

MAUDE EVENT REPORT (FOI)

SORTED BY DATE OF EVENT

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.



Date Received

MFR Report No: 2183553-2009-00033	Mfr Name: GE MEDICAL SYSTEMS, LLC	24-Jun-2009
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Event Date (B3): 03-Jun-2009	Event Report Type: INJURY	Adverse Event (B1): Y	Problem (B1): N
Report Date (B4): 03-Jun-2009	Event Outcome (B2): REQUIRED INTERVENTION		
Report Date (F8):	Reporter Occupation (E3): UNK - UNKNOWN	Event Location (F12):	
Date Mfr Rec'd (G4): 17-Jun-2009	Device Operator: HEALTH PROFESSIONAL	Report Source (G3): USER FACILITY	

Product Code: (RA)-SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGING (LNH)	
Device Age (F9):	Manufacture Date (H4): 01-Jul-2008
Expiration Date:	Single Use (H5): N
	Device Usage (H8): R

Event Description (B5):

Mfr 29-JUN-2009: IT WAS REPORTED THAT A PATIENT ENTERED THE BORE OF THE MAGNET WITH A KNIFE STRAPPED TO HIS ANKLE. THE KNIFE WAS ATTRACTED TO THE MAGNET, PULLED OUT OF THE HOLDER AND LACERATED THE PATIENT ON THE ABDOMEN. THE LACERATION REQUIRED MEDICAL TREATMENT AND STITCHES. THE PATIENT REPORTEDLY WAS SCREENED FOR FERROUS OBJECTS. DURING THE SCREENING, IT WAS ALLEGED THAT THE PATIENT STATED THAT HIS POCKETS WERE EMPTY.

Concomitant Medical Products:

UNK

Mfr Name: GE MEDICAL SYSTEMS, LLC
Address: 3200 N. GRANDVIEW BLVD.
 WAUKESHA, WI 53188
 UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):

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Additional Mfr Narrative (H10 & H11):

29-JUN-2009: THERE WAS NO EVIDENCE THAT THE SYSTEM MALFUNCTIONED. ADDITIONALLY, THE FIELD ENGINEER EXAMINED THE MR SYSTEM AND FOUND NO OBVIOUS DAMAGE. THE SITE HAS HAD MAGNET SAFETY TRAINING AND A MAGNET WARNING SIGN WAS POSTED ON THE DOOR. MAGNETS INHERENTLY ATTRACT FERROUS OBJECTS. THE MAGNET FUNCTIONED WITHIN SPECIFICATION WHEN IT ATTRACTED THE FERROUS OBJECT. THE USER DOCUMENTATION FOR THE SYSTEM INCLUDES INSTRUCTIONS CONCERNING ISSUES INHERENT TO STRONG STATIC MAGNETIC FIELDS USED WITHIN MRI AND PROPER EXCLUSION ZONES AND WARNINGS FOR MAGNETIC FIELD HAZARDS. THE SITE HAS RECENTLY IMPLEMENTED PROCEDURE TO REQUIRE EVERY PATIENT TO CHANGE INTO GOWN OR HOSPITAL-PROVIDED PANTS TO MITIGATE RECURRENCE OF THE EVENT.

DEVICE INFORMATION:

Brand: HDX TWINSPEED 3T

Device Type:

Device Type: 2395001-4

Catalog:

Serial: (*confidential*)

Lot:

Other ID:

Reprocessed & Reused: N