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Class 1 Recall: Bard® Composix® Kugel® Mesh X-Large Patch

This recall notice was superseded with [an updated notice on March 31, 2006](#), to include additional product codes and lot numbers recalled by the manufacturer.

Date Recall Initiated: December 22, 2005

Product: Bard® Composix® Kugel® Mesh X-Large Patch Oval with ePTFE with the following lot numbers:

- 41XMXXXX – M = 2002
- 41XNXXXX – N = 2003
- 43XMXXXX – M = 2002
- 43XNXXXX – N = 2003
- 43XOXXXX – O = 2004
- 43XPXXXX – P = 2005

(If the lot number does not contain either M, N, O or P as the 4th character the lot is not affected by this recall.)

Use: The Composix® Kugel® Mesh Patch is used to repair ventral (incisional) hernias caused by thinning or stretching of scar tissue that forms after surgery. The patch is placed behind the hernia defect through a small incision. The patch is then held open by a “memory recoil ring” that allows the patch to be folded for insertion and later spring open and lay flat once it is in place.

Recalling Firm: Davol, Inc., Sub. C.R. Bard, Inc.
100 Sockanossett Crossroad
Cranston , RI 02920

Reason for The "memory recoil ring" that opens the Composix® Kugel® Mesh Patch after it has been inserted into the

Recall: intra-abdominal space can break. This can lead to bowel perforations and/or chronic intestinal fistulae (abnormal connections or passageways between the intestines and other organs).

Public Contact: Robin Drago
VP Regulatory and Clinical Affairs
Davol, Inc., Sub. C.R. Bard, Inc.
100 Sockanossett Crossroad
Cranston , RI 02920
401-463-7000 x2389

FDA District: New England

FDA Comments: Davol, Inc. (a subsidiary of C.R. Bard) notified U.S. customers of the recall by letter on 12/27/05 via Federal Express. Customers should stop using the recalled product and return unused units to the company. For more information, customers can contact Bard Customer Service at 1-800-FOR-BARD or bard.help@crbard.com . Physicians may contact bard Medical Services and Support at 800 227-3357 or medical.services@crbard.com.

A copy of the company's press release regarding this recall can be found on the [Bard website](#).

Updated March 2, 2006

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