IMPORTANT PATIENT MANAGEMENT INFORMATION: Bard® Composix® Kugel Extra Large and Large Sized Patch Class I Recall

Product Code: 0010202, Bard® Composix® Kugel Large Oval, 5.4" x 7.0"
Product Code: 0010204, Bard® Composix® Kugel Large Circle, 4.5"
Product Code: 0010206, Bard® Composix® Kugel Extra Large Oval 8.7" x 10.7"
Product Code: 0010207, Bard® Composix® Kugel Extra Large Oval 10.8" x 13.7"
Product Code: 0010208, Bard® Composix® Kugel Extra Large Oval 7.7" x 9.7"
Product Code: 0010209, Bard® Composix® Kugel Oval, 6.3" x 12.3"

March 24, 2006

Dear Chief of Surgery:

This letter is intended to inform you of the voluntary recall of Bard® Composix® Kugel Extra Large and Large Sized Patches. **Immediately discontinue use of the specific product codes and lot numbers listed below. Additionally, please immediately distribute copies of this Important Patient Management Information to clinicians who may have implanted, or who may be managing, patients already implanted with one of these products under voluntary recall**. This information supplements information contained in the recall letters issued by Davol, a subsidiary of C. R. Bard, Inc. in December 2005 and January 2006 for the Extra Large Patches and March 2006 for the Large Patches.

Additionally, updated product Instructions For Use ("IFU") are included with this letter for those products not subject to this recall. These updated IFUs document the appropriate folding technique to be used for both Open Placement and Laparoscopic Placement for the Large Kugel Patches. Additional copies of these IFUs are available from Davol Customer Service by calling 1-800-531-4124.

SUMMARY OF THE PRODUCT RECALL COMMUNICATIONS:
Recall of our Extra Large and Large sized Bard® Composix® Kugel Patches is being conducted because we have identified the potential for PET recoil ring breakage which could potentially lead to patient complications such as abdominal pain, bowel perforation or chronic enteric fistulas. The following products and lot numbers are being recalled:

Product Code	Description	Lot Numbers Recalled
0010202†	Bard® Composix® Kugel Large Oval 5.4" x 7"	41*L****, 41*M****, 41*N**** 43*L****, 43*M****, 43*N****
0010204†	Bard® Composix® Kugel Large Circle 4.5"	41*L****, 41*M****, 41*N**** 43*L****, 43*M****, 43*N****
0010206	Bard® Composix® Kugel Extra Large Oval 8.7" x 10.7"	All Lot Numbers
0010207	Bard® Composix® Kugel Extra Large Oval 10.8" x 13.7"	All Lot Numbers

0010208	Bard® Composix® Kugel Extra Large Oval 7.7" x 9.7"	All Lot Numbers
0010209	Bard® Composix® Kugel Oval 6.3" x 12.3"	All Lot Numbers

†**Note: All 0010202 and 0010204 - product lots, with an "L", "M", or "N" in the fourth position are being recalled. The asterisk indicates a placeholder and any and all characters in these positions are subject to the recall.**

RECOMMENDATIONS:

We realize that each of your patients is unique and we support your clinical judgment in caring for them. Based on our review of reports received to date and the low incidence of patient injury observed to date, Davol believes that the great majority of patients who received either an Extra Large or Large Sized Bard® Composix® Kugel device subject to recall will be asymptomatic with the device functioning as intended. In such cases the risk of leaving the device in place may be less than the risk posed by removing it.

To further assist physicians in their patient care, Davol offers the following recommendations applicable to patients who have been implanted with one of the recalled devices:

- Identify: patients who have been implanted with one of the recalled devices;
- Communicate: advise patients of this recall and direct them to seek 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;
- Examine: symptomatic patients for conditions that could be associated with recoil ring breakage, including bowel obstruction, perforation or fistula, abdominal wall pain or infection, palpable abdominal wall mass, migration or movement of the ring to the abdominal wall, perineum or intra-abdominal organs;
- Evaluate: your patient's condition based on clinical signs and symptoms and using your clinical judgment. Please note that in some cases clinicians have reportedly intervened surgically to remove a broken ring without removing the adherent patch with good success. However, in more serious cases such as bowel obstruction or perforation or serious abdominal wall infection, you may wish to consider removing the entire patch; and
- Report: please report any problems that you encounter with this or any other Davol product to our Customer Quality Assurance Department at 1-800-556-6756 extension 2438.

OBSERVED RATE OF OCCURRENCE AND CLINICAL IMPLICATIONS:

Product Codes 0010206, 0010207 & 0010208 Bard® Composix® Kugel Extra Large Oval Patches: Through March 10, 2006, a total of 31 ring breaks were reported to us from the approximately 29,000 extra large size units distributed (approximately 0.109%). Of the 31 ring breaks reported, 20 involved patient injury, including,

- 11 cases where the broken ring migrated into or through the patient's abdominal wall, with associated infection in 2 cases;
- 1 case where the ring reportedly migrated into the vagina;
- 7 cases of bowel perforation reported in association with a broken ring;
- 1 case of bowel obstruction, which was repaired without removal of the mesh (causality to the broken ring has not been clearly established in this case);

- 1 reported death where the patient reportedly developed septic shock, consumptive coagulopathy and acute myocardial infarction after surgery to repair small and large bowel fistulas reportedly caused by perforation by the broken ring.

Product Code 0010202, Bard® Composix® Kugel Large Oval Patch: A total of 3 ring breaks have been reported to us from the approximately 24,000 units distributed between 2001 and 2003, for a reported occurrence rate of 0.0125%. Of those three reports, 1 involved patient injury (abdominal wall pain requiring explant of the recoil ring but not the patch) for a reported occurrence rate of 0.0041%.

Product Code 0010209, Bard® Composix® Kugel Oval Patch & Product Code 0010204, Bard® Composix® Kugel Large Circle: No reports of ring breakage have been reported in approximately 22,000 Large Circle patches or approximately 3,000 of the Oval patches. However, because of the similarity to the other products under recall, this product is being recalled as a precaution.

If you experience a ring break please return the product to Davol for a complete evaluation. To return the product call Davol Customer Service at 1-800-531-4124 to receive instructions on how to return the product.

Davol recognizes the impact of any product performance communication on both you and your patients and we sincerely regret the difficulties this recall may cause you and your patients. If you have any questions regarding this patient management communication, please contact Bard's Medical Services and Support Department at 1-800-562-0027. If you are a clinician who would like to speak with the Bard Medical Director please contact me at 1-908-277-8306.

Any adverse reactions or quality problems experienced with use of these products should be reported to the FDA MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, Md. 20852-9787, or on the MedWatch web site at www.fda.gov/medwatch.

Sincerely,

David Ciavarella, M.D.
Staff Vice President, Corporate Clinical Affairs