



GE Healthcare

**Pete McCabe**  
President and CEO  
GE Healthcare, Surgery  
384 Wright Brothers Drive  
Salt Lake City, Utah 84116  
U.S.A.  
Pete.mccabe@ge.com

**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**

May 18, 2007  
FMI: Aspirator Cleaning Probe

**To: Director/Manager of Radiology  
Director of Surgery**  
**Subject: Product Safety Issues**

### **Affected Products:**

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

- Straight Aspirator - 1000370-NAV
- 7 French Aspirator- 100936
- Keane - Moses Extended Straight Aspirator - 1000748
- 15 Degree Aspirator - 1003895
- Fried 45 Degree Aspirator – 1000541
- Kuhn 90 Degree Aspirator - 1000543-NAV

The above listed products are sterile packed single use disposable accessories to the InstaTrak 3500 Plus. GE Healthcare has identified a potential safety issue with the **cleaning probe (also termed catheter rod)** that has been packaged and shipped together with the above listed aspirators. This cleaning probe is used to unclog the cannula of the aspirators.

---

### **Potential Nylon Particle Transference:**

When the cleaning probe is used to unclog the cannula of an angled GE disposable aspirator, the cleaning probe may shed -small particles of sterile nylon material. This may be due to small burrs in the inside diameter of the open lumen and distal end of the aspirator. Although the cannula unclogging procedure would be performed outside of the nasal cavity, a remote chance exists that -small nylon particle/s may be transferred into the nasal cavity. It is likely that if these particles were transferred into the nasal cavity, they would be suctioned out during the routine surgical process.

**Solution:**

**Customers should stop using and dispose of the above-described cleaning probe.** Further shipment of this product in the near future will include a notification to the customer that even though the cleaning probes may be included with the device it **should not be used** and should be disposed of. Longer term, GEHC Surgery will no longer offer the cleaning probe for sale to customers.

**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,

A handwritten signature in cursive script that reads "Pete McCabe".

**Pete McCabe**  
President and CEO