PRODUCT RECALL

Baxter

Quality/Regulatory
S P SERVICES (UK) LTD
REAR OF BASTION HOUSE
HORTONWOOD 30/37
TELFORD
TF1 7XT

26th May 2021

FIELD SAFETY NOTICE

Baxter Medication Delivery, Nutrition, and Renal Care Products – Third-Party Incomplete Sterilisation Reports

Dear Customer,

Problem Description

Baxter Healthcare Ltd has been informed by one of our third-party sterilisation providers that **certain lots** of Medication Delivery, Nutrition, and Renal Care products, which are listed in Annex 1 of this notice, may not have been properly sterilised, or adequate documentation of sterilisation was not provided to Baxter. Therefore, Baxter is unable to guarantee sterility.

Baxter has no indication that using the impacted product lots would cause patient harm. This recall is being carried out because we have insufficient documentation of proper sterilization. It should be noted however, that at the end of each sterilization cycle, Biological Indicators (BI) introduced in the sterilization vessel together with manufactured lots are taken to an independent third-party testing lab and the results confirm sterilization efficacy. Furthermore, Baxter's complaint systems have not indicated any negative complaint trends related to these products. The vast majority of stock affected was shipped between 2016 and 2018.

After a thorough review, Baxter believes the risk to be low, however, is recalling the potentially impacted lots to keep patients as safe as possible.

Baxter used this third-party provider to sterilise the affected product lots which have been distributed in the United Kingdom. **Only products from the lots listed in Annex 1 are being removed from the market.**

Note that other Baxter products or product lots, not listed in Annex 1, may also be in your or your patients' possession. These products are considered safe to use because the raw data was analysed and deemed to be acceptable or products were not sterilised at the sterilisation site of concern.

Baxter is kindly asking that you take the following actions:

Action to be taken by Customers

1. Locate and quarantine all affected product from your facility. The product code and lot number can be found on the individual product and shipping carton.

2. Customers may continue to order <u>product lots which are not impacted by this recall</u> Contact Baxter Customer Service to order replacement product:

   Hospital: 0800 0289881 or servicecs@baxter.com

Home Dialysis: 0800 023 4002 (landline), 0370 609 9101 (mobile) or homecarecs@baxter.com

3. Complete the enclosed Baxter Customer Reply Form and return it to Baxter using one of the following options:
   - scanning and e-mailing it to uk_shs_fca@baxter.com
   - faxing it to 01635 206034

   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. This step is required, per regulatory mandates.

4. If you purchased this product from a distributor, please return their reply form as per 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 communication in accordance with your customary procedures.

7. If you have Home Patients who use these items, please notify them of this Product Recall.

The national regulatory authority (MHRA) is informed about this product recall.

If you have additional questions, please contact Baxter at uk_shs_fca@baxter.com.

Reporting product quality complaints:

- Call: 01604 704 603
- Fax: 01604 704 688
- Email: uk_shs_qa_complaints@baxter.com

Reporting adverse events with drugs:

- Call: 01635 206 360
- Fax: 01635 206 281
- Email: vigilanceuk@baxter.com

Kind regards,

Rachel Trace
Country Lead, UK and Ireland
Baxter Healthcare Ltd

Enclosure: Annex 1: Affected Product Table
Baxter Customer Reply Form