

Urgent Field Safety Notice  
SAFIL QUI+ UNDY 5/0 (1) 45CM DSMP13; Reference: G1046619; Batch: 115441  
Return of the Medical Device to the manufacturer

June 21<sup>th</sup>, 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 to you 3 boxes (36 units) in March 2016 of this product, see details:

Product information:

Reference name: SAFIL QUI+ UNDY 5/0 (1) 45CM DSMP13  
Reference number: C1046619, G1046619 and X1046619  
Batch: 115441

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 21<sup>th</sup>, 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](mailto:vigilance_CT@bbraun.com).

**B. Braun Surgical, S.A.**

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,



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

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