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

-Mfr report #	08005629
-TGA DIR #	

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)	17.12.2008
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)	-

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.

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).

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18 DEC 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 148559. ? 92689.
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)

The surgeon believes that the device may have been placed off midline. Surgeon was unsure if the device migrated post-op. The device is not available for evaluation and the lot numbers not known at this time. The event as reported was not attributed to the device. No definitive conclusions can be made at this time. Based on the information provided it appears that the issue was related to the initial placement on the device being off midline.

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.)

NA

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)

NA

Countries where these similar adverse events occurred:

NA

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.

[redacted]

17/12/2008 08:28 PM

To "TGA (E-mail)" <IRIS[redacted]
cc
bcc
Subject DIR 08005629 FINAL

FULL HEADER

DOCUMENT NOT YET CLASSIFIED

For you review

[redacted]

Johnson & Johnson Medical and Janssen Cilag

Australia and New Zealand

Johnson & Johnson MEDICAL

[redacted]

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