Integra Issues URGENT Worldwide Recall of NeuroBalloon™ Catheter

Integra LifeSciences Corporation, Plainsboro, New Jersey, has initiated a worldwide recall of the NeuroBalloon Catheter. There were a total of 1,924 units distributed, 258 in the United States of America 1,586 in the European Union and 80 in other countries. A total of eight (8) complaints regarding the inflation or deflation of the NeuroBalloon Catheter were received by Integra. All complaints occurred outside the United States. No patient injuries have been reported. As a result of the investigation performed by Integra, it was determined that this condition could exist during pre-implant testing or during the procedure. Integra issued a voluntary recall of the affected lots of the NeuroBalloon Catheter on July 2, 2010. The FDA is expected to classify this recall as a Class I recall. Class 1 recalls are FDA's most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

The NeuroBalloon Catheter is intended for dilation of cerebral membrane fenestrations under direct or endoscopic visualization during intracranial procedures. The NeuroBalloon Catheter is not implanted and is removed and discarded after surgery.

The potential issue should be readily detectable since complications concerning inflation or deflation of the balloon component can be immediately observed by the physician or technician prior to or during use. Therefore if any of the products from the affected lots have been used in patients, Integra does not recommend any change to the standard post-surgical follow-up plan for those patients. The patient's physician should continue to exercise his or her clinical judgment with any periodic patient follow-up.

The recall includes the following catalog numbers and lot identifications:

NeuroBalloon Catheter, Catalog Number 7CBD10, Lot Numbers 0157983, 0158170, 0158391, 0158587, 0158739, 0159085, 0159411, 0159499, 0159938, 0161630, 0161857.

Affected product was distributed by Integra (USA) in: USA (Alabama, Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Illinois, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, Pennsylvania, Texas, Utah, Vermont), Argentina, Australia, Canada, France, Taiwan, and United Kingdom

Integra has notified its distributors and customers by overnight mail on July 2, 2010 and has arranged for return of all unused recalled products.

Healthcare practitioners with questions may contact the company at **1-800-654-2873 (Follow Returns & Repairs Prompt) Monday through Friday, 8:00 am to 5:00 pm (EST).**

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online or by regular mail.

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail:** use postage-paid FDA form 3500 available at:
  www.fda.gov/MedWatch/getforms.htm.
  Mail to MedWatch PO Box 3002, Rockville, MD 20847-3002

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