theta

Device Incident Report

Released By : Matthew Grant on 25/06/2015 15:11:06

Print

Form Details

Form ID:	Template Code:	Template Name:	Form Date:
165525	DIR	Device Incident Report	13/09/2012
Signed Status:	**Division:**	**Organisational Area:**	**Revision:**
SIGNED	Office of Product Review	Device Vigilance and Monitoring	20

Report Information Section

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
28523	2012/021025		Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed			13/09/2012
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
13/09/2012	14/09/2012	25/09/2012	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
28/11/2014			Yes
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Surgeon		For IRIS Meeting	

Event Description for Website Publication:

Delamination of the ceramic coating causing early failure requiring revision procedure.

Clinical Event Information:

Delamination of the ceramic coating causing early failure requiring revision procedure.

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

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Revision hip replacement.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
RID			
Reporter Title:	**First Name:**	**Surname:**	
[redacted]	[redacted]	[redacted]	
Position:		**Company/Institution:**	
ORTHOPAEDIC SURGEON			
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
[redacted]		[redacted]	[redacted]
Country:	**Postcode:**	**Phone:**	**Fax:**
	[redacted]	[redacted]	
Mobile:	**Email:**		**Last External Submission By:**

Initial Reporter Section

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 118430 118430

Therapeutic Licence Type: Product Licence Category: Device Class: GMDN / UMDN Code:
Medical Device Included Class IIb 33717

GMDN / UMDN Text: Brand Name:
Prosthesis, internal, joint, hip, resurfacing Eska resurfacing ceramic hip replacement

Initial Device Description:
Eska resurfacing ceramic hip replacement

Usage of Device: Software Version:
Single Use

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:
Discarded

Access Contact Phone: Access Contact Fax:

Manufacturer Information Section

Manufacturer Name: Manufacturer Client Id: Address 1:
Eska Implants GmbH and Co 45325

Address 2: Town/Suburb: State/Province: Country:
<> Australia

Postcode: Phone: Fax:

Email: Manufacturer Informed: Date Aware of Adverse Event:

Contact Title: Contact First Name: Contact Surname:

Supplier Information Section

Supplier Name: Address 1: Address 2:
ESKA AUSTRALIA

Town/Suburb: State: Postcode: Phone:

Fax: Email: Supplier Informed:
Yes

Date of Supplier Contact: Contact Title: Contact First Name: Contact Surname:
10/05/2010

Contact Phone: Contact Fax:

Risk Analysis

Statistics Checklist Section

Date: Assessed By: For website publication: Ready for Publication: Exclude report from DIRE:
14/09/2012 [redacted] 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 Routine

DIRE Meeting Notes:
Closed - Advice from Jorge Garcia, no letters sent.

Sponsor Investigation

Sponsor Information Section

Search Sponsors:	Name:		Client #:
eska	Eska Australia		45270
Attention To:	Address 1:	Address 2:	Town/Suburb:
[redacted]	72 South Street		RYDALMERE
State:	Postcode:	Phone:	Fax:
NSW	2116	02 9420 9001	

Email: [redacted]

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:

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 Involved

Other Devices

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

Related DIR Information

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

Incident Details

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

Investigation Information - Samples

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

Investigation Information - Correspondence

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
		26/09/2012	09/10/2012			

Questionnaire Sent			
Reporter Notification Sent	26/09/2012		
41JA letter	16/10/2012	29/10/2012	22/10/2012

Investigation Problem Types

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
Manufacturing process	Assembly	

Investigation Outcomes

Outcome Details

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

Investigation Summary

Recall Number:

Investigation Summary:

The NJRR data indicates that 12 implants have been used all likely from the same surgeon with 9 revisions of primary. Bionik implants were cancelled from the Australian Register of Therapeutic Goods (ARTG) on 12 June 2012 and are no longer used.

Attachment Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Email - discussion between Prof Graves and Dr ...	11	Form	
FILE		Ceramic options for Total Hip & Resurfacing	642	Form	
FILE		Clinical_assessment_Bionik System	791	Form	
FILE		hp_scan_2210201214250700	624	Form	
FILE		Summary of wear tests pairing CeraMetal_ESKA-Ceram	110	Form	
FILE		Surgical Technique-BS Resurfacing	4585	Form	
FILE		Eska Bionik Ceramic Rates	157	Form	

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
38043	DIR-REQ		Closed	howata	OPR Administration User	28/11/2014	Normal	0

Signature Details

Role	IRIS Investigator
User	howata - Anne Howatt

Signed At	28/11/2014 13:36:17
Comment	