

8th March 2021

Urgent Field Safety Notice

Product Code	1050052 and 1050044
Product Description	HISTOACRYL BLUE 0,5ML
Batches	220405N2, 220474N1, 220143N1, 220364N2, 220445N2

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.

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

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 April 3rd, 2021.

If more information is needed, please contact

For Product Information

[Redacted]

Tel : [Redacted]
[Redacted]

For Stock Returns

[Redacted]
[Redacted]

Tel : [Redacted]
[Redacted]

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

[Redacted]

[Redacted]

FSCA/RECALL CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND RETURN IT BY MAIL TO:
productcomplaints.bbmun@bbbraun.com

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

Product Code 1050052 and 1050044
Product Description HISTOACRYL BLUE 0,5ML
Batches 220405N2, 220474N1, 220143N1, 220364N2, 220445N2

☐ 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: