Urgent Field Safety Notice

Ambulatory Elastomeric Infusion Pumps
FA-2025-046
Manufacturer: BAXTER HEALTHCARE SA (ZURICH) - (Single Registration Number: CH-MF-000026124)
Type of Action: Important Product Information

November 2025

Dear Healthcare Provider

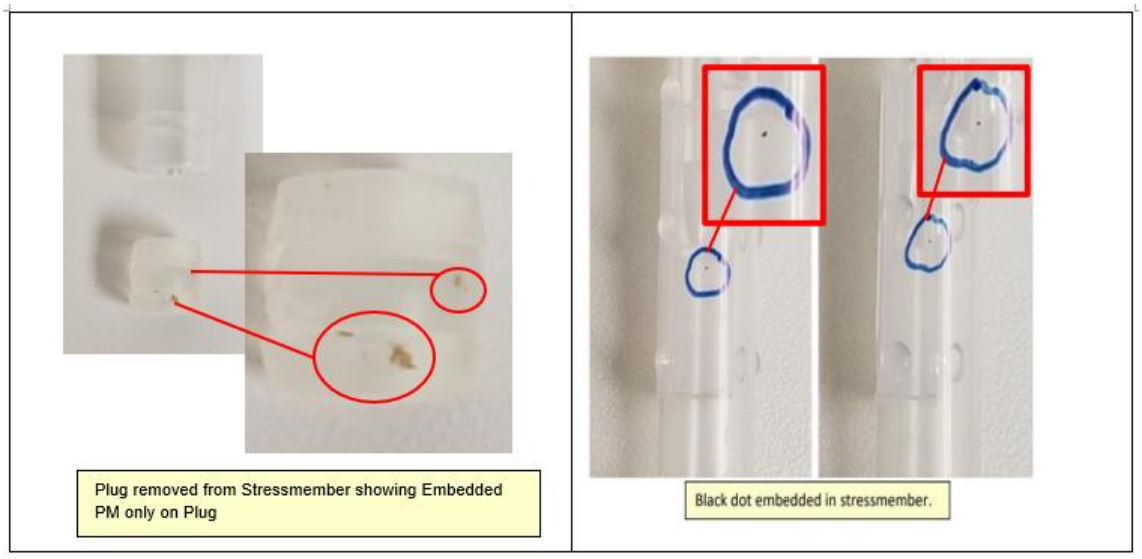
Problem Description

Baxter Healthcare Corporation is issuing an Important Product Information letter regarding complaints that have been received related to particulate matter in the stress member assembly and stress member plug of elastomeric infusion pumps (refer to images in Figure 1 below). Based on the evaluation of returned complaint samples, the observed particulate matter was identified as material inherent to the product, which is embedded within the stress member component (assembly or plug) and appears as a dark colored spot or 'burn mark.' These spots are cosmetic in nature and do not affect the quality, safety, or efficacy of the elastomeric infusion pump.

Since the particulate matter is embedded within the material of the stress member assembly or stress member plug, it will not become dislodged during use. Further, elastomeric infusion pumps are designed with a 5-micron filter inside the bladder to prevent particulate matter inside the bladder from moving out of the bladder and downstream of the fluid path.

Baxter Healthcare Corporation has implemented improvement actions to reduce the frequency of embedded particulate matter. Nonetheless, we'd like to inform you of specific product codes and lots, shown in the affected product table below.

Figure 1



Affected Product

Product Code	Description	Lot #	Expiration Date
2C2008K	INFUSOR LV2 5 days Elastomeric pump	24G014	01-Jul-27
2C2114K	Intermate 1h Nominal Flow Rate 250ml/h Single Pouch	24F010	01-June-27
2C2122K	Intermate 1h Nominal Flow Rate 250ml/h Multipack	24G006	01-Jul-27

Hazard Involved

Based on Baxter's investigation, this issue of embedded particulate matter in the elastomeric infusion pump stress member assembly and stress member plug is cosmetic and does not pose a risk to patient safety. However, a delay in treatment may occur if the embedded particulate matter is noticed by the end user and they discard the unit without a replacement readily available. To date, Baxter has not received any reports of patient injury related to this issue.

Actions to be Taken by Customers

1. Disseminate this information to anyone who may interact with elastomeric infusion pumps from the affected lots, including patients and care-givers administering the therapy with the device.

2. As the embedded particulate matter is a cosmetic issue, if the customer is not satisfied with the device they can reach out to their Baxter local sales representative for a replacement.

3. Complete the enclosed customer reply form and return it to Baxter, 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.

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

5. 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.

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 Important Product Information in accordance with your customary procedures.

Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, please contact Baxter.

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

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

Sincerely,

Baxter Healthcare Corporation

Enclosures: Baxter Customer Reply Form

(Customer communication)

CUSTOMER REPLY FORM related to Important Product Information letter dated NOVEMBER 2025

Product Name: see customer letter

Product code: see customer letter

Serial/Batch Number: see customer letter

Please complete and return one copy of this form per facility either by fax or by e-mail to Baxter as confirmation that you have received this notification.

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

Please list the specific products and serial/lot numbers in your facility below*:

Product Code	Serial/Lot number

*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	_____