



Genzyme Biosurgery
55 Cambridge Parkway
Cambridge, MA 02142
T 617-494-8484

Urgent Field Safety Notice
LeGoo Endovascular Occlusion Gel
FSCA Reference Number: CR01450
Type of action – Product Removal

Date: June 19, 2013

Attention: //////////////////////////////////

Details on affected devices:

LeGoo Endovascular Occlusion Gel
Catalog #'s

- 10-0025, 10-0050, 10-0100, 10-0250, 10-0500, 10-1000
- LG50IT, LG100IT, LG250IT

All Lots

Description of the problem:

The recent implementation of additional enhanced visual inspection measures for work in-process material resulted in detection of particulate matter, primarily fibers, in filled LeGoo Endovascular Occlusion Gel syringes. The identity of the fibers (up to 3 mm in size) included acrylic, polyester, nylon paper, and cotton. In consideration of the controls and processes that had been in place for prior manufactured lots, it has been determined that Genzyme cannot provide with sufficient assurance that LeGoo material distributed to the market is essentially free of particulate matter.

LeGoo is a water-soluble, biocompatible polymer with reverse thermo-sensitive properties allowing it to be injected as a soft viscoelastic gel that forms an elastic plug within the vessel. LeGoo is indicated for temporary endovascular occlusion of blood vessels up to 4 mm in diameter below the neck.

Based on the review of QA investigation results to date, Adverse Events in Safety Database, Complaints in the complaints database, and Literature references it can be concluded that the theoretical medical risk associated with the potential deviation is remote when exposed to the defect. The theoretical risk of introduction of fiber particles in the bloodstream could include inflammation, foreign body reaction, blockage of blood vessels, thrombosis and injury to tissue and/or organs. Given the potential of syringes to contain particulate matter, a FSCA is being initiated.



Genzyme Biosurgery
55 Cambridge Parkway
Cambridge, MA 02142
T 617-494-8484

Advice on action to be taken by the user:

- Please confirm if you have any remaining LeGoo inventory. If you do, please complete the attached form. Put it aside in an isolated area until it has been returned.
- Please identify all accounts that may have inventory of LeGoo. If there are accounts that may have inventory, please reply and indicate estimated quantity. In the interim, notify your accounts verbally that LeGoo is under a FSCA. In the meantime, you should request that they remove any LeGoo from inventory and isolate the inventory per hospital procedures.
- Please note, no surgeon should be using LeGoo in any procedures until further notice.
- For clinical questions - Call 781-932-0574 and select language and then select the option for medical information.
- Please return any product to:

DHL Supply Chain
Bijsterhuizen 11-27
6546 AR Nijmegen
The Netherlands

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersigned confirms that this notice has been notified to the appropriate Competent Authorities.

Matthew Hibbert
Genzyme Corporation, A Sanofi Company
175F New Boston St.
Woburn, MA 01801