

B. Braun Surgical, S.A.
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Urgent Field Safety Notice
OPTILENE 4/0 (1,5) 90CM 2XHRC22; Reference: C3090580; Batch: 115275
Return of the Medical Device to the manufacturer
Att. Aesculap AG. Germany

July 20th, 2016

Dear Sir or Madam,

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

From two complaints received from the market, the company detected that some units of complained reference/batch of Optilene had an incorrect suture inside. The Optilene suture thread is thinner (USP 5/0) than expected (USP 4/0).

We have checked our files and we sent 19 boxes (684 units) of the following product between March and June 2016 to six different Aesculap AG customers in Germany:

Reference name: OPTILENE 4/0 (1,5) 90CM 2XHRC22
Reference numbers: C3090580
Batch: 115275

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 August 20th, 2016.

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.

B. Braun Surgical, S.A.

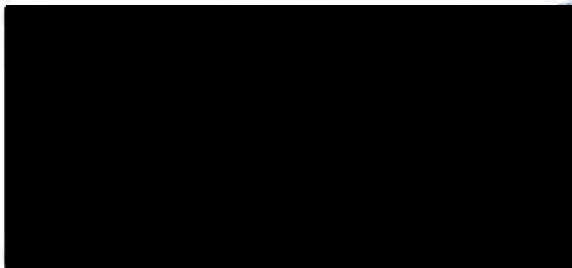
If you have any questions regarding this voluntary product recall, please contact us at the e-mail: vigilance_CT@bbraun.com.

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.

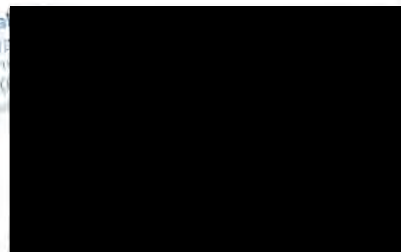
Thank you for your cooperation.

Yours faithfully,



B. Braun Surgical, S.A.

B. Braun Surgical
Carretera de Terres
08191 Rubí (Bar.)
Tel.: 93 836 62 00



B. Braun Surgical, S.A.

Enclosure 1: Customer distribution list

Customer	Reference	Box Quantity	Delivery date
[REDACTED]	C3090580	6	11.03.2016
[REDACTED]		1	14.03.2016
[REDACTED]		4	21.03.2016
[REDACTED]		4	22.04.2016
B. Braun Melsungen AG		1	12.04.2016
[REDACTED]		1	15.04.2016
[REDACTED]		1	14.06.2016
[REDACTED]		1	19.04.2016