Baxter

Product Recall

October 22, 2019

Dear Healthcare Provider:

Problem Description

Baxter Healthcare Corporation distributes EVA Dual Chamber Bags manufactured by The Metrix Company. The Metrix Company is issuing a product recall for EVA Dual Chamber Bags listed below due to the potential ability to leak. Please see the enclosed Medical Device Recall communication from the Metrix Company dated August 30, 2019.

Affected Products

Product Code	Product Description	Lot Numbers
H938901	1500 ml EVA Dual Chamber Bag - ExactaMix	63615-A2662
H938905	3000 ml EVA Dual Chamber Bag - ExactaMix	63630-A2659, 63630-A5340, 63630-A3968,

Do note: There are other identifiers and/or lots affected globally but not supply in Singapore. Kindly verify with Baxter if in doubt.

Actions to be taken by Customers

1. Locate and remove all affected product lots from your facility. The product code and lot number can be found on the individual product and 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. The affected product should be returned by contacting Baxter Sales Representative.
4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

The Health Sciences Authority has been notified of this action. If you have questions regarding this communication or if you have any other questions, please call your Baxter Sales Representative or e-mail to Sabrina Mok [redacted]

Please kindly report any quality problems or any adverse events associated with the product to the following personnel:

- Please report Product Complaints to singapore_productcomplaint@baxter.com
- Please report Adverse Events to singapore_patientsafety@baxter.com

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

[redacted]

Corynn Tan
Senior QA Manager
Baxter Healthcare (Asia) Pte Ltd
cc: Director of Pharmacy, Chairman Medical Board and relevant Head of Departments

Enclosure: The Metrix Company Medical Device Recall Letter
Baxter Customer Reply Form

Baxter

CUSTOMER REPLY FORM

PRODUCT RECALL

Metrix EVA Dual Chamber Bag- Exactamix

October 22, 2019

Please complete and sign this form.

Email a scanned copy to Sabrina Mok [redacted] as a confirmation that you have received this notification. A cover sheet is not required.

Please complete this reply form even if there is no remaining inventory at your facility. Ensure that all fields below are completed. Responding to this request will prevent unnecessary repeat notifications for this issue.

Please note that ***BAXTER CANNOT PROCESS UNSIGNED FORMS.***

Product Code	Product Description	Lot Numbers & Quantity
H938901	1500 ml EVA Dual Chamber Bag - ExactaMix	63615-A2662; Qty:_____
H938905	3000 ml EVA Dual Chamber Bag - ExactaMix	63630-A2659; Qty:_____ 63630-A5340; Qty:_____ 63630-A3968; Qty:_____

Completed By: _____ **Title:** _____
Print Name

Phone Number: _____

Signature: _____ **Date:** _____/_____/_____

Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.

THE METRIX COMPANY

URGENT:

MEDICAL DEVICE RECALL

Metrix Secure EVA Dual Chamber Bag

Date: August 30, 2019

Baxter Healthcare
Dear:

The purpose of this letter is to advise you that The Metrix Company is voluntarily recalling the Metrix Secure EVA Dual Chamber Bag 63615 & 63630 (Baxter - ExactaMix H938901 & H938905) – see attached spreadsheet. The recall of this product was initiated because there is potential for a leak when the dividing rod is removed from the channel whereby exposing the defect, if present, that could result in a sterile barrier failure.

No reports of death, illness or serious injury have been reported to The Metrix Company as a result of this issue. Our records indicate that you received one or more of the affected lots; see the details in the table below.

The Metrix Company is asking all customers to follow the steps below:

1. Recalled products must not be used.
2. Locate and quarantine all affected products.
3. Destroy all affected products and dispose/recycle in a manner consistent with your local waste disposal authority.
4. Complete the response form and return it to The Metrix Company according to the instructions on the form.

RECALLED PRODUCT LIST

Metrix Part #	Product Description	Lot Number	Qty in Cases
	See attached spreadsheet		

***** This recall should be carried out to the end user level. If you have further distributed this product, please identify your customers and notify them at once of this product recall. A notice of this recall should be sent to your customer.*****

THE METRIX COMPANY

For any questions please contact:

Michael Regan
Quality Assurance Manager
The Metrix Company
4400 Chavenelle Road
Dubuque, IA 52002
Phone: 563-556-8800
[redacted]

I can be reached Monday through Friday from 7:30 am to 5:00 pm central standard time.

This Urgent Voluntary recall is being made with the knowledge of the United States Food and Drug Administration (FDA).

Sincerely,

[redacted]

The Metrix Company

Attachments: Recall Acknowledgement and Receipt Form