B|BRAUN
SHARING EXPERTISE

B. Braun Surgical, S.A.
Carretera de Terrassa, 121
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España
www.bbraun.com

Urgent Field Safety Notice
MONOPLUS VIOLET 0(3,5)150CM HR48 LOOP(M)DDP; Reference B0024090 and batch 116182
Return of the Medical Device to the manufacturer
Att. B. Braun Medical A/S (Denmark)

September 4th, 2019

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling one reference-batch of MonoPlus®, a sterile synthetic absorbable monofilament surgical suture made from the homopolymer poly-p-dioxanone.

Description of the medical device deficiency

From a complaint received from the market, the company detected that some units of the above mentioned reference batch could have the inner pack not tight. The untightness of the inner pack (aluminium pouch) could accelerate the degradation of the suture thread, not fulfilling the product specifications.

Potential harms associated are

Operating time extension due to thread breakage during the procedure, wound dehiscence (i.e. incisional hernia, evisceration, burst abdomen), infection, bleedings, bad cosmetic result and need of medical intervention. In some applications as abdominal wall closure it would lead to life-threatening injury for the patient.

Identification of affected medical devices

We have checked our files and we sent to you 7 boxes (168 units) in August 2016 of this product, see details:

Reference name:	MONOPLUS VIOLET 0(3,5)150CM HR48 LOOP(M) DDP
Reference and batch number:	B0024090 and 116182

Actions to be taken

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 October 4th, 2019.

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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