URGENT: EXPANSION OF CLASS I PRODUCT RECALL AND PATIENT MANAGEMENT INFORMATION[1]

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: 0010209, Bard® Composix® Kugel Oval, 6.3" x 12.3"
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"

[1]This recall notice is an expansion to the Davol Class I recall of the Bard® Composix® Kugel® Extra Large Product Codes 0010206, 0010207, and 0010208. Supplemental Patient Management Information for all recalled product codes is found in Section II of this letter.

March 24, 2006

Dear Distributor,

Davol, Inc., a subsidiary of C. R. Bard, Inc. is voluntarily expanding the Class I Recall of the Extra Large sizes of its Bard® Composix® Kugel Patch to include certain lots of Bard® Composix® Kugel Large Oval and Large Circle Products and all lots of the Oval product, intended for ventral hernia repair.

I. Expanded Recall

Recall of our Extra Large Bard® Composix® Kugel Patches is being voluntarily expanded to **certain lots** of Large Oval and Large Circle products (product codes 0010202 & 0010204 respectively) and **all lots** of our Oval product (product code 0010209). Expansion of the recall to those sizes is being conducted because we have identified the potential for PET recoil ring weld breakage on lots of product code numbers 0010202 and 0010204 manufactured prior to and including December of 2003 and all lots of product code number 0010209. There is a risk that the welds could break under the stress placed on the large sized products during placement, which could lead to potential patient complications such as abdominal pain, bowel perforation or chronic enteric fistulas.

Action to be taken:

- **Immediately discontinue distribution of the specific product codes and lot numbers listed below;**
- **Inventory and quarantine your supplies of these specific products, and**
- **Please see the attached instructions for handling the recalled product.**
- **Send a copy of this letter and all attached documents to any customer who you have provided any of the affected recall product to.**

Please note that this recall is product code and lot specific. Lot numbers not included in this recall action may continue to be used. The recall is being expanded to the Large Bard® Composix® Kugel Patch product codes and lot numbers listed in Table 1:

Table 1: Recalled Product/Lots Large Sizes

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****
0010209	Bard® Composix® Kugel Oval, 6.3" x 12.3"	All Lot Numbers

Note: Product codes 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.
Product Code 0010209 – all product lots are subject to the recall

For convenience, Table 2 below provides you with a consolidated list of Bard® Composix® Kugel products that are currently under recall:

Table 2: Recalled Product/Lots Extra Large and Large Sizes

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; via this letter.
0010202	Bard® Composix® Kugel Large Oval, 5.4" x 7"	41*L****, 41*M****, 41*N**** 43*L****, 43*M****, 43*N****	March 24, 2006; via this letter.
0010204	Bard® Composix® Kugel Large Circle, 4.5"	41*L****, 41*M****, 41*N**** 43*L****, 43*M****, 43*N****	March 24, 2006; via this letter.

No other product codes or lot numbers are under recall. Contact Davol Customer Service for replacement or credit instructions and return authorization for all product codes. Please use the enclosed shipping cards and refer to the enclosed handling instructions for returning product.

Observed rate of occurrence:

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 manufactured between 2001 and 2003, for a reported occurrence rate of 0.0125%. Of those three reports, 1 involved patient injury (abdominal pain requiring explant of the recoil ring but not the patch) for a reported injury occurrence rate of 0.0041%.

Product Code 0010204, Bard® Composix® Kugel Large Circle & Product Code 0010209, Bard® Composix® Kugel Oval: No ring breaks have been reported in either of these products. However, because of the similarity to the other products under recall, these products are being recalled as a precaution.

II. Supplemental Patient Management Information

Attached please find a document entitled *"Important Patient Management Information: Bard® Composix® Kugel Extra Large and Large Sized Patch Class I Recall"*. This document applies to both the prior recall of Extra Large Kugel Patches and to the recall expansion described in this letter.

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. Please refer to this folding technique when placing these devices. Additional copies of these IFUs are available from Davol Customer Service by calling 1-800-531-4124.

Action to be taken:

- **Please immediately distribute copies of these important documents to customers and or clinicians who may have implanted, or who may be managing, patients already implanted with one of the products under recall (refer to Table 2 above).**

Please be advised that the appropriate regulatory agencies, including the U.S. Food and Drug Administration and other global regulatory authorities, have been advised of this voluntary recall and the supplemental patient management information included with this letter.

Please also be assured that Davol is committed to bringing products of the highest quality to market and we sincerely apologize for any inconvenience this may cause you or your patients. Should you have any questions, please contact Customer Service at 1-800-531-4124.

Sincerely,

Daniel LaFever
President