

Urgent Field Safety Notice  
Several code-batches of NOVOSYN  
Return of the Medical Device to the manufacturer  
Att. Users of above product

February 28<sup>th</sup>, 2024

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling some references/batches of Novosyn<sup>®</sup>. Novosyn<sup>®</sup> is a sterile, absorbable surgical suture material produced from a copolymer composed of 90% glycolide and 10% L-lactide. Novosyn<sup>®</sup> is coloured violet with the colouring D&C Violet No. 2 (C. I. 60725) to make it recognizable, but is also available undyed in the natural beige colour. The braided threads are treated with an absorbable synthetic coating consisting of a mixture of equal parts of a copolymer consisting of glycolide and L-lactide and calcium stearate so that they slide easily without causing a sawing effect.

Novosyn<sup>®</sup> sutures of this Field Safety Notice are indicated for general surgery, use particularly in gynaecology, and urology when an absorbable suture material is preferred. These involved Novosyn<sup>®</sup> sutures are indicated for ligation of anatomical structures with synthetic, absorbable, braided suture materials.

**Identification of affected medical devices:**

Reference name: NOVOSYN  
(Several references affected, see Annex 1)  
Reference and batch number: Detailed list in Annex 1

**Description of the medical device deficiency:**

From a routinely test in the final control laboratory, the company noticed that some units of the mentioned Novosyn 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:**

The use of these products in a patient could lead to transient or permanent inflammatory foreign body reaction, inflammation. Post-operative patient hyperthermia, infection, allergic reaction. Life threatening injury.

## B. Braun Surgical, S.A.

Common in all indications: infection dealing to risk of sepsis. In general surgery, gynaecology and urology: Treatment or reoperation is necessary. In wound closure (e.g. fascia, skin, subcutaneous tissue), can produce in addition, granuloma, seroma. Life threatening injury.  
Wound dehiscence, pain, haemorrhage, breakage during intervention. Treatment or reoperation is necessary. Life threatening injury.

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 March 28<sup>th</sup>, 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.

If you have any questions regarding this voluntary product recall, please contact us at the e-mail: [vigilance\\_CT@bbraun.com](mailto:vigilance_CT@bbraun.com).

We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,

**B | BRAUN**

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Annex 1. List of reference and batches involved in FSN\_Novosyn\_B Braun Surgical, S.A.

Reference	Batch	Description
C0068041N1	3403VK	NOVOSYN VIOLET 3/0 (2) 70CM HR26 (M) RCP
	3403VT	
	3403VX	
	3403VV	
C0068042N1	3403UH	NOVOSYN VIOLET 2/0 (3) 70CM HR26 (M) RCP
	3403WA	
	3403WT	
	3403WU	
	3404Y7	
	3404XD	
C0068092N1	3403VG	NOVOSYN VIOLET 1 (4) 70CM HR26S (M) RCP
C0068242N1	3402U6	NOVOSYN VIOLET 2/0 (3) 70CM HS26 (M) RCP
C0068431N1	3403VN	NOVOSYN VIOLET 2/0 (3) 70CM HS23 (M) RCP
C0068557N1	3403WM	NOVOSYN VIOLET 1 (4) 90CM HR40S (M) RCP
C0068562N1	3403UC	NOVOSYN VIOLET 1 (4) 90CM HR48 (M) RCP
	3403UB	
	3403UD	
C0068587N1	3403WK	NOVOSYN VIOLET 1 (4) 90CM HS40S (M) RCP
C0068591N1	3403VF	NOVOSYN VIOLET 0 (3,5) 90CM HR26S (M) RCP
C0069220N1	3403W5	NOVOSYN UNDYED 4/0 (1,5)45CM DS19 (M) RCP