

FDA Seizes All Medical Products From N.J. Medical Device Manufacturer

Monday, 23 April 2007

FOR IMMEDIATE RELEASE

P07-69

April 17, 2007

Media
Inquiries:

Heidi Rebello, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

U.S. Food and Drug Administration (FDA) investigators and U.S. Marshals today seized all implantable medical devices from Shelhigh, Inc., Union, N.J., after finding significant deficiencies in the company's manufacturing processes. The deficiencies may compromise the safety and effectiveness of the products, particularly their sterility.

The products include pediatric heart valves and conduits (tube-like devices for blood flow), surgical patches, dural patches (to aid in tissue recovery after neurosurgery), annuloplasty rings (to help repair heart valves) and arterial grafts. The tissue-based devices are used in many surgical settings, including open heart surgery in adults, children and infants, and to repair soft tissue during neurosurgery and abdominal, pelvic and thoracic surgery. Critically ill patients, pediatric patients and immuno-compromised patients may be at greatest risk from the use of these devices.

Physicians should consider using alternative devices. Physicians should also monitor patients with a Shelhigh implant for infections and proper device functioning over the expected lifetime of the device. Patients who think they may have received a Shelhigh device during surgery should contact their physician for more information. FDA will issue a Preliminary Public Health Notification to physicians and other health care professionals and a Preliminary Advice for Patients shortly with more information; those documents will be posted to FDA's Web site.

[Read Entire Article](#)