FDA recalls counterfeit surgical mesh

Mass Device

The Food & Drug Administration issued its highest priority recall for counterfeit versions of C.R. Bard's (NYSE:BCR) Davol Inc. brand. surgical mesh.

The federal watchdog agency warned that the fake versions of the product, commonly known as Marlex mesh, should not be used. Investigations by the FDA and Bard found most of the counterfeit product is labeled with genuine Bard lot numbers.

The Class I recall is an update to a March 11 warning [1] that announced the investigation.

Wayne, N.J. medical product distributor RAM Medical Inc. issued a voluntary recall March 5, but the FDA reclassified the distributor's recall as Class I June 2. That means the agency believes there's a risk of serious injury or death associated with the device in question.

The agency said [2] four sizes of the counterfeit flat sheet polypropylene surgical mesh, distributed from October 21, 2008 to October 27, 2009, were found by the FDA and Bard:

- 0112650 – Bard Flat Mesh 2” x 4”: Lots 43APD007 and 48HVS036;
- 0112660 – Bard Flat Mesh 10” x 14”: Lots HURL0336 and HUSD0629;
- 0112680 – Bard Flat Mesh 3” x 6”: Lots 43HPD027, 43HPD032, 43HPD034, HUSG0540, 43HDP027, HUSE0532, 43LPD507, HUSF0763, 43IOD011 and 43IPD038;
- 0112720 – Bard Flat Mesh 6” x 6”: Lot 43FQD327.

The agency is recommending that healthcare professionals closely examine their surgical mesh inventories to weed out any of the identified fakes and report other suspicious-looking products. Any truly ersatz or suspected counterfeit mesh products should be reported to Bard by calling (800) 556-6275 and to the FDA’s Office of Criminal Investigations by calling (800) 551-3989 or visiting http://www.fda.gov/OCI [3].

SOURCE [4]

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http://www.mdtmag.com/news/2010/06/fda-recalls-counterfeit-surgical-mesh

Links:
[1] http://www.massdevice.com/node/5940/

[2] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm203886.htm
[3] http://www.fda.gov/OCI1
[4] http://www.massdevice.com/news/fda-recalls-counterfeit-surgical-mesh