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

DOCUMENT 22

Mfr report # *	481-23/09
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)	13-01-2010
B) Date of adverse event (dd-mm-yyyy)	06-07-2009
C) Date mfr aware (dd-mm-yyyy)	06-07-2009
D) Date of next report (max 30 days from A)	N/A

Person (authorised representative) Submitting This Report

Name	[redacted]
Company	ESKA Implants AG
Address	Grapengießerstraße 34, 23556 Lübeck, Germany
Tel.	[redacted]
Fax	[redacted]
E-mail	[redacted]

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was *also* sent.

Bundesinstitut für Arzneimittel und Medizinprodukte, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany (Health Authority)

Dekra Certification GmbH, Handwerkstraße 15, 70565 Stuttgart, Germany (NB)

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: 25-05-2009 **Explant Date:** 06-07-2009

Damage of the articulating surface of the hip resurfacing femoral cup device after femoral neck fracture.

RECEIVED 14 JAN 2010

III- Healthcare Facility Information *Mandatory

Name	N/A
Address	Suite 310, Level 3, 203-233 New South Head Rd, Edgecliff NSW 2027
Tel	(02) 9327 7494
Fax	(02) 9327 8295
E-mail	N/K
Contact name at site of event	[redacted]

IV- Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	118430
GMDN Code	16-095 (UMDNS)

GMDN Code Text (eg catheters, central venous, peripherally inserted)

Prosthesis, Joint, Hip, Femoral Component (UMDNS)

Specific Device Information

Brand Name *	HIP SURF. REPL. CREAM "BS" CEM. W. NAIL, D=3MM, OD=48MM
Model # *	N/A
Catalogue #	10270248
Ser. or Lot #'s	1510801602
Mfr. Name*	ESKA Implants AG
Contact Name *	[redacted]
Address *	Grapengießerstraße 34, 23556 Lübeck, Germany
Tel *	[redacted]
Fax	[redacted]
E-mail *	[redacted]
ARTG Mfr. # *	N/A

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 *

The device is currently at an external laboratory (University of Applied Sciences München, Germany) and will be send back to the Manufacturer (ESKA Implants AG).

V- Results of Mfr's Investigation * *Mandatory*

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Summary of the Investigation result of the University of Applied Sciences München, Germany, No. 20090911-01, 2nd Jan 2010 (Translated by ESKA Implants AG, Germany, Jan 2010)

The investigated hip resurfacing femoral cup was revised because of a femoral neck fracture approx. 6 weeks after implantation. Extensive flakings of the articulating surface are apparent in the rim area of the hip resurfacing femoral cup. At the exposed metallic base material a polished area is visible caused by relative movements between the hip resurfacing femoral cup and the acetabular cup (patient's walking). The location of the polished area close to the rim of the cup allows us deriving from the load direction of the hip to conclude that the relative movements primarily took place after the fracture of the femoral neck and after the subsequent inclination of the prosthesis towards a varus position. Caused by the consecutive steep malposition of the hip resurfacing femoral cup a high contact pressure at the rim area of the hip resurfacing femoral cup was unavoidable. The root cause is still unclear. Different scenarios are possible. Low bonding strength between coating and basic substrate could have been the cause as well as abrasion caused by relative movements between the hip resurfacing femoral cup and the metal shell. On the other hand there are areas which clearly show that the bonding strength between base material and substrate was higher than the intrinsic strength within the coating. A definite statement about the damage mechanism is not possible. The reported clinical conditions as well as the described findings on the implant itself suggest most likely that subsequent to the femoral neck fracture and the consecutive high rim contact pressure an overload to the rim area lead to a spalling of the coating. A manufacturing failure leading to a insufficient bonding between substrate and layer seems unlikely to be the damage cause.

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.)

N/A

VI- Patient Information * *Mandatory as marked below*

Age (yrs, mths)	[redacted]	M/F	[redacted]	Wt. (kg)	[redacted]

Patient Focused Resolution of Events and Outcomes

Corrective action taken relevant to the care of the patient:

Revision of the product

Patient history (co-morbidities & medication):

N/K

* Patient outcome:

N/K

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

- INSERT "ESKA-CERAM" "BS" FOR OD=56MM, ID=48MM; Model# = 10390048; ARTG# = 118426

- METAL SHELL, CEM.LESS "BS", TiNb-,CaP-C., SCREW FIX. OD=56MM; Model# = 10201356; ARTG# = 118425

VII- Other Reporting Information *Mandatory

Mfr/Sponsor aware of other similar events? (*number or *rate)

No

Countries where these similar adverse events occurred:

N/A

Additional Comments

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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.

[redacted]

13/01/2010 22:13

To "'iris@tga.gov.au'" <iris@tga.gov.au>
cc [redacted]
bcc
Subject Medical Device Incident Report / Mfr report# 481-23/09 / final

FULL HEADER

DOCUMENT NOT YET CLASSIFIED

Dear Sir or Madam,

attached we are sending you the final report of our Medical Device Incident Report # 481-23/09.

Kind regards

[redacted]
Quality Management

Telefon: [redacted]
Telefax:
E-Mail: [redacted]
Internet: www.eska-implants.de

Sitz der Gesellschaft: Lübeck | Amtsgericht Lübeck HRB 8415 | USt.-Id.-Nr.: DE 259 097 802
AUFSICHTSRAT (Vors.): [redacted]
VORSTAND: [redacted]

ESKA Implants AG | Grapengießerstraße 34 | 23556 Lübeck

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