Baxter

Urgent Field Safety Notice - Recall

Y-Type Blood/Solution Infusion Sets
FA-2022-052
Manufacturer: Baxter Healthcare S.A.
(Single Registration Number: CH-MF-000026124)
Product Recall

02nd December 2022

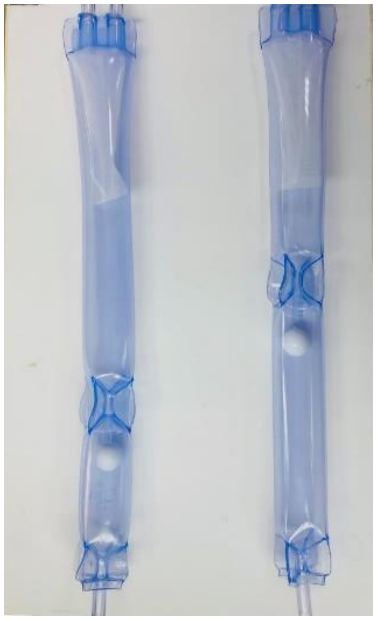
Dear Sir/Madam,

Problem Description

Baxter Healthcare Corporation is issuing a Recall for lots of Y-type Blood/Solution Sets listed below due to incorrect position (non-centered) of the drop former in the blood chamber. An example of a non-centered and centered blood chamber is shown in the picture below.

Image 1. Incorrect (non-centered) drop former image compared to the correct (centered) drop former image

Incorrect (non-centered drop former)



Correct (Centered drop former)

If the drop former is not in the center of the chamber, the set may not function as intended. Indeed, a shorter lower section of the blood chamber may impact the ability to prime the set and impact the flow performance. These product codes were distributed in Ireland between April 2022 and July 2022.

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Affected Product

Product Code	Product Description	Lot Number	Expiry Date	GTN Number
EMC9612	Y Type Blood/Solution Admin. Set	21I14T924	31-Aug-2024	05413760343648

Hazard Involved

A non-centered drop former in the blood chamber may lead to a delay in therapy, interruption of therapy, and/or the administration of damaged blood or blood products. There have been no reports of serious injury related to this issue.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Locate and quarantine all unused affected products at your facility. The product code and lot number can be found on the individual product package labeling and the shipping carton.

2. **Complete the enclosed customer reply form and return it to Baxter by e-mailing it to qa_dublin@baxter.com, even if you don't have any inventory**. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices. **This step is required, per regulatory authorities.**

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

Further information and support

For general questions regarding this communication or any product issue you are experiencing, contact Baxter at shs_customer_services_dublin@baxter.com or phone 01 206 5500.

Reporting product quality complaints:

• Email: SHS_Complaints_Dublin@baxter.com

Reporting adverse events with drugs:

• Email: vigilanceuk@baxter.com

The local Ministry of Health (MOH) has been notified of this action.

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

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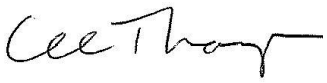
Yours faithfully



Lee Thompson

Product Manager – Medication Delivery and Acute Therapies Consumables

Baxter Healthcare Ltd.

CUSTOMER REPLY FORM related to Product Recall letter FA-2022-052 dated 02nd December 2022

Product Name: Y Type Blood/Solution Admin. Set
Product code: EMC9612
Batch Number: 21I14T924

Please complete and return one copy of this form per facility by e-mail (**qa_dublin@baxter.com**) as confirmation that you have received this notification.

Facility Name and Address: *(Please Print)*	
Reply Confirmation Completed By: *Print Name)*	
Title: *Print)*	
Email and/or Telephone Number (Including Area Code):	

Please quarantine all affected product and prevent from use

Please check boxes as appropriate:

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

☐ We do have the affected lots in our inventory and products have been quarantined.

Please list the quantity of the specific lot(s) to be returned below*:

Product Code	Lot number	Quantity in units to be returned
EMC9612	21I14T924	

*You may attach an additional sheet if required.

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	

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