

Gebrüder MARTIN GmbH & Co. KG
Product Management Electrosurgery /
Medical Lasers

29.12.2017 ip



Important Safety Notice

Recall of laser safety glasses, Product Number: 79-100-56-04
Our Reference Number: CPL 0522, Customer V-ID: «VID_»

Dear customer and user,

Within the scope of our global market surveillance, it is our duty to inform you of the risks to patients and users that may arise when using the affected products from Gebrüder Martin GmbH & Co. KG, the laser safety glasses 79-100-56-04.

We have found that the laser safety glasses noted above do not cover the wavelength of our laser units Diomax, Limax 60 and Limax 120, and therefore do not protect the eyes against laser light wavelengths of 980 nm and 1,320 nm to the extent mandated by law. Based on the information available, no patients, users, or third parties have been injured to date.

However, to prevent such potential injury we are taking the precaution of a recall.

Safety and procedure notes and corrective action:

To eliminate unnecessary risks, Gebrüder Martin is asking you to inspect all laser safety glasses shipped to you with the product number 79-100-56-04.

Gebrüder Martin GmbH & Co. KG
KLS Martin Platz 1 · 78532 Tuttlingen/Germany
Postfach 60 · 78501 Tuttlingen/Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

Registergericht: Stuttgart
Handelsregister: HRA 450196
USt.-Id.-Nr.: DE 142930777

Gesellschafter:
Karl Leibinger Medizintechnik,
Stuckenbrock Medizintechnik
Persönlich haftende Gesellschafterin:
Martin Verwaltungsgesellschaft mbH
Registergericht: Stuttgart
Handelsregister: HRB 450711
WEEE-Reg.-Nr. 40473755

Geschäftsführer:
Karl Leibinger, Christian Leibinger, Donat Stuckenbrock
Deutsche Bank Tuttlingen: BLZ 653 700 75 · Kto. 2 184 000
IBAN DE 25 6537 0075 0218 4000 00 · BIC DEUT DE 33 653
Kreissparkasse Tuttlingen: BLZ 643 500 70 · Kto. 10234
IBAN DE 15 6435 0070 0000 0102 34 · BIC SOLADE 31 TUT
Commerzbank AG, Filiale Tuttlingen: BLZ 694 400 07 · Kto. 0 241 215 300
IBAN DE88 6944 0007 0241 2153 00 · BIC COBADEFF694

The laser safety glasses are light grey and marked as follows on the packaging and the frame of the glasses:



An overview of the potentially affected batches delivered to you can be found in Attachment 2.

If you or your customers have such laser safety glasses, you may no longer use them. If used, they could endanger your own health and that of your staff and patients.

Therefore, please inform us by 31 January 2018 whether the above-mentioned product is still in stock at your premises or at the premises of your customers, and please return said products to Gebrüder Martin GmbH & Co. KG specifying our reference number "CPL 0522".

All returned laser safety glasses will naturally be replaced at our cost. Production and shipping of the product in question has been stopped until all reviews have been completed and all measures undertaken to eliminate the risk associated with use of this product. The competent authorities have also been notified.

Please ensure that your customers and the staff in charge of this application are notified of this safety notice and the instructions it contains. For this purpose please also fill out the form in Attachment 1 and return it to us.

We deeply regret any inconvenience you may experience because of this. The measures described above are of a preventive nature and designed to ensure your safety.

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IBAN DE88 6944 0007 0241 2153 00 · BIC COBADE33 694

Please keep this information at least until the measure has been completed.

Sincerely,

Gebrüder Martin GmbH & Co. KG,



Attachments

Attachment 1: Fax reply

Attachment 2: Shipping Summary

Gebrüder Martin GmbH & Co. KG
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IBAN DE 25 6537 0075 0218 4000 00 · BIC DEUT DE SS 653
Kreissparkasse Tuttlingen: BLZ 643 500 70 · Kto. 10234
IBAN DE 15 6435 0070 0000 0102 34 · BIC SOLADE S1 TUT
Commerzbank AG, Filiale Tuttlingen: BLZ 694 400 07 · Kto. 0.241 215 300
IBAN DE88 6944 0007 0241 2153 00 · BIC COBADEFF694

ATTACHMENT 1

Fax reply CPL 0522 to +49 7461 706-190 for Gebrüder Martin GmbH & Co. KG

V.-ID: «VID_» .Customer: «Name_des_Kunden__Name_of_customer», «Ort__Town»,
«LAND__Country»

We hereby confirm:

1) receipt of the letter "Important Safety Notice" from Gebrüder Martin, dated December 2017, with Attachments 1 and 2.

2) that the situation and risks have been understood.

3a) as specialized retailer/distributor:

that the content of the letter "Important Safety Notice" with Attachments 1 and 2 will be passed on to the end customers / users as soon as possible, the aim being to inspect the delivered and affected batches of the laser safety glasses 79-100-56-04 (Attachment 2).

3b) as user/operator:

that an inspection of the affected laser safety glasses 79-100-56-04 delivered to you (see Attachment 2) will be inspected as soon as possible and that the affected batches will be returned to Gebrüder Martin.

Place, date:

Name / position of the person signing:

Company / stamp and signature:
