B BRAUN
SHARING EXPERTISE

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

Urgent Field Safety Notice
OPTILENE 8/0 (0,4) 60CM 2XDR8; Reference: C3090887; Batch: 115105
Return of the Medical Device to the manufacturer
Att. Aesculap AG. Germany

April 6th, 2017

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling one reference/batch of Optilene, a non-absorbable, monofilament surgical suture.

From complaints received from the market, the company detected that some units of the complained reference/batch of Optilene 8/0 do not fulfill the needle attachment test.

In this particular case, Optilene 8/0 USP size with the double armed needle DR8 (1/8 circle, round body, 8mm) is particularly suitable for cardiovascular surgery. In case needle detaches during the intervention, it could provoke increased tissue trauma because it has to be sutured again, operating time extension and a re-operation could be necessary. Moreover, if the needle detaches and falls into the patient and can not be recovered, exist risk of embolism, foreign body reaction, encapsulation and potential need of additional test. Therefore, the risk is considered critical for the patient.

We have checked our files and we sent 2 boxes (72 units) of the following product in April 2015 to a client in Germany:

Reference name:	OPTILENE 8/0 (0,4) 60CM 2XDR8
Reference numbers:	C3090887
Batch:	115105

In enclosure 1 there is the customer distribution list.

Please identify and quarantine if you still have the listed product in your warehouse.

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 May 8th, 2017.

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 we have reported to the Competent Authority this recall. Please check your national regulations and proceed accordingly.

We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,

[redacted]

B. Braun Surgical, S.A.

[redacted]

B. Braun Surgical, S.A.

Enclosure 1: Customer distribution list

Customer	Reference	Box Quantity	Delivery date
[redacted]	C3090887	2	06.04.2015