Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)

Reporting Template Version 7.2.1

European Union Medical Devices Vigilance System

Import XML | Align form after import

Section 1: Administrative information

1.1 Corresponding competent authority

a Name of receiving national competent authority (NCA)
MHRA Devices

b EUDAMED number of NCA

c Reference number assigned by NCA for this incident
[redacted]

d Reference number assigned by EUDAMED for this incident

1.2 Date, type, and classification of incident report

a Date of submission: 2021-10-07 (e.g. 2012-10-23)

b Date of incident (e.g. 2012-10-23): 2021-08-25 to 2021-08-25

c Manufacturer awareness date: 2021-08-25 (e.g. 2012-10-23)

d Type of report
- ○ Initial
- ○ Follow up
- ○ Combined initial and final
- ○ Final (Reportable incident)
- ◉ Final (Non-reportable incident)

e In case of initial and follow-up reports, please indicate the expected date of the next report
(e.g. 2012-10-23)

f Classification of incident
- ○ Serious public health threat
- ○ Death
- ○ Unanticipated serious deterioration in state of health
- ◉ All other reportable incidents

1.3 Submitter information

1.3.1 Submitter of the report

a ◉ Manufacturer ○ Authorised representative ○ Other, please specify

b Manufacturer's reference number for this incident
[redacted]

c	If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted - NCA's local reference number - EUDAMED's reference number - Manufacturer's reference number		
d	If this incident is covered under an FSCA, please provide the relevant numbers: - NCA's local FSCA reference number - EUDAMED's FSCA reference number - Manufacturer's FSCA reference number		
e	Periodic Summary Report (PSR) ID		
f	If the incident occurred within a PMCF/PMPF investigation; please provide the Eudamed ID of that PMCF/PMPF investigation		
1.3.2	**Manufacturer information**		
a	Manufacturer organisation name B. Braun Surgical, S.A.		
b	Single registration number		
c	Contact's first name [redacted]	d	Contact's last name [redacted]
e	Email [redacted]@bbraun.com	f	Phone [redacted]
g	Country ES - Spain		
h	Street Carretera de Terrassa,	i	Street number 121
j	Address complement N/A	k	PO Box N/A
l	City name Rubí	m	Postal code 08191
1.3.3	**Authorised representative information**		
a	Authorised representative organisation name		
b	Single Registration Number		
c	Contact's first name	d	Contact's last name
e	Email	f	Phone
g	Country		

h	Street	i	Street number
j	Address complement	k	PO Box
l	City name	m	Postal code

1.3.4 Submitter's details if not also manufacturer or authorised representative

a	Registered commercial name of company B. Braun Surgical, S.A.		
b	Contact's first name [redacted]	c	Contact's last name [redacted]
d	Email [redacted]@bbraun.com	e	Phone [redacted]
f	Country ES - Spain		
g	Street Carretera de Terrassa,	h	Street number 121
i	Address complement N/A	j	PO Box N/A
k	City name Rubí	l	Postal code 08191

Section 2: Medical device information

2.1 Unique Device Identification (UDI)

a	UDI device identifier/Eudamed ID: Unknown	b	UDI production identifier: Unknown
c	Basic UDI-DI/Eudamed-DI: Unknown	d	Unit of use UDI-DI:

2.2 Categorisation of device

a Medical device terminology

○ EMDN ◉ GMDN ○ UMDNS(ECRI) ○ GIVD/EDMS ○ Other, please specify

b Medical device nomenclature code: 58777

2.3 Description of device and commercial information

a Medical device name (brand/trade /proprietary or common name)

H STOACRYL BLUE T SSUE ADHES VE 0 5ML

b Nomenclature text/Description of the device and its intended use

H stoacryl s a ster le, l qu d t ssue adhes ve cons st ng of n-butyl-2-cyanoacrylate For easy v sual assessment of the

c	Model: H STOACRYL	d	Catalogue/reference number: 1050052
e	Serial number:	f	Lot/batch number: 219393N2
g	Software version:	h	Firmware version:
i	Device manufacturing date (e.g. 2012-10-23): 2019-08-31	j	Device expiry date (e g. 2012-10-23): 2021-08-31
k	Date when device was implanted (e.g. 2012-10-23): to	l	Date when device was explanted (e.g. 2012-10-23): to

m If precise implant/explant dates are unknown, provide the duration of implantation

Number of years: Number of months: Number of days:

n	Implant facility:	o	Explant facility:

p

	Notified body (NB) ID number(s) (if applicable)	Notified body (NB) certificate number(s) of device (if applicable)
1	0123	G7 18 02 25701 080
2		

q Please indicate the date of one of the following:

○ First declaration of conformity

◉ The device first CE marked

○ First placed on the market

○ First put into service

○ If software, date first made available

Year: 2011 Month: 12

2.4	**Risk class of device when placed on market**
a	[redacted]
b	
c	
2.5	**Market distribution of device (region/country)** **(according to the best knowledge of the manufacturer)**
a	[redacted]
2.6	**Use of accessories, associated devices or other devices**
a	Relevant accessories used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)
b	Relevant associated devices used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)
Catheter but not more information regarding the catheter used.	

Section 3: Incident information derived from healthcare professional/facility/patient/lay user/other

3.1 Nature of incident

a Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)

Incident / Failure Description [redacted] presented for [redacted] Decision made for thoracic epidural insertion for perioperative analgesia under anaesthesia
Method of insertion Asleep, left lateral, skin clean with chlorhexidine spray and allowed to air dry, blue gauze used to further wipe the area in single motion from cranial to caudal motion, 16G tuohy needle used and catheter inserted, tuohy needle removed

Slight ooze noted at catheter/needle insertion site, a drop of histoacryl applied - this resulted in exothermic reaction causing a diathermy like pop followed by a small plume of smoke and a skin burn
Catheter patency was checked with flushing and aspirating and no leaks identified Catheter dressed and utillised for perioperative analgesia

Further clinical update - 31 08 2021
1 It resulted in a skin burn at the site of application Of more concern was the possibility that it may have have burnt/damaged the epidural catheter Luckily this does not occur and the catheter was safely extracted
2 Epidural catheter insertion and securing - a drop was applied at epidural catheter insertion site at the skin
3 There was a slight delay to the overall procedure by 15-20 mins
4 Wound was cleaned with chlorhexidine spray and allowed to air dry Furthermore, area was wiped down with gauze prior to initiation of epidural insertion

3.2 Medical device problem information

a IMDRF Medical device problem codes (Annex A)

Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code: A0303	Code: A2304	Code:	Code:	Code:	Code:

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b Number of patients involved: 1

c What is the current location of the device?

- ○ Healthcare facility/carer
- ○ Distributor
- ○ Patient/user
- ○ Discarded
- ○ In transit to manufacturer
- ○ Remains implanted
- ◉ Manufacturer
- ○ Unknown
- ○ Other:

d Operator of device at the time of the incident

- ◉ Healthcare professional
- ○ Patient/lay user
- ○ Other, please describe

e Usage of device (as intended)

- ◉ Initial use
- ○ Reuse of a single use medical device
- ○ Reuse of a reusable medical device
- ○ Re-serviced/refurbished/fully refurbished
- ○ Problem noted prior use
- ○ Other:

f Remedial actions taken by healthcare facility, patient or user subsequent to the incident

3.3 Patient information

a IMDRF 'Health Effect' terms and codes (Annex E, F)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E)	Code E170501	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code F1908	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b Age of patient at the time of the incident
years [ ] months [ ] days [ ]

c Gender [redacted]

d Body weight (kg)

e List any of the patient's prior health condition or medication that may be relevant to this incident

3.4 Initial reporter (can be healthcare professional of facility, patient, lay user)

a Role of initial reporter
(●) Healthcare professional ( ) Patient ( ) Lay user ( ) Other, please specify

b Name of healthcare facility where incident occurred
NHS - Queen Elizabeth Hospital

c Healthcare facility report number (if applicable)

d	Contact's first name [redacted]	**e**	Contact's last name [redacted]
f	Email [redacted]	**g**	Phone
h	Country [redacted]		
i	Street [redacted]	**j**	Street number
k	Address complement [redacted]	**l**	PO Box
m	City name [redacted]	**n**	Postal code [redacted]

Section 4: Manufacturer analysis

4.1 Manufacturer's preliminary comments

a For **initial** and **follow-up** reports: preliminary results and conclusions of manufacturer's investigation

b Initial actions (corrective and/or preventive) implemented by the manufacturer

c What further investigations do you intend in view of reaching final conclusions?

4.2 Cause investigation and conclusion

a **For Final (Reportable incident):** Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion

b **For Final (Non-reportable incident):**Fill out rationale for why this is considered not reportable

Histoacryl was used to fix catheter at the skin, not indicated in the instructions for use of the product Therefore, this case is also considered an off-label use

There are no previous complaints of this code-batch We manufactured and distributed in the market 3,875 units of this code-batch There are no units in our stock

We have received one open ampoule (without tip) to analyze this case Without closed samples a proper analysis cannot be performed Furthermore, the sample has been received on 23 September 2021, after the expiry date (31 August 2021)

The Device History Record has been reviewed and no deviations have been found

Before applying Histoacryl, the wound should be clean and dry, without blood present in the area When Histoacryl gets in direct contact with the blood of the wound the reaction is very fast, it cannot be discarded smoke formation in the wound area and also heat (sensation of burning)

In the Warnings of the instructions for use of the product is indicated that Histoacryl should not be applied to wet or bleeding wounds Excess moisture (such as water or alcohol) or blood presence, may accelerate polymerisation, resulting in the generation of excess heat

Also, in the Side effects paragraph The use of this product leads to an exothermic polymerisation reaction The released heat may result in a sensation of warmth Cyanoacrylates can be associated with a limited period of local sensitisation or irritation reaction in the application area

c Is root cause confirmed?

○ Yes ◉ No

d Has the risk assessment been reviewed?

◉ Yes ○ No If 'No', rationale for no review required:

If the risk assessment has been reviewed, is it still adequate?

◉ Yes ○ No

Results of the assessment:

The overall residual risk is acceptable, Histoacryl still has a favourable benefit-risk balance.

The overall residual risk is acceptable, Histoacryl still has a favourable benefit-risk balance.

e

IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)

Coding with IMDRF terms is a mandatory requirement.	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
IMDRF Cause investigation: Type of investigation (Annex B)	Code B01	Code B11	Code B14	Code	Code	Code	Code	Code

IMDRF Cause investigation: Investigation findings (Annex C)	Code C20	Code	Code	Code	Code	Code	Code

IMDRF Cause investigation: Investigation conclusion (Annex D)	Code D12	Code D1103	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

f

IMDRF Component codes (Annex G)

Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Component' codes (Annex G)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

g

Description of remedial action/corrective action/preventive action/field safety corrective action (FSCA)

(For a FSCA, fill in the FSCA form)

No remedial/corrective/preventive/field safety corrective actions are implemented at this moment.

h

Time schedule for the implementation of the identified actions

i

Final comments from the manufacturer on cause investigation and conclusion

With the information received, we do not see any manufacturing fault or material defect that could have caused the incidence. The incident is considered an off-label use as the indication is not included in the instructions for use of the product, and more related to a known side-effect of the product already included in the instructions for use of the device.

4.3 Similar incidents (for Final (Reportable incident))

4.3.1 Use of IMDRF terms and codes for identifying similar incidents

a

Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes
Tick-mark which code or combination of codes were used for identifying similar incidents.

	Choice 1
IMDRF code relating to most relevant 'Medical device problem' (Annex A)	☐
IMDRF code relating to most relevant 'Investigation finding' (Annex C, 'Cause investigation')	☐

☐ Other – enter description of what similar incidents are based on and the rationale why the above IMDRF codes were not used

4.3.2 Use of in-house terms/codes for identifying similar incidents (only for transition period)

a

If similar incident were not identified by IMDRF codes but by in-house codes, please provide the codes and terms below.

	Choice 1	
Code/term for most relevant medical device problem	Code	
	Term	
Code/term for most relevant root cause evaluation	Code	
	Term	

☐ Other – enter description of what similar incidents are based on and the rationale why the above codes were not used

4.3.3 Number of similar incidents and devices on the market

a

Indicate on which basis similar incidents were identified regarding the device or device variant:

○ Model ○ Software ○ Lot/Batch ○ Product platform ○ Other variant

Details of the selection made above

b

Indicate to what criteria the number of devices on the market (also known as denominator data) is based on (tick the most appropriate):

- ○ Devices placed on the market or put into service
- ○ Units distributed within each time period
- ○ Number of tests performed
- ○ Number of episodes of use (for reusable devices)
- ○ Active installed base
- ○ Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period
- ○ Number of devices implanted
- ○ Other -describe

c	Enter the number of similar incidents and devices on the market for the indicated time periods You must use yearly time periods unless: A: a different time period has been specified by the European vigilance Working Group B: the device has not been on the European market for more than three years

	Time period (N) Year to date = incident year (e.g. 2012-10-23)		Time period (N-1) calendar year one year before incident (e.g. 2012-10-23)		Time period (N-2) calendar year two years before incident (e.g. 2012-10-23)		Time period (N-3) calendar year three years before incident (e.g. 2012-10-23)	
Start date	2021-01-01		2020-01-01		2019-01-01		2018-01-01	
End date								
	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market
Country of incident								
EEA + CH + TR								
World								

d	Comments on how similar incidents and associated number of devices on the market were determined

Section 5: General comments

Coded summary of report (will be auto populated from previous selections)

Medical device name

H STOACRYL BLUE T SSUE ADHES VE 0 5ML

Basic UDI-DI	Unknown		
UDI device identifier	Unknown	UDI production identifier	Unknown

IMDRF adverse event reporting terms and codes

IMDRF=International Medical Device Regulators Forum. Coding with IMDRF terms is a mandatory requirement.

IMDRF clinical signs, symptoms, conditions codes	E170501							
IMDRF health impact codes	F1908							
IMDRF Medical device problem codes	A0303	A2304						
IMDRF Component codes								
IMDRF Cause investigation: Type of investigation	B01	B11	B14					
IMDRF Cause investigation: Investigation findings.	C20							
IMDRF Cause investigation: Investigation conclusion.	D12	D1103						

Submission of this report does not 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.

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

Before signing and submitting

Check the form | Save as PDF

Date

Signature/Digital Signature

Send as XML file — Submit XML by Email

Send as PDF file — Submit PDF by Email

3.1 a - Provide a comprehensive description of the incident

Incident / Failure Description [redacted] presented for [redacted] Decision made for thoracic epidural insertion for perioperative analgesia under anaesthesia.
Method of insertion: Asleep, left lateral, skin clean with chlorhexidine spray and allowed to air dry, blue gauze used to further wipe the area in single motion from cranial to caudal motion, 16G tuohy needle used and catheter inserted, tuohy needle removed.

Slight ooze noted at catheter/needle insertion site, a drop of histoacryl applied - this resulted in exothermic reaction causing a diathermy like pop followed by a small plume of smoke and a skin burn.
Catheter patency was checked with flushing and aspirating and no leaks identified. Catheter dressed and utillised for perioperative analgesia.

Further clinical update - 31.08.2021:
1. It resulted in a skin burn at the site of application. Of more concern was the possibility that it may have have burnt/damaged the epidural catheter. Luckily this does not occur and the catheter was safely extracted.
2. Epidural catheter insertion and securing - a drop was applied at epidural catheter insertion site at the skin
3. There was a slight delay to the overall procedure by 15-20 mins.
4. Wound was cleaned with chlorhexidine spray and allowed to air dry. Furthermore, area was wiped down with gauze prior to initiation of epidural insertion.

4.2 b - Fill out rationale for why this is considered not reportable

Histoacryl was used to fix catheter at the skin, not indicated in the instructions for use of the product. Therefore, this case is also considered an off-label use.

There are no previous complaints of this code-batch. We manufactured and distributed in the market 3,875 units of this code-batch. There are no units in our stock.

We have received one open ampoule (without tip) to analyze this case. Without closed samples a proper analysis cannot be performed. Furthermore, the sample has been received on 23 September 2021, after the expiry date (31 August 2021).

The Device History Record has been reviewed and no deviations have been found.

Before applying Histoacryl, the wound should be clean and dry, without blood present in the area. When Histoacryl gets in direct contact with the blood of the wound the reaction is very fast, it cannot be discarded smoke formation in the wound area and also heat (sensation of burning).

In the Warnings of the instructions for use of the product is indicated that: Histoacryl should not be applied to wet or bleeding wounds. Excess moisture (such as water or alcohol) or blood presence, may accelerate polymerisation, resulting in the generation of excess heat.

Also, in the Side effects paragraph: The use of this product leads to an exothermic polymerisation reaction. The released heat may result in a sensation of warmth. Cyanoacrylates can be associated with a limited period of local sensitisation or irritation reaction in the application area.

4.2 h - Time schedule for the implementation of the identified actions

No remedial/corrective/preventive/field safety corrective actions are implemented at this moment.

4.2 i - Final comments from the manufacturer on cause investigation and conclusion

With the information received, we do not see any manufacturing fault or material defect that could have caused the incidence. The incident is considered an off-label use as the indication is not included in the instructions for use of the product, and more related to a known side-effect of the product already included in the instructions for use of the device.