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Therapeutic Goods Administration [IncPrint]

Device Incident Reports

Full Details Report

New File Req 33

DOCUMENT 20

20

DIR /20669 Prosthesis, internal, joint, hip, resurfacing/Eska Implants GmbH and Co

Exempt/Not on Artg: N

Syst/Artg No ARTG / 118430

Ecri Code: 33717 Prosthesis, internal, joint, hip, resurfacing

Device: Hip prosthesis (mfr# 481-23/09)

Model No: Batch No: Serial No: 1510801602

Manufacturer: Eska Implants GmbH and Co 45325
DDR

Sponsor: Eska Australia 45270
Unit 4 4-6 Chaplin Drive
LANE COVE NSW 2066 AU

Contact: [redacted] Phone: [redacted] Fax: [redacted]

Reporter Details: Confidential: No

[redacted]

ESKA Implnats
Grapengiebe 34,
Lubeck, Germany

Phone: 45189000-41

Incident Description: 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.
Summary of the Investigation: 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.
(see diary)

Full Details Report

DIR /20669 Prosthesis, internal, joint, hip, resurfacing/Eska Implants GmbH and Co

Date Received:	14/01/2010
Date Entered:	25/01/2010
Date Completed:	16/02/2010
Date Closed:	16/02/2010
Associated Files:	S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC20669.DOC

Device Type - Sterile:	N
- Reusable:	N
Sample Received:	N
Classification:	Routine
Potential Outcome:	Serious Injury
Actual Outcome:	Serious Injury
Injured Party:	Patient
Reporter Category:	Other - Sponsor
Type of Incident:	Mechanical
Cause of Incident:	Mechanical
Investigation Result:	Not Investigated
Recommendation:	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.
Investigator Name:	[redacted] 25/01/2010

***** End Of DIR / 20669 *****

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

[redacted]
Eska Australia
Unit 4 4-6 Chaplin Drive

LANE COVE NSW 2066

Dear [redacted],

DEVICE INCIDENT REPORT DIR 20669 - Prosthesis, internal, joint, hip, resurfacing/Eska Implants GmbH and Co

We have now completed our evaluation of the incident reported to the Therapeutic Goods Administration concerning the above device.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, complete with closing recommendations is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please do not hesitate to contact me here in Canberra on (02) 6232 8477.

Yours sincerely,

[redacted]

Email
FAXED
16/02/10

Incident Report and Investigation Scheme
Market Vigilance and Monitoring Section
Therapeutic Goods Administration

16/02/2010

messagemanager@tga.gov.au
16/02/2010 04:36 PM

To [redacted]
cc
bcc
Subject Fax sent: Completion Letter for DIR 20669 [SEC=UNCLASSIFIED]

UNCLASSIFIED

To: [redacted] Eska Australia
Fax number: +61294209002
Status: Sent
Completed: Tuesday, 16 February 2010 at 4:36 PM
Pages sent: 4 of 4
Duration: 41 seconds
Received fax CSID: 94209002
MSN: 179919

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