

Product Recall

EASYGRIP FLO-41 Precision MIS Delivery System FA-2022-012 Recall

11th April 2022

Dear Sir/Madam,

Problem Description

Baxter Healthcare Corporation is issuing a Recall for two lots of EASYGRIP FLO-41 listed below due to the potential use of product after their expiry date. The human-readable expiry dates printed on the primary and secondary package labelling are in the correct YYYY-MM-DD format, however Baxter identified that the expiry date encoded in the 2D barcode on this labelling is in YY-DD-MM format. If only the 2D barcode is used to identify the product expiry date, and the user is under the impression the date is in YY-MM-DD format, there is potential for these lots to be used past the actual expiry date.

Lot number	Human Readable Expiry Date on Labeling (Correct) YYYY-MM-DD	2D Barcode Expiry Date at Scan (Incorrect) YY-DD-MM
0000357425	2024-03-08	24-08-03
0000366117	2024-04-07	24-07-04

The product codes and lot numbers affected by this issue are listed below and were distributed in Ireland between April 2021 and October 2021.

Affected Product

Product Code	Product Description	Lot Number	Expiry Date
ADS201865	EASYGRIP FLO-41 Precision MIS Delivery System	0000357425	8 Mar 2024
		0000366117	7 Apr 2024



Hazard Involved Sterility cannot be assured for product used beyond the expiry date. 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. Locate and quarantine any unused affected product from your facility. The product code and lot number can be found on the individual product package labeling.
2. Contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at shs_customer_services_dublin@baxter.com or phone 01 206 5500 between the hours of 9:00 am and 5:00 pm Monday 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.
3. **Complete the enclosed customer reply form and return it to Baxter by e-mailing it to qa_dublin@baxter.com, 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 distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

Further information and support For general questions regarding this communication or any product issue you are experiencing, contact Baxter at shs_customer_services_dublin@baxter.com or phone 01 206 5500.

Reporting product quality complaints:

- Email: SHS_Complaints_Dublin@baxter.com

Reporting adverse events with drugs:

- Email: vigilanceuk@baxter.com

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



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

Sincerely,

A handwritten signature in black ink, appearing to read 'Aaron Dallimore', with a long horizontal flourish extending to the right.

Aaron Dallimore
Marketing Manager – Advanced Surgery
Baxter Healthcare Limited



CUSTOMER REPLY FORM related to Product Recall letter dated 11th April 2022

Product Name: EASYGRIP FLO-41 Precision MIS Delivery System

Product code: ADS201865

Batch Number: 0000357425, 0000366117

Please complete and return one copy of this form per facility by e-mail (qa_dublin@baxter.com) as confirmation that you have received this notification.

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

Please check boxes as appropriate:

- 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.

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	
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