

Urgent Field Safety Notice
MONOSYN VIOLET 6/0 (0.7) 70CM HR17; Reference: C0022002; Batch: 116343
Return of the Medical Device to the manufacturer
Att. B. Braun Medical SIA. Latvia

January 30th, 2017

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling several reference/batches of Monosyn, a synthetic absorbable sterile surgical monofilament suture.

From a routinely test in the control laboratory, the company noticed that the degradation test results in some Monosyn reference-batches were not fulfilling product specifications.

Depending on the indication where the suture is used, it could provoke dehiscence (i.e. skin wound dehiscence, anastomotic leakage) that might lead to permanent impairment or life-threatening injury, as well as, infection, bad cosmetic result or hemorrhage. Potential need of treatment or reparation may not be discarded. Product functionality is not guaranteed for the intended use during shelf life.

We have checked our files and we sent to you one box (36 units) in October 2016 of one of the affected products, see details:

Reference name: MONOSYN VIOLET 6/0 (0.7) 70CM HR17
Reference number: C0022002
Batch: 116343

Please identify and quarantine if you still have the listed product in your warehouse.

Please 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,



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R&D, Regulatory Affairs and
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