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

DIR : 2 - ID : 136147

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

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
17689	2007/009825	IRF#382	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		17/03/2008	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
31/03/2008	03/04/2008		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
10/04/2008			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Clinical Event Information:

Patient with an M-COR Hip Replacement System presented with a dislocated hip after sitting down into a very low chair. The patient had the primary total hip replacement procedure with an M-COR hip system, including another manufacturer's acetabular cup system 14 days prior to dislocation. Following the dislocation, the surgeon elected to replace the acetabular cup, which also required the M-COR system femoral neck and head to be removed to gain better access to the cup. As a precaution of engineering reasons the neck and head were also replaced during the revision procedure. The MCOR femoral stem was left in place.

14FEB08.
The decision by the surgeon to conduct the revision surgery in this case was not related to the MCOR system devices.

No corrective actions were required or taken as event was not directly related to the M-COR system devices.

Report sourced from sponsor (ref: IRF#382).

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:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
Ra			
Reporter Title:	**First Name:**	**Surname:**	
	Manoja	Ranawake	
Position:		**Company/Institution:**	
Regulatory Affairs Officer		Advanced Surgical Design & Manufacture	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2/12 Frederick Street		St Leonards	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2065	(02) 9439 4448	(02) 9439 4441
Mobile:	**Email:**		
	m.ranawake@pldortho.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:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		130874	130874
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
Medical Device	Included	Class IIb	35666
GMDN Text:		Brand Name:	
Prosthesis, internal, joint, hip, femoral component			
Initial Device Description:			
M-COR Hip Stem System			
Usage of Device:	Software Version:		
Model #:	Serial #:	Batch #:	Lot #:
M-COR Fem Neck 47	47-000101/2264		
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:
Portland Orthopaedics Limited		32827	
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:
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	Yes	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 #:
Po	Portland Orthopaedics (Aust) Pty Ltd		42862
Attention To:	Address 1:	Address 2:	Town/Suburb:
Manoja Ranawake	Unit 3 / 44 McCauley Street		MATRAVILLE
State:	Postcode:	Phone:	Fax:
NSW	2036	(02) 9700 1533	(02) 9666 8544
Email:			
m.ranawake@pldortho.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

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Completion Notification	10/04/2008				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC1

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 : 26128

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Att
26128	DIR-REQ		Closed	theta	IRIS Coordinator	10/04/2008	Normal	0

Signature Details

Role	IRIS Investigator
User	theta - Theta Technologies
Signed At	10/04/2008 00:00:00
Comment	Automatically signed off closed DIR forms as part of data migration