0054544-28/07/2021-DGDMF-MDS-A - Allegato Utente 3 (A03)

B|BRAUN
SHARING EXPERTISE

**B. Braun Surgical, S.A.**
Carretera de Terrassa, 121
08191 Rubí
España
www.bbraun.com

Urgent Field Safety Notice
MONOSYN UNDYED 5/0 (1) 45CM DGMP13; Reference: C0023706; batch: 119183
Return of the Medical Device to the manufacturer
Att. Users of above products

July 27th, 2021

Dear Sir or Madam,

B. Braun Surgical, S.A. is recalling the reference C0023706 batch 119183 of Monosyn®. 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.

**Description of the medical device deficiency**

From a vigilance case received from the market, the company detected that traces of foam or glue could remain on the needle after suture removal from the packaging in some units of the above-mentioned reference batch. The BfArM competent authority asked to B. Braun Surgical, S.A. to initiate a FSCA.

**Potential harms associated**

In the routine clinical practice, the nursing staff checks the material suitability after opening. In the case that OR nurses or other medical staff noticed that the needle contains some particles, the suture would be discarded without being implanted on the patient. Therefore, no harm for the patient is expected, probably a delay in the surgical intervention.
In the improbable case that the defective unit was not detected before use, it could provoke toxic or foreign body reaction such as suture extrusion or inflammation. Treatment or further wound care could be necessary. It is worth to mention that although the needle could have traces of foam or glue on the needle, the product is sterile.

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.

**Identification of affected medical devices**

Reference name: MONOSYN UNDYED 5/0 (1) 45CM DGMP13
Reference and batch number: C0023706 and 119183

**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 27th, 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,

B|BRAUN
B. Braun Surgical, S.A.
Carretera de Terrassa, 121
08191 Rubí (Barcelona)
Tel.: 93 586 62 00

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.