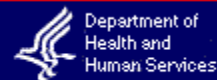




U.S. Food and Drug Administration



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

**\*This recall notice was superseded with [an updated notice on January 24, 2007](#), to include additional product codes and lot numbers recalled by the manufacturer.\***

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

**Product:** **\*This recall notice was updated on March 31, 2006, to include additional product codes and lot numbers recalled by the manufacturer since the first list was issued ([see previous announcement](#)) . 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"	41*L****, 41*M****, 41*N****, 43*L****, 43*M****, 43*N****	March 24, 2006
0010204	Bard® Composix® Kugel® Large	41*L****, 41*M****, 41*N****,	March 24, 2006

Circle, 4.5"

43\*L\*\*\*\*, 43\*M\*\*\*\*, 43\*N\*\*\*\*

<b>Use:</b>	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.
<b>Recalling Firm:</b>	Davol, Inc., Sub. C.R. Bard, Inc. 100 Sockanossett Crossroad Cranston, RI 02920
<b>Reason for Recall:</b>	The "memory recoil ring" that opens the Composix® Kugel® Mesh Patch can break under the stress of placement of the large sized 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).
<b>Public Contact:</b>	Robin Drago VP Regulatory and Clinical Affairs Davol, Inc., Sub. C.R. Bard, Inc. 100 Sockanossett Crossroad Cranston, RI 02920 401-463-7000 x2389
<b>FDA District:</b>	New England
<b>FDA Comments:</b>	<ul style="list-style-type: none"> <li>• Surgeons and hospitals should stop using the recalled product and return unused units to the company.</li> <li>• 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.</li> <li>• Davol, Inc. (a subsidiary of C.R. Bard) notified U.S. customers of the recall by letter on 12/27/05 via Federal Express.</li> <li>• 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 <a href="#">Bard website</a>.</li> <li>• For more information, customers can contact Bard Customer Service at 1-800-FOR-BARD or <a href="mailto:bard.helpline@crbard.com">bard.helpline@crbard.com</a> . Physicians may contact bard Medical Services and Support at 800 227-3357 or <a href="mailto:medical.services@crbard.com">medical.services@crbard.com</a>.</li> </ul>

Updated March 31, 2006

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