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 # *	490-32/09 53
TGA DIR #	19

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)	12-02-2010
B) Date of adverse event (dd-mm-yyyy)	09-09-2009
C) Date mfr aware (dd-mm-yyyy)	11-09-2009
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.

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

II- Clinical Event Information *Mandatory

escription of event or problem

If the device is an implantable device indicate both implant and explant dates below

Implant Date: 17-09-2008 Explant Date: 09-09-2009

The entire hip has been pushed in the Lateral direction.

RECEIVED
16 FEB 2010

III- Healthcare Facility Information *Mandatory

Name	N/K		
Address	N/K		
Tel	N/K	Fax	N/K
E-mail	N/K		
Contact name at site of event	Dr. Chan		

IV- Device Information Primary Device *Mandatory

Generic Device Information

Device ARTG # *	118427
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 *	ADAP.HIP STEM,PART.STRUCT. GHE CEM.LESS,TiNb-,CaP-C.,COLLARL. 3/LG=110MM R
Model # *	N/A
Catalogue #	11090373
Ser. or Lot #'s	1770707304
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 in possession of the manufacturer (ESKA Implants AG, Germany).

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

Manufacturers Device Analysis Results

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

The inspection of the dual cone adapter shows that the implant most likely had not been fully connected initially. The combination of the not fully connected dual cone adapter and the high acting moments caused by the higher length of the custom made dual cone adapter, in comparison with our CE-marked dual cone adapters, lead to a slowly loosening and finally to the complete loosing of the connection between hip stem and dual cone adapter. The dimensional inspection of the other implants shows no deviations to the date of manufacturing except some minor wear.

With the right initial connetion there would have been no risk with regard to the CE-marked product.

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/K

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 #

- METAL-INSERT SILVER "BS" FOR OD=52MM ID=38MM; Model# = 10225238; ARTG# = 118429

- METAL HEAD BIOSURF SILVER "BS" T12/14 OD=38MM X-LONG; Model# = 10250438; ARTG# = 118428

- METAL SHELL,CEM.LESS "BS" TiNb-,CaP-C.,SCREW FIX.OD=52MM; Model# = 10201352; ARTG# =

- X-LONG DUAL CONE 10°; Model# = 98000001 (custom made); ARTG# = 118441

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.

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.**

[redacted]

13/02/2010 01:08 AM

To "'iris@tga.gov.au'" <iris@tga.gov.au>
cc [redacted]
bcc
Subject Medical Device Incident Report / Mfr report# 490-32/09 / final rep

FULL HEADER

DOCUMENT NOT YET CLASSIFIED

Dear Sir or Madam,

attached we are sending you the final report of our Medical Device Incident Report # 490-32/09.

Kind regards

[redacted]
Quality Management

Telefon: [redacted]
Telefax: [redacted]
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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winmail.dat Medical_Device_Final_Report_490-32-09.doc

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