**bob instruments GmbH**

Department Quality Assurance

Safety representative for medical devices

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|  |  |  |  |
| --- | --- | --- | --- |
| **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** |
|  |  |  |  |

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

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

|  |
| --- |
| **Detailed description of the incident:** |
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|  |  |
| --- | --- |
| **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:** |
|  |  |

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| --- |
| **Age of the patient at the time of the incident:** |
|  |

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

|  |  |
| --- | --- |
|  | (Stamp) |
| Location |
|  |
| 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>

# Änderungshistorie

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| --- | --- | --- | --- | --- | --- |
| **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