

DCN-Nr.:
27

Dok.-Nr.:
FB 8.2.3

Dok.-Bez.:
Reportable incident



Reportable incident acc. to EU MDR Art. 87



AS Medizintechnik GmbH
Sattlerstraße 15
78532 Tuttlingen
Germany

Phone: +49/7461/966 32-6
Fax: +49/7461/966 32-88
www.AS-Medizintechnik.de
info@AS-Medizintechnik.de

To:

AS Medizintechnik GmbH
Department Regulatory Affairs
Sattlerstrasse 15
D - 78532 Tuttlingen

From:

Customer ID no:	<input type="text"/>
Company:	<input type="text"/>
Department:	<input type="text"/>
Street:	<input type="text"/>
ZIP / City:	<input type="text"/>
Contact person:	<input type="text"/>
Phone:	<input type="text"/>
Email:	<input type="text"/>

Information to the product:

Item no.	Item description	LOT / Serial no.	Qty	Invoice no.	Delivery no.
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Additional information (for implants only):

Date of implantation	Date of removal	Duration of implantation <small>(If the exact dates are unknown)</small>
<input type="text"/>	<input type="text"/>	<input type="text"/>

Accessories and / or with product connected devices (if applicable):

Information to the incident:

Date of incident:

Detailed description of incident:



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Reference number of report of operator (if known):

Quantity of affected persons (if known):

Operator of the medical product at time of incident:

- Professional operator
- Patient
- Others (please explain)

Usage of medical product:

- First practice
- Reuse of single use product
- Reuse of reusable medical product
- Maintained respectively repaired medical product
- Damage, respectively problem recognized before operation
- Others (please explain)

Patient information:

Gender of patient (if relevant):

Weight of patient (if relevant):

Date of birth of patient:

Age of patient:

Short term and long term consequences of incident for the patient:

Precautions of the health care facilities, which have been necessarily required as a result of the incidence:

Information to the health care facility:

Name of facility:

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Phone:	<input type="text"/>
E-Mail:	<input type="text"/>

Notice:

We point out that no announcement of the incident could be affected without the required information. Please fulfil this form complete and attach to the product.

City: Date:

Signature: _____

Durch AS Medizintechnik GmbH auszufüllen:

Received by (name): _____

Date of knowledge: _____

Signature: _____