

Flo-Rester, Flo-Thru, Vascular Probe, Ma Recette.**FA Number: FA-2024-007****Manufacturer: SYNOVIS LIFE TECHNOLOGIES INC. (ST. PAUL) (SRN US-MF-000028264)****Type of Action: Important Product Information**29th February 2024

Dear Sir/Madam,

**Problem
Description**

Baxter is issuing an Important Product Information letter to communicate that the Surgical Tools marketing brochures distributed for the products listed in Table 1 below contain inaccurate content that does not align with the products' Instructions for Use (IFU). **All products listed in Table 1 below are safe to use as the issue is only with the marketing brochures.**

These products must be used by medical professionals while following the associated product IFU to ensure they are used safely and effectively.

Table 1 – Products Referenced in the Brochure

| Product Description | Product Codes |
|---|----------------------|
| Flo-Rester Disposable Internal Vessel Occluder | Refer to Enclosure A |
| Flo-Thru Intraluminal Shunt | |
| Vascular Probe Intravascular Probe | |
| Ma Recette Mitonnee Leg MP 6 | |

Please discard all copies of the marketing materials listed in Table 2 below.

Table 2 – Affected Marketing Materials

| Reference Number | Title | Beginning Distribution Date |
|------------------|---|-----------------------------|
| UKI-AS20-220001 | UKI Surgical Tools Brochure April 2022 | 10-May-22 |
| UKI-AS20-210002 | UKI Surgical Tools Brochure December 2021 | 8-Dec-21 |

**Hazard
Involved**

If the products listed above are not used according to the instructions outlined in the IFU, serious health consequences may occur. These include conditions linked with ischemia of various lengths and/or harms inherent to prolonged surgery. There have been no reports of adverse events related to this issue.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Healthcare providers may continue to safely use the products listed in Table 1 above while following the associated Instructions for Use.
2. Cease any further distribution of the Surgical Tools marketing brochures listed above. All copies of the materials listed in Table 2 should be promptly discarded. The reference numbers can be found at the bottom of the last page of the brochures.
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.
4. If you distributed a copy of this brochure 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 qa_dublin@baxter.com.

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

Reporting product quality complaints:
• Email: SHS_Complaints_Dublin@baxter.com

Reporting adverse events with drugs:
• Email: vigilanceuk@baxter.com



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

Sincerely,

A handwritten signature in blue ink that reads "Ana Santos". The signature is written in a cursive style and is enclosed within a light blue rectangular border.

Ana Santos
Business Unit Head Advanced Surgery UKIN
Baxter Healthcare Limited

Enclosure:

Enclosure A: Affected product table

Enclosure B: Customer Reply Form.



Enclosure A: Affected product table.

| Product Code | Product Description |
|--------------|-------------------------------|
| 50100 | FLO-RESTER DISP 12MM 1.00MM |
| 50125 | FLO-RESTER DISP 12MM 1.25MM |
| 50150 | FLO-RESTER DISP 12MM 1.50MM |
| 50175 | FLO-RESTER DISP 12MM 1.75MM |
| 50200 | FLO-RESTER DISP 12MM 2.00MM |
| 50225 | FLO-RESTER DISP 12MM 2.25MM |
| 50250 | FLO-RESTER DISP 12MM 2.50MM |
| 50275 | FLO-RESTER DISP 12MM 2.75MM |
| 50300 | FLO-RESTER DISP 12MM 3.00MM |
| 50350 | FLO-RESTER DISP 12MM 3.50MM |
| 50400 | FLO-RESTER DISP 12MM 4.00MM |
| 60100 | FLO-RESTER DISP 30MM 1.00MM |
| 60175 | FLO-RESTER DISP 30MM 1.75MM |
| 60200BIOS | FLO-RESTER DISP 30MM 2.00MM |
| 60200BIOS | MA RECETTE MITONNEE LEG MP 6 |
| 60250BIOS | FLO-RESTER DISP 30MM 2.50MM |
| 60275 | FLO-RESTER DISP 30MM 2.75MM |
| 60300 | FLO-RESTER DISP 30MM 3.00MM |
| 60350 | FLO-RESTER DISP 30MM 3.50MM |
| 7081015ES | VASCULAR PROBE ES 8CM 1-1.5MM |
| FT12100 | FLO-THRU INTRALUM 1.00 |
| FT12125 | FLO-THRU INTRALUM 1.25 |
| FT12150 | FLO-THRU INTRALUM 1.50 |
| FT12175 | FLO-THRU INTRALUM 1.75 |
| FT12200 | FLO-THRU INTRALUM 2.00 |
| FT12225 | FLO-THRU INTRALUM 2.25 |
| FT12250 | FLO-THRU INTRALUM 2.50 |
| FT12275 | FLO-THRU INTRALUM 2.75 |
| FT12275 | FLO-THRU INTRALUM 2.75 |
| FT12300 | FLO-THRU INTRALUM 3.00 |



Enclosure B: Customer Reply Form

Customer Reply Form

(Important product information letter FA-2024-007 dated 29th February 2025)

Product Name: per Enclosure A

Product code: per Enclosure A

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>(Please Print Name)</i> | |
| Title: <i>(Please Print)</i> | |
| Email and/or Telephone Number (Including Area Code): | |

| | |
|--|--|
| Signature/Date: REQUIRED FIELD | |
|--|--|

Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.