Baxter

Urgent Field Safety Notice

PERI-GUARD Repair Patch and SUPPLE PERI-GUARD Repair Patch
FA-2024-010
Manufacturer: SYNOVIS LIFE TECHNOLOGIES INC. (ST. PAUL) (SRN US-MF-000028264)
Safety Alert

01st March 2024

Dear Sir/Madam,

Problem Description

On March 7, 2022, Baxter implemented labeling changes on CE-marked **Peri-Guard** Repair Patch and **Supple Peri-Guard** Repair Patch products including removal of the indications for abdominal wall defect and hernia (diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal and umbilical) repair from the Instruction for Use (IFU).

The indications on the labeling changed from:

For use as a prosthesis for pericardial closure and soft tissue deficiencies which include: defects of the abdominal and thoracic wall, hernias (diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal and umbilical), and intracardiac and great vessel repair.

To:

For use as a prosthesis for pericardial closure and soft tissue deficiencies which include: defects of the thoracic wall, and intracardiac and great vessel repair.

Baxter has since received seven (7) complaints reporting infection/abscess, all of which were received from one and the same clinic in Italy. Six (6) of the complaints were determined to be correlated to "off-label" use of **Peri-Guard** Repair Patch (multiple product codes) in abdominal surgery.

As these changes in indications may not have been taken into account by all product users, Baxter is informing customers of the changed intended use (limitation of the use) to ensure the correct use of the devices in the market.

Affected Product

Product Code	Description	Lot Number
PC0404N	**Peri-Guard** Repair Patch, 4x4cm	All within expiry
PC0608N	**Peri-Guard** Repair Patch, 6x8cm	All within expiry
PC0814N	**Peri-Guard** Repair Patch, 8x14cm	All within expiry
PC1016N	**Peri-Guard** Repair Patch, 10x16cm	All within expiry
PC1225N	**Peri-Guard** Repair Patch, 12x25cm	All within expiry

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PC0404SN	**Supple Peri-Guard** Repair Patch, 4x4cm	All within expiry
PC0608SN	**Supple Peri-Guard** Repair Patch, 6x8cm	All within expiry
PC0814SN	**Supple Peri-Guard** Repair Patch, 8x14cm	All within expiry
PC1016SN	**Supple Peri-Guard** Repair Patch, 10x16cm	All within expiry

Hazard Involved

The change was not driven by any known safety concerns. However, there is a lack of clinical data supporting the safety and effectiveness of the **Peri-Guard** Repair Patch and **Supple Peri-Guard** Repair Patch for abdominal wall and hernia defect repair. As such, these indications are no longer approved for CE-Marked **Peri-Guard** Repair Patch and **Supple Peri-Guard** Repair Patch and should be considered "off-label" in the European Union.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Clinicians may continue to use the **Peri-Guard** Repair Patch and **Supple Peri-Guard** Repair Patch products listed above however, clinicians should be aware of the recent removal of the product abdominal wall defect and hernia repair indications from the IFUs.

2. Complete the enclosed customer reply form and return it to Baxter by scanning and 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.

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 or any product issue you are experiencing, contact Baxter at qa_dublin@baxter.com

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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 appreciate your attention to this matter and apologise for any inconvenience this may cause you and your staff.

Sincerely,

Ana Santos
Business Unit Head Advanced Surgery UKINordics
Baxter Healthcare Limited

Enclosure: Customer reply form

Customer Reply Form FA-2024-010 PERI-GUARD Repair Patch and SUPPLE PERI-GUARD Repair Patch

(URGENT FIELD SAFETY NOTICE 01ST MARCH 2024)

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

Facility Name and Address: *(Please Print)*	
Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
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.

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