GE Healthcare

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

Fax-Back Acknowledgement Requested

UPDATE
URGENT SAFETY ADVISORY

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

November 6, 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 InstaTrak 3500, ENTrak 2500 and other GE Healthcare Surgery Navigation Systems**.**

THIS IS AN UPDATE TO THE URGENT SAFETY ADVISORY DATED AUGUST 17, 2009

Our records indicate that your facility has one or more of the following GEHC Surgery 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 InstaTrak 3500, ENTrak 2500 and other GE Healthcare Surgery navigation systems for image guided surgery procedures.

GE Healthcare now indicates cleaning instructions for both **manual and automatic** cleaning of the instruments.

Solution:

Manual cleaning instructions and automatic cleaning instructions have been updated and are enclosed. Customers may use either the manual or automatic cleaning method to effectively clean the products prior to sterilization.

If you have any questions or concerns regarding this issue, please do not hesitate to contact the service team for further information at 800-784-7378. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO
GE Healthcare Surgery

Doug Uelmen
Vice President, Quality Assurance and Regulatory Affairs
GE Healthcare Surgery

Manual Cleaning Instructions

Navigation Instrumentation

Required Equipment

- Sonication unit with a frequency range of 40-44 kHz
- Potable water, lukewarm (80-90°F, 27-32°C)
- Sterile purified water, purified water, water for injection (WFI)
- Enzymatic detergent safe for use with metal instruments (example: EnzyCare2®, Enzol®).
- Soft bristled brush, pipe cleaner, and syringe
- Clean soft towel or gauze surgical sponge

Instruction

1. Immediately after use, disassemble all instruments that have removable parts. Moving parts should be in an open position when feasible. If the instruments cannot be cleaned immediately after use, maintain moisture by placing the instruments in a clean container and cover the container with a towel dampened with sterile purified water. The instruments may remain in this condition for a maximum of 15 minutes.
2. Remove all visible soil. Flush the instrument in running lukewarm potable water for a minimum of two minutes.
3. Prepare an enzymatic detergent safe for use with metal instruments according to the manufacturer's recommendations using potable water.
4. Submerge the instrument in the detergent and soak it for no less than 15 minutes.
5. After the 15 minute soak, but while submerged in the detergent water, vigorously scrub the instrument with a soft brush and agitate. Using a pipe cleaner or small diameter soft-bristle brush moistened with the detergent water, vigorously scrub any channels or gaps as necessary. Use a syringe to flush detergent water through any lumens. Maneuver moveable parts to loosen and remove any trapped soil. Scrub the instrument for a minimum of two minutes.
6. Remove the instrument from the detergent water and rinse it thoroughly in running lukewarm potable water, taking care to remove any visible detergent or particulate matter. Rinse and agitate the instrument in the running lukewarm potable water for a minimum of one minute. Use a syringe to flush potable water through any lumens.
7. In the sonication unit, prepare an enzymatic detergent safe for use with metal instruments according to the manufacturer's recommendations using potable water.
8. Submerge the instrument in the sonication unit and sonicate for a minimum of 30 minutes.
9. Remove the instrument from the sonication unit and rinse it thoroughly in running lukewarm potable water and agitate the instrument in the running potable water for a minimum of one minute. Use a syringe to flush potable water through any lumens.
10. Check the instrument. If any detergent residue is still visible, repeat step 9.
11. Perform a final rinse of the instrument with either purified water or water for injection (WFI) tested to USP, EP, or JP standards. Use a clean syringe to flush any lumens with the purified water or the WFI.
12. Dry thoroughly with soft towel or gauze surgical sponge.

Automatic Cleaning Instructions

Navigation Instrumentation

Required Equipment

- Soft bristled brush
- Sonication unit with a range of 40-44 kHz.
- Automatic Washer/Disinfector (example: STERIS® 444).
- Purified water (moistening towel)
- 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®).

Instruction

1. Immediately after use, disassemble all instruments that have removable parts. Moving parts should be in an open position when feasible. If the instruments cannot be cleaned immediately after use, maintain moisture by placing the instruments in a clean pan and cover the pan with a towel dampened with purified water. The instruments may remain in this condition for a maximum of 30 minutes.
2. Rinse the instrument in lukewarm water (80-90°F, 27-32°C) to remove all visible soil. Use a soft 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 in the sonication unit and sonicate for a minimum of 20 minutes.
5. Load the instruments into the automatic washer per the washer's instruction. Use the following wash-cycle parameters:

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