

Patient Safety Alert

Veterans Health Administration Warning System
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May 18, 2007

- Item:** Shelhigh, Inc. implantable medical products
- Specific Incident:** On April 17, 2007, the FDA seized all implantable medical products from Shelhigh, Inc. and on May 2, 2007, the FDA issued a press release disclosing a formal request to Shelhigh, Inc., of Union, New Jersey *“to recall all of its medical products remaining in the marketplace including hospital inventories, because of sterility concerns.”* Shelhigh, Inc. does not agree with the FDA position and consequently is not implementing the requested recall.
- FDA states that the company’s deficiencies could compromise the safety and effectiveness of the products. The affected products include heart valves, conduits, surgical patches, dural patches (to aid in tissue recovery after neurosurgery), annuloplasty rings to repair heart valves, and arterial grafts. These products have been issued under supplier names of Shelhigh, Inc., Integra NeuroSciences, and Integra LifeSciences Corp.
- Actions:**
1. By COB May 21, 2007 determine if you have any of the affected medical products listed in Attachment A, remove them from inventory and sequester.
 2. Immediate action should be taken to purchase alternative medical products from other suppliers to replace the affected items.
 3. By close of business (COB) May 25, 2007, notify all primary care physicians of the potential for contamination of the specified Shelhigh, Inc., Integra NeuroSciences, and Integra LifeSciences Corp products listed in Attachment A. Notification is to be provided so that these physicians are aware of this issue, especially if patients under their care have already received one of the implants.
 - a) Retrieve and review a list of your patients with the affected products, sent to your facility Patient Safety Manager under separate cover by secured FedEx. This list includes all the patients in the VHA Prosthetics database that have implanted products that are the subject of this notification. As this list may not be complete also complete action 3.b) below.
 - b) Review your patient records for all patients with implanted Shelhigh, Inc., Integra NeuroSciences, and Integra LifeSciences Corp products to identify those implanted with affected products.

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4. Only in emergency cases should any of the sequestered medical products be used. Every effort should be made to obtain alternative medical products from other suppliers before any sequestered medical products are released for use. The release of any sequestered medical products requires the review and written approval from the Chief of Staff or Acting Chief of Staff.

Addl. Information: See FDA web site for Questions and Answers at:
<http://www.fda.gov/cdrh/news/shelhighrecall.html>

A separate data request is under development by VA Central Office Surgical Services (111B) regarding patients with implanted Shelhigh medical products. Contact Ms. Sharon Graves at (202) 273 8504 or Dr. Gerald McDonald at (202) 273 8505 with any questions.

Source: FDA

Contact: Bryanne Patail, Biomedical Engineer, VA National Center for Patient Safety (734) 930-5852

Attachment A

Affected Medical Products	
Brand Name	Company's Name and Address
<ul style="list-style-type: none"> • Shelhigh BioRing™ (annuloplasty ring) • Shelhigh Gold™ perforated patches • Shelhigh Internal Mammary Artery • Shelhigh No-React® Dura Shield • Shelhigh No-React® EnCuff Patch • Shelhigh No-React® Pericardial Patch • Shelhigh No-React® PneumoPledgets • Shelhigh No-React® VascuPatch • Shelhigh No-React® Stentless Valve Conduit • Shelhigh No-React® Tissue Repair Patch/UroPatch™ • Shelhigh Pericardial Patch • Shelhigh Pre Curved Aortic Patch (Open) • Shelhigh Pulmonic Valve Conduit No-React® Treated • Shelhigh BioConduit™ stentless valve • Shelhigh BioMitral™ tricuspid valve • Shelhigh Injectable Pulmonic Valve System • Shelhigh MitroFast® Mitral Valve Repair System • Shelhigh NR2000 SemiStented™ aortic tricuspid valve • Shelhigh NR900A tricuspid valve 	<p>Shelhigh, Inc. 650 Liberty Avenue , Union New Jersey 07083 or 67-71 East Willow Street Milburn, NJ 07041</p>
<ul style="list-style-type: none"> • Endura No-React Dural Substitute 	<p>Integra NeuroSciences or Integra LifeSciences Corp. 311 Enterprise Drive Plainsboro, NJ 08536</p>