Therapeutic Goods Administration
Device Incident Reports
Full Details Report

DIR /18893 Fixation system, internal, spinal, bone screw/DePuy Spine

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Exempt/Not on Artg: N

Syst/Artg No ARTG / 148559

Ecri Code: 43257 Fixation system, internal, spinal, bone screw

Device: Charite TDR (mfr# 08005630)

Model No: **Batch No:** **Serial No:**

Manufacturer: DePuy Spine 50415
GBR

Sponsor: Johnson & Johnson Medical Pty Ltd T/A Depuy Australia 10380
PO Box 476
MT WAVERLEY VIC 3149 AU

Contact: D . Phone: Unknown when m Fax: [redacted]

Reporter Details: Confidential: No

Position: [redacted]

Institution: Johnson & Johnson Pty Ltd
1-5 Khartoum Road
NORTH RYDE NSW 2113 AUST

Phone: [redacted]

Incident Description: 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 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.
Patient outcome: Satisfactory as far as we are aware
Using two Charite implants in one patient is an off label use. Charite is approved for use as a one level implant only. Surgeon implanted two discs. This goes against the information that is recommended in the Instructions For Use (IFU) supplied with each device. Charite device was not returned for evaluation and the lot numbers are unknown.

No definitive conclusions can be made at this time. At this time no connection can be made between the event and any shortcomings of the device or information provided with the device.
Similar events: Not provided as off label use
Report sourced from Sponsor.

Date Received: 18/12/2008
Date Entered: 03/02/2009
Date Completed: 12/02/2009
Date Closed: 12/02/2009

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Associated Files: S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC18893.DOC

Device Type - Sterile: N
- Reusable: N
Sample Received: N
Classification: Routine
Potential Outcome: Serious Injury
Actual Outcome: Serious Injury
Injured Party: Patient
Reporter Category: Other - Sponsor
Type of Incident: Mechanical
Cause of Incident: Mechanical
Investigation Result: Not Investigated
Recommendation: No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.
Investigator Name: [redacted] 03/02/2009

***** End Of DIR / 18893 *****