

User Name: _____
Account Number: 01080001
Supplier: _____
Brand: HISTOACRYL BLUE/
LAPFIX/PROSET OFX
AITS Status: ☐ Not transferred to AITS
☒ Transferred to AITS

MHRA Ref No: _____
Submitted Date: 09/03/2021
Suppliers Ref: _____ & _____
Model No: 1050044; 1050052;
E3A3517C8DE8B4048025868F
0055A0FD

Summary Info

Summary information

Report type FSCA

Date of this report 09 Mar 2021

Manufacturer's internal report reference number _____ & _____

Brand name HISTOACRYL BLUE/ LAPFIX/PROSET OFX

Model code or number 1050044; 1050052;

MHRA reference number _____

Identify to what other NCAs this report was also sent



Incidence reference number assigned by NCA

Name of coordinating NCA, if applicable _____

Submission of this report does not, in itself, represent a

Manufacturer's disclaimer

conclusion by the manufacturer and / or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Device Details

Device Details**Reporter's Information****Reporter Status**

- ☐ Manufacturer
☐ Authorised Representative
☒ Others

Reporter Status Other

Other Reporting Bodies

NCP Organisation

B Braun Medical Limited

NCP Name**NCP address**

Thorncliffe Park

NCP city

Sheffield

NCP Postal code

S35 2PW

NCP telephone**NCP facsimile****NCP Email address****NCP Country**

GB

Manufacturer Contact Details**Manufacturer name**

B. Braun Surgical, S.A.

Manufacturer contact name**Manufacturer address**

Carretera de Terrassa 121

Manufacturer city

Rubí

Manufacturer Postal code

08191

Manufacturer telephone

935866200

Manufacturer facsimile**Manufacturer Email address**

@bbraun.com

Manufacturer country

ES

Authorized Representative Details**Authorized Representative name****Authorized Representative contact name****Authorized Representative address****Authorized Representative city****Authorized Representative Postal code****Authorized Representative phone****Authorized Representative fax****Authorized Representative Email address****Authorized Representative country**

DE

Device information**Device class**

MDD Class III

Nomenclature system

GMDN

Nomenclature code

58777

Nomenclature code defined in text

Surgical adhesive/sealant, synthetic polymer

Brand name

HISTOACRYL BLUE/ LAPFIX/PROSET OFX

Model code or number

1050044; 1050052;

Catalogue code or no.

N/A

Serial number

N/A

Batch number	220405N2 220474N1 220143N1 220364N2 220445N2
Software version number	N/A
Date of Manufacture	
Device Expiry Date	
Unique Device Identification (UDI) of suspected Device	
UDI Device Identifier	
Device approval information	
Regulatory/Competent Authority who Approved device	
CE Mark	
Notified Body ID Number	0123
Other 3rd party who approved device	
Document approval number	
Details of additional devices / accessories involved in the incident	
Additional information	N/A

FSCA Description

Description of FSCA	
Background information and reason for the FSCA	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.
Description and justification of the action (corrective / preventive)	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. In consequence, a recall of the total units distributed of the involved Histoacryl products is considered necessary.
Advice on actions to be taken by distributor and user	Return to the manufacturer the remaining stock of the product.
Progress of FSCA, together with reconciliation data	
Attached	<input checked="" type="checkbox"/> Field Safety Notice (FSN) in English <input type="checkbox"/> FSN in national language <input checked="" type="checkbox"/> FSN Others
Attached (Other)	
FSN Status	<input type="radio"/> Draft <input checked="" type="radio"/> Final
Time schedule for the implementations of the different actions	3 months.

Distribution and Comments		
Distribution		
The medical device has been distributed in the following countries:		
Within EEA and Switzerland SK, SI		
Candidate Countries		
All EEA, Candidate Countries and Switzwerland		
Others		
Comments		
Include any additional comments here		

Attached Files		
Field	Date	Comments
Incident Details	09/03/2021	