

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

April 21<sup>st</sup>, 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<sup>st</sup>, 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](mailto:vigilance_CT@bbraun.com).

We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,


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**B | BRAUN**

**B. Braun Surgical, S.A.U.**

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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 0 (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 0 (3,5)70CM HR22S (M)DDP |
| C0024176  | 121243 | MONOPLUS VIOLET 6/0(0,7)45CM DSMP11(MDDP |
| C0024238  | 121375 | MONOPLUS VIOLET 4/0(1,5)90CM 2XHR22(MDDP |
| 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 0 (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 0 (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 |