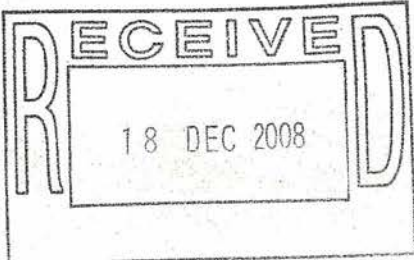




-Mfr report #	08005629
-TGA DIR #	

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information	
<b>Report Type (select one)</b>	
Initial <input type="checkbox"/>	Follow-Up <input type="checkbox"/>
Final <input checked="" type="checkbox"/>	Trend <input type="checkbox"/>
<b>Report Category</b>	
S Pblc Hlth Threat <input type="checkbox"/>	Death/Serious Injury <input type="checkbox"/>
Other <input checked="" type="checkbox"/>	
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)	-
<b>Person (authorised representative), submitting this report</b>	
One <input type="radio"/>	[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 <i>also</i> sent.	

Clinical Event Information
<b>Description of event or problem</b>
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).


III- Healthcare Facility Information	
Name	Dalcross
Address	
Tel	
Fax	
E-mail	
Contact name at site of event	

IV- Device Information	
<b>Generic Device Information</b>	
Device ARTG #	TBC <span style="float: right;">148559.</span>
GMDN Code	TBC <span style="float: right;">? 92689.</span>
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 [Redacted]
E-mail	[Redacted]
ARTG Mfr. #	DePuy International (England)[18332]

<b>Operator of Device at Time of Event (select one)</b>	
HC Profnal <input checked="" type="checkbox"/>	Other Caregiver <input type="checkbox"/>
Patient <input type="checkbox"/>	N/A <input type="checkbox"/>
<b>Usage of Device</b>	
Single Use <input checked="" type="checkbox"/>	Reuse of Single Use <input type="checkbox"/>
Reuse of Reusable <input type="checkbox"/>	Re-serviced/Refurbished <input type="checkbox"/>
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
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**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.



To "TGA (E-mail)" <IRIS [redacted]>

cc

bcc

17/12/2008 08:28 PM

Subject DIR 08005629 FINAL

FULL HEADER

DOCUMENT NOT YET CLASSIFIED

For you review



Johnson & Johnson Medical and Janssen Cilag

Australia and New Zealand



1-5 Khartoum Road  
North Ryde  
NSW, 2113

PO Box 134  
North Ryde  
NSW, 1670

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