Class I Medical Device Recall: Davol Inc., XenMatrix Surgical Graft

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: January 11, 2011

Product: XenMatrix Surgical Graft

Affected Lot Numbers (Beginning with the following 4 letters)
HUTF, HUTI, HUTJ, HUTK, HUTL, HUUA, HUUB, HUUC, HUUD, HUUE, HUUF, HUUG, HUUH, and HUUJ

This product was manufactured from June 1, 2010 through October 31, 2010 and distributed from July 1, 1010 through October 31, 2010.

Use: This product is used in hernia and abdominal wall repair.

Recalling Firm:
Davol, Inc., Subsidiary of C.R. Bard, Inc.
100 Crossings Boulevard
Warwick, Rhode Island 02996

Reason for Recall: Testing cannot confirm that all units of XenMatrix Surgical Graft are within FDA requirements for endotoxin levels. Several lots have been found to have elevated endotoxin levels. Endotoxins (pyrogens) are substances found in certain bacteria that, at elevated levels, can cause serious illness which can be fatal.

Public Contact: Davol Customer Service: 1-800-556-6275

FDA District: New England

FDA Comments:

On January 6, 2011, the company sent its customers a recall letter requesting that the recalled units be returned. The company asked its customers to contact Davol Customer Service at 1-800-556-6275 for instructions on how to return the products. A FAX sheet was included with the letter, which is to be completed and FAXed to, 1-401-825-8753**.**

Class 1 recalls are the 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.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the FDA's Safety Information and MedWatch Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

SOURCE [2]

Source URL (retrieved on *03/07/2015 - 12:10am*):
http://www.mdtmag.com/news/2011/03/class-i-medical-device-recall-davol-inc-xenmatrix-surgical-graft?qt-video_of_the_day=0

Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm
[2] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm245714.htm