



MGB Endoskopische Geräte GmbH Berlin

Geschäftsführung / CEO
 Schwarzschildstraße 6
 12489 Berlin – Germany
 Tel.: +49 (0)30 6392-7000
 Fax: +49 (0)30 6392-7002
 E-Mail: info@mgb-berlin.de
 www.mgb-berlin.de

MGB · Schwarzschildstraße 6 · 12489 Berlin - Germany

To all customers

Berlin, 19.02.2019

Urgent security information:

Medical product safety information

Reference: R-2019-1

Affected products: GRP Handles 429-77015(N), 429-77020(N), 429-77030(N)

Dear customer/dealer,

With this letter we would like to inform you that the MGB Endoskopische Geräte GmbH Berlin initiates an unsolicited recall of the GRP handles with and without ratchet due to a change of performance.

This recall applies to all products from the period 01/2008 to 01/2019.

GRP handles with HF-connector REF: 429-77015(N) LOT: AE...AQ¹

GRP handles with HF-connector and ratchet REF: 429-77020(N) LOT: AE...AQ¹

GRP handles with HF-connector and ratchet REF: 429-77030(N) LOT: AE...AQ¹

¹ Encoded monthly: 1st letter: month (A: January, B: February,... M: December)
 2nd letter: year (E: 2008, F: 2009,... Q: 2019)

This corrective action is carried out with the knowledge of the competent supervisory authorities.

Health risk	Low risk of electric shock and possible burns of the surgeon
Actions	<ol style="list-style-type: none"> 1. Check your inventory and immediately lock affected products. Instruct all users (surgeons, customers) to block the product. 2. Send the completed return form by mail, fax or e-mail to MGB. 3. Return the blocked products to MGB. 4. The return form must also be completed and returned if you no longer have a product in stock, as we must document this information for our records. 5. Please ensure that this safety information is passed on within your organization to all persons who need to know about it. 6. To ensure the effectiveness of the action, keep this information and the resulting action in mind until the recall is completed.

General Management
 Dongjoo Kang, Kwang Seog Song
 Tel.: +49 (0)30 6392-7000
 Fax: +49 (0)30 6392-7002
 www.mgb-berlin.de

Handelsregister HRB 61110
 Amtsgericht
 Berlin-Charlottenburg
 Steuernr.: 37/12720116
 USt-IdNr.: DE184229983

Landesbank Berlin
 Kto.-Nr.: 1523337032
 BLZ: 10050000
 IBAN: DE92100500001523337032
 SWIFT-BIC: BELADEBE

Commerzbank AG
 Kto.-Nr.: 0699999200
 BLZ: 10080000
 IBAN: DE61100800000699999200
 SWIFT-BIC: DRESDEFF100



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It is the goal of MGB Endoskopische Geräte GmbH Berlin to deliver only the highest quality products and to provide you with unlimited support.

We are actively investigating this matter to find a long-term solution as fast as possible.

Please return all affected handles together with the attached return form to MGB as far as possible until 22.02.2019:

MGB Endoskopische Geräte GmbH Berlin

Schwarzschildstr. 6

12489 Berlin - Germany

Tel.: +49 (0)30 6392-7040

Fax: +49 (0)30 6392-7011

E-Mail: recall@mgb-berlin.de

www.mgb-berlin.de

Please return the return form even if you have no GRP handles from us in your stock.

All returned products will be credited to your customer account.

Availability of alternative products:

We will contact you and introduce you to available alternatives that may be considered substitutes.

We regret any inconvenience that you, your patient or your staff may have incurred or may have incurred in connection with this recall.

If you have any questions or need more information, please contact our service department at the numbers listed above.

We thank you for your support and understanding.

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12459 Berlin

Please send this form via mail to the address on the left. Alternatively you can send us a signed scan per email to recall@mgb-berlin.de or via fax to +49 (0)30 6392 7011. Thank you!

Return form R-2019-1

Hereby we confirm the reception of the security information for the recall:

Reference: R-2019-1

In our stock we have

- affected products we will return (quantity: pieces).
no affected products.

Company:
Distributor:
Name:
Address:
Email:
Phone:
Comment:

Date

Signature

With my signature I assure that I informed all my customers and/or users about the recall and took every necessary actions.