



GE Healthcare

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Certified Mail Return Receipt Requested

URGENT REMOVAL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THIS ISSUE

November 8, 2006

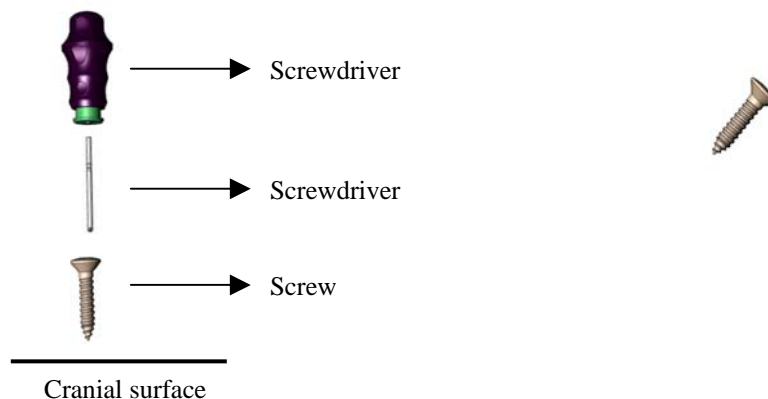
To: Surgery Director

Subject: Product Safety Issues- Product Removal

Affected Products: Axxess Cranial Screw (Accessory used with GE OEC InstaTrak™ 3500 Plus/ ENTrak™ Plus System)

Our records indicate that your healthcare facility has an Axxess Cranial Screw (GE P/N 1008370-NAV or 1008372-NAV) for use with the InstaTrak™ 3500 Plus or the ENTrak™ Plus Systems. **DISCONTINUE USE OF THIS DEVICE AS SOON AS YOU RECEIVE THIS LETTER.** A GE Field Service Representative will visit you in the next few weeks to remove this product from your site.

The Axxess Cranial Screw (GE P/N 1008368-NAV) is a self-tapping, self-drilling screw and is an accessory used in conjunction with the Axxess Cranial Tri-Pin Kit (GE P/N 1008374-NAV).



In addition, the Axxess Cranial Screw may be found as a component of the following items:

1008370-NAV Axxess Cranial Starter Kit with Transmitter
1008372-NAV Axxess Cranial Starter Kit without Transmitter
1008376-NAV Axxess Cranial Screw Driver Kit

GEHC OEC has received reports of a few instances of the Axxess Cranial Screws breaking while inserting the screws. This product was distributed from January 2006 to July 2006. Though we are not aware of any adverse events related to the complaints received for this product, there is a remote possibility that breaking of such screws could lead to a health hazard. Therefore, we are carrying out a product removal at this time.

Actions required:

- 1. Immediately discontinue use of the Cranial Axxess Screw(s).**
2. Place the Cranial Axxess Screw(s) in a secure location to await pick up and removal by a GEHC Field Service Representative.

At this time GEHC OEC is evaluating replacements for the Cranial Axxess Screw. Your facility will be contacted when a replacement for the Cranial Axxess Screw is available

Please convey this information to all users of the GEHC OEC InstaTrak™ 3500 Plus or OEC ENTrak™ Plus System. Please contact GE Healthcare Customer Service at 1-800-874-7378 or 1-801-536-4688 for any questions.

Thank you,

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