

[Display/View\Correspondence](#)

AITS Incident No: [REDACTED] Investigation level = Trending &amp; 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	None	Current Status of Investigation	
Serious Public Health Threat?	No	Manufacturer	B. Braun Surgical, S.A.
Incident Classification	All other reportable incidents	Report Type	Final (Non-reportable incident)
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

Eudamed  
Number of  
NCA  
Reference  
Number  
assigned by  
EUDAMED for  
this incident

Signals  
AIM File

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	Sheffield	Address	
Postcode	S35 2PW		
Country	GB		
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
		Organisation	
	Manufacturer	Manufacturer	
Other Reporter	B. Braun Medical Ltd.		
Country			
Date Received	22/10/2021	Expected Date of Next Report 10/01/2022	

Device: Core Information

<b>Core Information</b>	<a href="#">Additional Devices</a>	<a href="#">Sample/Decontamination</a>
BH Code	68/21	From User Report on web
Device Description	Adhesive Control Devices	Product Name
Item Description	Liquid skin adhesive/sealant	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
		GMDN

Batch Number / Lot Number	Unknown	Nomenclature Code	58777
Software Version	219393N2	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		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		Number of Medical Devices involved	
Approximate Age of Device (FDA)		Device Accessories (FDA)	
Current location of Medical Device	Unknown		
Location of device, if other			
Name and Address of Reprocessor (FDA)			
Mfr Ref Number		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 Address for Letters	Manufacturer	Supplier's Group Name	
Manufacturer's Group Name	Braun and Company Limited	Supplier	-
Manufacturer	B. Braun Surgical, S.A.		
Manufacturer's Single Registration Number		Supplier's Address	
Manufacturer's Address	N/ACarretera de Terrassa,121N/A	Supplier's Town/City	
Manufacturer's Town/City	RubÃ	Supplier's Postcode	
Manufacturer's Postcode	08191	Supplier's Country	
Manufacturer's Country	ES	Supplier Contact	
Manufacturer Contact		Supplier Phone No.	
Manufacturer Phone No		Supplier E-Mail	
Manufacturer E-Mail	@bbraun.com	Where did you get the device?	
		Other please specify	
Authorised Group Name		Name of where you got device	
Authorised Representative			
Authorised representative's Single Registration Number		Address	
Authorised Address		N/A	
Authorised Town/City		Name of Person	
Authorised Postcode		Phone	
Authorised Country		Can we send your personal details to the medical device manufacturer?	
Authorised Contact		Submitter Group Name	
Authorised Phone		Submitter	B. Braun Surgical, S.A.
Authorised Email		Submitter Address	N/A Carretera de Terrassa 121 N/A
NCP Group Name		SubmitterTown/City	RubÃ
NCP Name	B Braun Medical Ltd (UK) - Hypodermic needles etc.)	Submitter Postcode	08191
NCP Address	Thorncliffe Park	Submitter Country	ES
NCP Town/City	Sheffield	Submitter Contact	
NCP Postcode	S35 2PW		
NCP Country	UK		
NCP Contact			

NCP Phone [REDACTED] Submitter Phone [REDACTED]  
 NCP Email [REDACTED] 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
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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
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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
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Date of Incident	01/01/2019	Date of Incident To	14/10/2021	Reported as vigilance?	Yes	Reported Device Cause/Effect
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Reported Actual Injury	None	Reported Clinical Effect	None	Potential Injury	Serious
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Reported Actual Injury

Type of Incident	Number of people injured / Number of patients involved	1	Event Problem Code (FDA) (Patient & Device)
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If Implanted Date From	If Explanted Date From	Implant Duration	Days Months Years
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If Implanted Date To	If Explanted Date To
Implant Facility Name	Explant Facility Name

Incident/Failure Description:

The Coroner has informed us three additional cases at [REDACTED]. These additional cases are not deaths but events where details are not known.

Additional information has been requested.

This report is for third new case.

The MHRA reference numbers of the previous cases are: [REDACTED] (B. Braun Surgical ref. [REDACTED]) and [REDACTED] (B. Braun Surgical ref. [REDACTED]).

Final (Non-reportable incident)

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The Coroner has informed us three additional cases at [REDACTED]. These additional cases are not deaths but events where details are not known.

Additional information has not been provided.

This report is for third new case. Manufacturer's reference numbers for the other two new cases are [REDACTED] (Reference assigned by MHRA: [REDACTED]) and [REDACTED] (Reference assigned by MHRA: [REDACTED]).

The MHRA reference numbers of the previous cases are: [REDACTED] (B. Braun Surgical ref. [REDACTED]) and [REDACTED] (B. Braun Surgical ref. [REDACTED])

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			
	1st level			
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)	F24 - Insufficient Information	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 15/10/2021			
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 other  
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	28/10/2021
Data Input Complete	28/10/2021	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 28/10/2021		
Pre-Triage Comments			Change Recommendation why:
Triage Decision	Trending & Surveillance by [REDACTED] on 28/10/2021		

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	28/10/2021	Reporter	Reporter	Reporter
Pre-Triage Complete	28/10/2021	Manufacturer	Manufacturer	Manufacturer 28/10/2021
Triage Complete	28/10/2021	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 03/03/2022	Reminders: Is a reminder required? Yes	Referred Out: Agreed to Refer Out
Passed to Unit Admin for scanning		Rationale for Not Reporting Received	Earliest date for next reminder	Letter Sent on
Attached to AITS Record		Attached to AITS Record		
Passed to RO		Passed to RO 03/03/2022		
Received by RO		Received by RO 03/03/2022		
Alternative Initial Letter		Returned with closure decision	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 *	B22 - Insufficient Information Available	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) *	C20 - No Findings Available	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) *	D15 - Cause Not Established	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) \*  
If you think the  
incident is unique and  
a suitable IMDRF term  
is missing, briefly  
explain  
Concluded Clinical  
Risk \*

Investigation  
Conclusion 6  
(Level 2) \*  
  
Concluded  
as vigilance?  
\*

Outcome \*

#### Manufacturers Preliminary Analysis:

At this time, we have only received that there are three additional cases with product Histoacryl (reference 1050052). 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:

Final (Non-reportable incident)

=====

**No remedial/corrective/preventive and Field Safety Corrective Actions are applicable at this time.**

Manufacturers Final Comments:

Final (Non-reportable incident)

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Without samples or more information a suitable analysis cannot be performed. Nevertheless, we take note of this incidence and if any sample or more information is received in the future, we will re-open the case and analyse it.

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

We have only received that there are three additional cases with product Histoacryl (reference 1050052) but no further data has been provided regarding these cases.

The involved batch number or possible batches have not been received. As no batch number is available, the batch manufacturing record cannot be reviewed.

On the other hand, without samples or more information, we are not in position of studying if the involved product does not fulfil the specifications. In consequence, a proper analysis cannot be done and the case is not confirmed due to lack of evidence. Nevertheless, we take note of this incidence and if any sample or more information is received in the future, we will re-open the case and analyse it.

Is root cause confirmed? No

Has the risk assessment been reviewed? Yes

If 'No' rationale for no review required

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

Risk Assessment result

The residual risk of Histoacryl not being functional is accepted for all approved indications.

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

Date Investigation Completed \*

Date File Closed & moved to Surveillance

28/10/2021

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 similar 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 /2022			
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 /2021			
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 /2020			
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 /2019			
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				