PRODUCT RECALL

May 17, 2016

Dear Director of Materials Management:

Problem Description

Baxter Healthcare Corporation is issuing a voluntary product recall for the product codes and lots listed below due to the potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use. This issue was identified as a result of an increase in complaints for COSEAL. The affected lots were distributed between February 2016 and April 2016.

Affected Product (Singapore)

Product Code	Product Description	Lot Numbers	Expiration Date	UDI
934070	COSEAL Surgical Sealant Kit, 2mL	HA160136	01/31/2017	5413765404610
934071	COSEAL Surgical Sealant Kit, 4mL	HA160151	01/31/2017	5413765404627
934071	COSEAL Surgical Sealant Kit, 4mL	HA151035	10/31/2016	5413765404627

Affected Product (Globally)

There are other lots affected globally but not Singapore. Do verify with Baxter Sales Representative if in doubt.

Product Code	Product Description	Lot Numbers	Expiration Date	UDI
934071	COSEAL Surgical Sealant Kit, 4mL	HA151205	11/30/2016	5413765404627
934071	COSEAL Surgical Sealant Kit, 4mL	HA151036	10/31/2016	5413765404627
934071	COSEAL Surgical Sealant Kit, 4mL	HA151026	09/30/2016	5413765404627
934071	COSEAL Surgical Sealant Kit, 4mL	HA160229	02/28/2017	5413765404627
934072	COSEAL Surgical Sealant Kit, 8mL	HA151038	10/31/2016	5413765404634
934072	COSEAL Surgical Sealant Kit, 8mL	HA151220	12/31/2016	5413765404634
934072	COSEAL Surgical Sealant Kit, 8mL	HA151037	10/31/2016	5413765404634
934072	COSEAL Surgical Sealant Kit, 8mL	HA151028	09/30/2016	5413765404634

934072	COSEAL Surgical Sealant Kit, 8mL	HA160114	12/31/2016	5413765404634
934072	COSEAL Surgical Sealant Kit, 8mL	HA160115	01/31/2017	5413765404634
934072	COSEAL Surgical Sealant Kit, 8mL	HA160222	02/28/2017	5413765404634

Hazard Involved

Uneven mixing can result in incomplete hydrogel formation or product with "watery" consistency. Gel formation in the PEG syringe could result in difficulty or inability to extrude the product. COSEAL is not intended as a substitute for standard surgical hemostatic, sealing and adhesion prevention techniques. If any of the above mentioned situations were to occur, surgeons would have to either use a new kit, or use alternative standard surgical methods (e.g., compression, clips, sutures, lavage, etc.) to control the respective surgical problem. In cases where gel formation or sealing does not occur within 30 seconds from application, the instructions for use instructs users to flush the site with saline and aspirate the material, and re-apply COSEAL or use alternative treatment techniques. No adverse health consequence is reasonably expected to result from this issue. To date, there have been no reports of serious injury associated with this issue.

Actions to be taken

1. Locate and remove all affected product lots from your facility. The product code and lot number can be found on the individual product or shipping carton.

2. Complete the enclosed Baxter Customer Reply Form and return it to Baxter by scanning and e-mailing to Baxter Sales Representative. Returning the Baxter Customer Reply Form promptly will prevent you from receiving repeat notices.

3. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

We apologize for any inconvenience this may cause you and your staff. All the hospital pharmacy/ purchaser and distributor have been informed. The Health Sciences Authority has been notified of this product recall. ***However, there is no similar complaint reported in Singapore for the affected lot.***

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

- Please report to Samantha Yu at samantha_yu@baxter.com.
- Please report Product Complaints to singapore_productcomplaint@baxter.com
- Please report Adverse Events to Singapore_patientsafety@baxter.com

Sincerely,

[redacted]

Corynn Tan
QA Manager
Baxter Healthcare (Asia) Pte Ltd

Enclosure: Baxter Customer Reply Form

Baxter

CUSTOMER REPLY FORM

Product Recall

May 17, 2016

Please complete and return this form to the email ID listed below as confirmation that you have received this notification by **May 23, 2016 (Monday)**. A cover sheet is not required.

Attention: Samantha Yu
Email: samantha_yu@baxter.com

Facility Name and Address:	
Name: **(Please Print Name)**	
Title: **(Please Print)**	
Telephone Number:	

Product Code	Product Name	Lot Number	Quantity to be returned
934071	COSEAL Surgical Sealant Kit, 4mL	HA160151	
934071	COSEAL Surgical Sealant Kit, 4mL	HA151035	
934070	COSEAL Surgical Sealant Kit, 2mL	HA160136	

Your signature below indicates understanding the contents of the attached letter; performing the actions as outlined in the letter, as needed; and dissemination of this information to staff and other services or facilities, as applicable.

Signature/Date: REQUIRED FIELD	

PLEASE ENSURE THE REPLY FORMS CONTAIN YOUR NAME, TITLE, SIGNATURE AND DATE IN THE ABOVE FIELDS.

RESPONDING TO THIS REQUEST WILL PREVENT THE RECEIPT OF UNECESSARY REPEAT NOTIFICATIONS CONCERNING THIS ISSUE.