



IMPORTANT DEVICE REMOVAL & PRODUCT ALERT

GE Healthcare
OEC Medical Systems, Inc.

384 Wright Bros. Drive
Salt Lake City, UT 84116-2862

May 31, 2006
FMI 15043

Dear Health Care Provider,

It has come to our attention that there is a potential concern associated with the GE Healthcare Navigation Anterior Cervical Post (GE P/N 1006385 or 1006385-NAV an accessory used with the InstaTrak 3500 Plus and 9800 C-Arm Navigation Systems. Because the quality of our products is of paramount concern to GE, we request your immediate attention to help us resolve this matter.

The weld between the post body and the screw was not properly formed in several devices, and the weld can fail even when minimal force is used. Our concern is that if this occurs the screw might have to be removed from the bone by other means and that the scheduled procedure could not continue.

According to our records, your facility purchased this product either in a kit or separately. We will replace it as soon as the product is available at no cost to you. This notification applies to all GE Anterior Cervical Posts (GE P/N 1006385) in commercial distribution and is not limited to any specific lot number. This issue does not affect the GE Healthcare Posterior Threaded Bone Pin (GE PN 1003997).



Please do the following to
facilitate this removal:

4" Anterior Cervical Post – Actual Size

- 1. Identify and discontinue using this product (GE P/N 1006385 or 1006385-NAV)**
- 2. Complete and return attached form**
- 3. Communicate this information to your OR Staff and users of the InstaTrak 3500 Plus, or 9800 C-Arm Navigation Systems.**

GE appreciates your awareness and cooperation in order to remedy this potential health concern. Call GE Healthcare Customer Service at (800) 874-7378 Option 1 if you have additional questions.

Sincerely yours,

Kenneth F. Miles, Ph.D.
GE Healthcare - Interventional Cardiology & Surgery
Vice President Quality Assurance and Regulatory Affairs