import XML | fix + save

fill with test data #1

new case, keep base data

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.7en
2012-12-03

1 Administrative information

To which NCA(s) is this report being sent?

[redacted]

Type of report

- ○ Initial report
- ◉ Follow-up report
- ○ Final report

Date of this report

2021-04-22

Reference number assigned by the manufacturer

[redacted]

FSCA reference number assigned by NCA

[redacted] (ref. assigned by [redacted])

Incidence reference number assigned by NCA

Name of the co-ordinating NCACompetent Authority (if applicable)

[redacted]

2 Information on submitter of the report

Status of submitter

- ◉ Manufacturer
- ○ Authorised Representative within EEA and Switzerland
- ○ Others: (identify the role)

3 Manufacturer information	new

Name	
B. Braun Surgical, S.A.	
Contact Name	
[redacted]	
Address	
Carretera de Terrassa 121	
Postcode	**City**
08191	Rubí
Phone	**Fax**
[redacted]	
E-mail	**Country**
[redacted]@bbraun.com	ES - Spain

4 Authorised Representative Information

new

Name	
Contact Name	
Address	
Postcode	City
Phone	Fax
E-mail	Country DE - Germany

5 National contact point information

new

National contact point name B. Braun Surgical, S.A.	
Name of the contact person [redacted]	
Address Carretera de Terrassa 121	
Postcode 08191	City Rubí
Phone [redacted]	Fax
E-mail [redacted]@bbraun.com	Country ES - Spain

6 Medical device information

new

Class

- ○ AIMD Active implants
- ◉ MDD Class III
- ○ MDD Class IIb
- ○ MDD Class IIa
- ○ MDD Class I
- ○ IVD Annex II List A
- ○ IVD Annex II List B
- ○ IVD Devices for self-testing
- ○ IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
GMDN	58777

Nomenclature text

Surgical adhesive/sealant, synthetic polymer

Commercial name/ brand name / make

HISTOACRYL/ LAPFIX/PROSET OFX

Model number	Catalogue number
1050044; 1050052; 9381104; 1050060; 1050071; 1050165;	N/A
Serial number(s)	**Lot/batch number(s)**
N/A	Several, see attachment
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number

0123

Accessories / associated devices (if applicable)

N/A

Software version number (if applicable)

N/A

7 Description of the FSCA

Background information and reason for the FSCA

Follow-up 2 FSCA Background information and reason for the FSCA:

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.

Follow-up FSCA Background information and reason for the FSCA:

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 these additional batches should be done.

Initial 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. 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.

Advice on actions to be taken by the distributor and the user

Return to the manufacturer the remaining stock of the product.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

3 months.

Attached please find	FSN Status
☒ Field Safety Notice (FSN) in English	○ Draft FSN
☐ FSN in national language	◉ Final FSN
☒ Others (please specify)	
List of the affected products (update).	

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☒ BE	☒ BG	☒ CH	☒ CY	☒ CZ	☒ DE	☒ DK
☐ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE
☒ IS	☒ IT	☐ LI	☒ LT	☒ LU	☒ LV	☐ MT	☒ NL
☒ NO	☒ PL	☒ PT	☒ RO	☒ SE	☒ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland

Others:

BR, CN, KR, AU, AE, RU, CL, EC, ZA, PY, NZ, MY, PA, TW, PS, CR, MX, AR, QA, HK, JP, KE, AL, CO, EG, FJ, ID, IL, IN, LK, MA, PE, PH, SA, SG

8 Comments

The article code-batches affected in this additional recall 2 have been distributed in the following 65 countries:

EEA countries: CY, IS, LT, LU, LV, CZ, NO, IE, DK, GR, ES, DE, IT, FI, CH, NL, PT, PL, SE, FR, AT, BG, BE, SK, HU, SI and HR.

RoW countries: AL, CO, EG, FJ, ID, IL, IN, LK, MA, PE, PH, RO, SA, SG, SV, TH, TR, UY, VN, MX, MY, NZ, PA, RU, TW, HK, EC, JP, PY, AR, CN, KR, GB, BR, AU, AE, CL and ZA.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised 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.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail