

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: 2183553-2009-00004	Mfr Name: GE MEDICAL SYSTEMS, LLC	30-Jan-2009
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Event Date (B3): 31-Dec-2008	Event Report Type: INJURY	Adverse Event (B1): Y Problem (B1): N
Report Date (B4): 31-Dec-2008	Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)	
Report Date (F8):	Reporter Occupation (E3): OTHER	Event Location (F12):
Date Mfr Rec'd (G4): 26-Jan-2009	Device Operator: HEALTH PROFESSIONAL	Report Source (G3): HEALTH PROFESSIONAL

Product Code: (RA)-SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGING (LNH)	
Device Age (F9):	Manufacture Date (H4): 01-May-1994
Expiration Date:	Single Use (H5): N
	Device Usage (H8): R

Event Description (B5):

Mfr 04-FEB-2009: A PATIENT REPORTEDLY WAS INJURED WHEN A MAGNETIC SANDBAG FLEW INTO THE BORE. THE SANDBAG WAS ON THE PATIENT TABLE HOLDING AN IV LINE WHEN THE PATIENT WAS BROUGHT INTO THE MAGNET ROOM. THE PATIENT SUSTAINED A LACERATION ON A TONGUE, A BRAIN HEMORRHAGE, AND FACIAL AND NECK BRUISING.

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): No

Remedial Action (H7):**Correction/Removal No (H9):****Additional Mfr Narrative (H10 & H11):**

04-FEB-2009: INVESTIGATION IS ONGOING.

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DEVICE INFORMATION:

Brand: SIGNA ADVANTAGE

Device Type:

Device Type: 46-328456G1

Catalog: NA

Serial: (*confidential*)

Lot: NA

Other ID:

Reprocessed & Reused: N