B BRAUN

B. Braun Surgical SA
Carretera de Terrassa, 121
Dirección Postal: Apartado 6
08191 Rubí (Barcelona)
España
Tel.: 93 586 62 00*
Fax: 93 588 10 96
www.bbraun.es

Urgent Field Safety Notice
DAFILON BLUE 2/0 (3) 45CM DSMP24 (M) ; Reference: C0936324; Batch: 614055
Return of the Medical Device to the manufacturer

[redacted]

July 15th, 2014

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling various reference/batches of Dafilon and Flexocrin, a synthetic non absorbable sterile surgical monofilament sutures.

From a complaint received from the market, the company detected that some units of complained reference/batch of Dafilon had an incorrect product. After first analysis of the reference/batch complained it has been detected that all pouches of the product, have polypropylene thread inside instead of polyamide thread (Dafilon). After the extended analysis, it is detected that there are more reference/batches of Dafilon and Flexocrin affected.

The defective devices can not be easily detected as the difference in the composition of two threads (polypropylene and polyamide) is almost not visually noticeable.

We have checked our files and we sent the following affected product to some clients in Germany:

Reference name:	DAFILON BLUE 2/0 (3) 45CM DSMP24 (M)
Reference number:	C0936324
Batch:	614055

7 boxes of this product were sent to 6 different customers between April and June 2014.
In enclosure 1 there is the customer distribution list.

Please identify and quarantine if you still have any of the listed products in your warehouse.
Check with your customers if they still have any of the listed products in their warehouse. If yes, ask them to send the products back to you immediately.
Once you have all affected units for return please identify them with the RMA number 1681 and the word Recall in a visible area of the box and send them to:

B.Braun Surgical, S.A.
Almacén C05-Att. Lorenzo Colorado
Carretera de Terrassa 121
08191 Rubí
Barcelona
Spain

Please, fill out the attached "Recall Confirmation Form" and send the completed form to us by August 15th, 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-mails: esther.pont@bbraun.com and sanja.kondic@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
B. Braun Surgical, S.A.
Carretera de Terrassa, 121
08191 Rubí (Barcelona)
Tel.: 93 586 62 00

[redacted]

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

Regulatory Affairs Manager / Safety Officer
CoE CT
B. Braun Surgical, S.A.

B BRAUN
SHARING EXPERTISE

B. Braun Surgical, S.A.
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08191 Rubí (Barcelona)

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Urgent Field Safety Notice
DAFILON BLUE 2/0 (3) 45CM DSMP24 (M) ; Reference: C0936324; Batch: 614055
DAFILON BLUE 2/0 (3) 90CM GS51; Reference: C0935611; Batch: 614063
DAFILON BLUE 2/0 (3) 90CM DS35; Reference: C0934801; Batch: 614065
Return of the Medical Device to the manufacturer

[redacted]

July 15th, 2014

Dear Sir or Madam,

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From a complaint received from the market, the company detected that some units of complained reference/batch of Dafilon had an incorrect product. After first analysis of the reference/batch complained it has been detected that all pouches of the product, have polypropylene thread inside instead of polyamide thread (Dafilon). After the extended analysis, it is detected that there are more reference/batches of Dafilon and Flexocrin affected.

The defective devices can not be easily detected as the difference in the composition of two threads (polypropylene and polyamide) is almost not visually noticeable.

We have checked our files and we sent the following products to some clients in Germany:

Reference name:	DAFILON BLUE 2/0 (3) 45CM DSMP24 (M)
Reference number:	C0936324
Batch:	614055

15 boxes of this product were sent to 5 different customers between April and June 2014.
In enclosure 1 there is the customer distribution list.

Reference name:	DAFILON BLUE 2/0 (3) 90CM GS51
Reference number:	C0935611
Batch:	614063

4 boxes of this product were sent to 1 customer in April 2014.
In enclosure 1 there is the customer distribution list.

Reference name:	DAFILON BLUE 2/0 (3) 90CM DS35
Reference number:	C0934801
Batch:	614065

3 boxes of this product were sent to 2 customers between April and May 2014.
In enclosure 1 there is the customer distribution list.

Please identify and quarantine if you still have any of the listed products in your warehouse.

Check with your customers if they still have any of the listed products in their warehouse. If yes, ask them to send the products back to you immediately.
Once you have all affected units for return please identify them with the RMA number 1668 and the word Recall in a visible area of the box and send them to:

B.Braun Surgical, S.A.
Almacén C05-Att. Lorenzo Colorado
Carretera de Terrassa 121
08191 Rubí
Barcelona
Spain

Please, fill out the attached "Recall Confirmation Form" and send the completed form to us by August 15th, 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-mails: esther.pont@bbraun.com and sanja.kondic@bbraun.com.

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Thank you for your cooperation.

Yours faithfully,

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