

Urgent Field Safety Notice_update 2

Several batches of HISTOACRYL BLUE 0,5ML; references 1050044, 1050052

HISTOACRYL TRANSPARENT 0,5ML; reference 1050060, 1050071

Return of the Medical Device to the manufacturer

Att. Users of above product

April 22nd, 2021

Dear Sir or Madam,

In March 2021, B. Braun Surgical, S.A. informed that voluntarily recalling some reference/batches of Histoacryl products. The company identified some batches where the adhesive could not polymerize completely after its application. Histoacryl is a sterile, liquid tissue adhesive consisting of n-butyl-2-cyanoacrylate.

Description of the medical device deficiency

Continuing the investigation, the company identified new additional batches where the adhesive could not polymerize completely after its application. The tested products did not show the normal curing behaviour, providing lower adhesives forces than expected. A recall of these new additional batches is initiated, based on Regulatory Risk, because they potentially do not fulfil the product specifications. Nevertheless, the clinical risk is considered acceptable.

Potential harms associated

Histoacryl can be used for wound closure, mesh fixation or sclerotherapy in gastric varices according to the approved indications. The initial risk assessment of the incident, considering the preliminary information available on the product characteristics, led us to a conservative approach, not accepting the potential risk for patients. Nevertheless, a deeper investigation has led us to update the risk assessment of the product and now the risk has been considered acceptable.

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

B. Braun Surgical, S.A.

necessary mainly because according to the Instructions For Use (IFU), Histoacryl must be used in conjunction with and not in substitution of subcuticular sutures. In case that the defective units were not detected, could cause wound dehiscence, local infections, pain, irritation, inflammation, impaired aesthetic outcome, operating time extension and could need medical treatment or re-intervention using another closure device. As per our experience and knowledge, defective devices in that indication would be discarded and no serious harms would be expected to the patient, only a delay in the intervention if it is the case.

In the case of mesh fixation, the adhesive force is mainly needed to avoid the mesh displacement during the surgical intervention because after the abdominal wall closure the mesh will remain in a natural manner fixed by the surrounding layers, no higher loads are supported by the adhesive and, in consequence, no risks for patients except an operating time extension if the medical staff decide to apply an alternative fixation technique.

In the particular case of sclerotherapy use, after a deep analysis of the samples it can be concluded that the behavior of the adhesive is according to the requirements and only a slight delay in the polymerization can be seen, therefore the potential harm could led to a manageable situation only causing operating time extension due a potential requirement of an alternative medical intervention.

Identification of affected medical devices

Reference name: HISTOACRYL®
(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 May 22nd, 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.

B. Braun Surgical, S.A.

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,

The logo for B. Braun, consisting of the letters 'B' and 'BRAUN' in a stylized, bold font.

B. Braun Surgical, S.A.
Carretera de Terrassa, 121
08191 Rubí (Barcelona)
Tel. 93 586 62 00

A handwritten signature in blue ink, appearing to read 'Miguel Ángel Benade'.

Miguel Ángel Benade
Global Manager of Quality &
Technical Responsible (Spain)
B. Braun Surgical, S.A.

A handwritten signature in blue ink, appearing to read 'Martina Laporte'.

Martina Laporte
Quality and Regulatory Affairs Director
CoE Closure Technologies
B. Braun Surgical, S.A.