Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Form # MDIR02, for use by medical device manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR02

Last revised: June 2005 3/5

| | |
|---|---|
| -Mfr report # | 08005629 |
| -TGA DIR # | |

Same as next 08005629

# IRIS: Medical Device Incident Report Investigation Scheme

## I- Administrative Information

**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) | 05.08.2008 |
| B) Date of adverse event (dd-mm-yyyy) | 24.07.2008 |
| C) Date mfr aware (dd-mm-yyyy) | 24.07.2008 |
| D) Date of next report (max 30 days from A) | 05.09.2008 |

**Person (authorised representative), submitting this report**

| | |
|---|---|
| Name | [redacted] |
| Company | Johnson & Johnson Medical Pty Ltd |
| Address | 1-5 Khartoum Rd North Ryde |
| | NSW 2113 |
| Tel. | [redacted] Fax [redacted] |
| E-mail | [redacted] |

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

## II- Clinical Event Information

**Description of event or problem**

Patient had a Charite TDR size 4 at the L5/S1 level. The Charite TDR was sitting off lateral to midline. This was causing the spine to form an acute scoliosis at the instrumented level and extending into the levels above. The surgeon removed the Charite Disc without observable complications and implanted an ALIF cage (6986-00-067) with supplemental fixation in the form of an AEGIS plate (1871-50-025) plus trans-lamina/trans-facet screws (Synthes).

RECEIVED
- 6 AUG 2008

## III- Healthcare Facility Information

| | |
|---|---|
| Name | Dalcross |
| Address | |
| Tel | Fax |
| E-mail | |
| Contact name at site of event | |

## IV- Device Information

**Generic Device Information**

| | |
|---|---|
| Device ARTG # | TBC |
| GMDN Code | TBC |

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

TBC

**Specific Device Information**

| | |
|---|---|
| Brand Name | Charite TDR sz4 |
| Model # | Unknown |
| Catalogue # | |
| Ser. or Lot #'s | Unknown |
| Mfr. Name | DePuy International Leeds UK |
| Contact Name | [redacted] |
| Address | |
| Tel. | [redacted] Fax |
| E-mail | [redacted] |
| ARTG Mfr. # | DePuy International (England)[18332] |

**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

Not provided

## V- Results of Mfr's Investigation

**Manufacturers Device Analysis Results**

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

To be provided

**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.)

## VI- Patient Information (rpt. if required)

| Age (yrs, mnths) | 39 | M/F | M | Wt. (kg) | Unk |
|---|---|---|---|---|---|

**Patient-focused resolution of events and Outcomes**

Corrective action taken relevant to the care of the patient:

Revision

Patient outcome:

Satisfactory as far as we are aware

List of other devices involved in the event

## VII- Other Reporting Information

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

Countries where these similar adverse events occurred:

Additional Comments

**Submitting this report:**

By mail: Reply Paid 32
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris[redacted]

**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.**

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Last revised: June 2008 v2

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| Ser. or Lot #'s | Unknown |
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| Contact Name | [redacted] |
| Address | |
| Tel. | [redacted] Fax |
| E-mail | [redacted] |
| ARTG Mfr. # | DePuy International (England)[18332] |

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