



GE Healthcare

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Certified Mail Return Receipt Requested

## URGENT REMOVAL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THIS ISSUE

January 24, 2007

To: Surgery Director

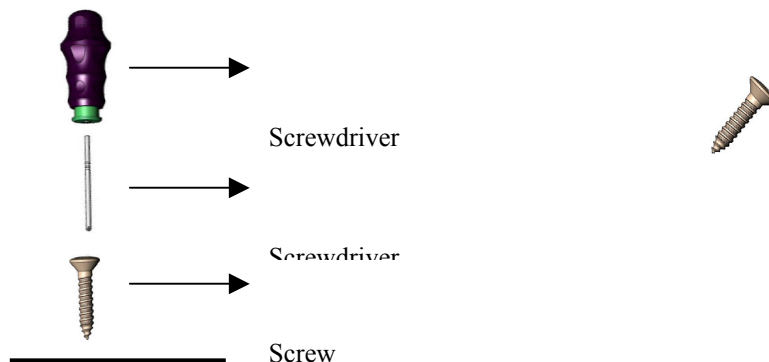
Subject: Product Safety Issues- Product Removal

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

NOTE: A previously distributed communication regarding this matter reflected an incorrect date of January 24, 2006. The correct date is January 24, 2007 as reflected in this communication.

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 to remove this product from your site as indicated in the enclosed instructions.

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).



Cranial surface

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. Follow the attached instructions for the preparation of the Cranial Axxess Screw(s) for pick up and contact your GEHC Field Service Representative at 1-800-874-7378 or 1-801-536-4688 to arrange for pick up.
3. 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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