

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: 3003768277-2009-0061	Mfr Name: PHILIPS MEDICAL SYSTEMS NEDERLAND B.V.	06-Jul-2009
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Event Date (B3): 05-Jun-2009	Event Report Type: INJURY	Adverse Event (B1): Y Problem (B1): N
Report Date (B4): 17-Jun-2009	Event Outcome (B2): REQUIRED INTERVENTION	
Report Date (F8):	Reporter Occupation (E3): OTHER	Event Location (F12):
Date Mfr Rec'd (G4): 17-Jun-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-Aug-2007
Expiration Date:	Single Use (H5): N
	Device Usage (H8): R

Event Description (B5):

Mfr 21-JUL-2009: THIS REPORT IS BEING FILED UPON NOTIFICATION FROM OUR MR MANUFACTURER IN OTHER COUNTRY, THE NETHERLANDS TO SUBMIT THIS INCIDENT THAT OCCURRED IN ANOTHER COUNTRY. PROBLEM: PT WAS BEING PREPARED BY THE MR TECHNICIAN FOR A MR SCAN. THE PT ATTENDANT ENTERED THE MR ROOM WITH SCISSORS IN HIS POCKET. WHEN HE WAS TRYING TO ASSIST WITH THE PT, THE SCISSORS FLEW FROM HIS POCKET INTO THE MR TECHNICIAN'S FOREHEAD. HE WAS IMMEDIATELY OPERATED ON AND THE SCISSORS WERE REMOVED FROM HIS HEAD.

Concomitant Medical Products:

NA

Mfr Name: PHILIPS MEDICAL SYSTEMS

Address: PO BOX 10.000
VEENPLUIS 4-6
BEST,
NETHERLANDS

Device Available for Evaluation: Y**Device Evaluated by Manufacturer (H3):** Yes**Remedial Action (H7):****Correction/Removal No (H9):****Additional Mfr Narrative (H10 & H11):**

21-JUL-2009: (CONCLUSIONS) - (OTHER) - IT IS A KNOWN ISSUE THAT NO MAGNETIC MATERIALS SHOULD BE BROUGHT INTO THE MR EXAMINATION ROOM. THE INSTRUCTIONS FOR USE CONTAIN EXTENSIVE WARNING RELATED TO THIS ISSUE.

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DEVICE INFORMATION:

Brand: ACHIEVA 1.5T

Device Type: LNH (MAGNETIC RESONANCE DIAGNOSTIC DEVICE)

Device Type: 781196

Catalog: NA

Serial: (*confidential*)

Lot: NA

Other ID:

Reprocessed & Reused: N