

AITS Incident No: [REDACTED] Investigation level = Trending & Surveillance

Summary

Incident Number	[REDACTED]		
Report Type	Incident	Reported as Vigilance	Yes
Initial Review of FSN by TMG?	No		
Reporting Organisation	B. Braun Surgical, S.A.	Action	Trending & Surveillance Action Changed on: Reason Action changed:
Injury	Death	Current Status of Investigation	
Serious Public Health Threat?	No	Manufacturer	B. Braun Surgical, S.A.
Incident Classification	Death	Report Type	Initial
FDA?	No	Reporter has sent to the following	
RO is investigating?	No	Location of Incident / Name of Healthcare Facility	[REDACTED]
		Country of Occurrence	England
Is this a report of multiple events?	No		
Periodic Summary Report (PSR) ID			
Responsible Officer	A DSS RO	Field Actions	do we need this anymore?
Last 3 Monthly Review		Next Review Due on	
Clinical Investigation			
		Do not show for On Holds	
If the incident occurred within a PMCF/ PMPF investigation; please provide the Eudamed ID of that PMCF/ PMPF investigation			
Echo Incidents Known Incidents			

Similar
Incidents
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
reference
number
Manufacturer's
reference
number
If this incident
is covered
under an
FSCA, please
provide the
relevant
numbers:
NCA's FSCA
reference
Number
EUDAMED's
FSCA
reference
number
Manufacturer's
FSCA
reference
number

You will be able to import
a list of incident numbers
that this signal report
refers to.

If you change the incident
type from Signal Report
to something else then
this field will be
automatically emptied
(might do that overnight
OR just hide the field if
type is not Signal Report)
Buttons only visible on
Signals

[AIM File](#)

Eudamed
Number of
NCA

Reference
Number
assigned by
EUDAMED for
this incident

Origin			
Reporting Route	MORE	Acknowledgement Required No	
Xmlversion			
REPORTER DETAILS:		ALTERNATIVE CONTACT DETAILS:	
Reporter Name		Alternative Contact Name	
Position/Occupation		Position/Occupation	
Reporting Organisation	B. Braun Surgical, S.A.	Alternative Contact Details	
Address	N/A Carretera de Terrassa, 121 N/A	Facility Name	
Town/City	RubÃ	Address	
Postcode	08191		
Country	ES		
Telephone Number		Telephone Number	
Email Address	@bbraun.com	Email address	
Email Copy To			
Local Reference Number			
Laboratory		Consultant in Charge	
Report Source	Role	Health/Social Care	StHA
	Manufacturer	Organisation	
Other Reporter	Other Reporting Bodies	Manufacturer	
Country			
Date Received	06/10/2021	Expected Date of Next Report 10/01/2022	

Device: Core Information

Core Information	Additional Devices	Sample/Decontamination
BH Code	68/21	From User Report on web
Device Description	Adhesive Control Devices	Product Name
Item Description	Surgical tissue adhesive	Product Category
Model	HISTOACRYL	CE Mark
Brand	HISTOACRYL BLUE TISSUE ADHESIVE 0.5ML	Device Class
	class III	MDD Class III
MDD/AIMDD		IVDD
MDR		MDR Type
IVDR		IVDR Type
Catalogue No.	1050052	ECRI Code
Serial Number		Nomenclature System
Batch Number / Lot Number	Unknown	Nomenclature Code
	219393N2	GMDN
		58777
Software Version		Nomenclature text/ Description of the device and its intended use
		Histoacryl is a sterile, liquid tissue adhesive consisting of n-butyl-2-cyanoacrylate. For

easy visual assessment of the thickness of the layer which has been applied Histoacryl is coloured with D&C violet No. 2 dye. A colorless version, which does not contain dye, is also available. Histoacryl is supplied in 0.5 mL single use plastic ampoules. One ampoule should only be used in one patient. Each ampoule is sealed within an aluminium pouch in order to protect the ampoule from external contamination keeping at the same time the external sterility of the ampoule. Histoacryl remains liquid until exposed to water or water containing substances, including tissues. For easy assessment of the thickness of the layer which has been applied Histoacryl® is coloured blue with the dye D&C violet No. 2. A translucent version, which does not contain dye, is also available. Histoacryl is indicated for:

1. SKIN CLOSURE: Closure of skin wounds without tension (including clean surgical incisions and incisions from minimally invasive surgery), and simple, thoroughly cleansed, trauma-induced lacerations.
2. SCLEROTHERAPY: Sclerotherapy of large oesophageal or fundal varices.
3. MESH FIXATION: Fixation of hernia meshes, especially in inguinal hernia surgery.

Firmware Version

Legislation Category

Date Manufactured

Date Supplied

Expiry Date

UDI Device Identifier/Eudamed ID Unknown

UDI Production Identifier Unknown

Basic UDI-DI/Eudamed ID Unknown

Unit of use UDI-DI

Approximate Age of Device (FDA)

Current location of Medical Device Unknown

Location of device, if other

If other, Please Specify the medical device

Terminology

GMDN Code

Notified Body Number1 0123

Notified Body Number2

Notified Body Certificate Number 1 G7 18 02 25701 080

Notified Body Certificate Number 2

Notified Body Name

Number of Medical Devices involved

Device Accessories (FDA)

Name and Address of Reprocessor (FDA)		Regulatory/ Competent Authority who approved device	
Mfr Ref Number		Other 3rd party name who approved device	
IVD Annex 2 Device	No	Document Approval Number	
IVD Preservative			
IVD Accessory to Disease (IVD Only)			
Please indicate the date of one of the following	The device first CE marked		
If Software, date first made available	Year 2011 Month 12		
Default Address for Letters	Manufacturer	Supplier's Group Name	
Manufacturer's Group Name	B Braun	Supplier	-
Manufacturer	B. Braun Surgical, S.A.		
Manufacturer's Single Registration Number			
Manufacturer's Address	N/ACarretera de Terrassa,121N/A	Supplier's Address	
Manufacturer's Town/City	Rub�	Supplier's Town/City	
Manufacturer's Postcode	08191	Supplier's Postcode	
Manufacturer's Country	ES	Supplier's Country	
Manufacturer Contact		Supplier Contact	
Manufacturer Phone No		Supplier Phone No.	
Manufacturer E-Mail	@bbraun.com	Supplier E-Mail	
		Where did you get the device?	
		Other please specify	
Authorised Group Name			
Authorised Representative		Name of where you got device	
Authorised representative's Single Registration Number			
Authorised Address		Address	
Authorised Town/City		N/A	
Authorised Postcode			
Authorised Country			
Authorised Contact		Name of Person	
Authorised Phone		Phone	
Authorised Email		Can we send your personal details to the medical device manufacturer?	
		Submitter Group Name	
NCP Group Name		Submitter	B. Braun Surgical, S.A.
NCP Name		Submitter Address	N/A Carretera de Terrassa
NCP Address			121 N/A
		SubmitterTown/City	Rub�
NCP Town/City		Submitter Postcode	08191
NCP Postcode		Submitter Country	ES
NCP Country		Submitter Contact	
NCP Contact		Submitter Phone	
NCP Phone		Submitter Email	@bbraun.com
NCP Email			

	Time period 1:	Time period 2:	Time period 3:	Time period 4:
Start date				
End date				
Number of similar incidents:				
Country				
EU				
World				
Number of devices placed on the market:				
Country				
EU				
World				
Variant		Description		

Device: Prosthetic
Device: WMS
Device: Orthopaedic
Device: Pacemaker
Device: Breast Implants
Device: Haemostasis
Device: Cochlear Implants
Additional Devices

	Associated Device 1	Associated Device 2	Associated Device 3	Associated Device 4
Mfr Name				
Other				
(mfr not found in list)				
Brand Name				
Model Code or No.				
Catalogue Code or No.				
Serial No.				
Batch No.				
Software Version				
CE Marked				
NB ID				
Mfr Tel No (for IVD Kit)				
Supplier (for IVD Kit)				
Supplier Tel No (for IVD Kit)				
BH/SE Code				
Relevant associated devices				
used with device being reported				
on (Please list with				
corresponding manufacturer if				
different from device being				
reported on)				
Relevant accessories used with				
device being reported on				
(Please list with corresponding				
manufacturer if different from				
device being reported on)				
Device: Sample/Decontamination				

Date Received		Decontaminated by
MHRA Sample Number		Reporter
Quantity		Method Used
Location		Decontaminated by MHRA
Date Sent/Disposed		Method Used
Device Sent to Other		Photographed by MHRA
MHRA to retain the device	No	How sent
		Date to be retained until

Attachment Point: ▶

Sample/Decontamination Audit pre2010:

Incident

Date of Incident	01/01/2019	Date of Incident	29/09/2021	Reported as	Yes	Reported
From		To		vigilance?		Device Cause/
						Effect

Reported Actual Death
Injury

Reported Actual
Injury

Type of Incident

Reported
Clinical Effect

Number of 1
people injured /
Number of
patients
involved

Potential Injury
Potential Injury

Event Problem
Code (FDA)
(Patient &
Device)

If Implanted
Date From

If Explanted
Date From

Implant
Duration

Days
Months
Years

If Implanted
Date To
Implant Facility
Name

If Explanted
Date To
Explant Facility
Name

Incident/Failure Description:

The Coroner has informed us that he is investigating 2 deaths at [REDACTED]
[REDACTED] and has asked for more information about the product.

Additional information has been requested.

This report is for the first patient.

Was the patient
a confirmed
case of
Covid19?
Was this defect
confirmed with
another device?
If so, please
provide details of
the confirming
test:
Details of
Injury(to patient,
carer or
healthcare
professional)

Is this related to a Covid-19 diagnostic test?

Description of injuries/ treatments/ clinical effects:

Device Problem 1- (Level 1)	A26 - Insufficient Information	1st level hidden 1st level Device Problem 1- (Level 2)	Device Problem 1- (Level 3)	MHRA Specific
Device Problem 2- (Level 1)		Device Problem 2- (Level 2)	Device Problem 2- (Level 3)	
Device Problem 3- (Level 1)		Device Problem 3- (Level 2)	Device Problem 3- (Level 3)	
Device Problem 4- (Level 1)		Device Problem 4- (Level 2)	Device Problem 4- (Level 3)	
Device Problem 5- (Level 1)		Device Problem 5- (Level 2)	Device Problem 5- (Level 3)	
Device Problem 6- (Level 1)		Device Problem 6- (Level 2)	Device Problem 6- (Level 3)	

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain
Action taken by staff / manufacturer:

Manufacturer additional comments:

Health Effects

Annex E

Clinical Signs,Symptoms and conditions 1 - (Level 1)	E24 - Others	Clinical Signs,Symptoms and conditions 1 - (Level 2)	E2401 - Insufficient Information	Clinical Signs,Symptoms and conditions 1 - (Level 3)	MHRA Specific Clear MHRA Specific
Clinical Signs,Symptoms and conditions 2 - (Level 1)		Clinical Signs,Symptoms and conditions 2 - (Level 2)		Clinical Signs,Symptoms and conditions 2 - (Level 3)	
Clinical Signs,Symptoms and conditions 3 - (Level 1)		Clinical Signs,Symptoms and conditions 3 - (Level 2)		Clinical Signs,Symptoms and conditions 3 - (Level 3)	
Clinical Signs,Symptoms and conditions 4 - (Level 1)		Clinical Signs,Symptoms and conditions 4 - (Level 2)		Clinical Signs,Symptoms and conditions 4 - (Level 3)	

Clinical Signs,Symptoms and conditions 5 - (Level 1)	Clinical Signs,Symptoms and conditions 5 - (Level 2)	Clinical Signs,Symptoms and conditions 5 - (Level 3)	
Clinical Signs,Symptoms and conditions 6 - (Level 1)	Clinical Signs,Symptoms and conditions 6 - (Level 2)	Clinical Signs,Symptoms and conditions 6 - (Level 3)	
<p>Health Effects</p> <p>Annex F</p>			
Health Impact 1 - F02 - Death (Level 1)	Health Impact 1 -- (Level 2)	Health Impact 1 -- (Level 3)	MHRA Specific Clear MHRA Specific
Health Impact 2 - (Level 1)	Health Impact 2 - (Level 2)	Health Impact 2 - (Level 3)	
Health Impact 3 - (Level 1)	Health Impact 3 - (Level 2)	Health Impact 3 - (Level 3)	
Health Impact 4 - (Level 1)	Health Impact 4 - (Level 2)	Health Impact 4 - (Level 3)	
Health Impact 5 - (Level 1)	Health Impact 5 - (Level 2)	Health Impact 5 - (Level 3)	
Health Impact 6 - (Level 1)	Health Impact 6 - (Level 2)	Health Impact 6 - (Level 3)	
<p>If you think the incident is unique and a suitable IMDRF term is missing, briefly explain</p>			
Usage of Device	Initial use	Is this a report of multiple incidents ?	Yes
Other Usage of Device			Operator of Device at Time of the Event Other Operator of Device at Time of the Event
Manufacturer Contacted	No	Manufacturer awareness date 30/09/2021	
Manufacturer aware of similar adverse incidents		Number of adverse event reports received by the manufacturer with the same root cause	Countries where similar events occurred
<p>Relevant Tests, Lab Data (FDA):</p> <p>Other Relevant History (FDA):</p>			
<div style="border: 1px solid black; padding: 2px;">FSCA</div>			
FSCARF / FSN Attached?	Neither		
FSN Status			
FSCA reference number assigned by NCA			

Name of co-ordinating NCA and their incident reference
Advice on Actions to be taken by distributor and user
Progress of FSCA, together with reconciliation data
Attached

Time Schedule for the implementation of different actions
Background information and reason for the FSCA:
FSCA related attachments:
Description and justification of the Action (corrective/preventive):

Initial Reporter

Role of Initial Reporter healthcare professional
If other please specify
Name
Healthcare Facility (user) report reference number
Address
Town/City
Postcode
Country GB
Email
Phone
Contact Name
Job Title
Date of Awareness or Date of Report (FDA)

Legal

Litigation - hide for AITS4 hlr 042	No	Guarantee Claim - hide for AITS 4 HLR 42	No
Coroners Investigation	No	Police Investigation	No
		HSE Investigation	No
		Other Investigation	No
		create an attachment doc with suitable title & display in History view	

Patient

Patient Identifier (FDA)
Date of Birth
Age of patient at time of event
Unit of Age Years
Months
Days
Unknown
Gender
Weight in Kilograms
List of Devices involved with each patient
Patient-focused Resolution of Events and Outcomes
Corrective action taken relevant to the care of the patient
Patient Outcome
List any of patient's prior health condition or medication that may be relevant to this incident
Additional Details of Patient

Trend

Date the trend was identified
 Description narrative for identified trend
 Time period of trend analysis
 Established trigger level
 Have any of the trended events been submitted individually
 as reportable events under vigilance ?
 If Yes, please list how many and to which Competent
 Authority

PSR

PSR Type

If incidents described in a Field Safety Notice, Manufacturers

reference number for FSN/FSCA

Stage of PSR reporting based on

Nature of problem agreed for PSR reporting

Summary period agreed

The figures in the table below relate to

Information for PSR summary period

Investigation update for this period

Signal Detail

Triage

Responsible Unit	DSS	Responsible Officer	A DSS RO
Unit Manager	DSS PT	RO Telephone Number	
Team		Date Allocated	08/10/2021
Data Input Complete	08/10/2021	Team Manager	
		Select Alternative Initial Letter to be sent (if required)	
Trending Search:		Trigger	
Trending Strategy		Trigger Reached	
Pre-Triage Recommendation	Trending & Surveillance by [REDACTED] on 08/10/2021		
Pre-Triage Comments			Change Recommendation why:
Triage Decision	Trending & Surveillance by [REDACTED] on 08/10/2021		

Triage Comments

Safety Publications

Safety Warning Decision Record

FSN / SWDR 1

SWDR 1 : Problem Definition

SWDR 1 : Details of Mfrs corrective actions

SWDR 1 : MHRA Action

SWDR 1 : Unit Sign Off

SWDR 1 : TMG Reviews

SWDR 1 : Change Request

FSN / SWDR 2

SWDR 2: Problem Definition

SWDR 2: Details of Mfrs corrective actions

SWDR 2: MHRA Action

SWDR 2: Unit Sign Off
SWDR 2: TMG Reviews
SWDR 2: Change Request
FSN / SWDR 3
SWDR 3 : Problem Definition
SWDR 3 : Details of Mfrs corrective actions
SWDR 3 : MHRA Action
SWDR 3 : Unit Sign Off
SWDR 3 : TMG Reviews
SWDR 3 : Change Request
Correspondence

Default Address for Manufacturer Letters

Workflow:		Acknowledgement sent:	Conclusion Letters sent :	Trending & Surveillance letter sent :
Data Input Complete	08/10/2021	Reporter	Reporter	Reporter
Pre-Triage Complete	08/10/2021	Manufacturer	Manufacturer	Manufacturer 08/10/2021
Triage Complete	08/10/2021	Supplier	Supplier	Supplier
Received in AIC from Unit		Authorised Rep	Authorised Rep	Authorised Rep
			No Letter Required By: On:	
Manufacturer's Interim Response: Received		Manufacturer's Final Response: Received	Reminders:	Referred Out:
Passed to Unit Admin for scanning		Rationale for Not Reporting Received	Is a reminder required? Earliest date for next reminder	Agreed to Refer Out Letter Sent on
Attached to AITS Record Passed to RO Received by RO		Attached to AITS Record Passed to RO Received by RO Returned with closure decision	Yes 10/01/2022	
Alternative Initial Letter		MTS Letter		
Initial:		First Reminder:	Second Reminder:	Third Reminder:
Date Sent Reply Due Reply Received		Date Sent Reply Due Reply Received	Date Sent Reply Due Reply Received	Date Sent Reply Due Reply Received

Conclusion

[\(Click here for IMDRF Help\)](#)

Failure Cause
 Failure Effect
 Conclusion
 Conclude as no confirmed
 device problem
 Concluded
 Responsibility *

Cause Investigation
 Type of Investigation 1
 *

Type of
 Investigation
 2 *

Type of Investigation 3
 *

Type of
 Investigation
 4 *

Type of Investigation 5
 *

Type of
 Investigation
 6 *

Type of Investigation 7
 *

Type of
 Investigation
 8 *

Investigation Findings
 1 (Level 1) *

Investigation
 Findings 1
 (Level 2) *

Investigation
 Findings 1
 (Level 3) *

Concluded
 MHRA specific

Investigation Findings
 2 (Level 1) *

Investigation
 Findings 2
 (Level 2) *

Investigation
 Findings 2
 (Level 3) *

Investigation Findings
 3 (Level 1) *

Investigation
 Findings 3
 (Level 2) *

Investigation
 Findings 3
 (Level 3) *

Investigation Findings
 4 (Level 1) *

Investigation
 Findings 4
 (Level 2) *

Investigation
 Findings 4
 (Level 3) *

Investigation Findings
 5 (Level 1) *

Investigation
 Findings 5
 (Level 2) *

Investigation
 Findings 5
 (Level 3) *

Investigation Findings
 6 (Level 1) *

Investigation
 Findings 6
 (Level 2) *

Investigation
 Findings
 6(Level 3) *

Investigation
 Conclusion 1 (Level 1)
 *

Investigation
 Conclusion
 1 (Level 2) *

Investigation
 Conclusion 2 (Level 1)
 *

Investigation
 Conclusion
 2 (Level 2) *

Investigation
 Conclusion 3 (Level 1)
 *

Investigation
 Conclusion
 3 (Level 2) *

Investigation
 Conclusion 4 (Level 1)
 *

Investigation
 Conclusion
 4 (Level 2) *

Investigation
 Conclusion 5 (Level 1)
 *

Investigation
 Conclusion
 5(Level 2) *

Investigation
Conclusion 6 (Level 1)
*

Investigation
Conclusion
6 (Level 2) *

If you think the incident
is unique and a
suitable IMDRF term is
missing, briefly explain
Concluded Clinical
Risk *

Concluded
as
vigilance? *

Outcome *

Manufacturers Preliminary Analysis:

At this time, we have only received that two deaths occurred with product Histoacryl (reference [REDACTED]). We have requested additional information such as description of the event, type of surgery, when it occurred, batch number involved,... The results will be provided in the Final Report.

Initial Corrective Action:

No corrective/preventive actions are implemented at this moment.

Manufacturers Device Analysis Results:

Remedial Action/Corrective Action/Preventive Action:

Manufacturers Final Comments:

For Final (Non-reportable Incidents) fill out rationale for why this is considered not reportable

Is root cause confirmed?

Has the risk assessment been reviewed?

If 'No' rationale for no review required

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

Risk Assessment result

Manufacturers Time Schedule for the implementation of identified actions

Long Term

Corrective Action Agreed

Clinical Follow-up Required

Further Investigations Planned

In waiting to receive additional information of the cases.

Conclusion Description: *

NoNoNo No

Select MTS Letter

RO agrees complete and ready to move to surveillance

RO agrees complete and ready to move to surveillance - Not Specialist(Except Echo), so mainly Monitored & means AIC can send letter & MTS

Date Investigation Completed *

Date File Closed & moved to Surveillance

08/10/2021

No MHRA (Devices) investigation required. Incident referred out to:

Adverse

Event Type

Codes

Adverse

Event

Cause

Codes

FDA

Adverse

Event Term

Distribution of Incident report/FSCA:

EEA & GB

Switzerland

Outside

EEA,

Switzerland

&

Candidate

Countries

Candidate

Countries

Similar Incidents

SIMILAR INCIDENTS(FOR FINAL(REPORTABLE INCIDENTS))				
Use of IMDRF Terms and Codes for identifying similar Incidents				
Identification of similar Incidents using IMDRF Adverse Event Reporting terms and Codes				
IMDRF Code relating to most relevant 'Medical device Problem'				
IMDRF Code relating to most relevant 'Investigation finding'				
if other, - Enter the description of what similar Incidents are based on and rationale why the above IMDRF codes were not used				
Use of in-house terms/codes for identifying similar Incidents				
If similar incidents were not identified by IMDRF codes but by in-house code,please provide the codes and terms below:				
Code/Term for most relevant medical device problem				
Code				
Term				
Code/Term for most relevant root cause evaluation				
Code				
Term				
If other- enter description of what similiar incidents are based on and the rationale why the above codes were not used				
Number of Similar Incidents and devices on Market				
Indicate on which basis similar incidents are identified regarding the device or device variant				
Details of the above selected				
Indicate to what criteria the number of devices on the market (also known as denominator data) is based on:				
If other please describe				
Enter the number of similar incidents and devices on market for the indicated time periods				

unless:				
A. different period has been specified by European Vigilance Working Groups				
B. the device has not been on the European Market for more than three years				
TIMEPERIOD N Year to date = incident year (e.g. 2012-10-23)				
Start Date	01 /01 /2021			
End Date				
	No of Similar Incidents	No of Devices on Market		
Country of incident				
EEA + CH + TR				
World				
TIMEPERIOD N-1 calendar year one year before incident (e.g. 2012-10-23)				
Start Date	01 /01 /2020			
End Date				
	No of Similar Incidents	No of Devices on Market		
Country of incident				
EEA + CH + TR				
World				
TIMEPERIOD N-2 calendar year two years before incident (e.g. 2012-10-23)				
Start Date	01 /01 /2019			
End Date				
	No of Similar Incidents	No of Devices on Market		
Country of incident				
EEA + CH + TR				
World				
TIMEPERIOD N-3 calendar year three years before incident (e.g. 2012-10-23)				
Start Date	01 /01 /2018			
End Date				
	No of Similar Incidents	No of Devices on Market		
Country of incident				
EEA + CH + TR				

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