bob instruments best of basic instruments	**Formular** **Entry Form Insident (Accompanying document)**	**Nr.: 7322** 7569h_F_Rev 01

bob instruments GmbH

Department Quality Assurance

Safety representative for medical devices

Fax: (49) 7462 / 9448-50

Email: md.vigilance@bob-instruments.de

Customer-No.:			
Company:			
Department:			
Street:			
Postcode / place:			
Contact person:			
Tel.:		**Fax:**	
Email:			

Information about the product:

Item-No. / Ref	Item description	LOT / Serial-No.	Piece

Unique Device Identifier (UDI information): (Which is indicated on the product, the product label or on the product packaging)

Date of production:	Expiration date:	Date of implantation (only concerning implants):	Date of explantation (Only concerning implants):
JJJJ-MM-TT	JJJJ-MM-TT	JJJJ-MM-TT	JJJJ-MM-TT

Duration of implantation: (Only for implants and only when the exact implantation and explantation dates are known)

Equipment and /or equipment combined with the product (if applicable):

Details about the incident:

Date, on which the incident occurred:
JJJJ-MM-TT

Detailed description of the incident:

	Type of the reporting incident: (please check X):
	The product caused or contributed to a death of an patient or user;
	The product caused or contributed to a serious injury* of an patient or user;
	The product caused or contributed to a serious deterioration of the medical condition of an patient, by a user or another person;
	A surgical intervention was required to prevent or correct a serious injury * to a patient or user;
	A malfunction ** caused or contributed to a death or serious injury to an patient or user in the event of repetition.
	Is the product complete, i.e. all components and / or broken parts are present, no parts are left in the patient?

***serious injury** means an injury or illness, that

(1) is life-threatening.,
(2) resulted to an permanent handicap of an body function or an permanent damage to a body structure or
(3) requires medical or surgical intervention, to exclude a permanent handicap of an body function or a permanent damage to a body structure. Permanent means, irreversible handicap or damage to a body structure or -function expect minor handicaps or Damage.

**** MALFUNCTION** means the ailure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all clamims made in the labelling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marked. The term "malfunction" includes the following items:

(1) failure
(2) malfunction
(3) Inappropriate or inappropriate design
(4) Manufacturing error
(5) Instruction for use (e.g. obscurities, incorrect content)
(6) Failure in product or packaging marking
(7) User error

Reference number of the user report (if known):

Quantity of affected persons (if known):

Quantity of affected products (if known):	
User of the medical device at the time of incident: (please tick X):	
	Professional users
	Patient
	Others

Verwendung des Medizinproduktes (bitte ankreuzen X):	
	First utilization
	Reuse of a disposable product
	Reuse of a reusable medical device
	Maintained or repaired medical device
	other
	Defect or problem detected before use

Angaben zum Patienten – zur Patientin:

Patient identification no.:

Gender:	**Weight:**

Age of the patient at the time of the incident:

Short-term- and long-term effects of the incident for the patient:

Measures taken by the healthcare facility, which were necessary as a consequence of the incident:

Information on the health facility:

Name of the health facility:			
department:			
Street:			
ZIP / Location:			
Name of the reporter:			
Function of the reporter:			
Contact person (if not the reporter):			
Tel.:		**Fax:**	
Email:			

Location

(Stamp)

Name

Date / Signature

Notice:

We point out that without the required information (information) no report of the incident can take place.

Please complete this form completely and attach it to the product!

Reference:

Medizinprodukte-Sicherheitsplanverordnung MPSV:

https://www.gesetze-im-internet.de/mpsv/

EC MEDDEV Guidelines on a Medical Devices Vigilance System:

http://ec.europa.eu/growth/sectors/medical-devices/guidance_en

US FDA 21CFR Part 803 Medical Device Reporting

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803

1. Änderungshistorie

Revision	Datum	Prozess-verantwortlicher	Datum	Freigabe	Beschreibung der Änderung
01	05.03.2015	QM/Rainer Müller/rm	05.03.2015	QM/Anton Mittermüller/am	AeA 024/15
02	09.01.2019	QM/Anton Mittermüller/am	09.01.2019	GF/Joachim Schmid/js	AeA 130/18
03	29.06.2020	QM/Rainer Müller/rm	29.06.2020	GF/Joachim Schmid/js	AeA 133/20

Revision: Revisionsnummer im Format 00
Datum: Datum der Änderung im Format TT.MM.JJJJ
Name: Abteilung / Name / Kürzel des Autors der Änderungen
Änderungen: kurze Beschreibung der Änderung