TO BE COMPLETED BY THE ISSUER (DISTRIBUTOR OR HOSPITAL)

*** The incident report form must be duly fulfilled by the issuer ***

MANUFACTURER CONTACT → ✉ productcomplaint@balt-quality.com

Upon receipt, a BALT Representative will send you an acknowledgement with all the information needed for the complaint processing including the procedure for product return if available.

BALT REFERNCE:
(for BALT INTERAL USE ONLY)

1. ISSUER INFORMATION

1.1. **Issuer Name:**

1.2. **Issuer Title:**	1.5. **Company:**
1.3. **Contact (Email):**	1.6. **Address and Country:**
1.4. **Contact (Phone):**	1.7. **Issuer Reference:** *("NA" if no reference defined by the issuer)*

2. PRODUCT INFORMATION

2.1. **Product(s) Reference(s):** (name and part/model number)	2.3. **Lot Number(s):**
2.2. **Quantity:**	2.4. **Product(s) available for return:** ☐ Yes ☐ No

3. USER INFORMATION

3.1. **Incident Location (Hospital):**	3.3. **Physician Name:**
3.2. **Incident Location (Address and Country):**	3.4. **Physician Contact (Email/Phone):**

4. INCIDENT DESCRIPTION

4.1. **Incident Date** (DD/MM/YYYY)**:**

4.2. **Incident Description** *(procedure, pathology, associated products and accessories, chronology, etc.) ✋ the description shall be exhaustive: (pictures and procedure report shall be transmitted if available; all personal data shall be hidden before any communication to BALT):*

4.3. **Incident Occurrence:**
☐ Before use
☐ During use
☐ After use

4.4. **Patient Injury:**
☐ Death or Serious Injury
☐ No Patient Injury
Explanation:

4.5. **Has the incident been notified to your local competent authority?**
☐ Yes → Name of the Competent Authority: and # reference:
☐ No

4.6 **Is follow-up requested after conclusion of the incident investigation?**
☐ Yes
☐ No

4.7. **Additional comment if necessary:** *("NA" if no comment)*

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