B|BRAUN
SHARING EXPERTISE

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

July 22th, 2024

Dear Sir or Madam,

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

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 μ 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 and NOVOSYN CHD (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 these products in a patient could lead to a biological hazard leading to wound infection, foreign body reaction, abscess and fistula formation, suture stitch sinus, granuloma, seroma, risk of dehiscence, and sepsis that could lead to life-threatening injury; and to a functional hazard leading to wound dehiscence, pain, hemorrhage, increased tissue trauma which would need treatment or reoperation. Moreover, if needle is detached from the thread in a patient undergoing internal surgery and falls into the body, this could lead to embolism, foreign body reaction, encapsulation and potential need of additional test to recover the needle (e.g. X-Ray).

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 August 22th, 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 CP 168-24_B Braun Surgical

Code	*Product description*	*Batch*
B0024347	MONOPLUS VIO 1(4)150CM HRT43S LOOP(M)DDP	124152
B0024396	MONOPLUS VIOL 1(4)180CM HRT48 LOOP(M)DDP	124152
C0068994	NOVOSYN VIOLET 2/0 (3) 90CM GR65 (M) DDP	124214
C0068079	NOVOSYN VIOLET 3/0 (2) 20CM HR26 (M) DDP	124213
C1068123	NOVOSYN CHD VIOL 1 (4) 70CM HR37SS(M)DDP	124195
C1068313	NOVOSYN CHD VIOL 4/0(1,5)70CM HRC17(MDDP	124195
C1068374	NOVOSYN CHD VIO 1 (4) 70CM HRC30 (M) DDP	124195
C1068960	NOVOSYN CHD VIOL 1 (4) 70CM HRC40S(M)DDP	124195
C1068092	NOVOSYN CHD VIOL 1 (4) 70CM HR26S (M)DDP	124201
G0068046	NOVOSYN VIOLET 3/0 (2) 70CM HR30 (M) DDP	724187
C0068093	NOVOSYN VIOLET 2 (5) 70CM HR26S (M) DDP	724195
C0068220	NOVOSYN VIOLET 4/0 (1,5)45CM DS19 (M)DDP	724191
C0068557	NOVOSYN VIOLET 1 (4) 90CM HR40S (M) DDP	724194
C0088630	NOVOSYN VIOLET 3/0(2)4X70CM HR22TO(M)DDP	724196
C0088730	NOVOSYN VIOLET 3/0(2)4X45CM HR22TO(M)DDP	724195