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
Several batches of HISTOACRYL BLUE 0,5ML, references 1050052 and 1050044;
HISTOACRYL® LAPFIX; references 1052008 and 1050165 and
HISTOACRYL PROSET OFX; references 1052007 and 1051007
Return of the Medical Device to the manufacturer
Att. Users of above product

March 3rd, 2021

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling some reference/batches of Histoacryl products. Histoacryl is a sterile, liquid tissue adhesive consisting of n-butyl-2-cyanoacrylate. Additionally, some Procedure Packs that contain Histoacryl product are affected; those are Histoacryl Lapfix and Histoacryl Pro-Set OFX.

Description of the medical device deficiency

In some complaints received from the market, the company detected that the adhesive could not polymerize completely after its application. In other words, the product could not show the normal curing behaviour, providing lower adhesives forces than expected.

Potential harms associated

Histoacryl can be used for wound closure, mesh fixation or sclerotherapy in gastric varices according to the approved indications. Topical use only of Histoacryl products are not included as the risk is accepted for this indication in this FSCA. The potential harms associated for mesh fixation and sclerotherapy 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.

Identification of affected medical devices

Reference name:	**HISTOACRYL®, HISTOACRYL® LAPFIX** and **HISTOACRYL® PRO-SET OFX** (Several references affected, see attachment)
Reference and batch number:	Detailed 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. 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 "FSCA/Recall Confirmation Form" and send the completed form to us by April 3rd, 2021.

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 apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,

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