

B. Braun Surgical, S.A.
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Urgent Field Safety Notice

SAFIL QUI+ UNDY 5/0 (1) 45CM DSMP13; Reference: C1046619; Batch: 115441

Return of the Medical Device to the manufacturer

Att. B. Braun Medical A/S. Denmark

June 21th, 2016

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling one reference/batch of Safil Quick, a synthetic absorbable multifilament sterile surgical suture.

From complaints received from the market, the company detected that all units of the complained reference/batch of Safil Quick show the same defect, as a consequence the needle detaches very easily.

We have checked our files and we sent 1 box (36 units) of the following product in February 2016 to one client in Denmark:

Reference name: SAFIL QUI+ UNDY 5/0 (1) 45CM DSMP13
Reference number: C1046619
Batch: 115441

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 July 21th, 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.

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.


B. Braun Surgical, S.A.


We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,


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


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

Enclosure 1: Customer distribution list

Customer	Reference	Box Quantity	Delivery date
Århus Universitetshospital (NB	C1046619	1	23.02.2016