

Formblatt

8.2.3 Safety Information

FSN – FIELD SAFETY NOTES

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

SAFETY INFORMATION

Trade name of the affected medical devices

M.scio | FV915X, FV916X, FV913X, FV914X, FV924X, FV925X, FV922X, FV923X

Potsdam, the 2021-02-16

Sender

Christoph Miethke GmbH & Co.KG
Ulanenweg 2
14469 Potsdam

Recipient

- patients
- user
- operator
- distributor

Description of the non-conformity including root cause analysis

During an internal investigation by Miethke GmbH & Co. KG, it became obvious that the supplier had made a printing mistake in the operating IFU's to the M.scio. During the investigation we found a few IFU's that did not contain pages 1-2 and 35-36 (both double-sided). However, the majority of the tested IFU's contained these pages. Nevertheless, Miethke cannot exclude the possibility that IFU's with the missing pages were also enclosed with the products already delivered.

Also, it was found that the symbols/pictograms for the notes and warnings are not present in the printed IFU's. However, the notes and warnings are all included in the IFU (text) as intended. An inadequate setting copy for the IFU by Christoph Miethke GmbH & Co. KG was provided to the printing house.

We recommend strongly to execute the following actions.

It is not necessary to return the affected products. There is no risk for patients and users, as the product itself has no failure and no incorrect use of the product can occur.

Please review the Instructions for use to determine if they are correct. In case of incorrect instructions for use, the correct version can be downloaded from our home page "www.miethke.com". We will also be happy to send the corrected instructions for use upon request.

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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: Christoph Miethke GmbH & Co. KG

Contact person: Jana Kummerow

Position: Vigilance Coordinator

Tel.: +49 331 620 83-6617

Fax: +49 331 620 83-6640

E-Mail: complaints@miethke.com

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

Company: _____

Contact person: _____

Position: _____

Street | No. _____

Zip | place _____

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: _____