ADDRESS

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

22.12.2016 ip
Ina Pede

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Important Safety Notice

Recall concerning Venex 360° fiber - our reference number: CPL 0508
Item numbers: 79-350-00-04 / 79-350-00-22 / 79-350-01-04

Dear customer and user,

Within the scope of our global market surveillance and following a safety notice from our supplier, 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 Venex 360° laser fibers.

Our supplier reports that he has received a customer complaint concerning the above-mentioned product due to a fiber defect that was discovered by the user after a treatment. The resulting batch-related inspection showed an increased fracture rate for the glass body at the distal end of the radially emitting fiber. According to the customer no irregularity was found in the fiber when the inspection specified in the Instructions for Use was performed. Based on the information we have 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.

Advice on safety and conduct, and corrective action:

To eliminate unnecessary risks, Gebrüder Martin must ask you to inspect all the Venex 360° laser fibers that were delivered to you.

An overview of the potentially affected batches delivered to you can be found in Attachment 1.

If the Venex 360° laser fibers at your premises or at the premises of your customers are affected, they may no longer be used. If they are used, they could endanger the health of your patients.

Therefore, please inform us until 19th January 2017 whether the above-mentioned product is still in stock at your premises or at the premises of your customers and please return it to Gebrüder Martin GmbH & Co. KG with our reference number "CPL 0508".
Please let us know without delay if you have become aware of similar and/or other irregularities concerning the product.

The returned fibers will naturally be replaced at our cost.
Production and delivery of the affected product have been stopped until all investigations have been completed and all measures have been taken to eliminate the risk associated with using the product. The competent government agency was also notified.

Please make sure your customers and the employees responsible for this application are informed of this safety notice and the instructions it contains.
For this purpose please also fill out the form in Attachment 2 and return it to us.

We sincerely apologize for any inconvenience that this may cause you. The described measures are of a preventive nature and aimed at ensuring the safety of your patients.

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

Kind regards,

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

acting for	by
	
Uwe Ott Head of Product Management Electrosurgery / Medical Laser	Ina Pede Product Manager Electrosurgery / Medical Laser

Attachments

Attachment 1: Overview of potentially affected batches
Attachment 2: Fax reply
Attachment 3: Overview delivery scopes

ATTACHMENT 1
Overview of potentially affected batches

Item numbers **79-350-00-04 / 79-350-00-22 / 79-350-01-04**
with the following batches:

Outer carton batch	Sterile packaging batch
K9A	059201405
K9D	055201405
KAA	072201406
KAA	059201405
KAB	082201407
KAB	133201609
KAC	059201405
KAD	059201405
KAE	096201408
KAF	096201408
KAG	096201408
KAH	096201408
KAJ	096201408
KAK	096201408
KAL	096201408
KAM	133201609
KAN	133201609
KAO	133201609
KAP	133201609

ATTACHMENT 2
FAX reply CPL 0508 to +49 7461 706-190
for Gebrüder Martin GmbH & Co. KG

V. ID: ……..Customer:

We hereby confirm:

1) receipt of the letter "Important Safety Notice" from Gebrüder Martin dated December 2016 with Attachments 1, 2 and 3.

2) that the situation and risks have been understood.

3a) as a specialist trade partner:

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 Venex 360° laser fibers (Attachment 3).

3b) as a user/operator:

that an inspection of the affected Venex 360° laser fibers delivered to you (see Attachment 3) 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: