

FDA - Class I Recall and Safety Investigation of Counterfeit Polypropylene Surgical Mesh: Updated June 10, 2010

This is an update of FDA's [Initial Communication](#) on counterfeit polypropylene surgical mesh, which was issued on March 11, 2010. It contains additional information about the recall of this product and updates FDA's recommendations and activities.

Various sizes of counterfeit flat sheets of polypropylene surgical mesh have been marketed in the United States labeled with the C. R. Bard/Davol brand name. These meshes, specifically identified below, are **NOT** Bard-manufactured products. Surgical meshes of this kind are used to reinforce soft tissue where weakness exists, such as in the repair of hernias and chest wall defects.

Summary of Problem and Scope:

FDA's and Bard's investigations found the counterfeit product is labeled with the product codes and sizes of Bard Flat Mesh (commonly known as Marlex mesh). To date, the following four product sizes have been identified:

- 0112650 – Bard Flat Mesh 2" x 4"
- 0112660 – Bard Flat Mesh 10" x 14"
- 0112680 – Bard Flat Mesh 3" x 6"
- 0112720 – Bard Flat Mesh 6" x 6"

Investigations found most of the counterfeit product is labeled with genuine Bard lot numbers. Specific lots numbers for the four products can be found at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm203886.htm>

These counterfeit products were distributed from October 21, 2008 to October 27, 2009. Although counterfeiting of surgical mesh has occurred in the past, we are not aware of any other counterfeit mesh products being distributed at this time.

Voluntary Recall:

RAM Medical, Inc., a medical product distributor located in Wayne, New Jersey, initiated a voluntary recall of one lot of the counterfeit surgical mesh on March 5, 2010. RAM Medical expanded the recall on March 15, 2010 to include all of the above lots.

RAM Medical sold the counterfeit products to the distributors below, who then distributed them to hospitals or possibly other distributors:

- Amerimed Corporation
- Henry Schein Inc.
- Marathon Medical Corporation
- Medline Industries
- MMS - A Medical Supply Company
- Q-Med Corporation

Recommendations/Actions:

Healthcare professionals and facilities

- Do **NOT** use any surgical mesh from the lots listed above. Contact RAM Medical at 973-633-0400 for further instructions about returning it.
- Contact Bard at 1-800-556-6275 if you received one of the recalled lots from a distributor not listed above, as Bard might be able to confirm if the product is authentic.
- Carefully examine all manufacturers' polypropylene surgical mesh products, packaging and labeling for anything unusual that might indicate they are counterfeit. If you notice anything unusual or suspicious with any brand of surgical mesh product, including its packaging or labeling, contact the manufacturer.
- If you suspect that a counterfeit product was implanted in a patient, continue to monitor the patient for adverse events as you would any patient with an authentic polypropylene surgical mesh implant.
- Report any adverse events to FDA as instructed in the “Reporting Problems to FDA” section below.
- If you believe you have received counterfeit or suspect product, contact FDA's Office of Criminal Investigations by calling 800-551-3989 or by visiting the [Office of Criminal Investigations](#) website.

Patients

- Contact your surgeon if you have been implanted with a surgical mesh product and are experiencing any problems with it.
- If you are scheduled for a procedure that may require the use of surgical mesh, talk to your surgeon before the operation so you are confident you are not receiving surgical mesh from any of the recalled lots.

FDA Activities:

On June 2, 2010, FDA classified the distributor's voluntary recall as a Class I recall. Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of the product will cause serious adverse health consequences or death. An [FDA recall notice](#) was posted on the Medical Devices website. Here is what FDA has found in its laboratory analysis of the counterfeit mesh samples to date:

- The counterfeit samples are **not sterile** although labeled as sterile, which may mean increased risk for infection if implanted in a patient.
- They have a weave pattern and structure that is different from the authentic mesh. For example, the counterfeit mesh weave openings are larger than the authentic mesh.
- The counterfeit mesh does not have properly finished selvage edges as compared to the authentic mesh, which may allow the counterfeit mesh to unravel. The counterfeit mesh edges appear to be cut using heat, as the edge is fused or melted together.
- The packaging of the counterfeit samples is different from that of the authentic mesh.
 - The expiration dates shown on the labeling of some of the counterfeit product samples do not match.

The counterfeit mesh may not meet the authentic product's specifications, including strength and clinical performance.

FDA is continuing to test samples of the counterfeit mesh and will update this communication if additional information becomes available. FDA is also investigating to determine who is responsible for the counterfeiting and how the counterfeiting and distribution occurred.

Reporting Problems to FDA:

Prompt reporting of adverse events can help FDA identify and better understand the risks associated with medical devices. If you suspect a problem with counterfeit surgical mesh, we encourage you to file a voluntary report through [MedWatch, the FDA Safety Information and Adverse Event Reporting program](#). Healthcare personnel employed by facilities that are subject to [FDA's user facility reporting requirements](#) should follow the reporting procedures established by their facilities.

To help us learn as much as possible about the adverse events associated with counterfeit surgical mesh, please include the following information in your reports, if available:

- Manufacturer's name
- Product name (brand name)
- Date product was manufactured
- Expiration date
- Catalog number
- Lot number
- Size
- Date of implant
- Date of explant (if mesh was removed)
- Details of the adverse event and medical and/or surgical interventions (if required)

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@CDRH.FDA.GOV or 800-638-2041.

This information, including a link to FDA's March 11, 2010 Initial Communication, is posted on the FDA website at

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm203886.htm>.

Sincerely,
Brenda L. Evelyn, SBB(ASCP)
Office of Special Health Issues
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903