

TO WHOM IT MAY CONCERN

**Gebrüder Martin GmbH & Co. KG**  
Product Management  
Surgical Instruments  
Sterilization Container Systems

November 2019  
Johannes Gulde

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Fax: (07461) 706-312  
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## Important safety notice – Corrosion

### Recall of Scalpel blades

#### Our ref.: CPL 0553

Dear customer and user,

We would like to inform you that the scalpel blades which we have put on the market, have been found to have corrosion on the metal surface of the product in the sterile packaging.

It is our obligation to inform you of the risks to the user and patient that can arise when using the relevant product from Gebrüder Martin GmbH & Co. KG. The products shall immediately be taken out of usage. It is not allowed to use them anymore.

Our records show that you have potentially affected products. We therefore ask you to observe and follow the other sections of this safety notice.

**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 Stuckel  
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 33 102  
Commerzbank AG, Filiale Tuttlingen: BLZ 694 400 07 · Kto. 0 241 215 300  
IBAN DE88 6944 0007 0241 2153 00 · BIC COBADE33 694

**Advice on safety and conduct, and corrective action:**

In order to exclude risks, Gebrüder Martin GmbH & Co. KG must ask you to return all listed scalpel blades supplied to you with one of the batches listed below. The delivery period is from 25.07.2019 - 25.11.2019.

This concerns the following article numbers with one of the following batches:

| Article Number | Description                     | Figure No. |
|----------------|---------------------------------|------------|
| 10-155-10-04   | SCALPEL BLADE, NO. 10, STERILE  | 10         |
| 10-155-11-04   | SCALPEL BLADE, NO. 11, STERILE  | 11         |
| 10-155-12-04   | SCALPEL BLADE, NO. 12, STERILE  | 12         |
| 10-155-13-04   | SCALPEL BLADE, NO. 13, STERILE  | 13         |
| 10-155-15-04   | SCALPEL BLADE, NO. 15, STERILE  | 15         |
| 10-155-18-04   | SCALPEL BLADE, NO. 18, STERILE  | 18         |
| 10-155-20-04   | SCALPEL BLADE, NO. 20, STERILE  | 20         |
| 10-155-21-04   | SCALPEL BLADE, NO. 21, STERILE  | 21         |
| 10-155-22-04   | SCALPEL BLADE, NO. 22, STERILE  | 22         |
| 10-155-23-04   | SCALPEL BLADE, NO. 23, STERILE  | 23         |
| 10-156-12-04   | SCALPEL BLADE, NO. 12D, STERILE | 12D        |
| 10-156-15-04   | SCALPEL BLADE, NO. 15C, STERILE | 15C        |

**Batches:** B10199, B10278, B10304, B10321, B10322, B10323, B10324, B10325, B10326, B10327, B10328, B10329, B10330, B10331, B10332, B10333, B10680, B10683, B10684, B10685, B10690, B10691, B10692, B10693, B10694, B10695, B10705, B10706, B10708, B10709, B10710, B10712, B10713, C10050, C10120, C10121, C10122, C10123, C10124, C10125, C10126, C10154, C10155, C10156, C10158, C10160, C10161, C10162, C10163, C10164, C10165, C10166, C10167, C10168, C10169, C10221, C10223, C10224, C10227, C10228, C10229, C10237, C10684

In **Attachment 1** you will find an overview of the products delivered to you and which are potentially affected.

We will also be pleased to contact you if you wish. If so, please place an appropriate cross on the attached reply fax/document, indicating the telephone number and contact person, and return it by email to [lejla.tule@klsmartin.com](mailto:lejla.tule@klsmartin.com) or by fax to +49 7461 706 312.

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IBAN DE88 6944 0007 0241 2153 00 · BIC COBADEFF694

Please ensure that your customers and the user, as well as the members of staff responsible in this matter, are notified urgently of this safety notice and the instructions it contains.

We kindly ask you to send the listed scalpel blades urgently back to us. Please indicate CPL no. 0553 when returning the goods. The affected products will be taken back by us for your discharge.

We would like to apologize for any inconvenience that this may cause you. If you should have any queries, please contact Product Management, Ms. Lejla Tule, Tel. +49 7461 706 352, or send her an email at lejla.tule@klsmartin.com.

Please keep this notice at least until the measure have been completed.

Kind regards

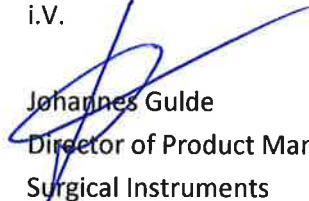
Gebrüder Martin GmbH & Co. KG  
A company of the KLS Martin Group

i.V.



Reinhold Bücher  
Head of Quality Management  
Safety Officer pursuant to the German  
Medical Devices Act

i.V.



Johannes Gulde  
Director of Product Management  
Surgical Instruments  
Sterilization Container Systems

### **Attachments**

Attachment 1, overview list  
Reply letter

**Reply letter to +49 7461 706-312 or via email to lejla.tule@klsmartin.com  
to Gebrüder Martin GmbH & Co. KG**

**TO WHOM IT MAY CONCERN**

**Important safety notice | Corrosion | CPL 0553  
Scalpel blades**

We hereby confirm:

Receipt of the letter "Important safety notice" from Gebrüder Martin GmbH & Co. KG dated November 2019 with Attachment 1.

That the content of the letter "Important safety notice" with Attachment 1 will be forwarded promptly to our customers to facilitate return of the delivered scalpel blades, as referred in Attachment 1.

There are still ..... pieces of the mentioned items at our house / with our customers.

Please arrange a collection from the following address:

|  |  |
|--|--|
| <b>Name Customer / Company /<br/>Hospital / User</b> |  |
| <b>Street, Place, Country</b>                        |  |
| <b>Contact person</b>                                |  |
| <b>Phone no./email</b>                               |  |

We would like to be contacted by Gebrüder Martin GmbH & Co. KG.

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Name:..... Phone no.: .....

Email:.....

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Place, Date

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Name / Position of the signatory

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Company/ Institution / Stamp and signature

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