006 (AUS).

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:
Australia.

Type of Problem (Level 1)	Type of Problem (Level 2)
Mechanical	Unintended Movement
Cause of Problem (Level 1)	**Cause of Problem (Level 2)**
Not product related	Off-label, unapproved or contra-indicated use

Outcome of Investigation

Reviewed, for Trending Purposes Only

Summary of Investigation:
This report describes the use of an uncemented prosthesis being used with cement. Subsequently the cement mantle has failed causing the implant to move. The use of this implant in this manner is user error.

The TGA monitors use as well as safety and performance of medical devices. This type of problem is known to occur occasionally.

No further investigation will occur at this time.

Date Completed:
03/01/2014

***** End of DIR 29257 *****

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Email Message

From:	s22 [redacted] @tga.gov.au]
To:	
Cc:	s22 [redacted] @stryker.com]
Sent:	14/01/2014 at 9:04 AM
Received:	
Subject:	DIR 29257 - Completion Letter [SEC=UNCLASSIFIED]
Attachments:	DIR 29257 - Completion Letter.pdf

Medical Device Incident Report Investigation Scheme (IRIS)
Office of Product Review
Therapeutic Goods Administration (TGA)
Email: iris@tga.gov.au
Fax: 02 6232 1713
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers can now update their reports by logging into the Medical Device Incident Reporting (MDIR) system using their eBS user name and password.
The MDIR system allows users to submit initial, follow-up and final reports and to review reports already submitted to the TGA.
A user guide and FAQ are available from the âTrainingâ section of the eBS portal, or from the TGA website.
*To ensure you are receiving all your correspondence, please update your contact details with the IRIS team. Please note: Only employees in your company who are listed on the ebs can be contacted about incident reports.

You will need this to access the IRIS database, please see attached form:

https://www.ebs.tga.gov.au/ebs/home.nsf/0/9538f48466eb6eadca25764a0002b931/$FILE/eBS%20Access%20Request%20Form.pdf

If you have any issues please contact eBs on 1800 010 624.

Online reporting ~
Sponsors / Manufacturers:
http://www.tga.gov.au/safety/problem-device-report-industry.htm
Medical Device Users:
http://www.tga.gov.au/safety/problem-device-report-user.htm

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22

File Reference: 2012/023261

Stryker Australia Pty Ltd
PO Box 970
ARTARMON NSW 1570

Attention: s22

DEVICE INCIDENT REPORT DIR 29257 - ARTG # 152396 - Prosthesis, internal, joint, hip, acetabular component

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact me on s22

Yours sincerely

s22

Incident Report and Investigation Scheme
Device Vigilance and Monitoring
Office of Product Review
Therapeutic Goods Administration

14/01/2014

DIR 29257 - ARTG # 152396 - Prosthesis, internal, joint, hip, acetabular component

Reporter Reference #: 308279

Date of Adverse Event:
s22

Date of Initial Report:
27/02/2012

ARTG #:
152396

Brand Name:
Trident PSL HA Solid Back

Device Class:
Class III

Model #:
540-11-54F

Serial #:
34877201

Software Version:

Batch #:

Lot #:

Manufacturer:
Howmedica Osteonics Corporation [9211]

Sponsor:
Stryker Australia Pty Ltd [1251]
PO Box 970

ARTARMON NSW 1570

Contact Name:
s22

Phone:
s22

Fax:
(02) 9467 1042

Email:
s22 @stryker.com

Reporter:
s22

Stryker Australia Pty Ltd
8 Herbert Street
St Leonards New South Wales 2065

Email:
s22 @stryker.com

Confidential: No

Phone: s22
Fax: 02 9467 1042

Date of Implant:
s22

Date of Explant:
s22

Other Devices Involved:
TRIDENT 10° X3 INSERT 32mm ID, 623-10-32F, ARTG # 128021

Clinical Event Information:
The acetabular cup had came away from the cement mantel and slipped down out of Acetabulum. The patient required unanticipated revision surgery due to pain and difficulty walking.

Patient Outcome/Consequences:
Patient successfully revised.

Device Analysis Results:
An event regarding loosening of a cemented Trident shell was reported. The event was confirmed. Visual Inspection: The returned Trident Shell has a 40mm x 15mm area of cement on its peripheral rim on one side of the device. There are sporadic areas of fibrous bone ongrowth on the back-side of the shell. There are also many shiny wear marks on the back-side, indicating micro-motion during in-vivo use. The returned head and liner are unremarkable apart scratching which was most likely caused during explantation.
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A review of Stryker's records indicates that the reported devices were manufactured and accepted into final stock with no reported discrepancies.

Corrective/Preventative Actions:
No action is required t this time. The event did not involve a product problem indicating a non-conformity, adverse trend or unanticipated hazard.
Product surveillance will continue to monitor for trends.
Stryker reserves the right to re-evaluate this investigation if additional relevant information becomes available.

Details of Similar Events:
0.00008 similar events per sales (WW), 0.0006 (AUS).

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:
Australia.

Type of Problem (Level 1)	Type of Problem (Level 2)
Mechanical	Unintended Movement
Cause of Problem (Level 1)	**Cause of Problem (Level 2)**
Not product related	Off-label, unapproved or contra-indicated use

Outcome of Investigation

Reviewed, for Trending Purposes Only

Summary of Investigation:
This report describes the use of an uncemented prosthesis being used with cement. Subsequently the cement mantle has failed causing the implant to move. The use of this implant in this manner is user error.

The TGA monitors use as well as safety and performance of medical devices. This type of problem is known to occur occasionally.

No further investigation will occur at this time.

Date Completed:
03/01/2014

***** End of DIR 29257 *****

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Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

Form Date: 08/12/2014
SIGNED

DIR : 20 ID : 295808

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
36008		705649	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22	08/12/2014
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
30/11/2015	08/12/2014		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
09/12/2015	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Revision Surgery due to infection.

Clinical Event Information:

Revision Surgery due to infection.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22	s22	s22

Patient Focused Corrective Action Taken:

Revision surgery – Washout and debridment on s22 and all implants removed on s22

Patient History:

Document 40

NK

Patient Outcome/Consequences:

Procedure completed successfully.

Other Devices Involved:

V40 CoCr Lfit Head – Cat No: 6260-9-044
Trident PSL HA Cluter – Cat No: 542-11-56F
X3 Polyer Liner

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Principal - Regulatory Affairs		Stryker	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	02 9467 1042
Mobile:	**Email:**		**Last External Submission By:**
	s22 @stryker.com		s22 _1251 - 30/11/2015 16:42

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			Yes
Search Reporter By Surname:	**Initial Reporter #:**		
s22			
Title:	**First Name:**	**Surname:**	
s22	s22	s22	
Position:		**Company/Institution:**	
s22		s22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**

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s22	s22	s22	s22
Postcode:	Phone:	Fax:	Mobile:
s22			
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35666
GMDN / UMDN Text:		Brand Name:	
Prosthesis, internal, joint, hip, femoral component		Accolade Hip Stem, Size 5.5, 127 degree	

Initial Device Description:

Accolade Hip Stem, Size 5.5, 127 degree

Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
60215537	NA	NA	14575402
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation		9211	325 Corporate Drive
Address 2:	Town/Suburb:	State/Province:	Country:
	Mahwah	NJ	United States

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Postcode:	Phone:	Fax:	
07430	s22	02 9467 1042	
Email:		**Manufacturer Informed:**	**Date Aware of Adverse Event:**
s22 @stryker.com		Yes	s22
Contact Title:	**Contact First Name:**	**Contact Surname:**	
Mr	s22	s22	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Postcode:**	**Phone:**
Fax:	**Email:**		**Supplier Informed:**
Date of Supplier Contact:	**Contact Title:**	**Contact First Name:**	**Contact Surname:**
Contact Phone:	**Contact Fax:**		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
01/12/2015	s22	Yes	Yes	☑
Sample Received:	**Sterile:**	**Reusable:**	**Single Use:**	**Potential Effect:**
No	Yes	No	Yes	Serious Injury
Actual Effect:	**Injured Party:**			**Risk Frequency:**
Serious Injury	Patient			Sometimes
Risk Severity:	**Risk Detectability:**	**Classification:**	**Investigated:**	**Date of DIRE Meeting:**
Serious	Unlikely	Not Investigated	No	
DIRE Meeting Notes:				

Document 40

The device has not been highlighted as an implant of concern through the NJRR – Monitor

Sponsor Information Section

Search Sponsors:	Name:		Client #:
1251	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	02 9467 1042

Email:

s22 [redacted] @stryker.com

Investigation Information Section

Device Analysis Results:

A material analysis was performed and no material or manufacturing issues were observed on the device. A review of the devices history and complaints showed that all devices for the reported lot (of which no other events have been reported) were manufacturer and accepted into final stock with no reported discrepancies.The exact cause of the event however could not be determined because insufficient information was provided. Additional information, including additional medical records and x-rays are needed to fully investigate the event. If further information becomes available this investigation will be re-opened.

Corrective/Preventative Actions:

No action is required at this time as there is no indication to suggest a product non-conformity or unanticipated hazard. Product Surveillance will continue to monitor for trends.

Details of Similar Events:

Number of similar events = [redacted]
Number of devices sold worldwide = 7215
Similar Event Rate % = 0.0139

Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

United States

Additional Comments:

NA
DIR closed 9/12/2015

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Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text
211868	Howmedica Osteonics Corporation	Stryker Australia Pty Ltd	LFIT V40 FEMORAL HEAD - Metallic femoral head prosthesis	0X0MRA	6260-9-044	Metallic femoral head prosthesis
152442	Howmedica Osteonics Corporation	Stryker Australia Pty Ltd	Trident PSL HA Cluster Actebular Shell - Prosthesis, internal, joint, hip, acetabular component	27398201	542-11-56F	Acetabulum prosthesis

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

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Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes	

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Other	Other	Infection	

Investigation Problem Causes

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Device not returned		

Investigation Outcomes

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

National Joint Replacement Register (NJRR) was reviewed, no further action at this stage, the TGA will continue to monitor.

Flow Details : DIR-REQ - Device Incident Request : 48981

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach

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48981	DIR-REQ		Closed	s22	OPR Administration User	09/12/2015	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	09/12/2015 13:04:39	
Comment		

Created By Theta Technologies - 08/12/2014 10:40:54

Template Revision Released by s22 on 25/06/2015 15:11:06

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Form Date: 03/06/2014
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 20 ID : 278038

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
34311		530779	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22 [redacted]	03/06/2014
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
30/11/2015	02/06/2014		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
09/12/2015			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Stem subsidence by 2.5 cm and patient reported thigh pain.

Clinical Event Information:

Stem subsidence by 2.5 cm and patient reported thigh pain.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
s22 [redacted]	s22 [redacted]	s22 [redacted]

Patient Focused Corrective Action Taken:

Removal of Accolade TMZF stem and 32mm standard LFIT V40 head and revision to Exeter Stem and LFIT 32mm V40 +4 head

Patient History:

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NK

Patient Outcome/Consequences:

Patient successfully revised

Other Devices Involved:

6260-9-132 32MM STD LFIT V40 HEAD

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
Mr	s22	s22	
Position:		**Company/Institution:**	
Principal - Regulatory Affairs		Stryker	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
8 Herbert Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	s22	02 9467 1042
Mobile:	**Email:**		**Last External Submission By:**
	s22 @stryker.com		s22 _1251 - 30/11/2015 14:26

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			No
Search Reporter By Surname:	**Initial Reporter #:**		
s22			
Title:	**First Name:**	**Surname:**	
s22	s22	s22	
Position:		**Company/Institution:**	
s22		s22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
s22		s22	s22

Postcode:	Phone:	Fax:	Mobile:
s22	s22		

Email:

s22

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		145594	145594

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	35666

GMDN / UMDN Text:	Brand Name:
Prosthesis, internal, joint, hip, femoral componen	Accolade Stem size 3.5

Initial Device Description:

Accolade Stem size 3.5

Usage of Device:	Software Version:
Single Use	

Model #:	Serial #:	Batch #:	Lot #:
6021-3535	N/K	N/K	41955104

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Howmedica Osteonics Corporation	9211	325 Corporate Drive

Address 2:	Town/Suburb:	State/Province:	Country:
	Mahwah	NJ	United States

Postcode:	Phone:	Fax:

07430	s22		
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
s22 @stryker.com		Yes	s22
Contact Title:	Contact First Name:	Contact Surname:	
Mr	s22	s22	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
30/11/2015	s22	Yes	Yes	☑
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	Yes	No	Yes	Serious Injury
Actual Effect:	Injured Party:			Risk Frequency:
Serious Injury	Patient			Rarely
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Serious	Unlikely	Not Investigated	No	

DIRE Meeting Notes:

The device has not been highlighted as an implant of concern through the NJRR – Monitor

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Sponsor Information Section

Search Sponsors:	Name:		Client #:
stryker	Stryker Australia Pty Ltd		1251
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 970		ARTARMON
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1570	s22 [redacted]	(02) 9467 1042
Email:			
s22 [redacted] @stryker.com			

Investigation Information Section

Device Analysis Results:

Examination of the returned device showed evidence of fibrous on-growth on the stem's surface. Furthermore, all devices for the reported lot (of which there were no similar events reported) were manufactured and accepted into final stock with no reported discrepancies. However,the exact cause of the event could not be determined because insufficient information was received. Further information such as x-rays, operative reports, patient history & follow-up notes are needed to investigate this event further and if this information becomes available, this investigation will be reopened

Corrective/Preventative Actions:

No action is required at this time as there is no indication to suggest a product non-conformity or unanticipated hazard. Product Surveillance will continue to monitor for trends.

Details of Similar Events:

Number of similar events s22 [redacted]
Number of devices sold worldwide = 36143
Similar Event Rate % = 0.00277

Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

United States

Additional Comments:

NA
DIR closed 9/12/2015

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text
211868	Howmedica Osteonics Corporation	Stryker Australia Pty Ltd	LFIT V40 FEMORAL HEAD - Metallic femoral head prosthesis	44997202	6260-9-132	Metallic femoral head prosthesis

Related DIR Information - Click **New** to begin entering information.

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes

List of Problem Type Codes - Click **[N]** to begin entering information.

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Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Mechanical	Unintended Movement		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Investigation did not reveal a root cause		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

National Joint Replacement Register (NJRR) was reviewed, no further action at this stage, the TGA will continue to monitor.

Flow Details : DIR-REQ - Device Incident Request : 46449

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
46449	DIR-REQ		Closed	s22	OPR Administration User	09/12/2015	Normal	0

Signature Details

Role	IRIS Investigator

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User	s22 [redacted]	
Signed At	09/12/2015 12:19:45	
Comment		

Created By Theta Technologies - 02/06/2014 15:45:09

Template Revision Released by s22 [redacted] on 25/06/2015 15:11:06

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22

File Reference: 2012/008562

Stryker Australia Pty Ltd
PO Box 970
ARTARMON NSW 1570

Attention: s22

DEVICE INCIDENT REPORT DIR 26109 - ARTG # 152396 - Prosthesis, internal, joint, hip, acetabular component

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact me on s22 .

Yours sincerely

s22

Incident Report and Investigation Scheme
Device Vigilance and Monitoring
Office of Product Review
Therapeutic Goods Administration

04/04/2012

DIR 26109 - ARTG # 152396 - Prosthesis, internal, joint, hip, acetabular component

Reporter Reference #: 267217

Date of Adverse Event:
s22

Date of Initial Report:
18/07/2011

ARTG #:
152396

Brand Name:
Ceramic Liner

Device Class:
Class III

Model #:

Serial #:
N/K

Software Version:

Batch #:
N/K

Lot #:
N/K

Manufacturer:
Howmedica Osteonics Corporation [9211]

Sponsor:
Stryker Australia Pty Ltd [1251]
PO Box 970

ARTARMON NSW 1570

Fax:

Contact Name:
s22

Phone:
s22

Email:
s22 @stryker.com

Reporter:
s22

Stryker Australia
8 Herbert Street
St Leonards New South Wales 2065

Email:
s22 @stryker.com

Confidential: No

Phone: s22
Fax: 02 9467 1042

Other Devices Involved:
N/A

Clinical Event Information:
Following patient fall, cup had moved which subsequently resulted in sublaxation. The ceramic liner was replaced and a Biolox ceramic femoral head with a longer neck was implanted.

Patient Outcome/Consequences:
Revision surgery it was noted that the Trident cup was solid and unable to be moved, indicating that the cup was placed in a vertical position at the patients primary surgery.

Device Analysis Results:
An event regarding dislocation of a Trident hip was reported on s22 . The event was not confirmed.
The exact cause of the event could not be determined however the reported dislocation in this obese patient may be due to the vertical positioning of the shell, as noted in Strykers technical report for dislocation. It is noted in the review of the provided x-rays by a clinical professional that the shell on the right hand side is vertically placed. It is not possible to determine if the shell was placed in this position at the primary surgery or if it was displaced after the reported trauma the patient suffered. No further investigation for this event is possible at this time because no devices and insufficient information was received by Stryker Orthopaedics. If devices and/or additional information

Corrective/Preventative Actions:
No action is required at this time as there was no indication of a product non-conformance or adverse trend. Product Surveillance will monitor for trends.

Details of Similar Events:
Unable to calculate, no Lot or Catalogue # provided.

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

Type of Problem (Level 1)	Type of Problem (Level 2)
Mechanical	Unintended Movement

Cause of Problem (Level 1)	Cause of Problem (Level 2)
Not product related	Event related to patient condition or anatomy
Not product related	User error caused or contributed to event

Outcome of Investigation

Not investigated

Summary of Investigation:
No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Date Completed:
04/04/2012

***** End of DIR 26109 *****

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Email Message

From:	s22 [redacted] @stryker.com]
To:	IRIS [SMTP:IRIS@tga.gov.au]
Cc:	
Sent:	18/07/2011 at 1:59 PM
Received:	18/07/2011 at 1:59 PM
Subject:	Initial IRIS - PER 267217
Attachments:	Initial IRIS PER 267217.doc

To Whom It May Concern

Please find initial IRIS relating to PER 267217.

Please do not hesitate to contact me should you have any questions or concerns.

Regards

s22 [redacted]

_____
Regulatory Affairs Associate
Stryker South Pacific

t: s22 [redacted]

- Initial IRIS PER 267217.doc

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03
Last revised: December 2008

Mfr report # *	267217
TGA DIR #	

I- Administrative Information *Mandatory

Report Type (select one)

Initial [X] Follow-Up [ ] Final [ ] Trend [ ]

Report Category

S Pblc Hlth Threat [ ] Death/Serious Injury [ ] Other [X]

A) Date of this report (dd-mm-yyyy)	18/07/2011
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	s22
D) Date of next report (max 30 days from A)	16/08/2011

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert St, St Leonards NSW 2065

Tel.	s22	Fax	(02) 9467 1042
E-mail	s22@stryker.com		

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

None

II- Clinical Event Information *Mandatory

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: NK Explant Date: s22

Following patient fall, cup had moved which subsequently resulted in sublaxation. The ceramic liner was replaced and a Biolox ceramic femoral head with a longer neck was implanted.

III- Healthcare Facility Information *Mandatory

Name	s22
Address	s22

Tel	s22	Fax	s22
E-mail	s22		
Contact name at site of event	s22		

IV- Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	NK
GMDN Code	35661

GMDN Code Text (eg catheters, central venous, peripherally inserted)

NK

Specific Device Information

Brand Name *	NK
Model # *	Ceramic Liner
Catalogue #	NK
Ser. or Lot #'s	NK
Mfr. Name*	NK
Contact Name *	s22
Address *	NK

Tel *	s22	Fax	(02) 9467 1042
E-mail *	s22@stryker.com		
ARTG Mfr. # *	NK		

Operator of Device at Time of Event (select one)

HC Prof'nal [X] Other Caregiver [ ] Patient [ ] N/A [ ]

Usage of Device*

Single Use	[X]	Reuse of Single Use	[ ]
Reuse of Reusable	[ ]	Re-serviced/Refurbished	[ ]

Device Disposition/Current Location *

NK

V- Results of Mfr's Investigation *Mandatory

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Pending manufacturer's investigations.

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

Pending manufacturer's investigations.

VI- Patient Information *Mandatory as marked below

Age (yrs, mths)	s22	M/F	s22	Wt. (kg)	s22

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

Removal and replacement of right acetabular components.

Patient history (co-morbidities & medication): NK
* Patient outcome: NK
* List of other devices involved in the event: *if other implants involved – list brand, model & ARTG #* NK
VII- Other Reporting Information ****Mandatory***
Mfr/Sponsor aware of other similar events? (*number or *rate) NK
Countries where these similar adverse events occurred: NK
Additional Comments
None

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Guidance on how to complete this form

NB: Sections or fields marked with an ✱ are mandatory minimum requirements for a complete report

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time)

If some of the applicable information required in this form is not available by the time the deadline (2, 10, or 30 days) for the particular category of report has expired, a report should be submitted containing all the available information. Such a report should be marked "initial" in Section I.

The form may be filled long-hand or electronically using Word® - simply <tab> to the appropriate field and type the required information. The form can then be submitted by fax or mail or saved and attached to an email and sent to the email address provided. *This instructions page should not be included in the submission (This section is not protected and may be deleted).*

The following provides some guidance on what information is required in some parts of the form. It is envisaged that the fields not mentioned in this explanatory note are self-explanatory.

Section I – Administrative Information

Report Type, Initial: The first report that the reporter (sponsor, manufacturer) is submitting about an event. The reporter expects to have to submit further information about the event at a later date.

Report Type, Follow-up: Additional information to a previous (initial, follow-up or final) report.

Report Type, Final: The last report that the reporter expects to submit about an event. It is possible for the final report to also be the initial report about an event. If so, please indicate by crossing both boxes.

Report Type, Trend: Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called "trend" reports.

Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

Report Category, Death/Serious Injury: Choose this category where the event subject of the report resulted in the death or serious injury of a patient, user or other person.

Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

Section II – Clinical Event Information

Provide as much detail about the event as possible, including what happened and what lead up to the vent (eg the type of surgery or treatment) If the device is implantable, provide date of implant & explant.

Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event: Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

Section VII - Other Reporting Information

Mfr/Sponsor aware of other similar events? (# or rate): If there have been other similar events reported to either the sponsor or

the manufacturer enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold for example12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none, write “0” or “nil”.

When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.

A final report is considered to be a complete report and therefore all fields marked with an ✱ must be completed.

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Email Message

From:	s22 @stryker.com]
To:	IRIS [SMTP:IRIS@tga.gov.au]
Cc:	
Sent:	19/03/2012 at 4:07 PM
Received:	19/03/2012 at 4:07 PM
Subject:	IRIS final aprroval
Attachments:	s22 s22 s22 Final IRIS PER 267217.docx

To whom it may concern,

Please see attached final IRIS reports for your approval.

Kind regards,

s22

Regulatory Affairs Co-ordinator

Stryker South Pacific

8 Herbert Street

St Leonards, NSW 2065

Australia

t: s22

f: +61 (0)2 9467 1042

s22 @stryker.com

-s22 -
s22 Final IRIS PER 267217.docx

IRIS: Medical Device Incident Report Investigation Scheme

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Last revised: December 2008

Mfr report # *	267217
TGA DIR #	

I- Administrative Information * *Mandatory*

Report Type (select one)

Initial [ ] Follow-Up [ ] Final [X] Trend [ ]

Report Category

S Pblc Hlth Threat [ ] Death/Serious Injury [X] Other [ ]

A) Date of this report (dd-mm-yyyy)	14/03/2012
B) Date of adverse event (dd-mm-yyyy)	s22
C) Date mfr aware (dd-mm-yyyy)	s22
D) Date of next report (max 30 days from A)	NA

Person (authorised representative) Submitting This Report

Name	s22
Company	Stryker Australia
Address	8 Herbert St, St Leonards NSW 2065
Tel.	s22 (02) 9467 1042
E-mail	s22@stryker.com

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

None

II- Clinical Event Information * *Mandatory*

Description of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: NK **Explant Date:** s22

Following patient fall, cup had moved which subsequently resulted in sublaxation. The ceramic liner was replaced and a Biolox ceramic femoral head with a longer neck was implanted.

III- Healthcare Facility Information * *Mandatory*

Name s22

Address	s22 [redacted]
Tel	s22 [redacted] Fax (02) 6332 9885
E-mail	s22 [redacted]
Contact name at site of event	s22 [redacted]

IV- Device Information Primary Device * *Mandatory*

Generic Device Information

Device ARTG # *	NK
GMDN Code	35661
GMDN Code Text (eg catheters, central venous, peripherally inserted)	NK

Specific Device Information

Brand Name *	NK
Model # *	Ceramic Liner
Catalogue #	NK
Ser. or Lot #'s	NK
Mfr. Name*	NK
Contact Name *	s22 [redacted]
Address *	NK
Tel *	s22 [redacted] Fax (02) 9467 1042
E-mail *	s22 [redacted]@stryker.com
ARTG Mfr. # *	NK

Operator of Device at Time of Event (select one)

HC Prof'nal [X] Other Caregiver [ ] Patient [ ] N/A [ ]

Usage of Device*

Single Use [X] Reuse of Single Use [ ]

Reuse of Reusable [ ] Re-serviced/Refurbished [ ]

Device Disposition/Current Location *

NK

V- Results of Mfr's Investigation * *Mandatory*

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

An event regarding dislocation of a Trident hip was reported on s22 [redacted]

The event was not confirmed.

The exact cause of the event could not be determined however the reported dislocation in this obese patient may be due to the vertical positioning of the shell, as noted in Strykers technical report for dislocation. It is noted in the review of the provided x-rays by a clinical professional that the shell on the right hand side is vertically placed. It is not possible to determine if the shell was placed in this position at the primary surgery or if

it was displaced after the reported trauma the patient suffered. No further investigation for this event is possible at this time because no devices and insufficient information was received by Stryker Orthopaedics. If devices and / or additional information become available, this investigation will be reopened.

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

No action is required at this time as there was no indication of a product non-conformance or adverse trend. Product Surveillance will monitor for trends.

VI- Patient Information * *Mandatory as marked below*

Age (yrs, mths) s22 M/F s22 Wt. (kg) s22

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

Removal and replacement of right acetabular components.

Patient history (co-morbidities & medication):

Clinically obese with a B.M.I. of 32.4. She had bilateral hip arthroplasties and these were both revised, possibly on s22 .

* Patient outcome:

Revision surgery it was noted that the Trident cup was solid and unable to be moved, indicating that the cup was placed in a vertical position at the patients primary surgery.

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

NA

VII- Other Reporting Information * *Mandatory*

Mfr/Sponsor aware of other similar events? (*number or *rate)

unable to calculate no Lot or Catalogue # provided.

Countries where these similar adverse events occurred:

NA

Additional Comments

None

Submitting this report:

By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Guidance on how to complete this form

NB: Sections or fields marked with an ✱ are mandatory minimum requirements for a complete report

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time)

If some of the applicable information required in this form is not available by the time the deadline (2, 10, or 30 days) for the particular category of report has expired, a report should be submitted containing all the available information. Such a report should be marked "initial" in Section I.

The form may be filled long-hand or electronically using Word® - simply <tab> to the appropriate field and type the required information. The form can then be submitted by fax or mail or saved and attached to an email and sent to the email address provided. *This instructions page should not be included in the submission (This section is not protected and may be deleted).*

The following provides some guidance on what information is required in some parts of the form. It is envisaged that the fields not mentioned in this explanatory note are self-explanatory.

Section I – Administrative Information

Report Type, Initial: The first report that the reporter (sponsor, manufacturer) is submitting about an event. The reporter expects to have to submit further information about the event at a later date.

Report Type, Follow-up: Additional information to a previous (initial, follow-up or final) report.

Report Type, Final: The last report that the reporter expects to submit about an event. It is possible for the final report to also be the initial report about an event. If so, please indicate by crossing both boxes.

Report Type, Trend: Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called "trend" reports.

Report Category, S Pblc Hlth Threat:: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manufacturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaning of this description.

Report Category, Death/Serious Injury: Choose this category where the event subject of the report resulted in the death or serious injury of a patient, user or other person.

Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

Section II – Clinical Event Information

Provide as much detail about the event as possible, including what happened and what lead up to the vent (eg the type of surgery or treatment) If the device is implantable, provide date of implant & explant.

Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event: Some events are caused by the combined action of two or more devices. List any other device(s) and their ARTG # that were being used at the time of the event if known.

Section VII - Other Reporting Information

Mfr/Sponsor aware of other similar events? (# or rate): If there have been other similar events reported to either the sponsor or

the manufacturer enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold for example12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none, write “0” or “nil”.

When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.

A final report is considered to be a complete report and therefore all fields marked with an ✱ must be completed.

In – Confidence

RECALL
File Barcode Only
F5500026353955

Document 45

Commercial In Confidence | TGA File

Therapeutic Goods Administration

2009/000504

Previous Part | Next Part

THERAPEUTIC ADMINISTRATION - POST MARKET MONITORING - Recalls - HA Coated Hip Stems Manufactured in Ireland Between December 2007 & January 2008 Various Lots - Stryker Australia Pty Ltd - Problems Including Recall Action - ODBT

Information relating to this file may have been saved to the Departmental Electronic Document Management System using the file number appearing on the label.

This file contains information concerning the private affairs of individuals, companies, organisations or other information obtained under assurance of confidentiality. When not in use, this file is to be stored in a locked cabinet or secured room.

Previous Part

Each officer must enter their own initials when clearing the folio.

Folio No.	Assignee	Date	Date Cleared	Initials
	s22 [redacted]	14/1/09		s22 [redacted]
			3/2/09	
		3/2/09	13/3/09	
			15/5/09	

Please do not hold this file when delays in action may exceed seven (7) days.

Later Part

Each officer must enter their own initials when clearing the folio.

Folio No.	Assignee	Date	Date Cleared	Initials

Archival Action

AFDA/RDA

N

F

F

2009/000504

In – Confidence

537 (0000)

Folios

The panel below is for the listing of folios on this file. As you add folios, please document folio number and title.

Folio Number	Title

Folios

The panel below is for the listing of folios on this file. As you add folios, please document folio number and title.

Folio Number	Title

Related File(s)

The panel below is for the listing of files on similar subjects. If you are aware of any related file(s) please add them to the list.

File Number	Title

Document 45

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

In reply please quote: RC-2009-RN-00018-3

Managing Director
Stryker Australia Pty Ltd
PO Box 970
ARTARMON NSW 1570

Attention: s22 [redacted]

Dear Sir/Madam

Re: Stryker HA Coated Hip Stems manufactured in Ireland between December 2007 and January 2008 Various Lots (see attached)
ARTG - 145521, 145595, 145594, 145593, 145597.

Thank you for your final report for your recall action involving the above product(s).

Copies of this report have been reviewed by key stakeholders within the Therapeutic Goods Administration on the effectiveness of the recall action.

This recall action is now considered to be completed in accordance with the requirements of the Uniform Recall Procedure for Therapeutic Goods and has been closed on the recalls database.

Please do not hesitate to contact me on the numbers below if you have any further concerns on this issue.

Yours sincerely

s22 [redacted]

Recalls Officer
Tel: s22 [redacted]
Fax: 02 6203 1451
Email: recalls@tga.gov.au

19/03/2009

MVMS
ACTION NOTE
REF NO: 2009-00018-3
DATE: 13 Mar 09
FROM: s22 [redacted]
PHONE:
√ **NO FURTHER ACTION REQUIRED**
FURTHER ACTION REQUIRED AS BELOW

NOTES:

SIGNATURE s22 [redacted]

39

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Minute

To: s22
Market Vigilance & Monitoring

Chief Auditor, OMQ

Noted 18.3.09

FINAL SUMMARY OF RECALL ACTION: RC-2009-RN-00018-3

Recall issue:

Product	Stryker HA Coated Hip Stems manufactured in Ireland between December 2007 and January 2008 - Various lots ARTG - 145521, 145595, 145594, 145593, 145597.
Problem	Specified lots of sprayed Hydroxyapatite (HA) hip stems did not meet Stryker's Internal Material Specification for tensile bond strength and crystallinity
Sponsor	Stryker Australia Pty Ltd
Recall Classification	Class III — Level: Hospital

Recall action:

Date recall notified	9/01/2009
Date recall agreed	12/01/2009
Recall started without delay?	YES
Reports provided on time?	YES
Overseas export agents contacted	YES
Final report location	Folio 37
No. of customers to be contacted	12
No. customers that responded:	12
All identified affected units recovered or corrected?	YES

Additional requirements:

Responsible entity:	Stryker Ireland Ltd
Client number:	40670
Root cause & remedial action:	Folio 36-37

Any additional requirements have been addressed: Requirements requested at folios 27 & 28 – The sponsors advice that patients not be followed up (folio 1) was agreed to as part of the recall (folio 12b). In addition to the recall letter a separate letter was sent to implanting surgeons about the recall (folio 5b).

Please advise if you wish the Recalls Unit to undertake any further action on this matter before it is closed out on our database.

s22
Recalls Unit
10/03/2009

s22 s22 @stryker.com>
Sent by: "s22 s22 @stryker.com>

03/02/2009 12:46 PM

To <Recalls@tga.gov.au>
cc s22 @stryker.com>
bcc
Subject RE: RC-2009-RN-00018-3 Stryker HA Coated Hip Stems - Final Report [SEC=UNCLASSIFIED]

UNCLASSIFIED

Hi s22

Please find attached an amended copy listing the actions taken by the manufacturer to address the issue.

Best Regards,

s22
Regulatory Affairs Associate

Stryker South Pacific
8 Herbert St
St Leonards NSW 2065
t: s22
f: +61 2 9467 1010
s22 @stryker.com

From: s22 @tga.gov.au [mailto:s22 @tga.gov.au] **On Behalf Of** Recalls@tga.gov.au
Sent: Friday, 30 January 2009 2:30 PM
To: SSP RA
Subject: Re: RC-2009-RN-00018-3 Stryker HA Coated Hip Stems - Final Report [SEC=UNCLASSIFIED]

Dear s22

Thank you for your final report.

We look forward to receiving the CAPA report as soon as it is available.

Regards,

s22
Recalls Unit

s22 @stryker.com>
Sent by: "s22 s22 @stryker.com>

30/01/2009 02:20 PM

To <recalls@tga.gov.au>
cc s22 @stryker.com>
Subject RC-2009-RN-00018-3 Stryker HA Coated Hip Stems - Final Report

Reporting Requirements

Reports can be submitted to the Recalls Unit by
Email: recalls@tga.gov.au
Facsimile: 02 6203 1451 or
Post: TGA Recalls Unit, TGA, PO Box 100, Woden ACT 2606

TGA Recall reference No. RC-2009-RN-00018-3

6 WEEK REPORT REQUIREMENTS

1. Have ALL the customers that you contacted responded to your requested recall/corrective action? Have customers confirmed their amount of affected product (including none) and that they agree to the recall/corrective action.	**[X] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% & detail the attempts made to contact non responding customers
2. (a) Recall - Have ALL customers returned or destroyed their affected units; or **(b) Correction - Have ALL customers with units requiring correction been identified?**	**[X] YES** **[X] No goods left to recall or correct**	**[ ] NO.** Please advise when this is expected to occur
3. Is the recall/corrective action progressing without major impediments? Eg The recall/corrective action is progressing as per the agreed timelines	**[X] YES**	**[ ] NO.** Please explain

CLOSE OUT REPORT REQUIREMENTS (by the agreed time)

1. (a) Recall - Has ALL returned stock been destroyed*?; or **(b) Correction - Have ALL units with customers been corrected (or been supplied with the correction?** *A Certificate of destruction is to be provided where the goods have been destroyed.	**[ ] YES**	**[X] NO.** All returned stock and items in Stryker inventory were quarantined and returned to the manufacturer.
2. What was the root cause of the defect that led to the recall/corrective action?	The root cause of this deviation was a malfunctioning HA gun. This particular HA gun malfunctioned between 7 December 2007 and 22 January 2008. Subsequently all batches of HA stems that were sprayed with the	

Attachment 1 Reporting Requirements

Please detail	malfunctioning HA gun between 7 December 2007 and 22 January 2008 were evaluated.
3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action? Please detail	Investigations carried out by the manufacturer indicated that an HA gun malfunction caused undetected process control deviations from the timeframe of December 7, 2007 through January 22, 2008, at which point the plasma gun was repaired. As a result of this finding, all product sprayed with either SAI or Cork powder was contained and all affected product in the market was subsequently recalled. The manufacturer has taken the following actions to address the issue: a) Preventative Maintenance schedule has been revised to include replacement of the complete 9MB gun hardware system on a monthly basis. All auxiliary attachments to the gun are checked and replaced as necessary during this inspection. b) Voltage is being recorded on a daily basis. If a voltage difference in excess of 2V between two consecutive readings is observed, Engineering support is notified and the complete APS system is investigated. c) Tensile testing is carried out on a weekly basis at a minimum and also when any change to machine hardware is carried out, i.e. Nozzle & Electrode replacement. d) Gauge R&R studies have been completed on both the Tensile Bond strength test method and the XRD test method and both have passed the acceptance criteria.

Recalls
Sent by: s22

02/02/2009 04:45 PM

To s22 /TGA/Health@TTRA
cc
bcc
Subject Re: Hospital Level, Medical Device Recall - Stryker HA Coated Hip Stems - Stryker Australia Pty Ltd - RC-2009-RN-00018-3 [SEC=UNCLASSIFIED]

UNCLASSIFIED

Dear s22

We have no further information as file is currently circulating. According to TRIM file is currently with s22

Kind regards,

s22
TGA Recalls

s22 TGA/Health

s22 TGA/Health

02/02/2009 04:11 PM

To Recalls@TTRA
cc s22 /TGA/Health@TTRA
Subject Re: Hospital Level, Medical Device Recall - Stryker HA Coated Hip Stems - Stryker Australia Pty Ltd - RC-2009-RN-00018-3 [SEC=UNCLASSIFIED]

Hi Recalls,
Do you have any more information on this recall? see s22 question re implanted devices below.

s22 , IRIS Coordinator
Medical Device Incident Report Investigation Scheme | Market Vigilance & Monitoring Section (MVMS) | Office of Devices, Blood & Tissues, TGA | PO Box 100, Woden ACT 2606 |
s22 @tga.gov.au | Ph: s22 | Fax: 02 6232 8555 | Freecall (Aust only): 1800 809 361

s22 /TGA/Health

s22 TGA/Health

16/01/2009 04:58 PM

To Recalls@TTRA
cc s22 /TGA/Health@TTRA
Subject Re: Hospital Level, Medical Device Recall - Stryker HA Coated Hip Stems - Stryker Australia Pty Ltd - RC-2009-RN-00018-3 [SEC=UNCLASSIFIED]

Could you please tell me if any of these products have been implanted? If so, what is the advice being given?

s22
If these stems have been implanted please review the advice with s22

Thanks
s22

s22 TGA/Health
02/02/2009 04:11 PM

To Recalls@TTRA
cc s22 TGA/Health@TTRA
bcc
Subject Re: Hospital Level, Medical Device Recall - Stryker HA Coated Hip Stems - Stryker Australia Pty Ltd - RC-2009-RN-00018-3 [SEC=UNCLASSIFIED]

UNCLASSIFIED

Hi Recalls,
Do you have any more information on this recall? see s22 question re implanted devices below.

s22, IRIS Coordinator
Medical Device Incident Report Investigation Scheme |Market Vigilance & Monitoring Section (MVMS) | Office of Devices, Blood & Tissues, TGA | PO Box 100, Woden ACT 2606 |
s22 *@tga.gov.au | Ph:* s22 *| Fax: 02 6232 8555 | Freecall (Aust only): 1800 809 361*

s22 /TGA/Health

s22 GA/Health
16/01/2009 04:58 PM

To Recalls@TTRA
cc s22 /TGA/Health@TTRA
Subject Re: Hospital Level, Medical Device Recall - Stryker HA Coated Hip Stems - Stryker Australia Pty Ltd - RC-2009-RN-00018-3 [SEC=UNCLASSIFIED]

Could you please tell me if any of these products have been implanted? If so, what is the advice being given?

s22
If these stems have been implanted please review the advice with s22

Thanks
s22

Director, Market Vigilance and Monitoring Section| Office of Devices, Blood and Tissues| TGA| PO Box 100| Woden ACT 2606

s22 | Freecall (Aust only): 1800 809 361
Recalls

Recalls
Sent by: s22
16/01/2009 03:23 PM

To #Recalls_Devices Group
cc #Recalls_State & Territory Recall Coordinators
Subject Hospital Level, Medical Device Recall - Stryker HA Coated Hip Stems - Stryker Australia Pty Ltd - RC-2009-RN-00018-3 [SEC=UNCLASSIFIED]

Please find attached a Medical Device Recall

RC-2009-RN-00018-3 Broadcast.doc

Regards,

s22 [redacted]
TGA Recalls

UNCLASSIFIED

Document 45

Recalls
Sent by: s22

30/01/2009 02:30 PM

To s22 @stryker.com>
cc
bcc
Subject Re: RC-2009-RN-00018-3 Stryker HA Coated Hip Stems - Final Report [SEC=UNCLASSIFIED]

UNCLASSIFIED

Dear s22

Thank you for your final report.

We look forward to receiving the CAPA report as soon as it is available.

Regards,

s22
Recalls Unit

s22 @stryker.com>

s22
s22 @stryker.com>
Sent by: s22
s22
s22 @stryk
er.com>

30/01/2009 02:20 PM

To <recalls@tga.gov.au>
cc s22 @stryker.com>
Subject RC-2009-RN-00018-3 Stryker HA Coated Hip Stems - Final Report

Attn: s22
Recall Ref No: RC-2009-RN-00018-3
Product Name: Stryker HA Coated Hip Stems
Sponsor Name: Stryker Australia
Dear s22

Please find attached a final report concerning recall RC-2009-RN-00018-3.

Best Regards,

s22

s22
Regulatory Affairs Associate

Stryker South Pacific
8 Herbert St
St Leonards NSW 2065
t: s22
f: +61 2 9467 1010
s22 @stryker.com

s22 s22 @stryker.com>
Sent by: "s22 s22 @stryker.com>

To <recalls@tga.gov.au>
cc s22 @stryker.com>
bcc
Subject RC-2009-RN-00018-3 Stryker HA Coated Hip Stems - Final Report

30/01/2009 02:20 PM

DOCUMENT NOT YET CLASSIFIED

Attn: s22
Recall Ref No: RC-2009-RN-00018-3
Product Name: Stryker HA Coated Hip Stems
Sponsor Name: Stryker Australia
Dear s22

Please find attached a final report concerning recall RC-2009-RN-00018-3.

Best Regards,

s22

s22
Regulatory Affairs Associate

Stryker South Pacific
8 Herbert St
St Leonards NSW 2065
t: s22
f: +61 2 9467 1010
s22 @stryker.com

RC-2008-RN-00018-3 Final report.doc

DOCUMENT NOT YET CLASSIFIED

Reporting Requirements

Reports can be submitted to the Recalls Unit by
Email: recalls@tga.gov.au
Facsimile: 02 6203 1451 or
Post: TGA Recalls Unit, TGA, PO Box 100, Woden ACT 2606

TGA Recall reference No. RC-2009-RN-00018-3

6 WEEK REPORT REQUIREMENTS

1. Have ALL the customers that you contacted responded to your requested recall/corrective action? Have customers confirmed their amount of affected product (including none) and that they agree to the recall/corrective action.	**[X] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% & detail the attempts made to contact non responding customers
2. (a) Recall - Have ALL customers returned or destroyed their affected units; or **(b) Correction - Have ALL customers with units requiring correction been identified?**	**[X] YES** **[X] No goods left to recall or correct**	**[ ] NO.** Please advise when this is expected to occur
3. Is the recall/corrective action progressing without major impediments? Eg The recall/corrective action is progressing as per the agreed timelines	**[X] YES**	**[ ] NO.** Please explain

CLOSE OUT REPORT REQUIREMENTS (by the agreed time)

1. (a) Recall - Has ALL returned stock been destroyed*?; or **(b) Correction - Have ALL units with customers been corrected (or been supplied with the correction?** *A Certificate of destruction is to be provided where the goods have been destroyed.	**[ ] YES**	**[X] NO.** All returned stock and items in Stryker inventory were quarantined and returned to the manufacturer.
2. What was the root cause of the defect that led to the recall/corrective action?	The root cause of this deviation was a malfunctioning HA gun. This particular HA gun malfunctioned between 7 December 2007 and 22 January 2008. Subsequently all batches of HA stems that were sprayed with the	

Attachment 1 Reporting Requirements

Please detail	malfunctioning HA gun between 7 December 2007 and 22 January 2008 were evaluated.
3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action? Please detail	Investigations carried out by the manufacturer indicated that an HA gun malfunction caused undetected process control deviations from the timeframe of December 7, 2007 through January 22, 2008, at which point the plasma gun was repaired. As a result of this finding, all product sprayed with either SAI or Cork powder was contained and all affected product in the market was subsequently recalled. A CAPA has been lodged and an investigation is being carried out to determine the appropriate preventative actions.

s22 "
s22 @stry
ker.com>
28/01/2009 02:27 PM

To <recalls@tga.gov.au>
cc s22 @stryker.com>
bcc
Subject RC-2009-RN-00018-3 Stryker HA Coated Hip Stems - 2 Week Report

DOCUMENT NOT YET CLASSIFIED

Attn: s22
Recall Ref No: RC-2009-RN-00018-3
Product Name: Stryker HA Coated Hip Stems
Sponsor Name: Stryker Australia
Dear s22

Please find attached a 2 week report concerning recall RC-2009-RN-00018-3.

Best Regards,

s22

s22
Regulatory Affairs Associate

Stryker South Pacific
8 Herbert St
St Leonards NSW 2065
t: s22
f: +61 2 9467 1010
s22 @stryker.com

RC-2008-RN-00018-3 2 Week Report.doc

DOCUMENT NOT YET CLASSIFIED

2009DD0504

Reporting Requirements

Reports can be submitted to the Recalls Unit by
Email: recalls@tga.gov.au
Facsimile: 02 6203 1451 or
Post: TGA Recalls Unit, TGA, PO Box 100, Woden ACT 2606

TGA Recall reference No. RC-2009-RN-00018-3

2 WEEK REPORT REQUIREMENTS

1. Has the recall/corrective action been initiated? Confirm that the agreed action has begun. Eg the approved recall letter has been dispatched.	**[X] YES**	**[ ] NO.** Please explain
2. Is the recall/corrective action progressing without major impediments? Eg The recall/corrective action is progressing as per the agreed timelines	**[X] YES**	**[ ] NO.** Please explain
3. The initial investigation findings have not changed the scope of the recall/correction Eg Additional units or products have not been identified with the same defect	**[X] YES**	**[ ] NO.** Please advise
4. For any product exported from Australia, the overseas supplier(s) has been informed of the recall/correction action being undertaken in Australia.	**[ ] YES** **[X] No exports**	**[ ] NO.** Please explain

MVMS

ACTION NOTE

REF NO: 2009/00050 4

DATE: 2nd Feb 09.

FROM: s22 [redacted]

PHONE: s22 [redacted]

IRIS – mvms.

☐ NO FURTHER ACTION REQUIRED

☐ FURTHER ACTION REQUIRED AS BELOW

NOTES:

* Request information regarding any of these afected prosthetics that have already been implanted.
* What is Stryker's plan for these implanted devices
* What communication has been initiated between Stryker and patients/clinicians for these implanted devices

SIGNATURE s22 [redacted]

s22 GA/Health
16/01/2009 04:58 PM

To Recalls@TTRA
cc s22 /TGA/Health@TTRA
bcc
Subject Re: Hospital Level, Medical Device Recall - Stryker HA Coated Hip Stems - Stryker Australia Pty Ltd - RC-2009-RN-00018-3 [SEC=UNCLASSIFIED]

UNCLASSIFIED

Could you please tell me if any of these products have been implanted? If so, what is the advice being given?

↑yes. Letter to surgeon @ FSB

s22
If these stems have been implanted please review the advice with s22

Thanks
s22

Director, Market Vigilance and Monitoring Section| Office of Devices, Blood and Tissues| TGA| PO Box 100| Woden ACT 2606

s22 | Freecall (Aust only): 1800 809 361
Recalls

Recalls
Sent by: s22
16/01/2009 03:23 PM

To #Recalls_Devices Group
cc #Recalls_State & Territory Recall Coordinators
Subject Hospital Level, Medical Device Recall - Stryker HA Coated Hip Stems - Stryker Australia Pty Ltd - RC-2009-RN-00018-3 [SEC=UNCLASSIFIED]

Please find attached a Medical Device Recall

RC-2009-RN-00018-3 Broadcast.doc

Regards,

s22
TGA Recalls

UNCLASSIFIED

Document 45

****
*** MULTI TX/RX REPORT ***
****

TX/RX NO	1539
PGS.	4
TX/RX INCOMPLETE	[23]
TRANSACTION OK	[01]062050997
	[02]00732341480
	[03]00298595165
	[04]01300360830
	[05]00362333904
	[06]00882743440
	[07]00893884988
	[08]00889227200
	[09]062663929
	[11]062431073
	[12]00362323310
	[14]00298953324
	[15]00396057982
	[16]00730045405
	[17]00882749438
	[18]00892148336
	[19]00262053300
	[20]000156448196806
	[25]00882260725
	[26]062443819
ERROR INFORMATION	-----

s22 [redacted]

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

PO Box 100 Woden ACT 2606
www.tga.gov.au
ABN 40 939 406 804

Facsimile

Date: 16/1/2009 **Total pages:** 4

TO: **ON RECEIPT OF THIS FAX, PLEASE DELIVER WITHOUT DELAY TO THE PERSON OR OFFICE NOMINATED AGAINST YOUR FAX NUMBER BELOW:**

Regarding: Recall Number: RC-2009-RN-000183

FROM: Recalls Unit **Telephone:** (02) 6232 8637
Facsimile: (02) 6203 1451

If you do not receive all pages, please telephone the sender immediately

MESSAGE:

All Recalls (Medicines and Medical Devices)
State & Territory Departments of Health:

ACT: s22 [redacted]

QLD:
NSW:
VIC:

TAS:
SA:

s22 [redacted]

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

PO Box 100 Woden ACT 2606
www.tga.gov.au
ABN 40 939 406 804

Facsimile

Date: 16/11/2009 **Total pages:** 4

TO: **ON RECEIPT OF THIS FAX, PLEASE DELIVER WITHOUT DELAY TO THE PERSON OR OFFICE NOMINATED AGAINST YOUR FAX NUMBER BELOW:**

Regarding: Recall Number: RC-2009-RN-00018-3

FROM: Recalls Unit **Telephone:** (02) 6232 8637
Facsimile: (02) 6203 1451

If you do not receive all pages, please telephone the sender immediately

MESSAGE:

All Recalls (Medicines and Medical Devices)
State & Territory Departments of Health:

ACT: s22
QLD:
NSW:
VIC:
TAS:
SA:
WA:
NT:

Others:
s22

Medicine Recalls Only
s22

s22

Have the State & Territory Recall Co-ordinators been advised by e-mail? ☑ **Yes** ☐ **No**

Sent by: s22

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

MEDICAL DEVICE RECALL

LEVEL:	Hospital	CLASS:	Class III
REFERENCE:	RC-2009-RN-00018-3	DATE AGREED:	12/01/2009

PRODUCT: Stryker HA Coated Hip Stems

Manufactured in Ireland between December 2007 and January 2008
Various item and lot numbers (see attached)

ARTG - 145521, 145595, 145594, 145593, 145597.

SPONSOR: Stryker Australia Pty Ltd

PHONE: s22 [redacted] 1800 803 601

REASON: Specified lots of sprayed Hydroxyapatite (HA) hip stems did not meet Stryker's Internal Material Specification for tensile bond strength and crystallinity.

Letters are expected to be dispatched by the sponsor within two working days of the agreed date.

INFORMATION BELOW NOT FOR CIRCULATION

Product Distribution: 12 Hospitals NSW, TAS, VIC & WA (see attached list)

Product export status: New Zealand

This action was first notified by Sponsor

[Classification system. Class I – Class I defects are potentially life-threatening or could cause a serious risk to health. Class II – Class II defects could cause illness or mistreatment, but are not Class I. Class III – Class III defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.
Class I & II recalls are considered to be safety related recalls]

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Reference No: RC-2009-RN-00018-3

STATE	HOSPITAL
NSW	s22 [redacted]
TAS	
VIC	
WA	

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au
Telephone: 02 6232 8444 Facsimile: 02 6232 8605 ABN 40 939 406 804

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Reference No: RC-2009-RN-00018-3

Item	Description	Lot
4845-0106	ABGII NO6 CEMENTLESS RIGHT V40	G1938525D
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G1871588E
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G2075932D
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G2075932D
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G2075933A
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G2093024A
6020-0435	ACCOLADE	25005901
6021-0537	ACCOLADE (127 DEG)	24992704
6021-4535	ACCOLADE (127 DEG) SIZE 4.5	24956301
6021-4535	ACCOLADE (127 DEG) SIZE 4.5	24973501
6041-0935	OMNIFIT M-HA HIP STEM C-TAPER	25060601
W6021-0335	ACCOLADE (127 DEG) SAMPLE	25309501
4845-0103	ABGII NO3 CEMENTLESS RIGHT V40	G2131092C
4845-0104	ABGII NO4 CEMENTLESS RIGHT V40	G2115997C
4845-0107	ABGII NO7 CEMENTLESS RIGHT V40	G1852741C
4845-0107	ABGII NO7 CEMENTLESS RIGHT V40	G1852741C
4845-0107	ABGII NO7 CEMENTLESS RIGHT V40	G1835616D
4845-0203	ABGII NO3 CEMENTLESS LEFT V40	G1898430E
4845-0203	ABGII NO3 CEMENTLESS LEFT V40	G1898430E
4845-0203	ABGII NO3 CEMENTLESS LEFT V40	G1925351E
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G2137098A
4845-0206	ABGII NO6 CEMENTLESS LEFT V40	G1885772D
4845-0206	ABGII NO6 CEMENTLESS LEFT V40	G1885772E
4845-0206	ABGII NO6 CEMENTLESS LEFT V40	G1885772E
4845-0206	ABGII NO6 CEMENTLESS LEFT V40	G1907526E
4845-0208	ABGII NO8 CEMENTLESS LEFT V40	G1542000C
6020-0335	ACCOLADE	25079901
6020-0335	ACCOLADE	25386101
6020-2530	ACCOLADE 132 SIZE 2.5	25138701
6020-3535	ACCOLADE 132 SIZE 3.5	25387303
6020-3535	ACCOLADE 132 SIZE 3.5	25387304
6020-4535	ACCOLADE 132 SIZE 4.5	25095501
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6021-0740	ACCOLADE (127 DEG)	25138602
6021-0740	ACCOLADE (127 DEG)	25138602
6021-4535	ACCOLADE (127 DEG) SIZE 4.5	25190701
6041-0730	OMNIFIT M-HA HIP STEM C-TAPER	25222401
6041-0730	OMNIFIT M-HA HIP STEM C-TAPER	25222401
6041-0830	OMNIFIT M-HA HIP STEM C-TAPER	25039401
6041-0935	OMNIFIT M-HA HIP STEM C-TAPER	25393701
6265-5113	CITATION TMZF SIZE 3 RIGHT	24495803
6265-5115	CITATION TMZF SIZE 5 RIGHT	24729102
6265-5115	CITATION TMZF SIZE 5 RIGHT	24729102
6265-5115	CITATION TMZF SIZE 5 RIGHT	24729102
6265-5115	CITATION TMZF SIZE 5 RIGHT	24729102
6265-5115	CITATION TMZF SIZE 5 RIGHT	24765402
6265-5116	CITATION TMZF SIZE 6 RIGHT	24404102

Recalls
Sent by: s22

16/01/2009 03:23 PM

To #Recalls_Devices Group
cc #Recalls_State & Territory Recall Coordinators
bcc
Subject Hospital Level, Medical Device Recall - Stryker HA Coated Hip Stems - Stryker Australia Pty Ltd - RC-2009-RN-00018-3 [SEC=UNCLASSIFIED]

UNCLASSIFIED

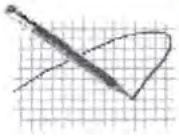
Please find attached a Medical Device Recall

RC-2009-RN-00018-3 Broadcast.doc

Regards,

s22
TGA Recalls

UNCLASSIFIED



s22 TGA/Health
13/01/2009 04:49 PM

To TGA Records Management@TTRA
cc
bcc
Subject New File Order [SEC=UNCLASSIFIED]

UNCLASSIFIED

Can I please order a new file with the following title:

Classification for the file will need to be 'Commercial in Confidence'.

THERAPEUTIC ADMINISTRATION - POST MARKET MONITORING - HA Coated Hip Stems manufactured in Ireland between Dec 2007 & Jan 2008 Various Lots - STRYKER AUSTRALIA PTY LTD - Problems Including Recall Action - TGAODBT

Regards,

TGA Recalls

UNCLASSIFIED

Document 45

TGA Records Management
Sent by: s22

14/01/2009 02:14 PM

To s22 /TGA/Health@TTRA
cc
bcc
Subject Re: New File Order
Marking

UNCLASSIFIED

Dear s22

Your file request is in progress & should be delivered to you within 24 hours.

Full details of the file are below.

2009/000504 THERAPEUTIC ADMINISTRATION - POST MARKET MONITORING - Recalls - HA Coated Hip Stems Manufactured in Ireland Between December 2007 & January 2008 Various Lots - Stryker Australia Pty Ltd - Problems Including Recall Action - ODBT

Some minor modifications may have been made to your request to comply with file titling standards. If you do notice any errors in the details above, please contact me to discuss.

Regards,

s22
Records Management Section
s22

s22 /TGA/Health

s22 TGA/Health
13/01/2009 04:49 PM

To TGA Records Management@TTRA
cc
Subject New File Order [SEC=UNCLASSIFIED]

Can I please order a new file with the following title:

Classification for the file will need to be 'Commercial in Confidence'.

THERAPEUTIC ADMINISTRATION - POST MARKET MONITORING - HA Coated Hip Stems manufactured in Ireland between Dec 2007 & Jan 2008 Various Lots - STRYKER AUSTRALIA PTY LTD - Problems Including Recall Action - TGAODBT

Regards,

TGA Recalls

UNCLASSIFIED

Document 45

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1518
CONNECTION TEL	00294671010
SUBADDRESS	
CONNECTION ID	
ST. TIME	12/01 09:04
USAGE T	01'21
PGS. SENT	4
RESULT	OK

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

PO Box 100 Woden ACT 2606
www.tga.gov.au
ABN 40 939 406 804

Facsimile

Date:	12/01/2009	Total pages:	4
TO:	Stryker Australia Pty Ltd	Telephone:	s22 [redacted]
Attention:	s22 [redacted]	Facsimile:	02 9467 1010
Regarding:	Stryker HA Coated Hip Stems manufactured in Ireland between December 2007 and January 2008 Various Lots (see attached) ARTG - 145521, 145595, 145594, 145593, 145597.	TGA Ref #: Your ref #	RC-2009-RN-00018-3
FROM:	s22 [redacted]	Telephone:	s22 [redacted]
Branch/Div.:	Recalls Unit	Facsimile:	(02) 6203 1451

If you do not receive all pages, please telephone the sender immediately

MESSAGE:

Thank you for your notification and draft action letter for the above product

Assessment of the proposed action

The proposed action has been classified as follows

Class of Recall:	**Class III**
Type of Recall:	**Medical Device Recall**
Recall Level:	**Hospital Level**
Reason for Recall – that will be provided to Parties listed in Appendix V of the URPTG.	**"Specified lots of sprayed Hydroxyapatite (HA) hip stems did not meet Stryker's Internal Material Specification for tensile bond strength and crystallinity"**
Product Distribution:	**12 Hospitals NSW, TAS, VIC & WA (see attached list)**

Approval of the proposed action correspondence

Recalls
Sent by: s22

12/01/2009 09:38 AM

To s22 @stryker.com>
cc s22 @stryker.com>,
s22 @stryker.com>
bcc
Subject Re: Recall: Stryker HA Coated Hip Stems

UNCLASSIFIED

Dear s22

Please find attached approval for the recall of the above device. I will also fax to you a signed copy.

Please note that the reporting requirements have changed and is explained in the approval letter as well there are now reporting templates. This is the minimum information required.

Feel free to give me a call if you have any questions.

Regards

s22

RC-2008-RN-00018-3 Approval.doc

UNCLASSIFIED

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

PO Box 100 Woden ACT 2606
www.tga.gov.au
ABN 40 939 406 804

Facsimile

Date:	12/01/2009	Total pages:	4
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Attention:	s22 [redacted]	Facsimile:	02 9467 1010
Regarding:	Stryker HA Coated Hip Stems manufactured in Ireland between December 2007 and January 2008 Various Lots (see attached) ARTG - 145521, 145595, 145594, 145593, 145597	TGA Ref #: Your ref #	RC-2009-RN-00018-3
FROM:	s22 [redacted]	Telephone:	s22 [redacted]
Branch/Div.:	Recalls Unit	Facsimile:	(02) 6203 1451

If you do not receive all pages, please telephone the sender immediately

MESSAGE:

Thank you for your notification and draft action letter for the above product

Assessment of the proposed action

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Class of Recall:	**Class III**
Type of Recall:	**Medical Device Recall**
Recall Level:	**Hospital Level**
Reason for Recall – that will be provided to Parties listed in Appendix V of the URPTG.	**"Specified lots of sprayed Hydroxyapatite (HA) hip stems did not meet Stryker's Internal Material Specification for tensile bond strength and crystallinity"**
Product Distribution:	**12 Hospitals NSW, TAS, VIC & WA (see attached list)**

Approval of the proposed action correspondence

The text of the letter is acceptable and it may be distributed to customers immediately. The TGA also notes the text of the letter to surgeons.

Please note:
1. Addressees for Recall Letters - Recall correspondence are to be addressed in accordance with Section G of the Uniform Recall Procedure for Therapeutic Goods (URPTG). In particular, where hospitals are involved, mail should be addressed to the "Chief Pharmacist" for medicines and to the "Chief Executive Officer" for device recalls. More targeted letters are acceptable as an adjunct to the recall.

2. Dispatch of correspondence – Recall letters are required to be dispatched within 2 working days of receiving this approval in envelopes as also described in Section G of the URPTG:
Urgent Medical Device Recall

However, it also acceptable to additionally dispatch this notification by facsimile or other electronic means to meet relevant time parameters

Reporting requirements

In accordance with the responsibilities of sponsors (Section H) of the URPTG, you are required to provide **reports on the progress of the recall action at or before two weeks and six weeks of the date of this correspondence.** A close out report on this matter is also expected at or before 3 months of the date of this correspondence.

Report type	**2 week**	**6 Week**	**Close out**
Due Date	27 January 2009	23 February 2009	13 April 2009

The minimum information required for these reports is listed in attachment 1 to this advice. If the information is available before the required time then it may be submitted earlier.

Should you require any additional advice or further assistance with the recall, do not hesitate to contact me using the above contact details

Yours sincerely

s22 [redacted]

Reporting Requirements

Reports can be submitted to the Recalls Unit by
Email: recalls@tga.gov.au
Facsimile: 02 6203 1451 or
Post: TGA Recalls Unit, TGA, PO Box 100, Woden ACT 2606

TGA Recall reference No. RC-2009-RN-00018-3

2 WEEK REPORT REQUIREMENTS

1. Has the recall/corrective action been initiated? Confirm that the agreed action has begun. Eg the approved recall letter has been dispatched.	**[ ] YES**	**[ ] NO.** Please explain
2. Is the recall/corrective action progressing without major impediments? Eg The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please explain
3. The initial investigation findings have not changed the scope of the recall/correction Eg Additional units or products have not been identified with the same defect	**[ ] YES**	**[ ] NO.** Please advise
4. For any product exported from Australia, the overseas supplier(s) has been informed of the recall/correction action being undertaken in Australia.	**[ ] YES** **[ ] No exports**	**[ ] NO.** Please explain

Attachment 1 Reporting Requirements

6 WEEK REPORT REQUIREMENTS

1. Have ALL the customers that you contacted responded to your requested recall/corrective action? Have customers confirmed their amount of affected product (including none) and that they agree to the recall/corrective action.	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% & detail the attempts made to contact non responding customers
2. (a) Recall - Have ALL customers returned or destroyed their affected units; or **(b) Correction - Have ALL customers with units requiring correction been identified?**	**[ ] YES** **[ ] No goods left to recall or correct**	**[ ] NO.** Please advise when this is expected to occur
3. Is the recall/corrective action progressing without major impediments? Eg The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please explain

CLOSE OUT REPORT REQUIREMENTS (by the agreed time)

1. (a) Recall - Has ALL returned stock been destroyed*?; or **(b) Correction - Have ALL units with customers been corrected (or been supplied with the correction?** *A Certificate of destruction is to be provided where the goods have been destroyed.	**[ ] YES**	**[ ] NO.** Please explain & advise when this is expected to occur
2. What was the root cause of the defect that led to the recall/corrective action? Please detail		
3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action? Please detail		

INITIAL ASSESSMENT FORM – RECALLS AND MEDICINE PROBLEM REPORTS

RECALLS REFERENCE NUMBER RC-2009-RN-00018-3

Product name:	Stryker HA Coated Hip Stems manufactured in Ireland between December 2007 and January 2008 Various item and lot numbers (see attached)
ARTG Number(s):	ARTG - 145521, 145595, 145594, 145593, 145597.
Sponsor/Supplier:	Stryker Australia Pty Ltd
Approval Area:	MEDDEV

Problem Description	Specified lots of sprayed Hydroxyapatite (HA) hip stems did not meet Stryker's Internal Material Specification for tensile bond strength and crystallinity
Product Affected:	Various item and lot numbers manufactured in Ireland between December 2007 and January 2008
Distribution of affected product:	12 Hospitals NSW, TAS, VIC & WA

Hazard Category:	Class III
Hazard description:	Negligible or minimal risk to patient (see Sponsor's Medical Assessment on file)

Proposed ACTION (supplied product)	Recall all affected devices and send letter to implanting surgeons to notify them of the problem.
Level of action	Hospital
Letter distribution	Mail
Customer action (s)	Return product
Patient follow up?	- Customer discretion
Sponsor Action	- Send to manufacturer
Expected close out date	3 months

Regulator agreement	*Agree with the hazard assessment?* (YES / NO) *Agree with proposed action & correspondence?* (YES / NO) *Signed:* s22 [redacted] *Date:*

Comments

[Classification system. Class I – Class I defects are potentially life-threatening or could cause a serious risk to health. Class II – Class II defects could cause illness or mistreatment, but are not Class I. Class III – Class III defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

12A

INITIAL ASSESSMENT FORM – Recalls and medicine problem reports

Document 45

RECALLS REFERENCE NUMBER «RecallProblem_report_number»

Class I defects are potentially life-threatening or could cause a serious risk to health.
Class II defects could cause illness or mistreatment, but are not Class I.
Class III defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons

11

Recalls Unit Notification Screening Sheet **Recall RC-2009-RN-00018-3**

Is the product in the notification a therapeutic good? *(i.e. it is not a food, cosmetic or excluded good)*
[ ] YES - continue with this checklist
[ ] NO - then REFER notification - Send to _____ = *'Not a therapeutic good'*

Has a tampering incident been identified?
[ ] NO - continue with this checklist
[ ] YES - see Tampering SOP - treat as 'Unknown Sponsor Action' – **CHECKLIST COMPLETE**

Are there any similar reports on RAMP?
[ ] NO - continue with this checklist
[ ] YES - order any relevant files to review previous actions or identify duplicate entries
Outcome _____

Is the product defective or subject to misuse? *(i.e. the issue is not an adverse reaction report or a complaint about dispensing or advertising)*
[ ] YES - continue with this checklist
[ ] NO - then REFER notification - Send to _____ = *'Not a Recalls related issue'*

Does the notification say that the product is supplied in Australia?
[ ] YES - continue with this checklist
[ ] UNKNOWN
[ ] An overseas GMP failure report with NO recall - REFER notification to the Chief Auditor
[ ] An AUSTRALIAN supplier can be identified electronically (via ARTG, Client or website)
[ ] possible TGA approved supply (i.e. when the product type is not on ARTG)
[ ] NO - then REFER notification - Place on 'Not relevant' file = *'No evidence of supply in Australia'*
Detailed reason _____

[ ] **Relevant electronic information (ARTG, Client, websites) has been reviewed & printed?**
Is the product an IVD? [ ], illegally supplied? [ ], or also or subject to an adverse reactions? [ ]

Has the sponsor started action in marketplace? *i.e. possible/actual recall not following the URPTG*
[ ] NO/UNKNOWN - continue with this checklist
[ ] YES - issue is treated as 'Unknown Sponsor Action' – **CHECKLIST COMPLETE**

Is the notification from the Sponsor or TGA regulator?
[ ] YES - continue with this checklist
[ ] NO/UNKNOWN - issue is treated as 'Unknown Sponsor Action' – **CHECKLIST COMPLETE**

Is a 'Recall' action proposed?
[ ] YES - issue is treated as 'Sponsor Recall Action'
[ ] NO - issue is treated as 'Sponsor Non Recall Action' *i.e. No Action, Safety Alert, Product Notification*

Have the five essential sets of information been provided in at least summary form?
Problem Product Product Distribution Hazard & Proposed Action

[ ] YES - **CHECKLIST COMPLETE**
[ ] NO - seek clarification from the sponsor - **CHECKLIST COMPLETE**
Essential information still required _____

Recall Coordinator s22 [redacted] Date 9/01/09

s22
s22 @stryker.com>
Sent by: s22
s22
@stryker.com>

To <TGA.Recalls@tga.gov.au>
cc s22 @stryker.com>
bcc
Subject Recall: Stryker HA Coated Hip Stems

08/01/2009 01:41 PM

DOCUMENT NOT YET CLASSIFIED

To Whom It May Concern:

Please be aware that we have been advised by Stryker Orthopaedics that they have initiated a lot specific recall of HA Hips Stems. I have attached the proposed letter for your review in addition to a report containing information relevant to the action. While the manufacturer technical and medical assessments do not show an increased health risk to patients, Stryker Australia has elected to also inform implanting surgeons of the action through a separate communication (attached).

Best Regards,

s22

s22
Regulatory Affairs Associate

Stryker South Pacific
8 Herbert St
St Leonards NSW 2065
t: s22
f: +61 2 9467 1010
s22 @stryker.com

Draft - Surgeon Communication - AUS.doc
TGA Recall Report -RA 2008-137 - HA Stems.doc
TGA Recall letter- RA 2008-137 - HA Stem v1.1.doc

DOCUMENT NOT YET CLASSIFIED

Risk Assessment

stryker

TGA Recall Report

Date: 08/01/2009

Sponsor Information			
Sponsor:	Stryker Australia	ARTG Numbers:	145521, 145595, 145594, 145593, 145597
Contact:	s22 [redacted]	Title:	RA Associate
Ph:	[redacted]	Email:	s22 [redacted]@stryker.com

Manufacturer Information			
Name:	Stryker Ireland Ltd		
Address:	IDA Industrial Estate Carrigtwohill County Cork, Ireland		

AFFECTED PRODUCTS

Product Description	Catalogue Number (Range):	Lot Number(Range):
HA Hip Stems	See Appendix A	See Appendix A

Product Overview

The hip stems detailed in this summary were HA sprayed in the Cork facility between 7 December 2007 and 22 January 2008. They were sprayed with HA Powder manufactured in house (Cork, Ireland) or with powder from SAI, an approved supplier.

The HA coated stems are used in press-fit applications and are made of titanium alloy (Ti6Al4V or TMZF). The HA coating is circumferentially located in the proximal area of the stem. Underlying substrate of HA coating is either grit based, plasma sprayed Ti, or arc deposited Ti, specific to the type of stem.

REASON FOR RECALL

Description of event(s):

Stryker® Orthopaedics has become aware that specified lots of sprayed HA hip stems did not meet Stryker's Internal Material Specification for tensile bond strength and crystallinity. The affects of this deviation can lead to accelerated release of HA particles, accelerated release of HA fragments and accelerated Ca (Calcium) and P (Phosphate) release from HA coating.

Potential Hazard

Potential hazards associated with this deviation include accelerated release of HA particles, accelerated release of HA coating fragments and accelerated Calcium/Phosphate release from the HA coating, patient risks associated with these potential hazards are negligible to minimal as described below.

Patient risk associated with the accelerated release of HA particles is negligible. HA particulate from the Stryker coating does not appear to be a cause of three-body wear and this conclusion remains unchanged regardless of any discrepancy – related increase in HA particulate. There is no evidence to support or suggest that any increase in HA particulate represents a potential primary cause of debris-mediated osteolysis, which involves very high concentrations (e.g., tens of billion per gram of tissue) of sub-micron size particles of materials normally considered to be relatively inert in their bulk form.

Patient risk associated with the accelerated release of HA coating fragments is minimal. Coating fragments arising from stress- or strain – related mechanisms would be present at the implant bone interface, which, again, has been shown to greatly inhibit debris migration. Coating adhesion and composition are more

imp ant with thicker coatings, e.g., 150-200 microns, which are known to be inherently weaker and less resistant to strain than those in the 50 micron thickness range.

Patient risk associated with accelerated calcium and phosphate release from the HA coating is negligible. Bone response is affected by dissolution kinetics, the stress environment, and the inherent stability of the implant. The dissolution kinetics of a Ca-P coating are a reflection of its entire composition, not just a single phase within the coating, and a marked change in dissolution would be relatively small compared to other Ca-P coatings.

With respect to risk mitigation factors, the only theoretical adverse effect (if any) that could take place is interference of HA-particulate debris with the metal-PE articulation of the implant. Use of ceramic bearings would prevent this potential adverse effect because of the much harder nature of the ceramic-ceramic articulation.

Technical and medical assessments do not show an increased health risk to patients and Stryker® Orthopaedics is therefore not recommending any additional patient follow-up at this time.

Root Cause:

The root cause of this deviation was a malfunctioning HA gun. This particular HA gun malfunctioned between 7 December 2007 and 22 January 2008. Subsequently all batches of HA stems that were sprayed with the malfunctioning HA gun between 7 December 2007 and 22 January 2008 were evaluated.

Corrective / Preventative action:

The following corrective and preventative actions have been initiated by the manufacturer:

1. Subject devices have been placed on quality hold within the manufacturing site and Stryker Distribution Sites.
2. A Recall Notice will be distributed to all customers informing them of the issue and requesting immediate quarantine and return of subject devices to Stryker.

Action proposed by the sponsor

1. Stryker plans to send a recall letter to customers who have purchased affected units.
2. Customers will be required to sign the reply form indicating that they received the letter and return of the affected product will be arranged.
3. A separate communication will be distributed to implanting surgeons.

DISTRIBUTION (across all products)	
85	# Imported
20	# Consignment (12 Customers)
12	# Inventory in SSP Control
1	# Exported to New Zealand (recall will also be carried out in NZ)
50	# Sold

Consignment Locations

Customer	State
s22	[redacted]

Im, iting Surgeons

Surgeon	State
s22	[redacted]

Appendix A: Affected Items

Item	Description	Lot
4845-0106	ABGII NO6 CEMENTLESS RIGHT V40	G1938525D
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G1871588E
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6021-0740	ACCOLADE (127 DEG)	25138602
6021-0740	ACCOLADE (127 DEG)	25138602
6021-4535	ACCOLADE (127 DEG) SIZE 4.5	25190701
6041-0730	OMNIFIT M-HA HIP STEM C-TAPER	25222401
6041-0730	OMNIFIT M-HA HIP STEM C-TAPER	25222401
6041-0830	OMNIFIT M-HA HIP STEM C-TAPER	25039401
6041-0935	OMNIFIT M-HA HIP STEM C-TAPER	25393701
6265-5113	CITATION TMZF SIZE 3 RIGHT	24495803
6265-5115	CITATION TMZF SIZE 5 RIGHT	24729102
6265-5115	CITATION TMZF SIZE 5 RIGHT	24729102
6265-5115	CITATION TMZF SIZE 5 RIGHT	24729102
6265-5115	CITATION TMZF SIZE 5 RIGHT	24729102
6265-5115	CITATION TMZF SIZE 5 RIGHT	24765402
6265-5116	CITATION TMZF SIZE 6 RIGHT	24404102

8 Herbert Street, St Leonards NSW 2065
PO Box 970, Artarmon NSW 1570, Australia
Ph: 61 2 9467 1000 Fax: 61 2 9467 1010

stryker®
Australia

«DATE» January, 2009

Surgeon Letter

«CUSTOMER»
«ADDRESS_1»
«CITY», «STATE» «POST CODE»

RE: Stryker HA coated stems manufactured in Ireland between December 2007 and January 2008

Dear Dr « INSERT SURGEON NAME »

In a previous letter, your hospital was advised that on insert day, January insert date 2009, Stryker initiated a product recall for a range of HA coated stem manufactured at our Cork, Ireland facility. We wish to clarify the scope of the recall and our recommendations for physicians. The scope of this recall includes a specified lot of HA Stems manufactured at our Cork, Ireland facility from the 7th of December 2007 to the 22nd of January 2008.

Stryker® Orthopaedics has become aware that specified lots of sprayed HA hip stems did not meet Stryker's Internal Material Specification for tensile bond strength and crystallinity. The affects of this deviation can lead to accelerated release of HA particles, accelerated release of HA fragments and accelerated Ca (Calcium) and P (Phosphate) release from HA coating.

Technical and medical assessments do not show an increased health risk to patients and Stryker® Orthopaedics is therefore not recommending any additional patient follow-up at this time. Although the implanting and treating physicians are in the best position to exercise medical judgment for their patients and should make the final decision on this point.

Potential hazards associated with this deviation include accelerated release of HA particles, accelerated release of HA coating fragments and accelerated Calcium/Phosphate release from the HA coating, patient risks associated with these potential hazards are negligible to minimal as described below.

Patient risk associated with the accelerated release of HA particles is negligible. HA particulate from the Stryker coating does not appear to be a cause of three-body wear and this conclusion remains unchanged regardless of any discrepancy – related increase in HA particulate. There is no evidence to support or suggest that any increase in HA particulate represents a potential primary cause of debris-mediated osteolysis, which involves very high concentrations (e.g., tens of billion per gram of tissue) of sub-micron size particles of materials normally considered to be relatively inert in their bulk form.

Patient risk associated with the accelerated release of HA coating fragments is minimal. Coating fragments arising from stress- or strain – related mechanisms would be present at the implant bone interface, which, again, has been shown to greatly inhibit debris migration. Coating adhesion and composition are more important with thicker coatings, e.g., 150-200 microns, which are known to be inherently weaker and less resistant to strain than those in the 50 micron thickness range.

Patient risk associated with accelerated calcium and phosphate release from the HA coating is negligible. Bone response is affected by dissolution kinetics, the stress environment, and the inherent stability of the implant. The dissolution kinetics of a Ca-P coating are a reflection of its entire composition, not just a single phase within the coating, and a marked change in dissolution would be relatively small compared to other Ca-P coatings.

With respect to risk mitigation factors, the only theoretical adverse effect (if any) that could take place is interference of HA-particulate debris with the metal-PE articulation of the implant. Use of ceramic bearings would prevent this potential adverse effect because of the much harder nature of the ceramic-ceramic articulation.

Our records indicate that you have implanted one or more of the lot codes involved and these patient records have been enclosed in Appendix A.

In consultation with the Therapeutic Goods Administration your Stryker® Orthopaedics Sales Representative has contacted your Hospital to arrange the return, and replacement, of any unused product.

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We stand by the safety and clinical performance of our implants, both those you have implanted and may implant in the future.

If you have outstanding issues or concerns not addressed in this letter, please contact your sales representative or s22 [redacted], Stryker Australia on t: s22 [redacted] or email: s22 [redacted]@stryker.com .

Thank you very much for your support,

Sincerely,

s22 [redacted]
Regulatory Affairs Manager

t: s22 [redacted]
f: +61 (0)2 9467 1010
m: s22 [redacted]

s22 [redacted]@stryker.com

Recall letter

stryker

South Pacific

MEDICAL DEVICE RECALL

To: Chief Executive Officer

Attn: Nurse Unit Manager – Operating Theatres

Date: 8 January 2009

ARTG No.: 145521, 145595, 145594, 145593, 145597

Product Affected: (Lot Specific)
A range of HA coated stems manufactured at Stryker's Cork facility between 07 December 2007 and 22 January 2008. (A detailed list is provided in Appendix A)

Product Issue:
Stryker® Orthopaedics has become aware that specified lots of sprayed HA hip stems did not meet Stryker's Internal Material Specification for tensile bond strength and crystallinity. The affects of this deviation can lead to ac[illegible]lerated release of HA particles, accelerated release of HA fragments and accelerated Ca (Calcium) and P ([illegible]sphate) release from HA coating. Patient risks associated with this manufacturing discrepancy are negligible to minimal. (Further details are provided in Appendix B).

We are recalling these affected products following consultation with the TGA.

Recommended Action:

1. Review the products specified in this notice and check your inventory for affected items.
2. Remove the affected items from your inventory and quarantine these until collected or returned.
3. To return these please contact your local Stryker Representative for either collection or instructions on how to forward these to your local Stryker Distribution Centre (see below for State addresses and telephone numbers).
4. Upon return please identify with your local Stryker Representative if you require replacement or a credit note for stock returned.
5. **Please complete and return a signed copy of the attached notification response**, acknowledging that you have received this notice, even if you no longer hold any of the affected products. Doing this will preclude further notices.
6. If any of the recalled stock could have been transferred from your hospital to another, please immediately let that hospital know of this recall. It would be appreciated if you would then telephone s22 on free-call 1800 803 601, so that we can make contact with that hospital.

We sincerely apologise for any disruption this may cause you.

Additional Information: Please contact s22, Regulatory Manager for general enquiries on 1800 803 601.

s22
Regulatory Affairs Manager
Stryker South Pacific

NSW Distribution Centre s22	**Western Australian Office** s22
Victorian Office s22	**South Australian Office** s22
Queensland Office s22	

Medical Device Recall Notification Response

The following affected units have been identified as being located at <Hospital Name>. Please review the list below adding any additional affected units located at your facility in the space provided. A complete list of affected units is available in Appendix A.

Item Number	Description	Lot	Located (Y/N)	Comments

We _____ *have received notification of the Product Recall*
Customer Name

concerning ***HA Hip Stems***.

☐ At the time of this notice, we did not hold any of the affected products, as detailed within the notification sent by Stryker.

☐ We have quarantined and will return all affected products to Stryker, being *_____* units as detailed above.
Quantity

☐ We have transferred the following product/s identified in this recall to another customer / hospital

(please provide the name/s of the organisation/s involved in any transfer):

Comments:

_____

_____

_____

_____

Signature _____ Name (Print) _____ Date _____

Title /Position _____ Contact Number _____

Please Return by Fax to (02) 9467 1010

Return form to:
Attention: s22 [redacted] - (RA 2008-137)
Stryker South Pacific
Mail
8 Herbert Street, St Leonards, NSW 2065
Facsimile
02 9467 1010
Enquiries
1800 803 601 (free-call) or s22 [redacted] (direct line – s22 [redacted])

Appendix A: HA Hip Stems - Affected Lot Numbers

Item	Description	Lot
4845-0106	ABGII NO6 CEMENTLESS RIGHT V40	G1938525D
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G1871588E
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G2075932D
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G2075932D
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G2075933A
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G2093024A
6020-0435	ACCOLADE	25005901
6021-0537	ACCOLADE (127 DEG)	24992704
6021-4535	ACCOLADE (127 DEG) SIZE 4.5	24956301
6021-4535	ACCOLADE (127 DEG) SIZE 4.5	24973501
6041-0935	OMNIFIT M-HA HIP STEM C-TAPER	25060601
W6021-0335	ACCOLADE (127 DEG) SAMPLE	25309501
4845-0103	ABGII NO3 CEMENTLESS RIGHT V40	G2131092C
4845-0104	ABGII NO4 CEMENTLESS RIGHT V40	G2115997C
4845-0107	ABGII NO7 CEMENTLESS RIGHT V40	G1852741C
4845-0107	ABGII NO7 CEMENTLESS RIGHT V40	G1852741C
4845-0107	ABGII NO7 CEMENTLESS RIGHT V40	G1835616D
4845-0203	ABGII NO3 CEMENTLESS LEFT V40	G1898430E
4845-0203	ABGII NO3 CEMENTLESS LEFT V40	G1898430E
4845-0203	ABGII NO3 CEMENTLESS LEFT V40	G1925351E
4845-0204	ABGII NO4 CEMENTLESS LEFT V40	G2137098A
4845-0206	ABGII NO6 CEMENTLESS LEFT V40	G1885772D
4845-0206	ABGII NO6 CEMENTLESS LEFT V40	G1885772E
4845-0206	ABGII NO6 CEMENTLESS LEFT V40	G1885772E
4845-0206	ABGII NO6 CEMENTLESS LEFT V40	G1907526E
4845-0208	ABGII NO8 CEMENTLESS LEFT V40	G1542000C
6020-0335	ACCOLADE	25079901
6020-0335	ACCOLADE	25386101
6020-2530	ACCOLADE 132 SIZE 2.5	25138701
6020-3535	ACCOLADE 132 SIZE 3.5	25387303
6020-3535	ACCOLADE 132 SIZE 3.5	25387304
6020-4535	ACCOLADE 132 SIZE 4.5	25095501
6021-0537	ACCOLADE (127 DEG)	25080702
6021-0740	ACCOLADE (127 DEG)	25138602
6021-4535	ACCOLADE (127 DEG) SIZE 4.5	25190701
6041-0730	OMNIFIT M-HA HIP STEM C-TAPER	25222401
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6265-5115	CITATION TMZF SIZE 5 RIGHT	24729102
6265-5115	CITATION TMZF SIZE 5 RIGHT	24765402
6265-5116	CITATION TMZF SIZE 6 RIGHT	24404102

Appendix B: HA Hip Stems – Potential Hazards

Technical and medical assessments do not show an increased health risk to patients and Stryker® Orthopaedics is therefore not recommending any additional patient follow-up at this time. The implanting and treating physicians are in the best position to exercise medical judgment for their patients and should make the final decision on this point. Please note that your signature on this form only confirms that you received this notification and does not obligate you to take any additional action beyond what is called for in this Field Safety Corrective Action notification letter.

Potential hazards associated with this deviation include accelerated release of HA particles, accelerated release of HA coating fragments and accelerated Calcium/Phosphate release from the HA coating, patient risks associated with these potential hazards are negligible to minimal as described below.

Patient risk associated with the accelerated release of HA particles is negligible. HA particulate from the Stryker coating does not appear to be a cause of three-body wear and this conclusion remains unchanged regardless of any discrepancy – related increase in HA particulate. There is no evidence to support or suggest that any increase in HA particulate represents a potential primary cause of debris-mediated osteolysis, which involves very high concentrations (e.g., tens of billion per gram of tissue) of sub-micron size particles of materials normally considered to be relatively inert in their bulk form.

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