ADDRESS

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

[redacted]

# Important safety notice

**Recall of dual pedal footswitches with SWAP mode - CPL 0509 item numbers: 80-821-03-04**

Dear customer,

Within the scope of our global market surveillance it is our duty to inform you of the risks to users and patients that may arise when using the affected product from Gebrüder Martin GmbH & Co. KG, the dual pedal footswitch with SWAP mode (item no.: 80-821-03-04).

Our market surveillance and the subsequent batch-related investigation of our dual pedal footswitch with SWAP mode have detected an assembly fault. The pedals of the dual pedal footswitch have been mounted on opposite sides, with the result that the positions of the yellow and the blue pedal have been reversed (see Attachment 1). The function and the control unit in the footswitch are unchanged, which means that the user may confuse the function during use.

The current instructions for use state that a specific current type is generated by pressing the "yellow" or "blue" pedal. (yellow → "activate cutting" / blue → "activate coagulation"). The switching of the pedal colors means that there is a risk of incorrect activation.

We refer to the function test specified in the instructions for use every time the device is used, which makes it relatively easy to determine whether the specified function is correct. Color and acoustic signals offer additional assistance with detection of the malfunction.
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:**

Gebrüder Martin requests you to check dual pedal footswitches with SWAP mode (item no.: 80-821-03-04) that you have received since **May 2016**.

**If the the dual pedal footswitches 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 patients.**

Please inform us by January 19, 2017, whether the above product at your premises or your customers' premises is in good condition.
Please let us know without delay if you have become aware of similar and/or other irregularities concerning the product.

We request you to return affected footswitches to us for replacement free of charge using our reference number CPL 0509.
Please make sure your customers 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 would like to apologize for any inconvenience. The described measures are of a preventive nature and aimed at ensuring the safety of your patients.

Kind regards,

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

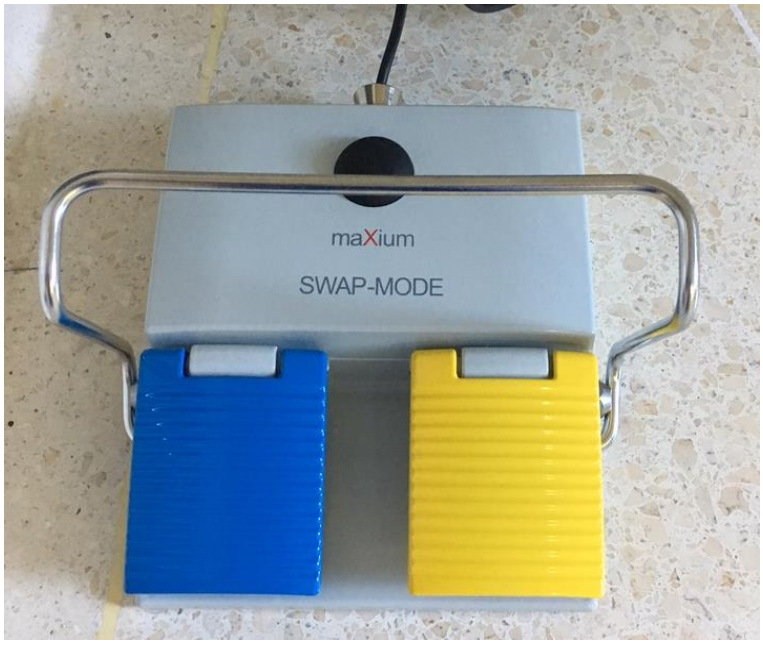
**Attachments**

**Attachment 1: Assembly**

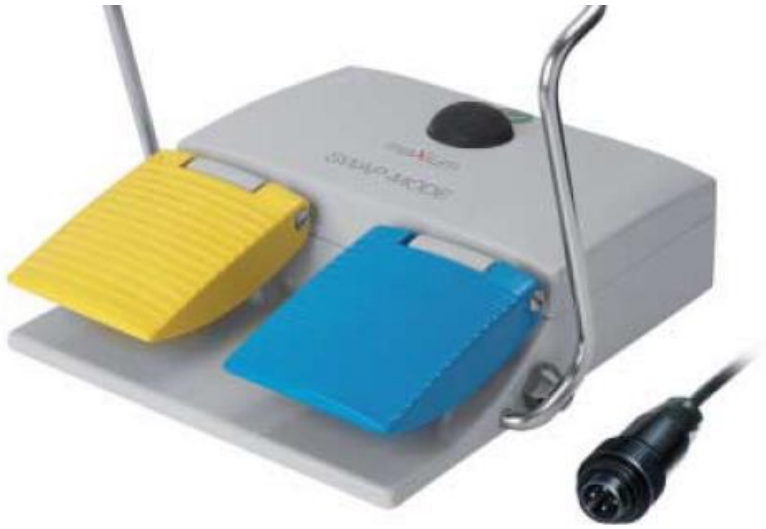
**Attachment 2: Fax reply**

# ATTACHMENT 1 Assembly

## Incorrect assembly




## Correct assembly



# ATTACHMENT 2 - Reply referring to CPL 0509
# FAX reply to +49 7461 706-190
# for Gebrüder Martin GmbH & Co. KG

We hereby confirm:

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

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 the dual pedal footswitch with SWAP mode.

3b) as a user/operator:

that the affected footswitches delivered to you will be inspected as soon as possible and that the affected footswitches will be returned to Gebrüder Martin.

Place, date:

_____

Name / position of the person signing:

_____

Company / stamp and signature: