

B. Braun Surgical, S.A.
Carretera de Terrassa, 121
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08191 Rubí (Barcelona)

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Urgent Field Safety Notice
NOVOSYN VIOLET 1 (4) 90CM HR40S ; Reference: C0068557; Batch: 116051
Return of the Medical Device to the manufacturer
Att. B. Braun Melsungen AG. Germany

June 13th, 2016

Dear Sir or Madam,

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

From a complaint received from the market, the company detected that some units of complained reference/batch of Novosyn had an incorrect suture inside. The product is labelled as Novosyn Violet USP 1, 90cm long and HR40s needle but the suture inside is Novosyn Violet USP 0, 70 cm long and HR30 needle.

The incorrect suture could be detected as the difference between the two needles is visually noticeable. Novosyn USP 1 thread has a 1/2 circle needle of 4 cm long and Novosyn 0 thread has a 1/2 circle needle of 3 cm long.

We have checked our files and we sent the following product to one client in Germany (to B. Braun Melsungen AG customers):

Reference name: NOVOSYN VIOLET 1 (4) 90CM HR40S
Reference number: C0068557
Batch: 116051

10 boxes of this product were sent to 1 customer in April 2016.
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 please identify them with the RMA number 1996 and the word Recall in a visible area of the box and send them to:

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

Please, fill out the attached "Recall Confirmation Form" and send the completed form to us by July 13th, 2016.

B. Braun Surgical, S.A.

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.

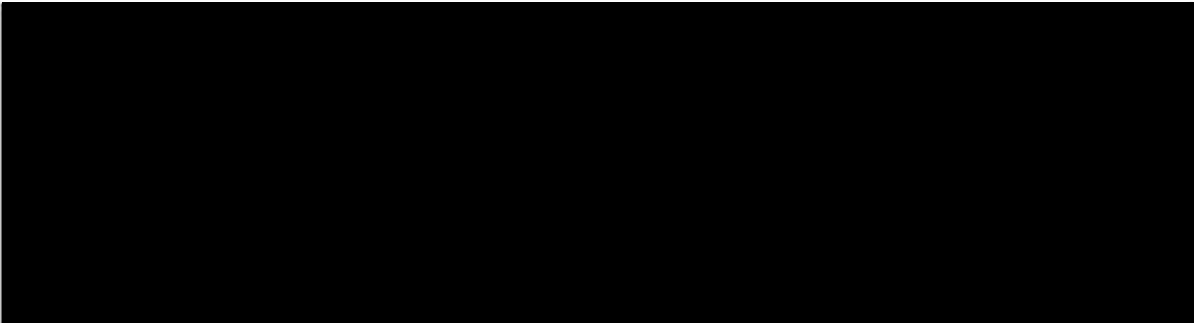
If you have any questions regarding this voluntary product recall, please contact us at the e-mail: vigilance_CT@bbraun.com.

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.

We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,



B. Braun Surgical, S.A.

B. Braun Surgical, S.A.

Enclosure 1: Customer distribution list

Customer	Reference	Box Quantity	Delivery date
[REDACTED]	C0068557	10	20.04.2016