B. Braun Surgical, S.A.
Carretera de Terrassa, 121
08191 Rubí
España
www.bbraun.com

15th March 2021

Urgent Field Safety Notice_ - update

Product Code	1050060
Product Description	HISTOACRYL TRANSPARENT 0,5ML
Batch	220473N3

Dear Sir or Madam,

In our previous communication dated March 3rd 2021, we informed that B. Braun Surgical, S.A. was voluntarily recalling some reference/batches of Histoacryl products. Histoacryl is a sterile, liquid tissue adhesive consisting of n-butyl-2-cyanoacrylate.

Description of the medical device deficiency

Continuing the investigation, the company detected additional product/batch where the adhesive could not polymerize completely after its application. The tested products do not show the normal curing behaviour, providing lower adhesives forces than expected. Therefore, a recall of these additional product/batch should be done.

Potential harms associated

Histoacryl can be used for wound closure, mesh fixation or sclerotherapy in gastric varices according to the approved indications. The potential harms associated for the indications are:

- Mesh fixation: Risk of herniation, foreign body reaction. Risk of infection, pain, irritation, inflammation. Need of medical treatment or reoperation. Operating time extension.

- Sclerotherapy: Non-stoppable hemorrhage, delayed embolization. Need of medical treatment or reoperation. Operating time extension. The potential harm could lead to a life-threatening injury or even death.

- Skin closure: Wound dehiscence or insufficient closure, bleedings. Risk of infection, pain, impaired aesthetic outcome, irritation, inflammation. Need of medical treatment or reoperation. Operating time extension.

For the approved indications, the defective device is usually detected during the use; therefore, no active actions are needed in treated patients.
If the device fails, the issue related to adhesive force should appear in a short-term period, expected in the first 48h after exposure.

In the particular case of skin closure, Histoacryl is intended to be used topically, in Hospitals or outpatient areas. If a delay in the polymerization occurs or even if the product is not functional it could be easily detectable by the sanitary staff. A delay in the polymerization in this indication is not directly linked to harm to the patient, in most of the cases re-intervention or an extra medical treatment could probably not be necessary mainly because according to the IFU, Histoacryl must be used in conjunction with and not in substitution of subcuticular sutures.

Identification of affected medical devices

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Actions to be taken

Please identify and quarantine all affected product in your warehouse.

Please ensure that all users of the affected product are informed about this safety information in your organization. If you have distributed the products to a third party, please forward a copy of this information or inform the below mentioned contact person.

Please, fill out the attached "FSCA/Recall Confirmation Form" and send the completed form to us by 15th April 2021.

If more information is needed, please contact

For Product Information
Mark Culf
National Business Development Manager
Tel : 07808716108
mark.culf@bbraun.com

For Stock Returns
Catherine Clulow
Team Leader Product Complaints
Tel : 0114 2259155
productcomplaints.bbmuk@bbraun.com

The Competent Authority MHRA has received a copy of this safety information.

We apologise for any inconvenience this may cause and thank you very much for your support.

Yours sincerely

Karen Jackson
Head of Regulatory Affairs, QM and Environmental

Catherine Clulow
Team Leader Product Complaints

FSCA/RECALL CONFIRMATION FORM update

PLEASE COMPLETE THIS FORM AND RETURN IT BY MAIL TO
productcomplaints.bbmuk@bbraun.com

We confirm that we have received and understood the File Safety Notice in relation to:

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Product Description	HISTOACRYL TRANSPARENT 0,5ML
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☐ We have received the notice and have stock to return.

Units to return:

Product reference	Product batch	Quantity in units

☐ We have received the notice and all stock has been used.

NAME:.....

POSITION:.....

CUSTOMER NAME
(SUBSIDIARY, DISTRIBUTOR, ETC): .....

DATE: .....

SIGNATURE: .....