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Therapeutic Goods Administration
Device Incident Reports
Full Details Report

DIR /20799 — **Prosthesis, internal, joint, hip, total/Eska Implants GmbH and Co**

Exempt/Not on Artg: N

Syst/Artg No ARTG / 118427

Ecri Code: 36315 Prosthesis, internal, joint, hip, total

Device: Femoral Component - (mfr ref: 490-32-09)

Model No: **Batch No:** **Serial No:** 1770707304

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]

Position: [redacted]

Institution: ESKA Implants AG
ESKA Implnats
Grapengiebe 34,
23556 Lubeck, Germany

Phone: [redacted]

Incident Description: Implant Date: 17/09/2008.
Explant Date: 09/09/2009.

The entire hip has been pushed in the Lateral direction.

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 connection there would have been no risk with regard to the CE-marked product.

Similar events: No.

Report sourced from sponsor.

Date Received: 16/02/2010

Date Entered: 19/02/2010

Therapeutic Goods Administration
Device Incident Reports
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DIR /20799 Prosthesis, internal, joint, hip, total/Eska Implants GmbH and Co

Date Completed: 10/03/2010
Date Closed: 10/03/2010

Associated Files: S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC20799.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: Sandra Byrne 19/02/2010

***** End Of DIR / 20799 *****

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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 20799 - Prosthesis, internal, joint, hip, total/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 8695.

Yours sincerely

[redacted]

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

E-MAILED
10/3/10

10/03/2010