

PRODUCT RECALL

03 August 2022

Dear Healthcare Provider

Problem Description Baxter Healthcare Corporation is issuing a Product Recall for the Adsorba Products listed below due to the potential presence of particulate matter within the cartridge. The affected lot numbers are listed in the enclosed Attachment A.

Affected Product	Product Code	Product Description	Lot Numbers	UDI	Expiration Dates
	101223	Adsorba Hemoperfusion Cartridge 300 C	1-441 1-450 1-451	07332414015473	31 May 2024

Hazard Involved If particulate matter is not detected before use, the particles may reach the vascular system of the patient with potential serious adverse health consequences. There have been no complaints or patient injury associated with this issue.

- 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 representative. Please complete the reply form even if you do not have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
 3. Contact Zuellig Pharma to arrange for return of the products.
 4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

The Malaysia MDA (Medical Device Authority) has been notified of this action. Any adverse events or quality problems experienced with the use of these products, please report to malaysia_productcomplaint@baxter.com.

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

Sincerely,

Yong Sook Voon
Quality Manager
Baxter Healthcare (Malaysia) Sdn Bhd

Enclosure: Baxter Customer Reply Form, Appendix 1

APPENDIX 1 - CUSTOMER REPLY FORM

PRODUCT RECALL

Adsorba Products

03 August 2022

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Please complete this reply form even if there is no remaining inventory at your facility. Completion of the information below indicates that you (1) understand the contents of the attached letter, (2) performed the actions outlined, and (3) disseminated this information, if applicable.

For Dealers, Wholesaler, Distributor/Reseller, or Original Equipment Manufacturer (OEM) Only
- Check this box to indicate that your company has disseminated this communication to your direct customers

Completed By: _____
Print Name

Title: _____

Phone Number: _____

Signature: _____

Date: ____/____/____

Email a completed copy to your Baxter representative as a confirmation that you have received this notification.