

Form # MDIR02, for use by medical device manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR02

	Last řevisea: June 2005	35
-Mfr report #	08005629	
-TGA DIR #		

IRIS: Medical Device Incident Report Investigation Scheme

IRIS: Medical	Device Incident Re	port Investigation	on Scheme	San	eas 1	ext	08005629
I- Admini	strative Inform	ation		III- Healt	hcare Fa		Information
Report Type (se	elect one)			Name [	Dalcross	W	
Initial 🖂	Follow-Up	Final 🔲	Trend	Address			
Report Categor	У	9					
S Pblc Hith Th	reat Death/Serio	us Injury 🔲	Other 🖂	Tel		Fax	
A) Date of this r	eport (dd-mm-yyyy)	05.08.2008	-	E-mail		,	\$
B) Date of adver	se event (dd-mm-yyyy)	24.07.2008		Contact name a	t site of event		
C) Date mfr awa	re (dd-mm-yyyy)	24.07.2008		IV- Devic	e Inform	ation	
D) Date of next r	report (max 30 days from A)	05.09.2008		Generic Device	Information		
Person (authori	sed representative), sub	mitting this repor	<u>t</u>	Device ARTG #	·	TBC	54
ne				GMDN Code		TBC	
Company	Johnson & Johnson Med	cal Pty Ltd		GMDN Code Te	ext (eg catheters, c	central venous	s, peripherally inserted)
Address	1-5 Khartoum Rd North R	yde		TBC			
NSW 2113				Specific Device Information			
Tel.	Fax			Brand Name	Charite TDF	R sz4	
E-mail			1 1	Model #	Unknown		27 - 3
	Regulatory Authorities, No	tified Bodies, etc., t	that this	Catalogue #			
report was also s	sent.			Ser. or Lot#'s	Unknown		
				Mfr. Name	DePuy Inter	rnational Le	eeds UK
			1	Contact Name			
			A.	Address			
Clinica	l Event Inform	ation		i.		- 18	1 1 P
Description of e	event or problem		. 2 1 1	Tel.		Fax	
	arite TDR size 4 at the L5	하지네요? 하시네이네 - 아이에 - (500) 7개		E-mail			
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			e levels	ARTG Mfr. # DePuy International (England)[18332]			
above. The surgeon removed the Charite Disc without observable complications and implanted an ALIF cage (6986-00-067) with			Operator of Device at Time of Event (select one)				
supplemental fixation in the form of an AEGIS plate (1871-50-025) plus trans-lamina/trans-facet screws (Synthes).			HC Prof nal ⊠ Other Caregiver ☐ Patient ☐ N/A ☐				
u ans-iamina/u an	s-lacet sciews (Synthes).		~	Usage of Device	<u>:e</u>	1.8	
			1.0	5w.2	Single Use	$\boxtimes$	Reuse of Single Use
	*	W 8		Reus	e of Reusable		Re-serviced/Refurbished
DECEIVED			Device Disposition/Current Location				
- 6 AUG 2008			Not provided				
	עיט	الا					
	ria dominio	-100					

V- Results of Mill's Investigation	VI- I aticii	t mion	mati	on (ipe	n nequ	meaj
Manufacturers Device Analysis Results	Age (yrs, mnths)	39	M/F	M	Wt. (kg)	Unk
(Specify, for this event, details of investigation methods, results, and conclusions)	Patient-focused	resolution	of even	ts and Outco	omes	
To be provided	Corrective action t	taken releva	ant to th	e care of the	patient:	
N N	Revision	tanon rolo ri	ant to th	o daro or tho	pationt	
, a v , a v	Revision			8		
*				÷		
(L) (a) (a)					8	
* ,		_		is:		20
, , , , , , , , , , , , , , , , , , , ,	Patient outcome:			1.0		
	Satisfactory as far	r as we are	aware			
	f					
и — — — — — — — — — — — — — — — — — — —						
# B	8					
	List of other devic	es involved	in the e	vent		
Remedial Action/Corrective Action/Preventive Action	VII Other	Banas	41	Inform	ation	
(Specify if/what action was taken for the reported specific event or for all similar type of	VII- Other				MA FEMALES	
events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)	Mfr/Sponsor awar	re of other s	imilar e	vents? (# or i	rate)	
	Countries where t	these simila	r advers	se events occ	urred:	
O .						
*	:+:					
					×	
*	Additional Comme	ente				
	Additional Commit	CIICS		*/		
9					27	
*	640					
e e e e e e	Submitting this I	report:				
	Since the same of the same	Paid 32				
	IRIS:			ident Report T 2606	Investigation	Scheme
		)) 2 6232 85				제작 1

By e-mail: iris

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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	Last revised: Juni	e ZUUBZZ
-Mfr report #	08005629	
-TGA DIR #		

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Inform	ation	III- Healthcare Facility Information				
Report Type (select one)		Name Dalcross				
Initial 🛛 Follow-Up 🔲	Final Trend	Address				
Report Category		* * * * * * * * * * * * * * * * * * * *				
S Pblc Hlth Threat Death/Seri	ous Injury   Other	Tel Fax				
A) Date of this report (dd-mm-yyyy)	05.08.2008	E-mail				
B) Date of adverse event (dd-mm-yyyy)	24.07.2008	Contact name at site of event				
C) Date mfr aware (dd-mm-yyyy)	24.07.2008	IV- Device Information				
D) Date of next report (max 30 days from A)	05.09.2008	Generic Device Information				
Person (authorised representative), su	omitting this report	Device ARTG # TBC				
ne		GMDN Code TBC				
Company Johnson & Johnson Med	ical Pty Ltd	GMDN Code Text (eg catheters, central venous, peripherally inserted)				
Address 1-5 Khartoum Rd North F	Ryde	TBC				
NSW 2113	in the second	Specific Device Information				
Tel. Fax		Brand Name Charite TDR sz4				
E-mail		Model # Unknown				
Identity of other Regulatory Authorities, No	otified Bodies, etc., that this	Catalogue #				
report was also sent.		Ser. or Lot #'s Unknown				
1 m	* <u>.</u>	Mfr. Name DePuy International Leeds UK				
		Contact Name				
		Address				
Clinical Event Inform	ation					
Description of event or problem	The state of the s	Tel. Fax				
Patient had a Charite TDR size 4 at the L5/S1 level. The Charite TDR		E-mail				
was sitting off lateral to midline. This was acute scoliosis at the instrumented level a	nd extending into the levels	ARTG Mfr. # DePuy International (England)[18332]				
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).		Operator of Device at Time of Event (select one)				
		HC Prof nal ☑ Other Caregiver ☐ Patient ☐ N/A ☐				
uans-lamina/uans-lacet sciews (cynules)	* * * * * * * * * * * * * * * * * * * *	Usage of Device				
	7 1	Single Use Reuse of Single Use				
DECEIVED  -6 AUG 2008		Reuse of Reusable Re-serviced/Refurbished				
		Device Disposition/Current Location				
		Not provided				
		The second second of the secon				
	To be at					

V- Results of Mfr's Investigation	VI- Patient Information (rpt. if required)
Manufacturers Device Analysis Results	Age (yrs, mnths) 39 M/F M Wt. (kg) Unk
(Specify, for this event, details of investigation methods, results, and conclusions)	Patient-focused resolution of events and Outcomes
To be provided	Corrective action taken relevant to the care of the patient:
	Revision
	TOVISION
	Tar and the same of the same o
*	
*	Patient outcome:
	Satisfactory as far as we are aware
*	
10 AV	
, s	List of other devices involved in the event
u = = = = = = = = = = = = = = = = = = =	List of other devices involved in the event
# V 2	
= 3 3	* * * * * * * * * * * * * * * * * * *
Remedial Action/Corrective Action/Preventive Action	VII- Other Reporting Information
(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.)	Mfr/Sponsor aware of other similar events? (# or rate)
	Countries where these similar adverse events occurred:
*	
	3 2 3
	Additional Comments
n d a a	
* *	Submitting this reports
	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

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.