

Formblatt

8.2.3 Safety Information

FSCA – FIELD SAFETY CORRECTIVE ACTION

Field Safety Note (FSN)

MENTIONED

SensorReservoir (FV911X, FV912X, FV920X, FV921X, FV905X, FV906X)

Potsdam, the 06.08.18

Sender

Christoph Miethke GmbH & Co.KG
 Ulanenweg 2
 14469 Potsdam

Recipient

- patients
- user
- operator
- distributor

Description of the non-conformity including root cause analysis

Medical devices have been marked in european countries with missing languages in the IFU.

The following countries are affected:

- * Denmark
- * Italy
- * Norway
- * Dutch

For the affected countries IFU's will be issued in electronical form to be placed on our web-site (www.mithke.com). It will be available soon.

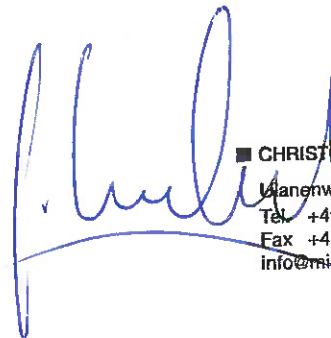
List of affected art.no.:

FV911X, FV912X, FV920X, FV921X, FV905X, FV906X

We recommend strongly to execute the following actions.

The customer do not need actions by himself. It is sufficient, in case of interest, to download the particular version of the IFU with the ringht language.

Please sign the acknowledgement (s. page 3 of 4) as proof that you have read this FSN.



■ CHRISTOPH MIETHKE GMBH & CO. KG
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 Tel. +49 (0) 331 620 83 0
 Fax +49 (0) 331 620 83 40
 info@miethke.com | www.miethke.com

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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**.

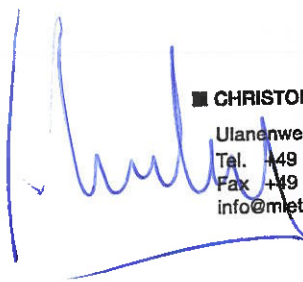
Contact Person

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

Company: Aesculap AG
 Contact person: Herr Christian Strobel
 Position: Vigilance Manager
 Tel.: +49 7461 95-31926
 Fax: +49 7461 95-1555
 E-Mail: vigilance_aag.de@aesculap.de

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

Company: n.a., because it is not a recall
 Contact person: n.a.
 Position: n.a.
 Street | No. n.a.
 Zip | place n.a.



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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: Aesculap AG
 Contact person: Herr Christian Strobel
 Position: Vigilance Manager
 Tel.: +49 7461 95-31926
 Fax: +49 7461 95-1555
 E-Mail: vigilance_aag.de@aesculap.de

Prozessverantwortung

Name	Abteilung	Abteilungsleiter
Franziska Ahrendt	QM Reklamationen / Vigilance	Jörg Knebel

Änderungshistorie

Version	Änderungsbeschreibung	Schulung?
1	Anpassung Kapitel entsprechend EN ISO 13485:2016	Ja

Glossar

Abkürzung	Beschreibung
FSCA	Field Safety Corrective Action
QM	Qualitätsmanagement

Mitgeltende Dokumente

Dokument Nr.
LI 3.0 Abkürzungen
AA 8.2.3 Vigilance Verdacht Meldepflicht