Baxter

Urgent

Product Recall

July 2014

Re: Recall of COSEAL Surgical Sealant 2ml and 4ml sizes

Dear Theatre Manager/Procurement Manager,

Baxter Healthcare Corporation is conducting a voluntary recall of several lots of COSEAL Surgical Sealant.

What is COSEAL Surgical Sealant?

COSEAL is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage, as well as enforcement of suture and staple lines in lung resection procedures; patients undergoing cardiac surgery to prevent or reduce the incidence, severity and extent of post-surgical adhesion formation; and patients undergoing laparotomy or laparoscopic abdomino-pelvic surgery as an adjunct to good surgical technique intended to reduce the incidence, severity and extent of post-surgical adhesion formation.

What is the reason for the recall?

The recall is being conducted as a precautionary measure due to out of specification results observed at the 18-month time point (out of 18-month licensed shelf life to expiration) during a COSEAL stability study.

The parameter that is out of specification is an indicator of possible failure for the product to gel appropriately. COSEAL's failure to gel does not represent risk for the patient's life. All other stability requirements were met.

The investigation into this issue is ongoing, and appropriate actions will be taken.

Which lots are affected by this recall?

COSEAL 2ml, Product Code 934073:

Lot Number	Expiration Date
HA130436	July 31, 2014
HA130636	November 30, 2014

Lot Number	Expiration Date
HA131230	May 31, 2015
HA140346	September 30, 2015

COSEAL 4ml, Product Code 934074:

Lot Number	Expiration Date
HA130538	October 31, 2014
HA130637	November 30, 2014
HA130721	December 31, 2014
HA130818	January 31, 2015
HA130919	February 28, 2015

Lot Number	Expiration Date
HA131115	April 30, 2015
HA131229	May 31, 2015
HA140230	July 31, 2015
HA140429	September 30, 2015
HA140345	September 30, 2015

Please note that this recall does not affect COSEAL 8 ml size.

What is the safety risk?

COSEAL's failure to gel results in no risk to the patient life, and has no potential to induce any harm, as stated in its IFU, COSEAL is an adjunct, and not a replacement for standard surgical techniques.

- In case of this malfunction (components not forming a hydrogel) another kit of COSEAL may be used.
- In the Application section of the IFU guidance is provided regarding what the user must do if the components do not polymerize:
  - "If the material remains "watery" and does not gel within approximately 30 seconds,

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flush the site with saline, and aspirate the material"
- "If the treated site fails to seal, blot the surface dry. Reclamping the vessel may be required to dry the field for reapplication of COSEAL. Reapply sealant."

- In instances in which the two PEG derivatives do not cross-link to form a hydrogel, other alternative methods are to be employed to seal the suture line of a vascular reconstruction or the staple/suture line of a lung resection.

Since the potential defect or malfunction occurs during surgery, and the surgeon has the ability to evaluate the results of the application (formation of the gel and seal of the treated region) in case of malfunction he/she will employ alternative treatment methods and techniques to solve the surgical problem. Therefore, failure of the COSEAL materials to form a hydrogel is not prone to induce death or serious injury.

What action does my facility need to take?

Our records indicate that you have received shipments that may be impacted by this issue. Baxter is asking you to take the following actions:

- Please check your inventory for the lot numbers being recalled, and complete and return the attached Inventory Response Form, even if the inventory is zero (0).
- Please discontinue use of any affected inventory.
- Contact Baxter's Customer Service unit at 01635 206630 to arrange for a return of any affected inventory.

What if I am a distributor?

If you further distribute this product, please:

- Immediately stop the usage/distribution of the lots noted above, and quarantine any units you may still have in your inventory.
- Notify your accounts of this recall immediately.
- Contact Baxter's Customer Service unit at 01635 206630 to arrange for a return of any affected inventory.

Should you have any clinical questions related to this please contact Surecall Baxter Medical Information on 01635 206345 or email surecall@baxter.com.

Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:
- Call: 01604 704 603
- Fax: 01604 704688
- Email: uk_shs_qad@baxter.com

Reporting adverse events with drugs:
- Call: 01635 206 360,
- Fax: 01635 206 281,
- Email: vigilanceuk@baxter.com

The MHRA has been informed of this recall.

We would like to apologise for any inconvenience that may have been caused by this action and appreciate your prompt cooperation in this matter.

Yours Sincerely,

Richard Coghill
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