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

DIR : 2 - ID : 139806

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

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
21406	2010/015912		Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		02/06/2010	
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
08/06/2010	09/06/2010		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
13/08/2010			Yes
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Specialist		For IRIS Meeting	

Clinical Event Information:

Fracture of neck component of THR.

Revision surgery.

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:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
Ri			
Reporter Title:	**First Name:**	**Surname:**	
Mr	Martin	Richardson	
Position:		**Company/Institution:**	
Surgeon			
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Suite 5A Level 2	1 Arnold Street	Box Hill	VIC
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	3128	(03) 9426 4333	(03) 9426 4321
Mobile:	**Email:**		

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

Usage of Device:	Software Version:

Model #:	Serial #:	Batch #:	Lot #:
		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 8344

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:

Diary Entry: 06/08/2010 - Contacted the reporter. Requested that the broken femoral joint prosthesis be sent to the TGA for examination.

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	13/08/2010				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\RC2

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			
Materials and chemistry			

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
No further action		

Recall Number:

Investigation Summary:

The fractured neck and the stem were returned to the TGA for analysis.

The markings on the stem are: Ti-6Al-4V 37x14-000117 - M-COR 37x14 ¿ 15,3 ¿
The markings on the neck are: M-COR ¿ 15,3 ¿ 47- 000085

This is a modular neck design, which was anteverted by approximately 15¿. The fracture was at the neck, at the top of the taper (where the taper emerges from the top of the stem). Details about the patients weight, age, mobility were requested but not provided.

Fracture analysis revealed a characteristic fatigue-mode failure. In fatigue failure, a crack is initiated from a point of weakness on the surface of the component under cyclic load. The crack grows slowly under cyclic loads which are below the ultimate tensile strength of the component. The component fails suddenly when there is not enough material left to support the applied load. Each of these stages of fracture propagation leaves a characteristic pattern on the fracture surface.

In this case, the point of weakness may have been an intrinsic flaw in the material, damage introduced during manufacture, or damage introduced intraoperatively - It was not possible to determine which.

Anteversion, offset, the patients weight and activity level would all contribute to crack initiation and propagation. However it should be noted that the MCOR hip is designed so that the anteversion and offset can be adjusted and that the neck may have failed even if the patients weight was normal.

The performance of the implant in the Australian National Joint Replacemet Register was checked. A total of 125 MCOR stems and necks have been implanted between 2007 and 2009. In that time the registry records one other revision due to subsidence. The recorded revision rate is 0.4 revisions per hundred component years. The average revision rate of similar implants is 0.8 revisions per 100 component years.

The MCOR Hip replacement system is no longer available in Australia for commercial reasons.

Implant facture is rare. This case appears to be isolated. No further action appears to be indicated

Flow Details : DIR-REQ - Device Incident Request : 29787

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Att
29787	DIR-REQ		Closed	theta	IRIS Coordinator	12/10/2010	Normal	0

Signature Details

Role	IRIS Investigator	
User	theta - Theta Technologies	
Signed At	12/10/2010 00:00:00	
Comment	Automatically signed off closed DIR forms as part of data migration	