



17/12/2008 08:36 PM

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

cc

bcc

Subject DIR 08005630 FINAL

FULL HEADER

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For you review



Johnson & Johnson Medical and Janssen Cilag

Australia and New Zealand



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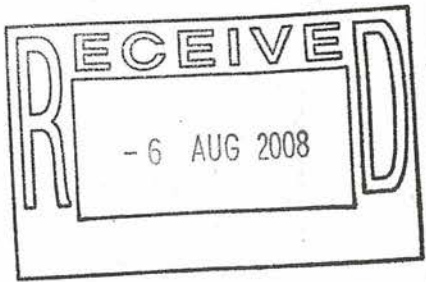
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-Mfr report #	08005630
-TGA DIR #	

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information		III- Healthcare Facility Information	
Report Type (select one) Initial <input checked="" type="checkbox"/> Follow-Up <input type="checkbox"/> Final <input type="checkbox"/> Trend <input type="checkbox"/>		Name North Shore Private Address	
Report Category S Pblc Hlth Threat <input type="checkbox"/> Death/Serious Injury <input type="checkbox"/> Other <input checked="" type="checkbox"/>		Tel _____ Fax _____ E-mail _____ Contact name at site of event _____	
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		IV- Device Information	
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]		Generic Device Information Device ARTG # TBC GMDN Code TBC GMDN Code Text (eg catheters, central venous, peripherally inserted) TBC	
Identity of other Regulatory Authorities, Notified Bodies, etc., that this report was <i>also</i> sent.		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 [Redacted]	
II- Clinical Event Information		Tel. [Redacted] Fax [Redacted] E-mail [Redacted]	
Description of event or problem <p>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.</p>		ARTG Mfr. # DePuy International (England)[18332]	
		Operator of Device at Time of Event (select one) HC Profnal <input checked="" type="checkbox"/> Other Caregiver <input type="checkbox"/> Patient <input type="checkbox"/> N/A <input type="checkbox"/>	
		Usage of Device 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)

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
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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)

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.