



Important product information
about reprocessed and altered
medical devices

Customer information

Important product information about reprocessed and altered medical devices

Customer information

Medical devices from our company bear not only the KLS Martin logo as a quality attribute, but also the required information¹, such as article number, batch or production identification and CE identification. With the logo, we guarantee that the product is manufactured with the utmost care, which also results in our guarantee promise.

According to law², the operator is responsible for the maintenance of the medical devices. In this regard, it is of great importance that a repair always is performed by authorized service providers in order to ensure conformity and that the validity of the processing instructions is not lost, as well as to maintain claims from the guarantee which we assume.

These requirements are generally not met by medical devices which are processed or repaired by unauthorized service providers.

¹ See EC Directive "Medical Devices" 93/42/EEC, Annex 1, Paragraph 13.3, Section 6 MPG

² See Section 3 MPBetreibV



If a medical device is substantially modified, it may no longer fulfil the legal security requirements which apply at the time of first being placed on the market. In such a case, the technical processor can become a “[...] *manufacturer of a reconditioned medical device within the meaning of the MPG*”³ and thereby the (new) distributor with the responsibility for the documentation which is relevant for authorization.

By means of a professional hygienic reprocessing and proper use in accordance with the instructions for use, maintenance measures can be kept low and the quality of the instruments can remain high.

³ See Böckmann/Frankenberger, Durchführungshilfen zum Medizinproduktegesetz Schwerpunkt Medizintechnik und In-vitro-Diagnostik [Implementation Aids to the Medical Devices Act, Focus on medical technology and in vitro diagnostics]

Examples of significantly modified medical products

Bipolar forceps

Bipolar forceps are used to prepare, grasp, manipulate and coagulate tissue.

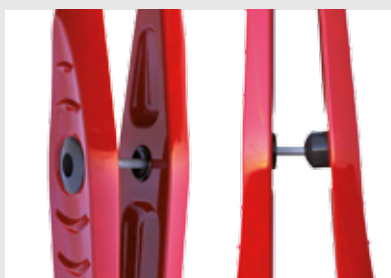
Possible problems in the event of improper repair:

- Replacement of the insulation with non-validated materials
- Replacement of the guide sleeve and connector with unauthorized spare parts
- Reworked geometry of the workload peaks can lead to a different bearing surface

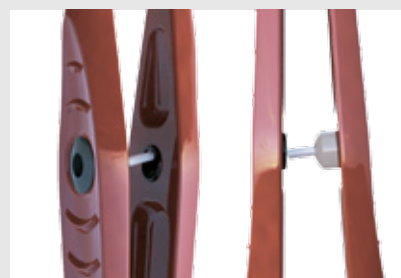
Result:

- Danger to the patient and the user
- Uncontrolled flashovers and burns
- Stress resistance and biocompatibility cannot be guaranteed

Repair by the manufacturer



Unauthorized/faulty repair



Recoilless mallet

With the help of other medical devices, mallets are used to prepare bones or to insert nails into them, for example.

Possible problems in the event of improper repair:

- Change or renewal of the welding seam
- Reworked surfaces with too much material removal
- Resulting lack of welding joint

Result:

- Risk of fracture
- Leakage of the filling
- Hygienic problem
- Risk of infection
- Consequential damages

Repair by the manufacturer



Unauthorized/faulty repair



Suction flushing pipe

Aspirators are used in medical technology to suction various liquids from the operating field, such as secretion, blood, fat or saline solutions.

Possible problems in the event of improper repair: :

- Insufficient solder joint
- Leakage, not fully functional, uncontrolled discharge of flushing fluid

Result:

- Risk of fracture
- Hygienic problem
- Risk of infection
- Consequential damages

Repair by the manufacturer



Unauthorized/faulty repair



Forceps

Forceps are used to hold and grip tissue, organs, medical supplies and materials.

Possible problems in the event of improper repair:

- The spring part was not properly reworked

Result:

- Forceps break during surgery
- Forceps do not grip when closing
- Delay in the gap of the spring part
- Forceps cannot be fully prepared

Repair by the manufacturer



Unauthorized/faulty repair



Examples of significantly modified medical products

Needle holders

Needle holders are used to grip and hold surgical suture needles during an operation.

Possible problems in the event of improper repair:

- Faulty solder joints, inadequately positioned jaw and arm parts
- Easy onset for corrosion, needle can fall out of the needle holder during operation, TC inserts can rupture during suturing

Result:

- Patient injury through uncontrolled suturing
- Aborted TC inserts can access the open operating field
- Complete cleaning of the defective soldering points cannot occur

Repair by the manufacturer



Unauthorized/faulty repair





marManagement

KLS Martin presents a concept for efficient instrument management in your clinic!
 The marManagement concept consists of three modules which can be used individually or combined:

Instrument Audit

- Quantitative and qualitative analysis of instruments
- Classification of the instruments according to different quality levels
 - reconditioned
 - in need of repair
 - in need of replacement
- The result is the documentation of the instruments with the appropriate quality level along with recommendations concerning cleaning and handling

Repair service marRep

- Repair with original manufacturer spare parts
- Service agreements
- Advantages through official repair:
 - Extended lifetime
 - Functional maintenance
 - Reduces absence of the products
 - Limited patient risk



Set optimization

- Improvement can only be achieved by means of continuous optimization
- Analysis of the instruments which are actually used during the surgery with the help of the user
- Reduction/optimization of the content of the tray to increase the efficiency of the clinics

KLS Martin App: Surgical Instruments, Education, Reprocessing



iOS



Android



Please scan one of the QR codes to download the KLS Martin App: **SER**

KLS Martin Group

KLS Martin Australia Pty Ltd.

Sydney · Australia
Tel.: +61 2 9439 5316
australia@klsmartin.com

KLS Martin India Pvt Ltd.

Chennai · India
Tel. +91 44 66 442 300
india@klsmartin.com

Martin Nederland/Marned B.V.

Huizen · The Netherlands
Tel. +31 35 523 45 38
nederland@klsmartin.com

KLS Martin LP

Jacksonville · Florida, USA
Tel. +1 904 641 77 46
usa@klsmartin.com

KLS Martin do Brasil Ltda.

São Paulo · Brazil
Tel.: +55 11 3554 2299
brazil@klsmartin.com

Martin Italia S.r.l.

Milan · Italy
Tel. +39 039 605 67 31
italia@klsmartin.com

Gebrüder Martin GmbH & Co. KG

Moscow · Russia
Tel. +7 499 792-76-19
russia@klsmartin.com

Gebrüder Martin GmbH & Co. KG

Shanghai · China
Tel. +86 21 5820 6251
china@klsmartin.com

Nippon Martin K.K.

Tokyo · Japan
Tel. +81 3 3814 1431
nippon@klsmartin.com

Gebrüder Martin GmbH & Co. KG

Dubai · United Arab Emirates
Tel. +971 4 454 16 55
middleeast@klsmartin.com

KLS Martin France SARL

Mulhouse · France
Tel. +33 3 8951 3150
france@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.

Penang · Malaysia
Tel.: +604 505 7838
malaysia@klsmartin.com

KLS Martin UK Ltd.

London · United Kingdom
Tel. +44 1189 000 570
uk@klsmartin.com

Gebrüder Martin GmbH & Co. KG

A company of the KLS Martin Group

KLS Martin Platz 1 · 78532 Tuttlingen · Germany
P.O. Box 60 · 78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

