

**Gebrüder Martin GmbH & Co. KG**  
Product Management Electrosurgery and  
Laser

17.12.2018  
Christian Tockweiler

Tel.: +49 7461 - 706-239  
Fax: +49 7461 - 706-190  
christian.tockweiler@klsmartin.com

**Additional information for monopolar electrode handles smartPen for active electrodes with 2.4 mm attachment, REF 80-210-21-04 und REF 80-210-23-04**

Dear Sir or Madam,

The purpose of this letter is to inform you about a product information voluntarily initiated by Gebrüder Martin GmbH & Co.KG when using the handle especially in combination with the corresponding monopolar active electrodes.

**Description of circumstances**

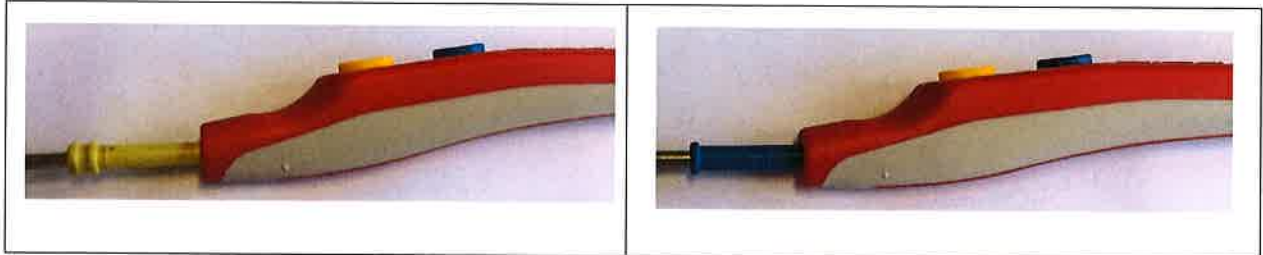
You receive this letter because you may be using one or more of the mentioned products above. Insert a sterile active electrode suitable for the surgical application (with a connection diameter of 4.0 mm, 2.4 mm, or 1.6 mm, depending on the electrode handle model) into the electrode socket of the reprocessed smartPen until the end stop is reached.

- The active electrode can be inserted in various rotation-protected positions.
- The hexagon of the active electrode must be covered by the tip of the smartPen.

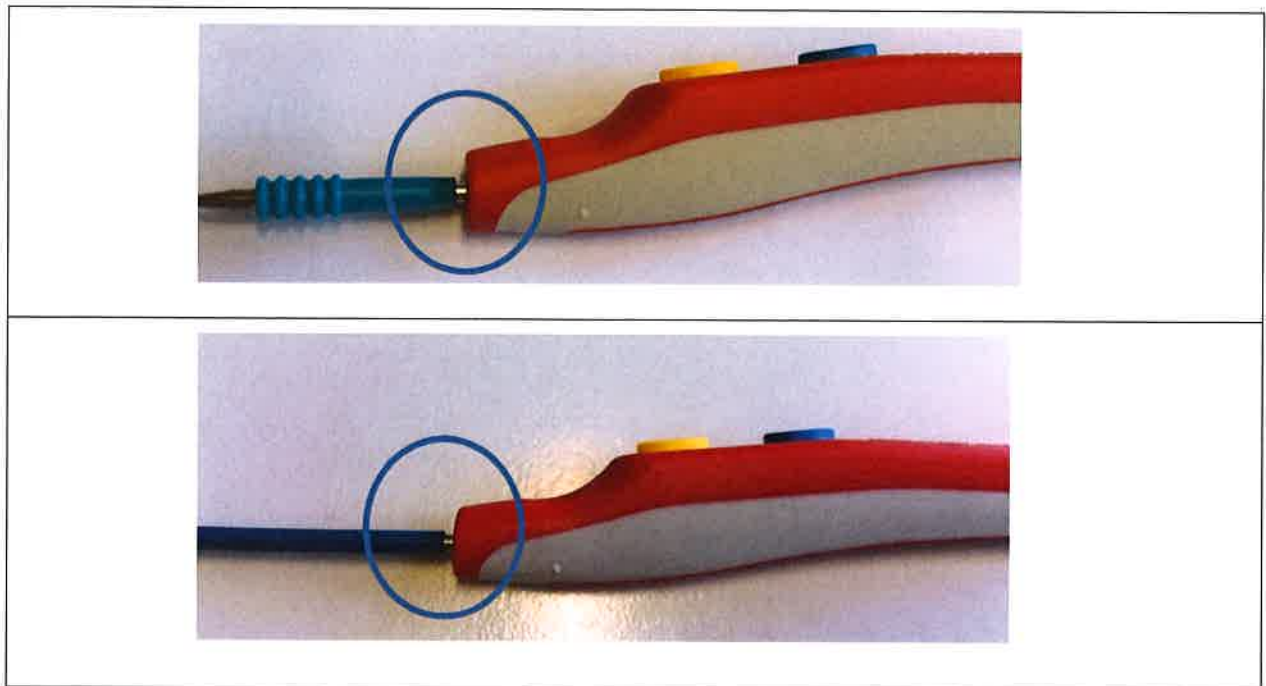
**Possible risks of a plug connection**

When inserting the monopolar active electrode, make sure that the electrode is inserted until the limit stop. **No metallic parts may be free or visible in the transition to the handle.** The electrode isolation and, if any, the six-edge must be obscured by the tip of the electrode intake of the handle.

In the following you will find corresponding illustrations of a properly inserted active electrode.



A handle electrode combination, in which metallic parts (see marker in the following illustrations) are free or can be seen, **must not be used** as this can lead to a bypass and a burning in the worst case.



### Transmission of this supplement product information

Please ensure that all users of these products and other persons to be informed in your organization are aware of this additional product information. If you have submitted the products to third parties, please forward a copy of this supplementary product information or inform the contact persons below. Please keep this information at least until you have informed all the people in your company to be informed.

### Gebrüder Martin GmbH & Co.KG

The Federal Institute of Medicines and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) has received a copy of this supplementary product information.

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.-IdNr.: 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 Stuckenbrock

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 31 TUT  
Commerzbank AG, Filiale Tuttlingen: BLZ 694 400 70 · Kto. 0 241 215 300  
IBAN DE 88 6944 0007 0241 2153 00 · BIC COBADE33 694

Please do not hesitate to contact us in case of any further questions.

With kind regards

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

i.V.



Reinhold Bücher  
Head of Quality Management/ RA

i.A.



Christian Tockweiler  
Senior Product Manager  
Electrosurgery and Laser