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

27th April 2021

Urgent Field Safety Notice_- update 2

Several batches of HISTOACRYL BLUE 0,5ML; references 1050044, 1050052
HISTOACRYL TRANSPARENT 0,5ML; reference 1050060, 1050071
Batch Numbers ; see attachment
Return of the Medical Device to the manufacturer

Att. Users of above product

Dear Sir or Madam,

In our previous communications dated March 8th and 15th, 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 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 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 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 22nd May 2021.

If more information is needed, please contact

For Product Information

[redacted]@bbraun.com

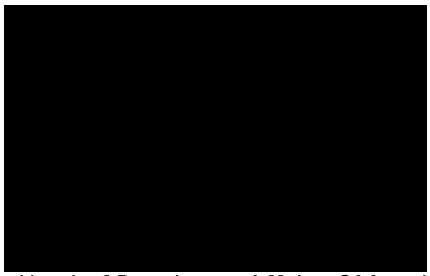
For Stock Returns

[redacted]@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



Head of Regulatory Affairs, QM and Environmental

Team Leader Product Complaints

ATTACHMENT

PRODUCT CODES: 1050044, 1050060,1050071,1050052

Batches

220394N2	220404N3	220405N1	220405N3	220412N3	220413N1
220415N2	220421N1	220431N2	220432N1	220432N2	220433N1
220434N1	220434N2	220434N3	220441N1	220441N2	220441N3
220442N1	220442N2	220395N2	220401N1	220403N1	220414N1
220411N2	220444N2	220414N2	220444N1	220444N3	220445N3
220451N1	220445N1	220481N1	220481N2	220481N3	220484N1
220484N3	220112N2	220141N1	220141N2	220142N1	220143N2
220105N2	220142N3	220142N2			