Formblatt
8.2.3 Safety Information

FSCA – FIELD SAFETY CORRECTIVE ACTION

Type of measure (e.g. recall, field safety note, preventive action)

MENTIONED

Trade name of the affected medical devices

Potsdam, 05.01.2023

Sender

Christoph Miethke GmbH & Co. KG

Ulanenweg 2

14469 Potsdam

Recipient

☐ patients

☑ user

☐ operator

☒ distributor

Description of the non-conformity including root cause analysis

After receiving two independent complaints (1x Sweden, 1x United Kingdom), it was determined from the transmitted images that the configuration of FX804T was assembled in reverse order.

Affected LOTs are: 20061916

Cause: human error

We recommend strongly to execute the following actions.

An immediate return of not yet used/implanted products to the manufacturer.
In the case of products that have already been implanted, there is no need for revision, as the function of the valves is fully given despite the reversed assembly sequence. If the position of the valves does not correspond to the sequence in the patient's card and the IFU, it is mandatory to note in the patient's card and in the patient file that the valves are implanted in a reverse configuration. In this way, a misinterpretation of the adjustability can be prevented and the treating physician can take this into account in the therapy/treatment.
Patient education by the treating physician is necessary to inform and reassure the patient that the sequence of the valves does not result in any functional restriction.

FSCA – FIELD SAFETY CORRECTIVE ACTION

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MENTIONED

Trade name of the affected medical devices

Passing on the information described
Please make sure that all users of the above obtained products and other relevant persons of your organization are aware of this **Field Safety Notice.** If you have passed the products of third parties, please forward a copy of this information or inform the contact person listed below.

Please keep this information at least until the action has been completed.

The **„BfArM"** has received a copy of this **Field Safety Notice.**

Contact Person

If you have any queries, please contact the contact persons listed below.

Company:	Christoph Miethke GmbH & CO KG
Contact person:	Joerg Knebel
Position:	Vice president, PRRC
Tel.:	+49331-620-83-0
Fax:	+49 331 620 83-40
E-Mail:	vigilance@miethke.com

Recall of devices, please forward the return of products to the following address.

Company:	Christoph Miethke GmbH & CO KG
Contact person:	Tracy Gothe
Position:	Complaints / Vigilance
Street | No.	Fritz-von-der-Lancken-Straße 10
Zip | place	14469 Potsdam | Germany

Receipt of acknowledgement

Notice

We hereby acknowledge the receipt of the **Field Safety Notice.** We ensure that all users of the above obtained products and other relevant persons in our organization are aware of this **Field Safety Notice**. If the products were submitted to third parties, we will forward a copy of this information or inform the company Christoph Miethke GmbH & Co. KG

Implementation of recommended actions

We confirm, that we will carry out or have carried out the previously described and strongly recommended actions.

place, date	Name of receiver	Stamp | signature

Return of acknowledgement of receipt

Company: _____

Contact person: _____

Position: _____

Tel.: _____

Fax: _____

E-Mail: _____

Prozessverantwortung

Name	Abteilung	Abteilungsleiter
[redacted]	QM Vigilance	[redacted]

Änderungshistorie

Version	Änderungsbeschreibung	Schulung?
1	Wiederherstellung des Dokumentes Version 2 vom 05.02.2020 im Rahmen der Einführung der (Medizinprodukte-) Verordnung (EU) 2017/745	Ja

Glossar

Abkürzung	Beschreibung
FSCA	Field Safety Corrective Action
QM	Qualitätsmanmagement

Mitgeltende Dokumente

Dokument Nr.
LI 3.0 Abkürzungen
LI 4.2 Aufbewahrungsfristen
AA 4.2.1 Gute Dokumentationspraxis
UP 8.2.3 Vigilanz