News & Events

FDA NEWS RELEASE
For Immediate Release: March 11, 2010
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Consumer Inquiries: 888-INFO-FDA

FDA Issues Warning on Counterfeit Surgical Mesh

Counterfeit polypropylene mesh products marketed as C. R. Bard/Davol

The U.S. Food and Drug Administration today warned health care providers and consumers about counterfeit surgical mesh being distributed in the United States under the C. R. Bard/Davol brand name. Surgical mesh products are used to reinforce soft tissue where weakness exists.

The warning is of particular significance to health care professionals and their patients with surgical mesh implants as well as hospitals and surgical centers, operating room medical professionals and staff, and purchasing and risk managers.

Investigations by the FDA and Bard show that the following products, sizes and lots of counterfeit flat sheet polypropylene surgical mesh are not manufactured by Bard. To date, four product sizes have been identified:

0112650 – Bard Flat Mesh 2”x 4”	Lot 48HVS036
Lot 43APD007	
0112660 – Bard Flat Mesh 10”x 14”	Lot HUSD0629
Lot HURL0336	
0112680 – Bard Flat Mesh 3”x 6”	Lot 43HPD027
	Lot 43HPD032
	Lot HUSG0540
	Lot 43HDP027
Lot HUSE0532	Lot 43LPD507
	Lot HUSF0763
	Lot 43IOD011
	Lot 43IPD038
0112720 – Bard Flat Mesh 6” x 6”	Lot 43FQD327

The FDA is recommending that health care professionals:

Do not use any counterfeit Bard surgical mesh from the lots listed
Carefully examine all manufacturers’ polypropylene surgical mesh products and packaging for lot numbers and anything unusual that might indicate counterfeit mesh
Contact Bard at 800-556-6275 if they think they have one of the counterfeit products
Contact the particular manufacturer if they notice anything unusual or suspicious with any other brand of surgical mesh product or packaging

The FDA also recommends that health care professionals continue to monitor patients for adverse events as they would any patient with an authentic polypropylene surgical mesh implant, if they suspect or know that counterfeit mesh has been implanted.

Patients should contact their surgeon if they experience problems that they think may be related to surgical mesh.

The FDA continues to gather information and data on the counterfeit mesh to better understand its potential public health impact. The agency also is working to determine who may be responsible and how the counterfeiting and distribution occurred.

At this time, the FDA does not know if the counterfeit surgical mesh meets the authentic product’s specifications, including its strength, sterility, or clinical performance. The FDA assessment of the counterfeit mesh and its potential risk to health is ongoing.

Health care professionals who believe they have received counterfeit or suspect product are asked to contact the FDA’s Office of Criminal Investigations at 800-551-3989 or by visiting the Web site at http://www.fda.gov/OCI[12].

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspec a problem with this or any counterfeit surgical mesh, the FDA encourages you to file a voluntary report through MedWatch, the FDA’s Safety Information and Adverse Event Reporting Program.

Health care professionals and consumers are encouraged to report serious adverse events (side effects) that may be related to the use of these counterfeit products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm [13]

Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm [14]. Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
Fax: 800-FDA-0178
Phone: 800-332-1088

Health care providers employed by facilities that are subject to FDA's user facility reporting requirements[15] should follow the reporting procedures established by their facilities.

For more information:

FDA’s Initial Communication: Safety Investigation of Counterfeit Polypropylene Surgical Mesh
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm203886.htm [16]

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EXHIBIT 6

RSS Feed for FDA News Releases[17] [what is RSS?[18]]

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