B BRAUN
SHARING EXPERTISE

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

Urgent Field Safety Notice
Several Reference and batches of SAFIL & NOVOSYN
Return of the Medical Device to the manufacturer
Att. Users of above product

June 6th, 2018

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling several reference/batches of Safil® and Novosyn®, a sterile, absorbable surgical multifilament sutures.

Description of the medical device deficiency

From an internal non conformity, the company detected that some units of the mentioned products have the pack damaged, as a consequence the product sterility is compromised.

Potential harms associated are

Wound infection (e.g. endomyometritis, localized/generalized peritonitis), abscess formation, adhesions, risk of wound dehiscence, sepsis that could lead to life-threatening injury.
Treatment or reoperation might be necessary.

We would not recommend any specific monitoring of the patients that have been treated with the involved products since there is a risk of infection innate in any type of surgery. The hospital should act according to their established protocol for such complications.

Identification of affected medical devices

Reference name:	**SAFIL®** (Several references affected, see attachment)
Reference and batch number:	Detailed list in the attachment

Reference name:	**NOVOSYN®** (Several references affected see attachment)
Reference and batch number:	Detailed list in the attachment

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 "Recall Confirmation Form" and send the completed form to us by July 6th, 2018.

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 inform you that in accordance with the European Guidelines this recall has to be reported to the Competent Authority. Please check your national regulations and proceed accordingly.

We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,

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