Important Customer Information: Third-Party Repairs of Bipolar Forceps

PRECISION ELECTROSURGERY
Made in Germany

Dear customers,

As a manufacturer of medical products, Sutter Medizintechnik GmbH is liable in accordance with national and European medical product laws and the Product Liability Act for the quality and safety of their products. These are only guaranteed if the products are used for their intended purpose and if regulations for use, reprocessing and repair are followed as stated in the manufacturer's instructions for use.

We have noticed an increased number of bipolar forceps that were originally manufactured by Sutter Medizintechnik and later repaired by other companies. This happens without our knowledge and without our approval. In some cases, significant product changes are made and the modified instruments are often defective or not marked at all.

We do not know about the extent to which the responsible people follow medical device regulations, including risk assessment, material selection, biocompatibility, manufacturing processes, and test criteria of our forceps.

According to the instructions for use, repairs of our products may only be carried out by us or by an assigned company. Otherwise any warranty and further liability claims against Sutter Medizintechnik expire.

Please note the following instructions regarding modified bipolar forceps:

- In case of significant changes, Sutter products repaired by third parties no longer meet our specifications and performance characteristics, so that we can no longer guarantee the effectiveness and safety of the products.
- According to medical device legislation, the modification of products may correspond to a new introduction on the market. Under certain circumstances, the user/hospital or repair company may become the manufacturer themselves according to the Medical Devices Act and bears responsibility in the event of damage. In this case, a new conformity assessment procedure involving a Notified Body must also be carried out.
- Incorrect labelling of the products corresponds to a violation of the medical device legislation. If the CE marking is removed from an instrument as a result of a repair, the liability of Sutter Medizintechnik expires.

We ask you to take note of this information and to check whether you, as the operator, might unintentionally order repairs of Sutter products by external companies.

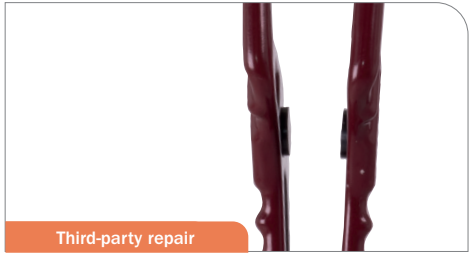
Thank you!

Examples of significant product changes:

Comparison of tips

The tips have been repaired, which significantly changes the characteristics of the forceps and may affect the performance.

Guide-Stop™



The patented Guide-Stop™ has been modified. This may change the spring force of the forceps and the tips may not close precisely.

Examples of significant product changes:

Connector and labeling (batch number und CE marking)

Front

Back

Original

Front

Back

Third-party repair

The connector of the CE-marked instrument has been replaced. The labeling indicates the mandatory batch number and CE marking according to §6 MPG and article 20 of the regulation (EU) 2017/745 (MDR).

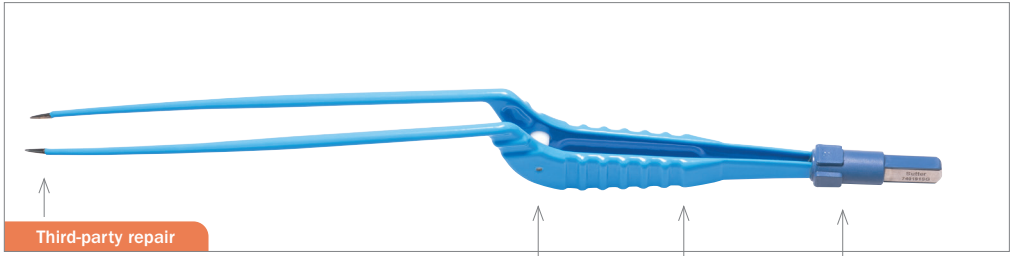
- If the batch number is missing, the instrument can no longer be traced. Thus, in case of manufacturer information or recall actions, the products cannot be assigned.
- Electrical safety according to the IEC standard may no longer be guaranteed.

We have informed the responsible regional council and our Notified Body about these facts.

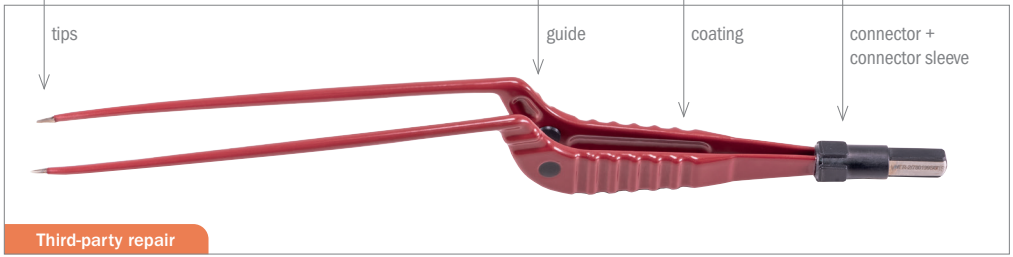
Examples for Significant Changes:

Full view

Original



Third-party repair



Third-party repair

Essential elements of the original product have been changed. These changes may affect product performance and result of the operation, and may also eliminate the mandatory traceability.

The images of the repaired forceps are actual examples.

Please do not hesitate to contact us if you have any questions.

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