**Central Drugs Standard Control Organization**
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
(Medical Devices and Diagnostics Division)
Email: ddcimd-cdsco@nic.in
Food & Drugs Administration Bhawan,
Kotla Road, New Delhi.

**F.No.29/Misc/03/2022-DC (192)** **Date: 21st July 2022**

**MEDICAL DEVICE ALERT**

## DEVICE

**Adsorba Hemoperfusion Cartridge 300 C (Product code – 101223, Lot no. 1-419, 1-430, 1-439, 1-440, 1-441) and Adsorba 300 C (Product code – 115264, Lot no. 1-507, 1-508, 1-509, 1-512, 1-513, 1-514 )**

## BACKGROUND

Hemoperfusion should be considered if: 1. After taking life threatening amounts of adsorbable drugs, deep coma and one of the following symptoms are observed: hypoventilation, hypotonia, hypothermia, worsening of the clinical state despite conservative medical management; 2. the patient has taken drugs of which the amount, composition and kind are unknown and the patient is deeply comatose. The Adsorba has proven a high degree of efficacy for the following drugs: barbiturates, organophosphates, bromocarbamide, paracetamol, ethchlorvynol, paraquat, meprobamate, phenacetin, methaqualone, salicylate. The use of hemoperfusion as a supplementary treatment does not mean that other conventional methods of treatment should be omitted; measures such as gastric lavage, establishment of free airway and assisted respiration, controlled electrolyte and water balance, and forced diuresis should be administered whenever indicated. Futher more it might be necessary to monitor carefully the blood levels of vital substances or drugs which also could be adsorbed during the hemoperfusion treatment. Access to the blood stream for hemoperfusion treatment can be obtained by normal hemodialysis methods.

Baxter Healthcare Corporation is issuing an Urgent Medical Device Recall for the the Adsorba Hemoperfusion Cartridge 300 C and Adsorba 300 C due to the presence of particulate matter within the cartridge.

## Reason for Recall

- There was recall due to the potential presence of particulate matter within the cartridge.

## Health Hazard

- If particulate matter is not detected before use, the particles may reach the vascular system of the patient with potential serious adverse health consequences.

## Who May Be Affected

- Any person with who have used an affected Adsorba Hemoperfusion Cartridge 300 C and Adsorba 300 C
- Health care providers who treat people using the affected Adsorba Hemoperfusion Cartridge 300 C and Adsorba 300 C

**Note:** CDSCO have not received any complaints from the market on this issue.

## FURTHER DETAILS & CONTACTS

M/s Baxter India Pvt. Ltd, Gurgaon, Haryana had issued an Urgent Medical Device Recall which is attached herewith this alert.

**M/s Baxter India Pvt. Ltd.**
5th Floor, Tower A
Building 9, DLF phase III.
DLF cyber city, Gurgaon 122002
Haryana, India
India_product_complaints@baxter.com
Tel +91-124-4500200
Fax +91-124-4500200

Baxter

# Urgent Medical Device Recall

June 23, 2022

Dear Director of Materials Management:

**Problem Description**

Baxter Healthcare Corporation is issuing an Urgent Medical Device Recall for the Adsorba Hemoperfusion Cartridge 300 C and ADSORBA 300C APAC 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 | See Attachment A | 07332414015473 | See Attachment A |
| 115264 | ADSORBA 300C APAC | | 07332414118174 | |

**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. Contact your Baxter sales representative for sales return and credit.
3. If you purchased this product directly from Baxter, complete the enclosed Baxter customer reply form mention the impacted product code, lot and associated lot quantity along with your contact details Name of facility location etc. and return it to Baxter by e-mailing it to India_product_complaints@baxter.com or sales representative email, 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. If you do not complete the acknowledgement (customer reply form), you will receive a phone call from Baxter sales or clinical representative on behalf of Baxter to confirm your receipt of this notification.
4. If you purchased this product from a distributor, contact your distributor for return and credit. Please note that the Baxter customer reply form is not applicable in this situation. 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.

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6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please conduct a consumer-level recall of the affected product that you distributed to customers and **check the associated box on the reply form**.

**Further information and support**

For general questions regarding this communication, contact Baxter Sales Representatives.

The India Ministry of Health (MOH) will be notified of this action. Any adverse events or quality problems experienced with the use of these products may be reported using one of the following options:

- Contact your Baxter sales representative.
- Emailing to Baxter at: India_product_complaints@baxter.com .

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

Sincerely,

Ramadoss Sathyanarayanan

Digitally signed by Ramadoss Sathyanarayanan
Date: 2022.06.24 09:55:58 +08'00'

Sathyanarayanan Ramadoss
Dir, QA-EA Mfg & Prod Surv-AP APAC QA
Baxter India Pvt Ltd.

Enclosure: Baxter Customer Reply Form
Attachment A: Affected Lot Numbers

# Attachment A: Affected Lot Numbers

Adsorba Products

| Product Code | Lot Number | Expiration Date |
|---|---|---|
| 101223 | 1-419 | 29-Feb-24 |
| 101223 | 1-430 | 30-Apr-24 |
| 101223 | 1-439 | 30-Apr-24 |
| 101223 | 1-440 | 31-May-24 |
| 101223 | 1-441 | 31-May-24 |
| 115264 | 1-507 | 30-Sep-24 |
| 115264 | 1-508 | 30-Sep-24 |
| 115264 | 1-509 | 30-Sep-24 |
| 115264 | 1-512 | 31-Oct-24 |
| 115264 | 1-513 | 31-Oct-24 |
| 115264 | 1-514 | 31-Oct-24 |