



GE Healthcare

GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.

Fax-Back Acknowledgement Requested

URGENT SAFETY ADVISORY

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT PRODUCT OF THESE ISSUES AND HOW TO ADDRESS THEM

August 17, 2009

FMI 15101

To: **Hospital Administrator**

Director of Surgery

Subject: **Product Safety Issues**

Affected Products: InstaTrak Button Probe, Debrider Attachments, Biopsy and Shunt Guides, Articulating Arm and Transmitter Arms used with the IT3500, ENTrak 2500 and other OEC Navigation Systems.

Our records indicate that your facility has one or more of the following GEHC OEC products:

- InstaTrak **BUTTON PROBE 4.7 cm**
- InstaTrak **DEBRIDER ATTACHMENT FOR USE W/MEDTRONIC XOMED STRAIGHTSHOT® MAGNUM II**
- InstaTrak **DEBRIDER ATTACHMENT FOR USE W/GYRUS DIEGO SYSTEM**
- InstaTrak **DEBRIDER ATTACHMENT FOR USE W/STRYKER HUMMER 2 AND HUMMER TPS**
- **SHUNT GUIDANCE SYSTEM**
- **BIOPSY GUIDANCE SYSTEM**
- **SHUNT GUIDE ARTICULATING ARM (used with Shunt and Biopsy Guide)**
- **TRANSMITTER ATTACHMENT ARM FOR MAYFIELD SKULLS CLAMP**
- **TRANSMITTER ATTACHMENT ARM W/ UNIVERSAL CLAMP**

These products are used in conjunction with the IT3500, ENTrak 2500 and other GE Healthcare Surgery Navigation systems for Image Guided Surgery procedures.

GE Healthcare has determined that the instructions for cleaning these instruments by hand prior to sterilization (Manual cleaning instructions) are not effective.

Solution:

Customers should immediately stop cleaning these instruments by hand (Do Not Use Manual Cleaning Instructions). These products can be effectively cleaned using the Automatic Cleaning Instructions (Enclosed with this Advisory).

The sterilization process, outlined in the instructions for use, is extremely robust and continues to provide a high degree of confidence that the instruments are safe and effective for surgical use. Changes to the cleaning method will not have a detrimental impact on the sterility assurance of products sterilized using the recommended sterilization cycle.

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

Thank you,



Pete McCabe
President and CEO
GE Healthcare Surgery



Elizabeth Blackwood
Vice President, Quality Assurance and Regulatory Affairs
GE Healthcare Surgery

AUTOMATIC CLEANING INSTRUCTIONS

Required Equipment

- Sonication Unit with a range of 40-44 kHz.
- Automatic Washer/Disinfector (example: STERIS® 444).
- Potable water (rinsing, sonication)
- Tap water (automatic washer)
- Enzymatic detergent safe for use with metal instruments (example: EnzyCare2®, Enzol®).
- Alkaline liquid detergent, safe for metal instruments (example: Criti-Klenz®).

Procedure

1. Disassemble all instruments that have removable parts. Moving parts should be in an open position when feasible.
2. Rinse the instrument in lukewarm water (80-90°F, 27-32°C) to remove all visible soil, using a soft bristled brush as necessary to remove any visible debris.
3. In the sonication unit, prepare an enzymatic detergent safe for use with metal instruments according to the manufacturer's recommendations.
4. Submerge the instrument in the detergent and sonicate for a minimum of 20 minutes.
5. Load the instruments into the automatic washer per the washer's instruction, and use the following wash-cycle parameters:

Phase	Recirculation Time (Minutes)	Water Temperature	Detergent Type and Concentration
Pre-wash	3	Cold: 22-24°C	N/A
Enzyme wash	3	Hot: 60-82°C	Enzymatic detergent per manufacturer's recommendation
Wash	3	Set temperature: 65.5°C	Alkaline liquid detergent per manufacturer's recommendation
Rinse	3	Hot: 60-82°C	N/A
Drying	15 @ 90°C	N/A	N/A