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URGENT: EXPANSION OF PRODUCT RECALL[1]

Bard® Composix® Kugel® Large Patch

Product Code: 0010202, Bard® Composix® Kugel® Large Oval, 5.4" x 7.0"
Product Code: 0010204, Bard® Composix® Kugel® Large Circle, 4.5"

[1]This recall notice is an expansion to the March, 2006 Davol recall of the Bard® Composix® Kugel® Product Codes 0010202 and 0010204. Supplemental Patient Management Information for all recalled product codes accompanies this letter.

18th January 2007

Dear Customer:

This letter is intended to inform you of actions being undertaken by Davol, a subsidiary of C. R. Bard, Inc., with the Large Sized Composix® Kugel® patches referenced in the header box at the top of this letter. Davol are expanding the recall action to all lots of the referenced product manufactured before October 2006 based on having received additional complaint reports of PET recoil ring breakage. Specific information about this recall action is discussed below. An upgraded product design for both product codes is available for immediate replacement.

EXPANDED RECALL

Davol is expanding the voluntary recall of Bard® Composix® Kugel® Large Oval and Large Circle Patches manufactured before October 2006. **Immediately discontinue use of the specific product codes and lot numbers listed on Attachment A of the enclosed Urgent Reply Form.** This information supplements information contained in the recall letters issued by Davol in December 2005 and January 2006 for the Extra Large Patches and March 2006 for the Large Patches.

Please note that this recall is product code and lot specific.
Lot numbers not included in this recall action may continue to be used.

No other product codes or lot numbers are subject to this recall.

Additionally, current product Instructions For Use ("IFU") are included with this letter as a reminder of the appropriate folding technique to be used for both Open Placement and Laparoscopic Placement for the Large Composix Kugel Patches.

SUMMARY OF THE PRODUCT RECALL COMMUNICATIONS:
Extension of the previous recall to specific lots of Bard® Composix® Kugel® Patches is being conducted because Davol has received additional complaint reports for PET recoil ring breakage on certain lots of product codes 0010202 manufactured. That rate of occurrence is defined below. There is a risk that the ring welds could break under stress placed on these products during placement, which could potentially lead to patient complications such as abdominal pain, bowel perforation or chronic enteric fistulas.

Observed Rate of Occurrence and Clinical Implications:
Product Code 0010202, Bard® Composix® Kugel® Large Oval Patch: A total of 6 ring breaks have been reported, and four of these complaints have been confirmed, from the approximately 25,835 units manufactured between January 1, 2004 and September 30, 2005, for a reported occurrence rate of 0.023%.

Incidents:

One (1) incident occurred during the mesh placement surgery and the product was not implanted.

One (1) incident of a broken ring was noted at the time of surgery and the ring was removed but the mesh was left implanted. No patient symptoms have been reported following this procedure.

One (1) incident was reported where a broken ring had migrated into the abdominal wall and was removed, leaving the mesh implanted.

One (1) incident was reported where the mesh was explanted as a response to reported abdominal pain and a broken ring was noted.

Two (2) inconclusive incidents were reported where bowel perforation and broken ring were noted at the time of explant.

Product Code 0010204, Bard® Composix® Kugel Large Circle: No ring breaks have been reported in this product. However, because of the similarity of the ring joint welding process and PET ring diameter, this product is being recalled as a precaution.

RECOMMENDATIONS:
We realise 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 any product from these specific lots of 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 your local Bard Sales Specialist.

An upgraded product design for both product codes is available for replacement. The new product component design is characterised by several important changes in these patches which include:

- Change from a 0.042" diameter recoil ring stock to a less rigid 0.030" diameter recoil ring stock (already used on other Bard® Composix® Kugel® product).
- Increase of the recoil ring weld strength by a factor of four
- Increase of the recoil ring weld overlap at the weld joint from 0.180" to 0.480"
- Inclusion of the most current product IFU to provide guidance to preclude inappropriate manipulation during surgical insertion of the product.

Product codes and lot numbers that contain the re-designed product and are not subject to this recall action can easily be identified on the case or unit package with the label stating ***"Redesigned for improved ring integrity"***. If your product is labelled in this way it is not affected by this product recall.

C.R. Bard GmbH in Germany is responsible for the coordination of this recall in your country. Our records show that your facility has purchased one or more of the referenced products; therefore we would like to ask you to take care that:

- all affected products in your warehouse are put on hold; **please discontinue distribution of these products immediately.**

- you inform all customers who have received any of the affected products about this recall and ask them to return these products.

- you fill out and fax back the Urgent Reply Form provided in the attachment in order to confirm how many products have already been used and how many will be returned to us.

- Please return all products to the following address:

  C. R. Bard GmbH
  Attention: [redacted]
  RGA-#01-07
  Wachhausstr. 6
  D-76227 Karlsruhe
  Germany

Replacement or credit note will be issued upon return of recalled product.

This recall is voluntary and we will be notifying your regulatory agency of this action immediately. Please be assured that Davol Inc. is committed to manufacturing medical products of the highest quality. We sincerely apologize for the inconvenience this action may create for you, your facility and your customers.

Please confirm the receipt of this letter by fax (No.: [redacted]) as soon as possible. In case of any further questions please contact our Customer Service at the following telephone number [redacted]

Sincerely,

C.R. Bard GmbH

[redacted]

[redacted]
Financial Controller

[redacted]

[redacted]
Director Regulatory Affairs
and Quality Systems

Attachments:
- Urgent Fax Reply Form
- Copy of current Instructions For Use