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Urgent Field Safety Notice

Some code-batches of MONOMAX, MONOPLUS, MONOSYN, NOVOSYN, PREMICRON, PREMIPATCH & SAFIL
 Return of the Medical Device to the manufacturer
 Att. Users of above products

December 15th, 2021

Dear Sir or Madam,

B. Braun Surgical, S.A.U. is voluntarily recalling some reference/batches of Monomax[®], MonoPlus[®], Monosyn[®], Novosyn[®], PremiCron[®], PremiPatch[®] and Safil[®].

Monomax[®] is a sterile extra long-term absorbable monofilament surgical suture made from poly(4-hydroxybutyrate) (C₄H₆O₂)_n polymer. Monomax[®] absorbable sutures are indicated for use in general soft tissue approximation when extended wound support is needed (more than 3 months) in abdominal fascial closure. Not for use in cardiovascular or neurological tissues, microsurgery, ophthalmic surgery, as well as for use in tissues in contact to acidic body fluids.

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.

Monosyn[®] is a sterile synthetic absorbable monofilament surgical suture produced from a copolymer of 72% glycolide, 14% ε -Caprolactone, 14% Trimethylenecarbonate. Monosyn[®] is indicated for use in general soft tissue approximation and/or ligation but not for use in cardiovascular or neurological surgery. Typical applications are subcutaneous and intracutaneous sutures, closing of episiotomy, gastro-intestinal anastomosis.

Novosyn[®] is a sterile, absorbable surgical suture material produced from a copolymer composed of 90% glycolide and 10% L-lactide. 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[®] is also indicated for ophthalmology and for microsurgery if an absorbable suture material is preferred.

PremiCron[®] is a sterile non-absorbable synthetic suture composed of polyester yarns made of polyethylene terephthalate (PET). PremiCron[®] is intended for use in soft tissue approximation of the wound edges to render possible an undisturbed wound healing. PremiCron[®] is indicated for use in general surgery, cardiovascular and vascular indications and reconstructive and plastic surgery, when surgical practice requires the use of a non-absorbable suture material.

PremiPatch[®] PTFE pledgets are pre-cut sections of nonabsorbable, undyed PTFE polytetrafluoroethylene), available in various sizes, two shapes (oval and rectangular), two felt types (firm, soft), either pre-pierced or

blind. PremiPatch® PTFE pledgets are intended to be used to mechanically reinforce fragile tissues or prostheses and prevent them from being torn or cut by the suture. PremiPatch® PTFE pledgets are indicated in cardiovascular surgery (e.g. valve replacement, cardiac injuries, ventricular septal defects), when a combination with a non-absorbable suture.

Safil® is a sterile, absorbable surgical suture material produced from polyglycolic acid. Safil® is indicated for applications where surgical practice requires the use of synthetic, absorbable, braided suture materials, particularly in the region of the gastro-intestinal tract, in gynaecology and urology and for subcutaneous sutures and ligatures. Safil® is also indicated for ophthalmology (e.g. strabismus operation) and for microsurgery (e.g. peripheral nerve anastomosis and still growing tissues) if an absorbable suture material is preferred.

Identification of affected medical devices

Reference name: MONOMAX VIOLET USP 2/0 & 1
MONOPLUS VIOLET USP 2, 1, 7/0, 6/0, 5/0 & 0
MONOSYN VIOLET USP 2/0, 1 & 3/0
NOVOSYN VIOLET USP 3/0, 2, 2/0, 4/0 & 1
PREMICRON GREEN USP 2/0
PREMIPATCH 6PTFE & 2 PTFE
SAFIL VIOLET 5

(Several references affected, see Annex 1)

Reference and batch number: Detailed list in Annex 1

Description of the medical device deficiency

From an internal nonconformity, the company detected that some units of the mentioned products could have the secondary package open, as a consequence the product sterility is compromised.

Potential harms associated

If second pack is broken and/or opened, it could lead to infection, wound dehiscence, sepsis leading a life-threatening injury, risk of potential reintervention, need of medical treatment.

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 January 15th, 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.

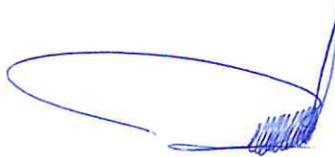
The competent authority, Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), has been informed about this field safety note.

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,



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Annex 1. List of reference and batches involved in B. Braun Surgical, S.A.U._FSN_2nd pack open

Code	Product description	Batch
B0024391	MONOPLUS VIOL 2(5)150CM HRT48 LOOP(M)DDP	121311
G0058715	NOVOSYN VIOLET 3/0 (2) 250CM ARO DDP	121301
B0068940	NOVOSYN VIOLET 2 (5) 150CM HR65 (M) DDP	121294
B0022492	MONOSYN VIOLET 2/0(3)90CM HR65 (M)DDP	121342
B0024099	MONOPLUS VIOLET 1 (4) 70CM HR76 (M) DDP	121342
B0041015	MONOMAX VIOLET 2/0 (3) 70CM HR37 (M)DDP	121343
B0041472	MONOMAX VIOLET 2/0 (3) 150CM HRT30(M)DDP	121343
B0041307	MONOMAX VIOLET 1(4)150CM HR43 LOOP(M)DDP	121344
B0068988	NOVOSYN VIOLET 2(5)150CM HRC48 LOOP(M)DDP	121345
B0041001	MONOMAX VIOLET 1(4)150CM FR65 LOOP(M)DDP	121343
B0022492	MONOSYN VIOLET 2/0(3)90CM HR65 (M)DDP	121362
B0041203	MONOMAX VIOLET 1(4)150CM HRT43S LOOPMDDP	121361
C0024501	MONOPLUS VIOLET 7/0(0,5)70CM DR10 (M)DDP	121294
B0024091	MONOPLUS VIOLE 1(4)150CM HR48 LOOP(M)DDP	121314
B0024396	MONOPLUS VIOL 1(4)180CM HRT48 LOOP(M)DDP	121342
C0026318	PREMICRON G 2/0(3)90CM 2XHRC26CVPF6 DDP	121302
C0026476	PREMICRON GRN 2/0(3)75CM 2XDRC18CVPF3DDP	121302
C0027992	PREMIPATCH 6PTFE SOFT PLEDGETS 9X5MMPEEL	121313
G1038232	SAFIL VIOLET 5 (7) 500CM C-SET DDP	121295
B0022290	MONOSYN VIOLET 1 (4) 140CM HR48 (M) DDP	121345
C0024802	MONOPLUS VIOLET 6/0(0,7)70CM 2XDR10(M)DDP	121342
C0027993	PREMIPATCH 2PTFE SOFT PLEDGET 16X7MMPEEL	121352
C0024224	MONOPLUS VIOLET 5/0(1)70CM 2XDR13B(M)DDP	121353
M0022939	MONOSYN VIOLET 3/0(2)8X45CM HR17 TO(M)TD	121314
M0088164	NOVOSYN VIOLET 2/0(3)8X45CM HR26STO(M)TD	121314
M0024949	MONOPLUS VIOLET 0(3,5)8X45CM HR37STO(M)TD	121354
M0024950	MONOPLUS VIOLET 1(4)8X45CM HR37S TO(M)TD	121352
M0088237	NOVOSYN VIOLET 4/0(1,5)8X70CM HR26TOMTD	121352
M0089133	NOVOSYN UNDYED 1(4)8X45CM HR37STO(M)TD	121355
C0026733	PREMICRON GRN 2/0(3)75CM 2XHR22 CVPF6DDP	121355
M0088241S	NOVOSYN VIOLETT 2/0(3)8X70CM HR26TO(M)TD	120431
C0026476	PREMICRON GRN 2/0(3)75CM 2XDRC18CVPF3DDP	121364
M0089133	NOVOSYN UNDYED 1(4)8X45CM HR37STO(M)TD	121361
B0024343	MONOPLUS VIO 1(4)150CM HRT40S LOOP(M)DDP	121362