

Christoph Miethke GmbH & Co. KG	Form Safety Information	Seite: 1 von: 3 Kapitel: 8.1.2
<p align="center">FSCA – FIELD SAFETY CORRECTIVE ACTION</p> <p align="center"><i>Type of measure (z.B. recall, field safety note)</i></p> <p align="center">Recall Field safety note</p> <p align="center">MENTIONED</p> <p align="center"><i>Trade name of the affected medical devices</i></p> <p align="center">Borehole Port</p>		

SENDER

Potsdam,
2015-12-01

Christoph Miethke GmbH & Co.KG
Ulanenweg 2
14469 Potsdam

RECIPIENT

- ☒ patients
☒ user
☐ operator
☒ distributor

DESCRIPTION OF THE PROBLEM INCLUDING ROOT CAUSE ANALYSIS CAUSE

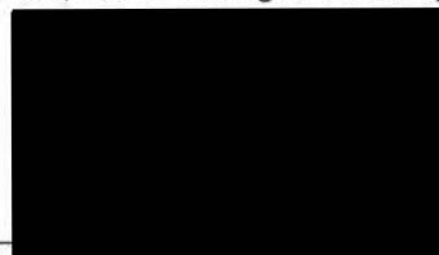
Through a personal fault of the employee employed for the packaging of products, there was a confusion between the Borehole Ports and Borehole Ports for pediatric use. The affected delivery batch is 20028021.

WE RECOMMEND STRONGLY TO THE NAMED RECIPIENT TO EXECUTE THE FOLLOWING MEASURES.

Please check whether the products concerned are already implanted.

If so, we can confirm that the fault detected does not represent a risk for the patient. The indication for both ports are identical. The Borehole Port for pediatric use is preferably used in children, but this is not mandatory. We are aware that Borehole Ports having a diameter of 20mm were implanted in children and Borehole Ports for pediatric use having a diameter of 14mm were implanted in adults. There is no risk for patients by the confusion described.

If the products are still in your stock, please send them immediately to Aesculap AG, Department QMV, Jana Zibulski, Am Aesculap Platz, 75832 Tuttlingen. Aesculap will order a replacement for you.



Christoph Miethke GmbH & Co. KG	Form Safety Information	Seite: 2 von: 3 Kapitel: 8.1.2
<p align="center">FSCA – FIELD SAFETY CORRECTIVE ACTION</p> <p align="center"><i>Type of measure (z.B. recall, field safety note)</i></p> <p align="center">Recall Field safety note</p> <p align="center">MENTIONED</p> <p align="center"><i>Trade name of the affected medical devices</i></p> <p align="center">Borehole Port</p>		

PASSING ON OF THE BELOW DESCRIBED PIECE OF INFORMATION

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 to third parties, please forward a copy of this piece of information or inform the contact person listed below.

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

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

CONTACT PERSON

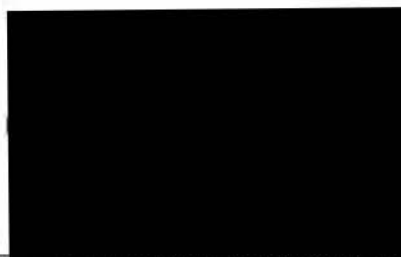
If you have any queries, please contact the contact persons listed below.

Frau Jana Zibulski
Tel.: +49 7461 95-31699
Fax.: +49 7461 95-1555
E-Mail: vigilance_aag.de@aesculap.de

RECALL OF DEVICES

PLEASE FORWARD THE RETURN TO PRODUCTS TO THE FOLLOWING ADDRESS

Aesculap AG
building 12 - Department QMV
Jana Zibulski
Am Aesculap-Platz
78532 Tuttlingen



Christoph Miethke GmbH & Co. KG	Form Safety Information	Seite: 3 von: 3 Kapitel: 8.1.2
<p align="center">FSCA – FIELD SAFETY CORRECTIVE ACTION</p> <p align="center"><i>Type of measure (z.B. recall, field safety note)</i></p> <p align="center">Recall Field safety note</p> <p align="center">MENTIONED</p> <p align="center"><i>Trade name of the affected medical devices</i></p> <p align="center">Borehole Port</p>		

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 piece of 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 measures.

_____	_____	_____
Place, date	Name of receiver	Stamp / signature

RETURN OF ACKNOWLEDGEMENT OF RECEIPT

Frau Jana Zibulski
Department QMV
Fax.: +49 7461 95-1555
E-Mail: vigilance_aag.de@aesculap.de

