



IRIS: Medical Device Incident Report Investigation Scheme

-Mfr report # 08005629

-TGA DIR #

Same as next 08005629

**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

ne [REDACTED]  
Company Johnson & Johnson Medical Pty Ltd  
Address 1-5 Khartoum Rd North Ryde

NSW 2113

Tel. [REDACTED] Fax [REDACTED]

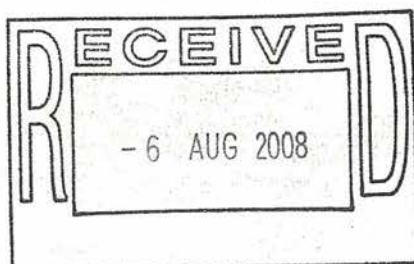
E-mail [REDACTED]

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).



**III- Healthcare Facility Information**

Name Dalcross

Address

Tel [REDACTED] Fax [REDACTED]

E-mail [REDACTED]

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 [REDACTED]

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
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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.





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me [redacted]  
Company Johnson & Johnson Medical Pty Ltd  
Address 1-5 Khartoum Rd North Ryde

NSW 2113

Tel. [redacted] Fax [redacted]

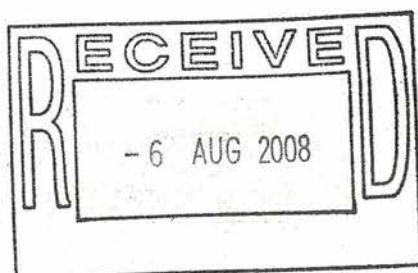
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Tel [redacted] Fax [redacted]

E-mail [redacted]

Contact name at site of event

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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]

Operator of Device at Time of Event (select one)

HC Profnal ☒ 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

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