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 or Signals

Eudamed Number of NCA

AIM File

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 Facility Name	
Address	N/A Carretera de Terrassa, 121 N/A	Address	
Town/City	RubÃ	N/A Carretera de Terrassa 121 N/A	
Postcode	08191		
Country	ES		
Telephone Number	[redacted]	Telephone Number	
Email Address	[redacted]@bbraun.com	Email address	
Email Copy To			
Local Reference Number			
Laboratory		Consultant in Charge	
Report Source	Role	Health/Social Care Organisation	StHA
	Manufacturer	Manufacturer	
Other Reporter Country	Other Reporting Bodies		
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	Soft tissue implants
Model	HISTOACRYL	CE Mark	
Brand	HISTOACRYL BLUE TISSUE ADHESIVE 0.5ML	Device Class	MDD Class III
MDD/AIMDD	class III	IVDD	
MDR		MDR Type	
IVDR		IVDR Type	
Catalogue No.	1050052	ECRI Code	
Serial Number		Nomenclature System	GMDN
Batch Number / Lot Number	Unknown 219393N2	Nomenclature Code	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 HistoacrylÂ® 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 oeÂ¬sophageal or fundal varices.
3. MESH FIXATION: Fixation of hernia meshes, especially in inguinal hernia surgery.

Firmware Version		If other, Please Specify the medical device Terminology	
Legislation Category		GMDN Code	
Date Manufactured		Notified Body Number1	0123
Date Supplied		Notified Body Number2	
Expiry Date		Notified Body Certificate Number 1	G7 18 02 25701 080
UDI Device Identifier/Eudamed ID	Unknown	Notified Body Certificate Number 2	
UDI Production Identifier	Unknown	Notified Body Name	
Basic UDI-DI/Eudamed ID	Unknown		
Unit of use UDI-DI			
Approximate Age of Device (FDA)		Number of Medical Devices involved	
Current location of Medical Device	Unknown	Device Accessories (FDA)	
Location of device, if other			

Name and Address of Reprocessor (FDA)			
Mfr Ref Number	[redacted]	Regulatory/ Competent Authority who approved device	
IVD Annex 2 Device	No	Other 3rd party name who approved device	
IVD Preservative		Document Approval Number	
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 Adress for Letters	Manufacturer		
Manufacturer's Group Name	B Braun	Supplier's Group Name	
Manufacturer	B. Braun Surgical, S.A.	Supplier	-
Manufacturer's Single Registration Number			
Manufacturer's Address	N/ACarretera de Terrassa,121N/A	Supplier's Address	
Manufacturer's Town/City	RubÃ	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	[redacted]	Supplier Phone No.	
Manufacturer E-Mail	[redacted]@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?	
NCP Group Name		Submitter Group Name	
NCP Name		Submitter	B. Braun Surgical, S.A.
NCP Address		Submitter Address	N/A Carretera de Terrassa 121 N/A
NCP Town/City		SubmitterTown/City	RubÃ
NCP Postcode		Submitter Postcode	08191
NCP Country		Submitter Country	ES
NCP Contact		Submitter Contact	[redacted]
NCP Phone		Submitter Phone	[redacted]
NCP Email		Submitter Email	[redacted]@bbraun.com

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

Attachment Point:

Sample/Decontamination Audit pre2010:

Incident

Date of Incident From	01/01/2019	Date of Incident To	29/09/2021	Reported as vigilance?	Yes	Reported Device Cause/ Effect	
Reported Actual Injury	Death	Reported Clinical Effect		Potential Injury			
Reported Actual Injury				Potential Injury			
Type of Incident		Number of people injured / Number of patients involved	1	Event Problem Code (FDA) (Patient & Device)			
If Implanted Date From		If Explanted Date From		Implant Duration		Days Months Years	
If Implanted Date To		If Explanted Date To					
Implant Facility Name		Explant Facility Name					

Incident/Failure Description:

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

Additional information has been requested.

This report is for the second 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		1st level hidden		
Device Problem 1- (Level 1)	A26 - Insufficient Information	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)

Health Effects

Annex F

Health Impact 1 - (Level 1)	F02 - Death	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)	
If you think the incident is unique and a suitable IMDRF term is missing, briefly explain					
Usage of Device	Initial use	Is this a report of multiple incidents ?	Yes	Operator of Device at Time of the Event	Healthcare professional
Other Usage of Device				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	
Relevant Tests, Lab Data (FDA):					
Other Relevant History (FDA):					

FSCA

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	[redacted]
Healthcare Facility (user) report reference number	
Address	[redacted]
Town/City	
Postcode	
Country	GB
Email	
Phone	[redacted]
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
Gender	Unknown
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
		RO Telephone Number	
Unit Manager	DSS PT	Date Allocated	08/10/2021
Team		Team Manager	
Data Input Complete	08/10/2021	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 Adress for Letters	Manufacturer

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:	Manufacturer's Final Response:	Reminders:		Referred Out:
Received	Received	Is a reminder required?	Yes	Agreed to Refer Out
Passed to Unit Admin for scanning	Rationale for Not Reporting Received	Earliest date for next reminder	10/01/2022	Letter Sent on
Attached to AITS Record	Attached to AITS Record			
Passed to RO	Passed to RO			
Received by RO	Received by RO			
	Returned with closure decision			
Alternative Initial Letter	MTS Letter			

Initial:	First Reminder:	Second Reminder:	Third Reminder:
Date Sent	Date Sent	Date Sent	Date Sent
Reply Due	Reply Due	Reply Due	Reply Due
Reply Received	Reply Received	Reply Received	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(Ecept 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 & Switzerland GB

Candidate Countries

Outside EEA, Switzerland & 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 Incients	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 Incients	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 Incients	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 Incients	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				