| | | | |
|---|---|---|---|
| User Name: | | MHRA Ref No: | [redacted] |
| Account Number: | 01080001 | Submitted Date: | 17/03/2021 |
| Supplier: | | Suppliers Ref: | [redacted] [redacted] & |
| Brand: | HISTOACRYL BLUE/ LAPFIX/PROSET OFX | Model No: | 1050044; 1050052;1050060 |
| | | | 19C0AE75EE0B5BA18025869A 003DA124 |

AITS Status: ○ Not transferred to AITS ● Transferred to AITS

Summary Info

## Summary information

| | |
|---|---|
| **Report type** | FSCA: Follow Up |
| **Date of this report** | 17 Mar 2021 |
| **Manufacturer's internal report reference number** | [redacted] [redacted] & [redacted] |
| **Brand name** | HISTOACRYL BLUE/ LAPFIX/PROSET OFX |
| **Model code or number** | 1050044; 1050052;1050060 |
| **MHRA reference number** | [redacted] |
| **Identify to what other NCAs this report was also sent** | [redacted] |
| **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<br>○ Authorised Representative<br>● Others |
| **Reporter Status Other** | Other Reporting Bodies |
| **NCP Organisation** | B Braun Medical Limited |
| **NCP Name** | [redacted] |
| **NCP address** | Thorncliffe Park |
| **NCP city** | Sheffield |
| **NCP Postal code** | S35 2PW |
| **NCP telephone** | [redacted] |
| **NCP facsimile** | [redacted] |
| **NCP Email address** | [redacted] |
| **NCP Country** | GB |
| **Manufacturer Contact Details** | |
| **Manufacturer name** | B. Braun Surgical, S.A. |
| **Manufacturer contact name** | [redacted] |
| **Manufacturer address** | Carretera de Terrassa 121 |
| **Manufacturer city** | Rubí |
| **Manufacturer Postal code** | 08191 |
| **Manufacturer telephone** | 935866200 |
| **Manufacturer facsimile** | |
| **Manufacturer Email address** | [redacted]@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** | |
| **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;1050060 |
| **Catalogue code or no.** | N/A |
| **Serial number** | N/A |

| | |
|---|---|
| **Batch number** | 220405N2 220474N1 220143N1 220364N2 220445N2, 220473N3 |
| **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.UPDATE 15.03.31 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 the additional batch should be done. |
| **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** | ☒ Field Safety Notice (FSN) in English<br>☐ FSN in national language<br>☒ FSN Others |

| | |
|---|---|
| **Attached (Other)** | |
| **FSN Status** | ○ Draft ● Final |
| **Time schedule for the implementations of the different actions** | 3 months. |

Distribution and Comments

## Distribution and Comments

**Distribution**

| | |
|---|---|
| **The medical device has been distributed in the following countries:** | |
| **Within EEA and Switzerland SK, SI** | [redacted] |
| **Candidate Countries** | [redacted] |
| **All EEA, Candidate Countries and Switzwerland** | |
| **Others** | [redacted] |

**Comments**

| |
|---|
| **Include any additional comments here** |

## Attached Files

| Field | Date | Comments |
|---|---|---|
| Incident Details | 16/03/2021 | |