B BRAUN
SHARING EXPERTISE

B. Braun Surgical, S.A.
Carretera de Terrassa, 121
Dirección Postal: Apartado 6
08191 Rubí (Barcelona)

Tel.: 93 586 62 00*
Fax: 93 588 10 96
www.bbraun.es

Urgent Field Safety Notice
DAFILON BLUE 2/0 (3) 75CM DS24 ; Reference: C0935360; Batch: 613514
Return of the Medical Device to the manufacturer
Att. B. Braun Adria D.O.O., Croatia

October 21th, 2014

Dear Sir or Madam,

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

From a complaint received from the market, the company detected that some units of complained reference/batch of Dafilon had an incorrect suture inside. The product is labelled as Dafilon blue 2/0 (3) 75CM DS24 but the suture is Silk black 2/0 size thread, 75cm long and DS24 needle.

The incorrect suture can be detected as the difference between the two threads is visually noticeable. Dafilon product is a blue monofilar suture and Silk product is a black braided thread. Both products are non absorbable sutures.

We have checked our files and we sent to you 1 box of this product in April 2014. Product details below:

Reference name:	DAFILON BLUE 2/0 (3) 75CM DS24
Reference number:	C0935360
Batch:	613514

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 please identify them with the RMA number 1732 and the word Recall in a visible area of the box and send them to:

B.Braun Surgical, S.A.
Att. Esther Pont
Carretera de Terrassa 121
08191 Rubí
Barcelona
Spain

Please, fill out the attached "Recall Confirmation Form" and send the completed form to us by November 21th, 2014.

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: esther.pont@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
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Carretera de Terrassa, 121
08191 Rubí (Barcelona)
Tel.: 93 586 62 00

Pau Turón
R&D, Regulatory Affairs and Quality Director CoE CT
B. Braun Surgical, S.A.

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Regulatory Affairs Manager / Safety Officer CoE CT
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