bob instruments best of basic instruments	**Formular** **Entry Form Complaint (Accompanying document)**	**Nr.: 7321** 7569h_F_Rev 01

Bob instruments GmbH
Service department
Weilatten 3

D-78532 Tuttlingen
Germany

Customer-No.:			
Company:			
Department:			
Street:			
Postcode / Place:			
Contact Person:			
Tel.:		**Fax:**	
E-Mail:			
Doc.-Ref.		**Date:**	

Information about the product:

Item-No. / REF	Item description	LOT / Seral-No.	Bob instruments Invoice No	Date of invoice	Piece

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

Exact description of the defect:
(e.g. marking of the product, sluggishness, corrosion at the lock etc. a simple does not work or no function is not sufficient and leads to delays and queries.)

Patients – results	
Was a patient involved?	☐ Yes ☐ No
What happened to the patient? How´s the patient doing?	

When was the malfunction discovered?		
☐ By the incoming inspection	☐ By the functional test	☐ In operation
☐ Others:		

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Status of the medical device?		
☐ New	☐ Used	☐ Repaired

If one or more questions answered with **YES,** the result is to perform a reporting obligation and further information´s are required absolutely necessary immediately. Please use the document **No. 7322 "Accompanying document - reporting of incidents"**, for Download www.bob-instruments.de/extranet/ or please contact us immediately.

E-Mail: md.vigilance@bob-instruments.de

Result of an Reporting obligation? (please check X)	
1. Caused the contributed the product to a death of a patient or user?	☐ Yes ☐ No ☐ Unknown
2. Caused the contributed the product to a serious injury* of a patient or user?	☐ Yes ☐ No ☐ Unknown
3. Caused the contributed the product to a serious deterioration of the medical condition of a patient, by a user or another person?	☐ Yes ☐ No ☐ Unknown
4. Was a surgical intervention required to prevent or correct a serious injury* to a patient or user?	☐ Yes ☐ No ☐ Unknown
5. Caused or contributed a malfunction** to a death or serious injury to a patient or user in the event of repetition?	☐ Yes ☐ No ☐ Unknown
6. Is the product incomplete or are components and/or broken parts missing or have parts remained in the patient?	☐ Yes ☐ No ☐ Unknown

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

(1) is life-threatening,
(2) resulted to a permanent handicap of a body function or a permanent damage to a body structure or
(3) requires medical or surgical intervention, to exclude a permanent handicap of a 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 failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labelling for the device. The intended performance of a device refers to the intended use for which the device is labelled 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

Other additional information:

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I hereby declare, that

☐ the enclosed medical device(s) have been decontaminated (i.e., cleaned, disinfected and sterilized)

CAUTION!

☐ the enclosed medical device(s) have **not** been decontaminated.

Location

Name (Stamp)

Date / Signature

Important NOTE!

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
02	01.06.2015	QM/Rainer Müller/rm	01.06.2015	VK/Peggy Krell	AeA 051/15
03	09.01.2019	QM/Anton Mittermüller/am	09.01.2019	GF/Joachim Schmid/js	AeA 130/18
04	13.03.2020	QM/Anton Mittermüller/am	13.03.2020	QM/Rainer Müller/rm	AeA 044/20

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