

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

April 21st, 2022

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
(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 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 or failure to provide adequate wound support (provoking i.e. hernia burst abdomen, gastrointestinal leakage) that could lead to a life-threatening injury, pain. Treatment or reoperation could be necessary.

If, as a consequence of thread degradation, the needle detaches from the thread during surgery, it could provoke impaired tissue trauma, operating time extension. Additional test (i.e. X-Ray) or re-intervention could be necessary.

B. Braun Surgical, S.A.U.

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.

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 May 21", 2022.

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,

BIBRAUN

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8. Braun Surgical, S.A.U.

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

Reference	Batch	Description
B0024079	121273	MONOPLUS VIOLET 2 (5) 90CM HR48 (M) DDP
B0024090	121164	MONOPLUS VIO 0(3,5)150CM HR48 LOOP(M)DDP
B0024119	121264	MONOPLUS VIOLET 2 (5) 90CM HS40 (M) DDP
B0024391	121264	MONOPLUS VIOL 2(5)150CM HRT48 LOOP(M)DDP
B0024396	121342	MONOPLUS VIOL 1(4)180CM HRT48 LOOP(M)DDP
B0024469	121245	MONOPLUS VIOLET 2 (5) 90CM HR40S (M) DDP
C0024005	121302	MONOPLUS VIOLET 7/0(0,5)70CM 2XHR6(M)DDP
C0024012	121244	MONOPLUS VIOLET 6/0(0,7)70CM HR17 (M)DDP
C0024027	121265	MONOPLUS VIOLET O (3,5) 70CM HR26 (M)DDP
C0024036	121172	MONOPLUS VIOLET 2/0 (3) 70CM HR30 (M)DDP
C0024045	121171	MONOPLUS VIOLET 3/0 (2) 70CM HR37 (M)DDP
C0024147	121263	MONOPLUS VIOLET O (3,5)70CM HR22S (M)DDP
C0024176	121243	MONOPLUS VIOLET 6/0(0,7)45CM DSMP11(M)DDP
C0024238	121375	MONOPLUS VIOLET 4/0(1,5)90CM 2XHR22(M)DDP
C0024436	121464	MONOPLUS VIOLET 2/0 (3) 90CM HR26 (M)DDP
C0024521	121382	MONOPLUS VIOLET 4/0(1,5)70CM HR17B(M)DDP
C0024530	121032	MONOPLUS VIOLET 3/0 (2) 70CM HR22B(M)DDP
C0024545	121263	MONOPLUS VIOLET O (3,5)90CM HRT40S(M)DDP
C0024626	121445	MONOPLUS VIOL 2/0 (3) 70CM 2XHR26 (M)DDP
C0024812	121251	MONOPLUS VIOL 6/0(0,7)70CM 2XDR12 (M)DDP
C0024812	121243	MONOPLUS VIOL 6/0(0,7)70CM 2XDR12 (M)DDP
C0024812	121245	MONOPLUS VIOL 6/0(0,7)70CM 2XDR12 (M)DDP
C0024843	121243	MONOPLUS VIOLET 6/0 (0,7) 70CM 2XHR10(M)
C0024897	121171	MONOPLUS VIOL O (3,5) 70CM 2XGR65 (M)DDP
C0024902	121243	MONOPLUS VIOLET 6/0(0,7)45CM HR13 (M)DDP
C2024034	121383	MONOPLUS VIOLET 4/0(1,5)70CM HR30 (M)RCP