GE Healthcare

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Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM (S) OF THESE ISSUES AND HOW TO ADDRESS THEM

March 22, 2007

To: **Surgery Director**

Director/Manager of Radiology

Subject: **Product Safety Issues**

Affected Products: **OEC® InstaTrak 3500 Plus FluoroTrak and FluoroCAT spinal applications used with Regular and Super C 9800 and 9600 C Arm systems**

Our records indicate that your facility has one or more of the products listed above. GEHC Surgery has identified through internal testing, issues that could impact the overall accuracy of the FluoroTrak and FluoroCAT spinal applications on the InstaTrak 3500 Plus system when used with either the 9" Regular C Arm or the "Super C" C Arm. **This issue could result in an injury to the patient due to incorrect anatomical location of an instrument during a procedure.**

Interim Solution:

Users are advised to stop usage of the FluoroTrak and FluoroCAT spinal applications on the InstaTrak 3500 Plus system. At this time, GEHC Surgery is evaluating solutions for the issues identified. Once a solution is identified A GEHC Surgery Field Service Representative will contact you to arrange for installation of the solution at no charge.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 Option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

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