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 6/0 (0.7) 45CM DS12; Batch: 111515
Return of the Medical Device to the manufacturer
Att. B. Braun Medical A/S

June 18th, 2012

Dear Sir or Madam,

We inform you that we have detected that some aluminum pouches of the above reference/batch had an incorrect product. The box and primary package labeling are according to the above reference but the internal cardboard and product is for Dafilon 3/0.

Apart from the different thread size also the needle size is different in the product. Dafilon 6/0 threads have a DS12 needle (3/8 c, 12mm) and Dafilon 3/0 a DS24 (3/8 c, 24mm). The defective devices can be easily detected as the different in the needle size is noticeable.

We have checked our files and we sent 1 box of this product in February 2012 to a customer in Denmark, details below:

Reference name:	DAFILON BLUE 6/0 (0.7) 45CM DS12
Reference number:	C0932060
Batch:	111515

If you still have this product in your warehouse or in your customer's warehouse, please be so kind to get in touch with your Supply Chain Management contact to return it along with the attached confirmation form. Once you have all affected units for return please identify them with the RMA number 1299 and the word Recall in a visible area of the box. If you need further details please contact your SCM collaborator.

You will receive replacement of these units by return.

This notice needs to be passed on all those who need to be aware within your organization at to any organization where the potentially affected devices have been transferred.

We inform you that in accordance with the European Guidelines we have reported to the National Competent Authority this recall. Please check your national regulations and proceed the communications to your Competent Authority if required. If further information is necessary do not hesitate to contact us.
We apologize the inconveniences we might have caused.

B|BRAUN B. Braun Surgical SA
Carretera de Terrassa, 121
E-08191 Rubí (Barcelona)
Spain

Sílvia Orús
Global CT Regulatory Affairs Manager

Manuel Hernández
Global CT QM and RA Director