



## ABOUT KUGEL® MESH PATCHES

Specific lot numbers of the Composix® Kugel® Mesh patches, used to repair ventral (incisional) hernias caused by thinning and stretching of scar tissue post-surgery, were recalled by manufacturer Davol, Inc., a subsidiary of C.R. Bard, Inc. starting in December 2005, with subsequent recall expansions in March 2006 and January 2007. The recall occurred after it was discovered that the "memory recoil ring," which opens the patch, can break under the stress of placement in the intra-abdominal space. This can lead to serious intestinal conditions such as bowel perforations and/or chronic intestinal fistulae (abnormal connections or passageways between the intestines and other organs).

In March 2006, the FDA sent a recall letter to physicians and patients advising patients implanted with one of the recalled lot numbers to seek immediate medical attention if they experience persistent or unexplained abdominal pain, fever, tenderness at the implant site, or other related symptoms. Patients should also contact their physician, if they have not done so, for further evaluation.

## DETAILS ON THE COMPOSIX® KUGEL® MESH PATCH RECALL

The Composix® Kugel® Mesh is subject to a Class 1 recall by the FDA initiated on December 22, 2005. A Class 1 recall is the highest level of recall. It is made when the FDA believes a medical product is dangerous or defective and predictably could cause serious health problems or death. From December 2005 to March 2006, additional product codes and lot numbers were recalled by the manufacturer. This list was again expanded to include additional product codes and lot numbers in January 2007.

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

**Use:** The Composix® Kugel® Mesh Patch is used to repair ventral (incisional) hernias caused by the 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 opened the Composix® Kugel® Mesh Patch can break under the stress of placement of the large size products in the intra-abdominal space. 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, ext. 2389.

**As this is a Class 1 recall the FDA requires that Davol, Inc., the manufacturer of the Composix® Kugel® Mesh:**

- Notify their customers (i.e. distributors or vendors), and direct them to notify the intended recipients of the device (i.e. other vendors, hospitals, nursing homes, outpatient treatment facilities, doctors, or individual patients). A notification contains the name of the device being recalled, identifying lot or serial numbers, the reason for the recall, and instructions about how to correct, avoid, or minimize the problem. It should also provide a telephone number for questions related to the recall.
- Issue a press release to notify the public, if appropriate, to minimize health consequences.
- If one has not received a recall notice then one should contact the surgeon who performed the operation to confirm whether or not they have the recalled product.

#### **FDA Comments**

- Surgeons and hospitals should stop using the recalled product and return unused units to the company.
- Patients 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.
- Davol, Inc. (a subsidiary of C.R. Bard, Inc.) notified U.S. customers of the recall by letter on December 27, 2005, 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, clarifying the proper insertion technique, and supplemental patient management information. A copy of the company's press release regarding this recall can be found on the Bard web site at [www.crbard.com](http://www.crbard.com).
- For more information, customers can contact Bard Customer Service at 1-800-FOR-BARD or [bard.help@crbard.com](mailto:bard.help@crbard.com). Physicians may contact Bard Medical Services and Support at 800-227-3357 or [medical.services@crbard.com](mailto:medical.services@crbard.com).