FSCA – FIELD SAFETY CORRECTIVE ACTION

Type of measure (z.B. recall, field safety note)

recall | field safety note

MENTIONED

Trade name of the affected medical devices

proGAV | proGAV 2.0

Potsdam,

2015-11-18

SENDER

Christoph Miethke GmbH & Co.KG
Ulanenweg 2
14469 Potsdam

RECIPIENT

- ☑ patients
- ☑ user
- ☐ operator
- ☑ distributor

DESCRIPTION OF THE PROBLEM INCLUDING ROOT CAUSE ANALYSIS CAUSE

Because of an organizational error the capbox for proGAV and proGAV 2.0 were exchanged. Presumably the proGAV 2.0 capboxen were used for the proGAV inculding the appropriate instructions for use, patient manual, patient data card , laminated card with recommendation for pressure levels and vice versa.

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

Please check whether the products concerned are already implanted. If yes, please report it to Aesculap AG , Department QMV, Am Aesculap Platz, 78532 Tuttlingen. In this case, you will receive (via Aesculap Tuttlingen) the correct product inserts (Instructions, Patient Manual, patient data card, card with recommendations for pressure leves) .

If the products are still in your stock, please send them immediately to Aesculap AG, Department QMV, Am Aesculap Platz , 78532 Tuttlingen. Aesculap will order a replacement for you.

The detected error has no impact on affected patients, because the products are labeled correctly and each Capbox also contains the matching product. The probability that there is a mix-up during implantation is extremely low, because all doctors received the product that they ordered.

[redacted]

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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.

Safety officer for medical devices

name: Jörg Knebel

phone.: +49 (0) 331 620 83-64

fax: +49 (0) 331 620 83-40

E-Mail: Jörg.Knebel@miethke.com

Vigilance representative

name: Franziska Ahrendt

phone +49 (0) 331 620 83 60

fax: +49 (0) 331 620 83 40

E-Mail: franziska.ahrendt@miethke.com

RECALL OF DEVICES
PLEASE FORWARD THE RETURN TO PRODUCTS TO THE FOLLOWING ADDRESS

Aesculap AG
Abteilung QMV
Am Aesculap Platz
78532 Tuttlingen

[redacted]

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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 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

Security officer of medical devices

name: Jörg Knebel

phone: +49 (0) 331 620 83-64

fax: +49 (0) 331 620 83-40

E-Mail: Jörg.Knebel@miethke.com

Vigilance representative

name: Franziska Ahrendt

phone: +49 (0) 331 620 83 60

fax: +49 (0) 331 620 83 40

E-Mail: franziska.ahrendt@miethke.com

■ CHRISTOPH MIETHKE GMBH & CO. KG

[redacted]