

EASYGRIP FLO-41 Precision MIS Delivery System

FA-2021-033

Important Product Information

29th June 2021

Dear Healthcare Provider:

Problem Description The EASYGRIP FLO-41 delivery system is intended for delivering compatible hemostatic agents to a bleeding site through a 5 mm or larger trocar.

Baxter has identified that the expiry date which is encoded into the 2D barcode located on the primary and secondary package labelling does not match the correct printed expiry date on the primary and secondary package labelling. The human-readable expiry dates printed on the primary and secondary package labelling are in the YYYY-MM-DD format, whereas the 2D barcode expiry date was encoded as the YY-DD-MM format.

Baxter is issuing this Important Product Information letter to communicate the discrepancy in the expiry date encoded into the 2D barcode and to inform customers that the correct expiration date is the human-readable date printed on the primary and secondary package labelling. The expiry date encoded into the 2D barcode presents itself after scanning the product.

	Product Code	Product Description	Lot Number	Expiration Date DD/MM/YYYY
Affected Product	ADS201865	EASYGRIP FLO-41 Precision MIS Delivery System	0000357425	08/03/2024

Hazard Involved An incorrect expiration date could lead to the use of expired product, which may subsequently lead to the hazardous situation of microbial contamination. This hazardous situation will not be realized as an analysis of the product lots in scope shows that they are within shelf life, even accounting for the incorrectly labelled expiration dates. There have been no reports of serious injury associated with this issue.

- Actions to be Taken by Customers**
1. Healthcare providers may continue to safely use the EASYGRIP FLO-41 delivery system while following the human readable expiry date printed on the primary and secondary package labelling, which are also listed in the table above.
 2. Complete the enclosed customer reply form and return it to Baxter by either faxing it to 01 206 5577 or scanning and e-mailing it to qa_dublin@baxter.com sending it by post to Baxter Healthcare Ltd. Unit 7 Deansgrange Business Park, Blackrock, Co. Dublin, 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.

3. 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, contact Baxter at qa_dublin@baxter.com

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

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

Reporting product quality complaints:

Reporting adverse events with drugs:

• Email: SHS_Complaints_Dublin@baxter.com

• Email: vigilanceuk@baxter.com

Sincerely,



Aaron Dallimore
Marketing Manager
Baxter Healthcare Limited

CUSTOMER REPLY FORM

(IMPORTANT PRODUCT INFORMATION LETTER DATED 29 JUNE 2021)

Product Name: EASYGRIP FLO-41 Precision MIS Delivery System

Product code: ADS201865

Batch Number: 0000357425

Please complete and return one copy of this form per facility by fax (Fax :01 206 5577), e-mail (qa_dublin@baxter.com) or by post to Baxter Healthcare Ltd. Unit 7 Deansgrange Business Park, Blackrock, Dublin, as confirmation that you have received this notification.

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

Signature/Date: REQUIRED FIELD	<hr/>
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Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information to your staff, other services and facilities, if applicable.