

Urgent Field Safety Notice
Several code-batches of MONOPLUS VIOLET USP 4/0
Return of the Medical Device to the manufacturer
Att. Users of above products

October 25th, 2021

Dear Sir or Madam,

B. Braun Surgical, S.A.U. is voluntarily recalling some reference/batches of MonoPlus®. MonoPlus® is a sterile synthetic absorbable monofilament surgical suture made from the homopolymer poly-p-dioxanone. MonoPlus® is indicated for use in general soft tissue approximation, especially in cases where an extended wound support of more than 4 weeks is desirable. MonoPlus® can also be used in the paediatric cardiovascular surgery. In vascular surgery, MonoPlus® is indicated for the suturing of autologous peripheral vessels.

Identification of affected medical devices

Reference name: MONOPLUS VIOLET USP 4/0
(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 control laboratory, the company noticed that the degradation test results in some MonoPlus reference-batches that share the same thread raw material were not fulfilling product specifications.

Potential harms associated

If the thread degrades earlier than expected in the body after surgery it could provoke wound dehiscence (e.g., anastomotic leaks), infection (e.g., periocular infection, endomyometritis, localized/generalized peritonitis, sepsis), that could lead to a life-threatening injury, pain. Treatment or reoperation could be necessary.

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

B. Braun Surgical, S.A.U.

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 November 25th, 2021.

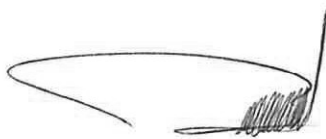
This notice needs to be passed on all those who need to be aware within your organization and to any organization where the potentially affected devices have been transferred.

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

We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,



Miguel Ángel Benade
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Technical Responsible (Spain)
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Martina Laporte
Quality and Regulatory Affairs Director
CoE OR Supply
B. Braun Surgical, S.A.U.

Annex 1. List of reference and batches involved in B. Braun Surgical, S.A.U._FSN_Monoplus

Description	Reference	Batch
MONOPLUS VIOLET 4/0(1,5)70CM HRT26(M)DDP	C0024304	121194
MONOPLUS VIOLET 4/0(1,5)70CM DS16(M)DDP	C0024539	121194
MONOPLUS VIOLET 4/0(1,5)45CM DSMP19(M)DDP	C0024907	121195
MONOPLUS VIOLET 4/0 (1,5)45CM DS16(M)DDP	C0024906	121196
MONOPLUS VIOLET 4/0(1,5)70CM HRT22(M)DDP	C0024294	121196
MONOPLUS VIOLET 4/0 (1,5)70CM DS19(M)RCP	C2024536	121211
MONOPLUS VIOLET 4/0(1,5)70CM HR20 (M)DDP	C0024679	121212
MONOPLUS VIOLET 4/0 (1,5)70CM HS18(M)DDP	C0024730	121212
MONOPLUS VIOLET 4/0(1,5)70CM DR15 (M)DDP	C0024524	121212
MONOPLUS VIOLET 4/0(1,5)70CM HR17B(M)DDP	C0024521	121212
MONOPLUS VIOLET 4/0(1,5)70CM HR17 (M)DDP	C0024014	121221
MONOPLUS VIOLET 4/0(1,5)45CM HSMP15(MDDP	C0024921	121223
MONOPLUS VIOLET 4/0 (1,5)45CM DS12(M)DDP	C0024193	121224
MONOPLUS VIOLET 4/0 (1,5)70 2XHR37(M)DDP	C0024644	121224
MONOPLUS VIOLET 4/0(1,5)90CM 2XHR26(MDDP	C0024437	121224
MONOPLUS VIOLET 4/0 (1,5)70CM DS24(M)DDP	C0024541	121224
MONOPLUS VIOL 4/0(1,5)70CM 2XHR26 (M)DDP	C0024624	121224
MONOPLUS VIOLET 4/0(1,5)70CM HRT22(M)DDP	C0024294	121224
MONOPLUS VIOLET 4/0 (1,5)70CM DR22(M)DDP	C0024537	121231
MONOPLUS VIOLET 4/0(1,5)70CM HRT26(M)DDP	C0024304	121231
MONOPLUS VIOLET 4/0 (1,5)45CM DS19(M)DDP	C0024909	121231
MONOPLUS VIOLET 4/0(1,5)70CM HR17B(M)DDP	C0024521	121231
MONOPLUS VIOLET 4/0(1,5)70CM DR18 (M)DDP	C0024534	121231
MONOPLUS VIOLET 4/0(1,5)90CM 2XHR26(MDDP	C0024437	121242
MONOPLUS VIOLET 4/0(1,5)45CM DSMP13(MDDP	C0024908	121242
MONOPLUS VIOL 4/0(1,5)70CM 2XHR26 (M)DDP	C0024624	121242