B BRAUN
SHARING EXPERTISE

B. Braun Surgical, S.A.
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España
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Urgent Field Safety Notice_update
Several batches of HISTOACRYL BLUE 0,5ML; references 1050044 and 9381104,
HISTOACRYL TRANSPARENT 0,5ML; reference 1050060
HISTOACRYL® LAPFIX; references 1052008 and 1050165 and
HISTOACRYL PROSET OFX; references 1052007
Return of the Medical Device to the manufacturer

Att. Users of above product

March 15th, 2021

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. 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

Continuing the investigation, the company detected additional batches 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 batches 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 harms 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

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 15th, 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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