B. Braun Medical Supplies Sdn. Bhd.
Registration No. 198001002641 (56425-H)
Crown Penthouse, Plaza IBM
8 First Avenue, Persiaran Bandar Utama
47800 Petaling Jaya
Selangor Darul Ehsan, Malaysia
Tel : 603-7841 4200 (Hunting Line)
Fax : 603-7729 7491
www.bbraun.com.my

YCH DISTRIPARK SDN BHD
Unit GF-1.5
Mapletree Logistics Hub-Shah Alam
Lot 10003, Jalan Jubli Perak 22/1A
Seksyen 22, 40300 Shah Alam, Selangor
Selangor

August 7, 2024

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling specific references/batches of Novosyn®.

**Novosyn®** are sterile multifilament braided synthetic, absorbable surgical suture materials produced from a copolymer composed of 90% glycolide and 10% L-lactide (PGLA 90/10). The braided threads are treated with an absorbable synthetic coating consisting of a mixture of equal parts of a copolymer (comprised of glycolide and L-lactide) and calcium stearate so that the suture slides easily without causing a sawing effect

Novosyn® is indicated for soft tissue approximation and/or ligation in general surgery, when surgical practice requires the use of synthetic, absorbable, braided suture material. Novosyn® sutures are also for use particularly in gynaecology and urology.

**Identification of affected medical devices:**

| | |
|---|---|
| Reference name: | NOVOSYN VIOLET 2 (5) 90CM HS48 (M) DDP |
| Reference and batch number: | Detailed list in Annex 1 |

**Description of the medical device deficiency:**

B. Braun Surgical identified a manufacturing issue and some units of the mentioned references/batches could have the package damaged, consequently the product sterility could be compromised in addition to a lack of tightness of the package. This lack of tightness of the package could accelerate the degradation of the suture thread, not fulfilling the product specifications.

**Potential harms associated:**

As per our experience and knowledge, the sutures with this defect will probably not be discarded before use as it is difficult to detect it since the defect is small and it is placed in the back side of the suture packaging.

The use of non-sterile or compromised sutures could lead to:

- Biological Hazard leading to wound infection, foreign body reaction, abscess and fistula formation, suture stitch sinus, granuloma, seroma. These complications can escalate to sepsis, a life-threatening condition.
- Functional Hazards related to thread degradation or compromised suture integrity can result in wound dehiscence, pain, haemorrhage, and increased tissue trauma. These complications may necessitate further treatment or reoperation to address the underlying issue and promote healing.
- Needle Detachment Risks. If a needle detaches from the suture during internal surgery, it poses a severe risk of embolism. Additionally, the needle can trigger a foreign body reaction and encapsulation within the body, potentially requiring additional tests (e.g., X-rays) and procedures for retrieval.

In those patients that the device has already been used, no additional follow-up is required. If the patient presents any of the described complications, the hospital protocol for such situations should be implemented accordingly.

**Actions to be taken:**

Please identify and quarantine if you still have the listed product in your warehouse.

Please check with your customers if they still have the listed product in their warehouse. If yes, ask them to send the product back to you immediately.

Once you have all affected units for return contact us for the management of the material.

Please, fill out the attached "FSCA/Recall Confirmation Form" and send the completed form to us by September 5th, 2024.

This notice needs to be passed on all those who need to be aware within your organization and to any organization where the potentially affected devices have been transferred.

In accordance with the European Regulations, we have reported this incidence to the National Competent Authority (NCA) of the European countries involved.

If you have any questions regarding this voluntary product recall, please contact us at the e-mail: rima_efriani.rusli@bbraun.com.

We apologize the inconveniences we might have caused.

If more information is needed, please contact;

Name: Rima Efriani Rusli
Title: Executive - Regulatory Affairs
Email: rima_efriani.rusli@bbraun.com
Telephone : +6012 477 5870

Name: Mohd Shahril Hisyam Mohd Sata
Title: Business Unit Manager
Email : shahril_hisyam.sata@bbraun.com
Telephone : +6012 609 6336

Thank you for your cooperation.

Yours faithfully,
**B. BRAUN MEDICAL SUPPLIES SDN BHD**

**RIMA EFRIANI RUSLI**
Executive - Regulatory Affairs

**MOHD SHAHRIL HISYAM MOHD SATA**
Business Unit Manager

## Annex 1. List of references and batches involved in FSN_FSCA QA 0608-24_B Braun Surgical

| Code | Product description | Batch |
|---|---|---|
| B0068463 | NOVOSYN VIOLET 2 (5) 90CM HS48 (M) DDP | 724224 |

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**FSCA/RECALL CONFIRMATION FORM**

**PLEASE COMPLETE THIS FORM AND RETURN IT BY MAIL TO:** rima_efriani.rusli@bbraun.com

We confirm that we have received and understood the File Safety Notice in relation to:

**FSCA QA 060-24**

☐ We have received the notice and have stock to return.

Units to return:

| Product reference | Product batch | Quantity in units |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

☐ We have received the notice and all stock has been used.

NAME:.....

POSITION:.....

CUSTOMER NAME
(SUBSIDIARY, DISTRIBUTOR,ETC): .....

DATE: .....

SIGNATURE: .....