BIB R A U N
SHARING EXPERTISE

**B. Braun Surgical, S.A.**
Carretera de Terrassa, 121
08191 Rubf
Espafia
www.bbraun.com

Urgent Field Safety Notice
BONE WAX STICK; Reference: 1029755; Batch: See attachment
Return of the Medica! Device to the manufacturer
Att . Users of Bone Wax Stick

February 8[1] 2017

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling several batches of Bone Wax Stick, an haemostat for mechanica! stilling of bleeding at bones. Bone Wax Stick is a sterile, non-absorbable mixture of beeswax (700/o) and vaseline (300/o).

**Description of the medica! device deficiency**

Some samples of Bone Wax Stick failed in the five years real time packaging stability studies. In a further check, the company noticed that some units of already manufactured batches were not fulfilling product specifications due toa failure in the packaging foil. The failure might imply that the product sterility could not be g ua rante ed. The company has decided that the risk-benefit ratio results in a non acceptable security level for the intended use of Bone Wax Stick.

**ldentification of affected medica! devices**

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|---|---|
| Reference name: | **BONE WAX STICK** |
| Reference number: | **1029755** |
| Batch: | **From 212055 to 216363** (full list in the attachment). |

**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. lf 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 8[1]h 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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