[redacted]

17/12/2008 08:36 PM

To "TGA (E-mail)" <IRIS[redacted]
cc
bcc
Subject DIR 08005630 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]

1-5 Khartoum Road
North Ryde
NSW, 2113

PO Box 134
North Ryde
NSW, 1670

DIR 08005630 Charite final.doc

DOCUMENT NOT YET CLASSIFIED

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 #	08005630
-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)	05.08.2008
B) Date of adverse event (dd-mm-yyyy)	30.04.2008
C) Date mfr aware (dd-mm-yyyy)	30.04.2008
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 unknown size at L4/5 & L5/S1 level. The Charite TDR at L5/S1 was sitting off lateral to midline and posterior. The position of the TDR was causing neural compression. The surgeon attempted a posterior approach due to prior anterior surgery. During surgery Dr Farey had commented on seeing damage to the exiting nerve root at the level of the L5/S1 TDR. Mobilisation of the TDR was attempted to move it ventrally but this was not possible. A decompression and pedicle screw fixation (Medtronic) was performed.

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- 6 AUG 2008

III- Healthcare Facility Information

Name	North Shore Private
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 size unknown
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)	Unk	M/F	F	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.