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

February 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 |

  

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|---|---|---|
| PC1016N | **Peri-Guard** Repair Patch, 10x16cm | All within expiry |
| PC1225N | **Peri-Guard** Repair Patch, 12x25cm | All within expiry |
| 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 either faxing it or scanning and e-mailing it or sending it by post, 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 purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

5. 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 *Safety Alert* in accordance with your customary procedures.

| | |
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| **Further information and support** | For general questions regarding this communication or any product issue you are experiencing, contact Baxter. |

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

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

Sincerely,

Baxter Healthcare Corporation

Baxter

# *CUSTOMER REPLY FORM*

*(SAFETY ALERT DATED XXXXXX (TO BE COMPLETED LOCALLY)*

***Product Name: (to be adapted locally)***
***Product code: (to be adapted locally)***
***Batch Number: (to be adapted locally)***

Please complete and return one copy of this form per facility either by fax (Fax :_____) or by e-mail (_____) as confirmation that you have received this notification.
A fax cover sheet is not required.
***(Can be adapted locally)***

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

☐ We have received the above mentioned letter and have disseminated this information to our staff, other services and facilities.

☐ We have received the above mentioned letter and have disseminated this information to customers/Home Patients. ***(to be adapted locally)***

☐ We have received the above mentioned letter and we ask Baxter to disseminate this information to customers/Home Patients. ***(to be adapted locally)***

| | |
|---|---|
| **Signature/Date:**<br>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.*