Baxter

Urgent Field Safety Notice

Flo-Thru Intraluminal Shunt
FA-2022-011
Recall

April DD, 2022 (to be adapted locally)

Dear Sir/Madam (to be adapted locally),

Problem Description

Baxter Healthcare Corporation is issuing a Recall to the user level for one lot of Flo-Thru Intraluminal Shunt listed below due to the potential presence of foreign matter adhered to the inside of the lumen of the device. The foreign matter is an adhesive used in the manufacturing process. If the product is used, this may expose patients to the foreign matter within the bloodstream where it could potentially become loose.

Affected Product

Product Code	Description	Lot #
FT12150	Flo-Thru Intraluminal Shunt	SP21J21-1584173 (SP21J211584173)

Hazard Involved

Use of a device with fixed foreign matter may cause diminished blood flow, turbulent blood flow and/or damage to blood components. Patient exposure to loose or mobile foreign matter may result in venous or arterial embolism, allergic reaction, inflammatory reaction or infection. There have been no reports of any injury related to this issue.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Immediately locate, isolate, and cease all use of the affected product. The product code and lot number can be found on the individual product pouch or shipping carton.

2. Contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at (insert local contact information) between the hours of 7:00 am and 6:00 pm Central Time, Monday

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through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling. (to be adapted locally)

3. Complete the enclosed customer reply form and return it to Baxter by either faxing it to (insert local contact information) or scanning and e-mailing it to (insert local contact information) or sending it by post to (insert local contact information), 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.**

4. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions

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

6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Device Correction in accordance with your customary procedures.

Further information and support (to be adapted locally)	For general questions regarding this communication or any product issue you are experiencing, contact Baxter at (insert local contact information), between the hours of (insert local information).

The local Ministry of Health (MOH) has been notified of this action. (to be adapted locally)

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

Sincerely,

Name (to be adapted locally)
Title (to be adapted locally)
Baxter Healthcare Corporation (to be adapted locally)

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CUSTOMER REPLY FORM related to Product Recall letter dated XXXXXX *(to be completed locally)*

Product Name: Flo-Thru Intraluminal Shunt
Product code: FT12150
Batch Number: SP21J21-1584173

Please complete and return one copy of this form per facility either by fax (Fax :_____) or by e-mail (_____) as confirmation that you have received this notification. A fax cover sheet is not required. ***(Can be adapted locally)***

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

Please check boxes as appropriate: *(to be adapted locally)*

☐ 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

*You may attach an additional sheet if required.

(Below paragraph to be removed locally if not applicable)

☐ I would like Baxter to contact my patients and will provide support as needed

☐ I will contact my home patients directly and will provide information to Baxter as it becomes available.

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	

TO BE COMPLETED BY BAXTER PERSONNEL *(Below paragraph to be removed locally if needed)*

Number of product effectively received:

Justification (if discrepancy):