

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.

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 or by fax to +49 7461 706 312.

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

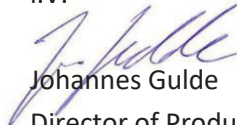
Gebrüder Martin GmbH & Co. KG
A company of the KLS Martin Group

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

**Customer: AS Semetron
Customer No.: 10002441
Customer -ID No.: 12**

**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:

Name Customer / Company / Hospital / User	
Street, Place, Country	
Contact person	
Phone no./email	

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

Name:..... Phone no.:

Email:.....

Place, Date

Name / Position of the signatory

Company/ Institution / Stamp and signature