B|BRAUN
SHARING EXPERTISE

**B. Braun Surgical, S.A.**
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Urgent Field Safety Notice
Several code-batches of MONOPLUS, MONOSYN, NOVOSYN, NOVOSYN CHD
Return of the Medical Device to the manufacturer
Att. Users of above product

August 5ft, 2024

Dear Sir or Madam,

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

**MonoPlus®** is a sterile synthetic absorbable monofilament surgical suture made from the homopolymer poly-p-dioxanone.

MonoPlus® is indicated in cases where an extended soft tissue wound support of more than 4 weeks is desirable.

**Monosyn®** is a sterile synthetic absorbable monofilament surgical suture produced from a copolymer of 72% glycolide, 14% ε-Caprolactone, 14% Trimethylenecarbonate.

Monosyn® is indicated for use in general soft tissue approximation and/or ligation in general surgery, gynaecology, urology, oral surgery, including skin closure, when surgical practice requires the use of an absorbable suture material but not for use in cardiovascular, ophthalmic or neurological tissues.

**Novosyn®** and **Novosyn® CHD** 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® CHD contains an antimicrobial coating of chlorhexidine diacetate at no more than 60 $\mu$ g/m.

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.

Novosyn® CHD does not have a particular indication. The indications for use are related to the intended purpose of softtissue approximation and ligation of anatomical structures with synthetic, absorbable, braided suture materials.

**Identification of affected medical devices:**

| | |
|---|---|
| Reference name: | MONOPLUS, NOVOSYN, MONOSYN and NOVOSYN CHD<br>(Several references affected, see Annex 1) |
| 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 5ft, 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: vigilance_CT@bbraun.com.

We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,


Miguel Ángel Benade
Global Manager of Quality &
Technical Responsible (Spain)
B. Braun Surgical, S.A.

Martina Laporte
Quality and Regulatory Affairs Director
CoE OR Supply
B. Braun Surgical, S.A.

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

| Code | Product description | Batch |
|---|---|---|
| B1068558 | NOVOSYN CHD VIOLET 2(5)90CM HR40S (M) DDP | 124245 |
| C0068066 | NOVOSYN VIOLET 1 (4) 70CM HR60 (M) DDP | 724231 |
| C0068647 | NOVOSYN VIOLET 1 (4) 90CM HRN45 (M) DDP | 724242 |
| C0088629 | NOVOSYN VIOLET 4/0(1,5)4X70CM HR22 TO M DDP | 724216 |
| B0068463 & G0068463 | NOVOSYN VIOLET 2 (5) 90CM HS48 (M) DDP | 724224 |
| B0068463& G0068463 | NOVOSYN VIOLET 2 (5) 90CM HS48 (M) DDP | 724241 |
| B0024091 & G0024091 | MONOPLUS VIOLE 1(4)150CM HR48 LOOP (M) DDP | 124243 |
| B0024568 | MONOPLUS VIOL 1(4)150CM HR40S LOOP (M) DDP | 124251 |
| B0022269& G0022269 | MONOSYN VIOLET 2 (5) 90CM HS40 (M) DDP | 124265 |
| B0068648 | NOVOSYN VIOLET 2 (5) 90CM HRN45 (M) DDP | 724252 |