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*This recall notice was superseded with an updated notice on March 31, 2006, to include additional product codes and lot numbers recalled by the manufacturer.*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 Recall:** 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.helpline@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