

Adresse

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

February 2013

Tel.: +49 7461 706-
Fax: +49 7461 706-312
@klsmartin.com

Important Safety Notice

Checking Dilator 24-492-15-01 (Dilator, De Bakey, Ø 1.5 mm, 19 cm) - Danger to Patients

Dear Customer and User,

based on our market surveillance activities, we have received information that the dilators 24-492-15-01 (Dilator, De Bakey, Ø 1.5 mm, 19 cm) marketed by us may be susceptible to fractures occurring on the soldered connection of the working end.

It is our responsibility to inform you about patient hazards that can be created when handling the above-mentioned product delivered by Gebrüder Martin GmbH & Co. KG because the soldered-on sleeve may come off at the working end.



Safety and action instructions and corrective measure:

To prevent avoidable risks, Gebrüder Martin is obliged to require you to check all delivered dilators 24-492-15-01 marked with lot "2B" (Dilator, De Bakey, Ø 1.5 mm, 19 cm).

For an overview of all potentially affected products you received from us, see Attachment 1.

Should you identify a lot "2B" dilator, item no. 24-492-15-01 (Dilator, De Bakey, Ø 1.5 mm, 19 cm), be sure to withdraw such product(s) from service at once! Non-compliance may put the life, physical integrity and health of your patients at risk. For the identification procedure, please see Attachment 2.

In any such case, please notify our Product Management PM1, Mrs. Janett Barth (tel. +49 7461 706 234 or email to janett.barth@klsmartin.com) as soon as possible.

We will gladly call you back if you wish – just let us know on the return fax form attached, indicating the contact person and his/her phone number and returning the completed form to the following fax address: +49 7461 706 312.

Please make sure that your customers or your users and responsible staff members will be duly informed of this Safety Notice and the instructions provided herein.

We offer you to replace all affected dilators free of charge.

We regret the inconveniences this may cause to you. The measures described are of a preventive nature in the service of patient safety.

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

Sincerely yours,

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



Marketing Manager
Safety Officer acc. to MPG
(Medical Devices Act)



Head of Product Management
Surgical Instruments
Container Systems

Attachment

Attachment 1: overview list

Attachment 2: identification instructions

Return-Fax

**Return FAX to +49 7461 706-312
to Gebrüder MARTIN GmbH & Co. KG**

**Customer:
Customer ID:**

Important Safety Notice: Checking dilator 24-492-15-01 (Dilator, De Bakey, Ø 1.5 mm, 19 cm) - danger to patients

We hereby confirm:

that we have received the "Important Safety Notice" letter of February 2013 by Gebrüder Martin GmbH & Co. KG, including Attachments 1 and 2.

That we will pass on the contents of the "Important Safety Notice" and the Attachments 1 and 2 to our customers without delay, requesting them to return all affected dilators 24-492-15-01 (Dilator, De Bakey, Ø 1.5 mm, 19 cm) marked with lot "2B" as supplied acc. to Attachment 1.

Please contact me / us directly at:

Name:..... Phone:

Email:

Place & date:

Name / position of signatory:

Firm / stamp & signature:

Attachment 2

Identification Instructions for Dilator 24-492-15-01 (Dilator, De Bakey, Ø 1.5 mm, 19 cm), lot "2B"

Identification of the affected dilator lot "2B":

Handle



Location of lot number