

Urgent Field Safety Notice
SAFIL VIOLET 2/0 (3) 12X45CM; Reference: C1038666; Batch: 116084
Return of the Medical Device to the manufacturer
Att. Aesculap AG. Germany

January 30th, 2017

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling one reference/batch of Safil, a sterile, absorbable surgical multifilament suture material produced from polyglycolic acid.

From a complaint received from the market, the company detected that some units of the above mentioned reference batch have the outer pack not properly sealed. The second pack protects the inner package from external contamination (microbial barrier). In case that second pack is open/broken, the product sterility is compromised.

We have checked our files and we sent to you 46 boxes (1656 units) between May and June 2016 of this product, see details:

Reference name:	SAFIL VIOLET 2/0 (3) 12X45CM
Reference number:	C1038666
Batch:	116084

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 March 2nd, 2017.

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 this recall has to be reported to the Competent Authority. 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.
Estrada de Terrassa
91 Rubí (Barcelona)
93 586 62 00



B. Braun Surgical, S.A.

Enclosure 1: Customer distribution list

Customer	Reference	Box Quantity	Delivery date
	C1038666	6	22.06.2016
	C1038666	6	06.06.2016
	C1038666	1	24.05.2016
		2	10.06.2016
		2	30.06.2016
	C1038666	2	08.06.2016
	C1038666	2	07.06.2016
	C1038666	2	08.06.2016
	C1038666	1	01.06.2016
	C1038666	1	20.05.2016
		1	23.06.2016
	C1038666	6	26.05.2016
		4	28.06.2016
	C1038666	2	23.06.2016
	C1038666	5	30.05.2016
		3	08.06.2016