Baxter

Urgent Field Safety Notice- Product Recall

29th July 2014

Re: Recall of COSEAL Surgical Sealant 4ml

Dear Customer,

Baxter Healthcare Corporation is conducting a voluntary recall of one lot 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 4ml, Product Code 934074:

Lot Number	Expiration Date
HA131229	31st May 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 also guidance is given what the user must do if the components do not polymerize:
  - "If the material remains "watery" and does not gel within approximately 30 seconds, 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 on 01 206 5500 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 to quarantine any units you may still have in your inventory.
- Notify your accounts of this recall immediately.
- Contact Baxter's Customer Service on 01 206 5500 to arrange for a return of any affected inventory.

Have Regulatory Authorities been informed?

Regulatory Authorities have been informed of this recall as required.

Who do I contact for questions or additional information?

If you have any questions regarding this recall or the use of COSEAL, please contact Baxter's Customer Service on 01 206 5500

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,

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Ian Gavigan
Quality Systems Manager
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 01 2065500

Inventory Response Form

Related to Product Recall letter dated 29th July 2014

COSEAL 4ml

Product code: 934074

Batch Number: HA131229

Please complete and return one copy of this form per facility either by fax (Fax: 01 206 5577) or by email (QA_Dublin@baxter.com). A fax cover sheet is not required.

Facility/ Institution:	
Address:	
Contact Person:	
Telephone:	

Distributor Notification:

☐ We do not further distribute this product

☐ We do further distribute this product, and have provided notification of this recall to our accounts

Our inventory

☐ We do not have any unit of the affected lots in our inventory.

☐ We do have the affected lots in our inventory, which have been quarantined, and will be returned:

COSEAL 4ml, Product Code 934074:

Lot Number	Expiration Date	Quantity
HA131229	31st May 2015	

Please quarantine all affected product and prevent from use until it is collected by Baxter

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date: REQUIRED FIELD	_____