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## Class 1 Recall: Bard® Composix® Kugel® Mesh Patch - Expansion

**Date Recall Initiated:** December 22, 2005

**Product:** \*This recall notice was updated on January 24, 2007, to include additional product codes and lot numbers recalled by the manufacturer since the first list was issued ([see previous announcements](#)). The expanded list below includes all recalled product codes and lot numbers.\*

Product Code	Description	Lot Numbers Recalled	Date Recalled
0010206	Bard® Composix® Kugel® Extra Large Oval, 8.7" x 10.7"	All Lot Numbers	December 2005 and January 2006
0010207	Bard® Composix® Kugel® Extra Large Oval, 10.8" x 13.7"	All Lot Numbers	December 2005 and January 2006
0010208	Bard® Composix® Kugel® Extra Large Oval, 7.7" x 9.7"	All Lot Numbers	December 2005 and January 2006
0010209	Bard® Composix® Kugel® Oval, 6.3" x 12.3"	All Lot Numbers	March, 24, 2006
0010202	Bard® Composix® Kugel® Large Oval, 5.4" x 7.0"	All Lot Numbers	January 10, 2007
0010204	Bard® Composix® Kugel® Large Circle, 4.5"	All Lot Numbers	January 10, 2007

**Use:** The Bard® 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 Bard® Composix® Kugel® Mesh Patch can break under the stress of placement of the large sized products in the intra-abdominal (inside the belly area) space. This can lead to bowel perforations (rupture) and/or chronic (recurring) intestinal fistulae (abnormal connections or passageways between the intestines and other organs).

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100 Sockanossett Crossroad  
Cranston, RI 02920  
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**FDA District:** New England

- FDA Comments:**
- Surgeons and hospitals should stop using the recalled product and return unused units to the company.
  - Patients who have who have been implanted with one of the recalled devices should seek medical attention immediately if they experience symptoms that could be associated with ring breakage such as unexplained or persistent abdominal pain, fever, tenderness at the implant site or other unusual symptoms.
  - It should be noted that product codes 0010202 and 0010204 were involved in both recall expansions. The lots produced prior to January 2004 were recalled during the March 2006 expansion. Since the March expansion Davol received 4 confirmed complaints of recoil ring breakage from product code 0010202. There were no complaints for product code 0010204.
  - On January 10, 2007, Davol, Inc. (a subsidiary of C.R. Bard) sent letters to health care professionals and distributors notifying them of the most recent expansion of this recall to include all numbers of Bard® Composix® Kugel® Large Oval and Large Circle Mesh Patches for product codes 0010202 and 0010204. Davol has also decided to withdraw from the market all remaining 0010202 and 0010204 products, manufactured from January, 2004 through October, 2006, which has the same component design as the manufacturing lots being recalled.
  - Davol notified U.S. customers of the initial recall by letter on 12/27/05 via Federal Express. On March 24, 2006, Bard issued letters to hospitals and health care professionals alerting them to the additional recalled products. The letters included updated Instructions for Use

(“IFU”) clarifying the proper insertion technique and Supplemental Patient Management Information. Copies of current product IFUs to be used for both Open Placement and Laparoscopic Placement for the Large Bard® Composix® Kugel® Mesh Patches are available from Davol Customer Service by calling 1-800-531-4124.

- An upgraded product design for both product codes is available for replacement. Product codes and lot numbers that contain the re-designed product can easily be identified on the case or unit package with the label stating “**Redesigned for improved ring integrity.**” If this label is affixed to your case stock and/or individual packages, this product is not affected by this market withdrawal and need not be returned to Davol.
- For more information, customers can contact Davol Customer Service at 1-800-531-4124. Physicians may contact Bard’s Medical Services and Support Department at 1-800-562-0027 or to speak with the Bard Medical Director, call 1-908-277-8306. A copy of the company’s press release regarding this recall expansion can be found on the [Davol website](#).

Updated January 31, 2006

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