Deutsch
English
Español
Français
Italiano
Português

Bipolares Versiegelungssystem marSeal5 plus/ - Maryland
Bipolar Sealing System marSeal5 plus/ - Maryland
Sistema de sellado bipolar marSeal5 plus/ - Maryland
Système de scellement bipolaire marSeal5 plus/ - Maryland
Sistema di sigillatura bipolare marSeal5 plus/-Maryland
Sistema de selagem bipolar marSeal5 plus/ - Maryland

Gebrauchsanweisung
Instructions for Use
Instrucciones de uso
Mode d’emploi
Istruzioni per l’uso
Instruções de utilização

CE 0297

REF 90-060-58-10
Revision 09
Date of Release: 2023-11

Contents

1 General Information

1.1 Manufacturer

Thank you for buying one of our products.

This product bears the CE marking, which means that it fulfills the basic requirements for the safety and performance of medical devices in the context of the applicable European regulations.

We are the manufacturer of this product:

KLS Martin SE & Co. KG

A company of the KLS Martin Group
KLS Martin Platz 1 · D-78532 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

1.2 Hotline

Should you have any questions on how to handle the device or product, or how to use it for clinical applications, please do not hesitate to contact Product Management:

Phone: +49 7461 706-0

E-mail: info@klsmartin.com

In case of technical questions and questions regarding maintenance contracts and training, please contact our Martin Service Center:

Phone: +49 7461 706-343

E-mail: service@klsmartin.com

NOTICE

Each item of packaging and some products are marked with a lot number (LOT) and a catalog number (REF). Please always provide LOT and REF in case of a complaint.

1.3 Obligation to Report Incidents

All serious adverse events occurring in connection with the product must be reported to the manfacturer and the respective authorities without delay.

1.4 Summary of Safety and Clinical Performance

The summary of safety and clinical performance of the medical device is available in the European Database on Medical Devices (EUDAMED).

1.5 Notes on this Document

⚠WARNING

Possible danger to life of patient, user and third parties if these Instructions for Use are not observed

Read and observe the Instructions for Use completely. In particular, be sure to note all cautionary and warning notices.

This document refers to persons of all genders alike. Reference to individual genders is avoided purely for reasons of improved readability.

The electronic version of these Instructions for Use can be requested at www.klsmartin.com.

1.6 Terms & Acronyms

Designation	Description
B1, B2	Bipolar outputs of the electrosurgical unit
CJD	Creutzfeldt-Jakob disease
HF	High frequency
HW	Hardware release
LTP	Low-temperature plasma sterilization
W/D	Washer-disinfector
PU	Packaging unit
CSSD	Central Sterile Services Department (central sterilization)

1.7 Validity of this Document

The marSeal5 plus can be operated with finger switches as well as with foot switches. The corresponding IQ connector supports Plug & Play. Software release 3.423 of the electrosurgical unit maxium® is required to use the marSeal5 plus.

1.8 Accompanying Documents

- Processing instructions marSeal5 plus/marSeal5 plus Maryland (REF 90-334-51-10)

2 Scope of Delivery

Designation	REF
marSeal5 plus, complete, tubular shaft 370 mm, Ø 5 mm, “IQ” connector, including cleaning tool and flushing adapter set	80-633-00-04
marSeal5 plus Maryland, complete, tubular shaft 450 mm, Ø 5 mm, “IQ” connector, including cleaning tool and flushing adapter set	80-633-01-04
marSeal5 plus Maryland, complete, tubular shaft 370 mm, Ø 5 mm, “IQ” connector, including cleaning tool and flushing adapter set	80-633-02-04
marSeal5 plus Maryland, complete, tubular shaft 230 mm, Ø 5 mm, “IQ” connector, including cleaning tool and flushing adapter set	80-633-03-04
marSeal5 plus handle	80-633-04-04
Tubular shaft 370 mm, Ø 5 mm, consisting of inner and outer tube	80-633-05-04
Tubular shaft Maryland 450 mm, Ø 5 mm, consisting of inner and outer tube	80-633-06-04
Tubular shaft Maryland 370 mm, Ø 5 mm, consisting of inner and outer tube	80-633-07-04
Tubular shaft Maryland 230 mm, Ø 5 mm, consisting of inner and outer tube	80-633-08-04
Cleaning tool	80-633-12-04
Flushing adapter set consisting of: Flushing adapter with Luer lock connection and silicone hose for the outer tube Flushing adapter with Luer lock connection and silicone hose for the inner tube	80-633-13-04
Consumables	
Sterile blade holder 370 mm, single-use, sales unit = 10 pcs	80-633-09-04
Non-sterile blade holder 370 mm, single-use, sales unit = 10 pcs	80-633-11-04
Sterile blade holder 230 mm, single-use, sales unit = 10 pcs	80-633-10-04
Non-sterile blade holder 230 mm, single-use, sales unit = 10 pcs	80-633-14-04
Sterile blade holder 450 mm, single-use, sales unit = 10 pcs	80-633-15-04
Non-sterile blade holder 450 mm, single-use, sales unit = 10 pcs	80-633-16-04

2.1 Inspection of the Delivery for Completeness and Correctness

Immediately upon receipt, the goods must be checked for completeness and freedom from damage.

Any transport damage must be reported immediately.

After delivery of the product, check the original packaging and the packaging seal for intactness.

Sterile products with a broken seal or damaged sterile packaging must be considered non-sterile and must not be released for use.

3 Intended Use

3.1 Intended Purpose

The bipolar sealing instrument marSeal5 plus is intended for permanent occlusion of veins, arteries and tissue bundles, with subsequent dissection of the sealed tissue using the same instrument. The instrument can be used in both open surgery and laparoscopy.

3.2 Indications

The indications result from the intended purpose.

3.3 Contraindications

- Tube ligation with the marSeal5 plus is not a reliable procedure for contraception
- Not for use on the appendix!

3.4 Clinical Benefit

Sealing of vessels and tissue bundles with subsequent separation and without instrument change.

3.5 Possible Adverse Effects

If used correctly, no product-specific side effects are known. The user is responsible for educating the patient about the possible side effects and complications associated with the surgical procedure.

3.6 Residual Risks

The user is responsible for informing the patient about existing residual risks in connection with the use of this product.

3.7 Patient Target Group

There are no restrictions regarding the patient target group.

3.8 Users

The products are to be used exclusively by qualified surgical staff.

Cleaning, disinfection and sterilization are carried out by trained qualified staff in the processing unit for medical products.

3.9 Ambient Conditions during Application

Application is restricted to the OR under proper surgical conditions or to medical areas intended for this purpose.

3.10 Limitations of Use

⚠WARNING

Danger of injury in case of insufficient qualification of the user!

Safe use of the marSeal5 plus in combination with the current type SealSafe® IQ requires the user to be familiar with the technology and applications of electrosurgery.

Instruments for electrosurgery may be used only by persons who have been specially trained or instructed in their use!

⚠CAUTION

Danger of injury from improper application and abuse or misuse!

Tube ligation with the marSeal5 plus is not a reliable procedure for contraception!

Not for use on the appendix!

⚠CAUTION

Danger of injury from an excessive number of processing cycles!

With each application, the wear of the instrument progresses. The instrument is designed for maximum of 50 applications, provided the instrument is cleaned and processed according to the information in the Instructions for Use and subjected only to loads typical for the respective indication. The possible number of applications depends heavily on the type of application, preparation and maintenance of the instrument. After 50 applications the instrument must be disposed and replaced with a new instrument.

- Use the cycle counter to mark the processing cycles already performed.

3.11 Warnings

⚠WARNING

Non-compliance with the safety measures may result in serious or even fatal injury to the patient!

⚠WARNING

Danger of explosion and fire from flammable gases!

No flammable anesthetic gases or oxidizing gases may be used in combination with the bipolar sealing system marSeal5 plus.

- Before sealing, ensure that no endogenous gases are present in the area of application.

⚠WARNING

Risk of burns upon contact of the active electrode with metallic parts!

Upon contact of the active electrode with metallic parts, shunts for the HF-current or concentrated leakage current paths can form. These can cause burns.

- The energized, blank metallic jaw part must have a safety distance of at least 1 cm from the metallic trocar end during activation!
- Do not touch any other metallic instruments or objects during activation!

⚠WARNING

Danger of electromagnetic interference in the presence of active implants!

In patients with pacemakers or other active implants, there is danger of interference with or damage to the active implant.

- Before performing the surgery, consult a cardiologist and the manufacturer of the pacemaker or active implant!

⚠WARNING

Danger of injury from hot surfaces!

The electrodes in the jaw part and the outer surfaces of the jaw part are so hot due to the heat conduction even after the sealing procedure that they can cause unintentional burns.

- Avoid contact with the jaw part and tissue contact immediately after sealing!

⚠WARNING

Danger of injury from unintentional contact with the patient's tissue!

Unintentional activation, e.g. via the foot switch, can lead to burns and electric shocks if the electrosurgical device is placed on the patient and thus comes into contact with tissue!

- Do not place temporarily unused instruments on the patient in the intervals between use!
  - Place instruments separately from the patient, e.g. on the instrument table!
- Seal only if the jaw part of the instrument is located within sight! Unintentional activation or movement of the instrument may result in injury to the patient!
- Do not touch any other metallic instruments or objects during the sealing process!
- Always avoid accidental tissue contact or contact with similar low-resistance materials (e.g. liquids) of the instruments!

⚠WARNING

Danger of injury for patient and user from improper application!

Improper application and abuse or misuse may result in injury to patient and user and/or premature wear of the sealing system!

- Clean and sterilize the marSeal5 plus before each use, see section 6 “Cleaning, Disinfection and Sterilization”, page 72.
- Insert and pull out the instrument into/from the trocar only with the jaw part closed!
- Use the bipolar sealing system only for its intended purpose, see section 7.1 “Functional Check”, page 88.
- Avoid touching exposed metal parts on the instrument (handle plate must be properly mounted on the handle), see section 4.1 “Assembling the Handle”, page 61.
- During the functional check, see section 7.1 “ Functional Check”, page 88, there is a danger of injury from the sharp blade! The sterile working method must at all times be carried out in such a manner that no contamination of the sterile surgical gloves and the sterile blade holder occurs.
  - Avoid touching the sharp blade!
  - Ensure that the blade never touches hard objects.
- Route the connection cable so that it touches neither the patient nor other cables, and does not form an obstacle. Protect the cable from mechanical damage (running over, crushing, bending)!
- Use of high-frequency devices can interfere with other devices!

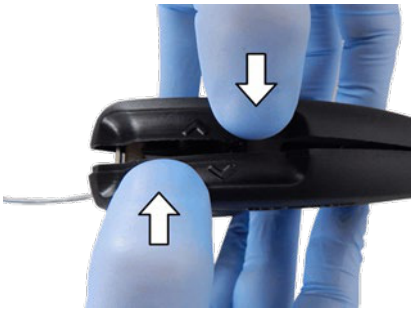
⚠WARNING

Possible danger to life for third parties in case of shipment of contaminated products!

In the case of return shipments, send only clean and disinfected products in sterile packaging.

4 Mounting / Installation

4.1 Assembling the Handle



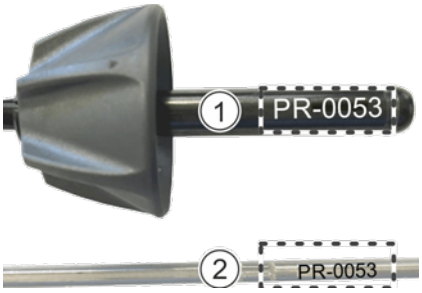
- Remove the handle and handle plate from the tray basket.
- Now press handle and handle plate together until the handle plate latches audibly. The two handle plates are held in place by magnets.

4.2 Assembling the Tubular Shaft

The tubular shaft consists of an outer tube and an inner tube.

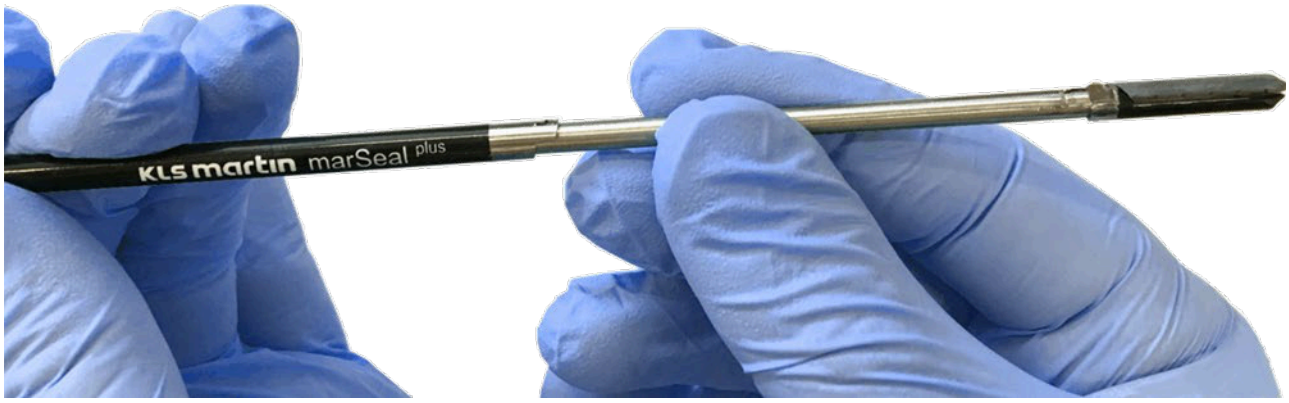
Outer tube (1)

Inner tube (2) with jaw part

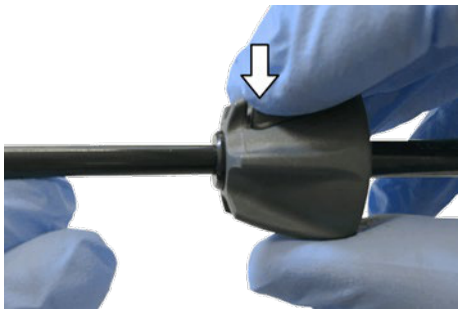


The outer tube (1) and the inner tube (2) are marked with a continuous serial number.

- Before each assembly, make sure that the two parts have the same serial number.

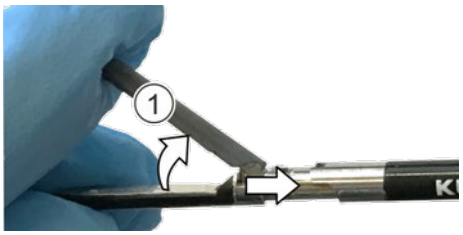


- Slide the inner tube into the front opening of the outer tube until a resistance can be felt.

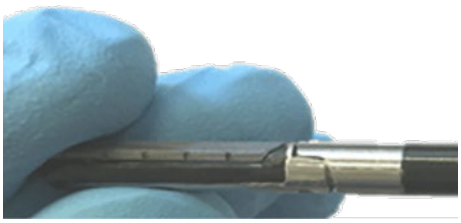


- As soon as resistance can be felt, push the button on the rotary wheel and slide the inner tube 1–2 cm deeper into the outer tube. Then release the button.

- Align the inner and outer tubes with each other by turning them until they are felt to click into place. The slot on the front edge of the outer tube and the bead on the movable jaw part are then in the correct position.



- Fully open the jaw part (1).
- Slide inner tube into outer tube until they are felt and heard to click into place.



- Close the jaw part.

- Inner and outer tubes are fixated.

4.3 Functional Check of the Tubular Shaft

- By pressing and pulling on the inner tube from the rear, make sure that the inner and outer tubes are fixated. If the tubes are properly fixated, the jaw part opens and closes.

5 Operation/Use/Application

5.1 Description of the Components

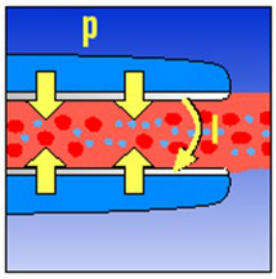
Illustration	Designation
Product components	
	marSeal5 plus, complete, with tubular shaft Ø 5 mm, length 370 mm, including cleaning tool and flushing adapter set The instrument tips and the shaft length vary depending on the model ordered.
	Handle with IQ connector
	Outer tube The shaft length varies depending on the model ordered
	Inner tube with jaw part The instrument tips and the shaft length vary depending on the model ordered
	Non-sterile blade holder 450 mm, single-use, sales unit = 10 pcs
	Non-sterile blade holder 370 mm, single-use, sales unit = 10 pcs
	Non-sterile blade holder 230 mm, single-use, sales unit = 10 pcs
	Instructions for Use: Bipolar sealing system marSeal5 plus and enclosure “Processing information according to DIN EN ISO 17664”

Illustration	Designation
Accessory Components for the Instrument	
	Sterile blade holder 450 mm, single-use, sales unit = 10 pcs
	Sterile blade holder 370 mm, single-use, sales unit = 10 pcs
	Sterile blade holder 230 mm, single-use, sales unit = 10 pcs
Illustration	**Designation**
Accessory Components for Cleaning	
	Cleaning tool
	Flushing adapter set consisting of: Flushing adapter with Luer lock connection and silicone hose for the outer tube Flushing adapter with Luer lock connection and silicone hose for the inner tube

The blade holder with integrated blade for tissue separation is a consumable. It is available both sterile and non-sterile. It is not included in the scope of delivery of the instrument and must be ordered separately, see section 7.2 “Consumables”, page 89.

5.1.1 Structure, Functionality and Performance Characteristics

The bipolar sealing instrument marSeal5 plus is intended exclusively for use with the electrosurgical unit maxium® (REF 80-042-00-04, REF 80-042-02-04 and REF 80-042-04-04, type ME 402) from software version V3.423, or new developments by the manufacturer. The IQ connector of the marSeal5 plus can be connected to the bipolar socket B 1 or B 2 of the electrosurgical units maxium®. The current type SealSafe® IQ is selected automatically. It can be used exclusively with IQ instruments (Plug & Play)!



The combination of mechanical pressure (p) and high-frequency current-induced coagulation (I) creates a reliable and permanent sealing zone on arteries, veins or tissue bundles. It is of vital importance that the pressure is maintained at a constant level for the entire duration of the application.

Vessels up to a maximum diameter of 7 mm can be permanently sealed. In the case of large vessels, double sealing applied side by side is recommended. The vessel can then be cut in the middle using the integrated blade.

The maximum sealing length is approx. 20 mm, of which a maximum of approx. 19 mm are cut.

The electrosurgical unit maxium® offers a bipolar coagulation current type that is adapted to the sealing of tissue and tissue layers and specifically designed for use with the marSeal5 plus:

- current type SealSafe® IQ for marSeal5 IQ and marSeal5 plus instruments.

The manufacturer guarantees reliable functioning for a maximum of 50 cycles, provided the instrument is cleaned and processed according to the information in the Instructions for Use and subjected only to loads typical for the respective indication.

For control, the instrument is equipped with a cycle counter, see section 3.10 “Limitations of Use”, page 58, which allows marking the number of processing cycles already performed. The number of processing cycles must not be exceeded.

NOTICE

Please note the information about the “Sealing using SealSafe® IQ” method and the description of the SealSafe® IQ current type in the Instructions for Use of the electrosurgical unit maxium®.

The permissible maximum voltage is 300 Vp.

NOTICE

For correct operation and adjustment, the Instructions for Use of the electrosurgical unit maxium® must be observed.

5.1.2 Combination Products and Accessories

NOTICE

The bipolar sealing instrument marSeal5 plus is intended exclusively for use with the electrosurgical unit maxium® (REF 80-042-00-04, REF 80-042-02-04 and REF 80-042-04-04, type ME 402) from software version V3.423, or new developments by the manufacturer. The IQ connector of the marSeal5 plus can be connected to the bipolar socket B 1 or B 2 of the electrosurgical units maxium®. The current type SealSafe® IQ is selected automatically. It can be used exclusively with IQ instruments (Plug & Play)!

NOTICE

For correct operation and adjustment, the Instructions for Use of the electrosurgical unit maxium® must be observed.

- Connect the connection cable of the marSeal5 plus to the bipolar HF output B1 or B2 of the electrosurgical unit maxium®.
  - The electrosurgical unit maxium® automatically supplies the required current type SealSafe® IQ with a factory default setting G3.

If a foot switch is required for activation of the sealing current, it must be selected separately

.

5.2 Before First Use and Before Each Further Use

- Observe the safety notes, see section 3.11 “Warnings”, page 58
- A functional check must be carried out before each use, see section 7.1 “Functional Check”, page 88

⚠WARNING

Risk of infection in case of non-sterile handling!

Non-sterile handling and improper sterilization can cause severe health risks for the patient!

The instruments must be cleaned and sterilized before the first and any further use, see section 5.2 “Before First Use and Before Each Further Use”, page 68.

- Products in sterile packaging, such as the sterile blade holder REF 80-633-09-04, can be used directly from their sterile packaging without further pre-treatment.
- After each use, one indicator must be removed from the cycle counter before re-sterilization, see section 3.10 “Limitations of Use”, page 58.

5.3 Application / Intraoperative Procedure

5.3.1 Connection to the Electrosurgical Unit maxium®

NOTICE

The bipolar sealing instrument marSeal5 plus is intended exclusively for use with the electrosurgical unit maxium® (REF 80-042-00-04, REF 80-042-02-04 and REF 80-042-04-04, type ME 402) from software version V3.423, or new developments by the manfuacturer. The IQ connector of the marSeal5 plus can be connected to the bipolar socket B 1 or B 2 of the electrosurgical units maxium®. The current type SealSafe® IQ is selected automatically. It can be used exclusively with IQ instruments (Plug & Play)!

NOTICE

For correct operation and adjustment, the Instructions for Use of the electrosurgical unit maxium® must be observed.

- Connect the plug or connection cable (8) of the marSeal5 plus to the bipolar HF output B1 or B2 of the electrosurgical unit maxium®.
  - The electrosurgical unit maxium® automatically supplies the required current type SealSafe® IQ with a factory default setting G3.

If a foot switch is required for activation of the sealing current, it must be selected separately.

5.3.2 Sealing

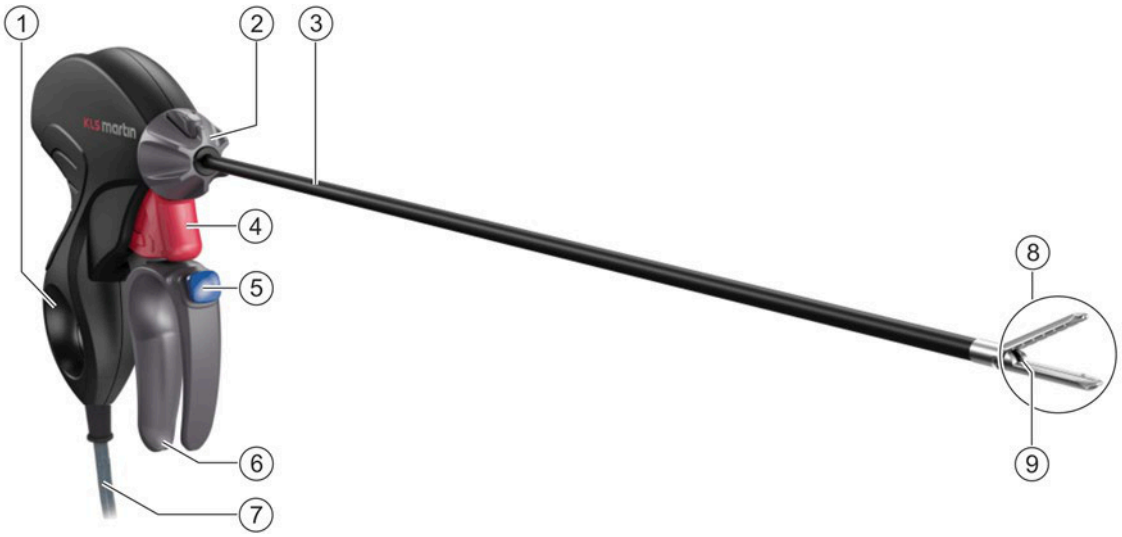


Fig. 5-1: Sealing

- Using the rotating wheel (2) of the tubular shaft, rotate the jaw part (8) to an ergonomically optimal position.
- Then grasp the tissue to be treated with the jaw part (8).
- Close and lock the jaw part (8). At the same time, press the movable handle (6) until the ratchet integrated in the handle (1) latches audibly.
- Activate the sealing current by pressing the blue button (5). The electrosurgical unit maxium® finishes the sealing process automatically and confirms this acoustically. This shuts down the current automatically before carbonization of the tissue can occur.
- Press the red pushbutton (4) of the blade trigger. Thereby the integrated blade (9) is pushed through the tubular shaft (3) and jaw part (8), cutting the sealed tissue.
- The latch of the jaw part is released by actuating the movable handle (6) again, and the jaw part (8) is opened.

⚠WARNING

Risk of infection in case of non-sterile handling!

Non-sterile use and improper sterilization can cause severe health risks for the patient!

- Sterility of the sterile blade holder (REF 80-633-09-04, REF 80-633-10-04, REF 80-633-15-04) can be guaranteed only if the packaging is undamaged.
- Do not use after the expiration date indicated on the packaging.
- Insert the sterile-packaged new blade holder only after the instrument has been sterilized and only in the sterile operating area.
- Blade holders are single-use items.
  - Remove the blade holder following each application!
  - Dispose of used blade holders!
- Never process blade holders!
- Never reuse blade holders!

⚠WARNING

Danger of injury or tissue damage from incorrect operation!

- Before starting the sealing process, verify that you have grasped the correct structures, in order to prevent inadvertent capture of healthy structures such as ureter, nerve tracts, intestinal loops, etc.!
- Permanent occlusion is possible for vessels up to 7 mm in diameter. Placing two seals side by side is recommended for large vessels. The integrated blade can then be used to cut between these. The maximum sealing length of the instrument is 20 mm, of which approx. 19 mm are cut.
- Ensure that the tissue structures to be sealed are not too thin. For the sealing process, the amount of tissue must sufficiently fill the space between the electrodes after latching them!

⚠WARNING

Danger of bleeding in case of improper application!

- Never press the blade trigger during vessel sealing. The blade must be retracted into the instrument; otherwise it will cause a short circuit, and no sealing will occur.
- Do not cut grasped tissue with the blade before completion of the sealing process!
- Perform cut only after the electrosurgical unit maxium® has properly signaled the end of the sealing process!
- Reliable vessel sealing is not guaranteed when the instrument's jaws are immersed into electrically conductive liquids, due to resulting current conduction through the liquid (shunt circuit)!
- Tissue particles can get caught in the electrodes, the blade guides and the joints. Such incrustations can impair the proper functioning of the instrument (due to electric shunts or blade holder jamming). Use the supplied cleaning tool, a brush or swab and sterile water to clean the instrument.

⚠WARNING

Danger of injury from hot surfaces!

As a result of heat conduction, the electrodes in the jaw part and the outer surfaces of the jaw part become very hot during the sealing process and remain so even after the sealing process has been completed, so they can cause accidental burns.

- Avoid touching the jaw part and contact with tissue during and immediately after the sealing process!

5.4 After Completion of the Application

NOTICE

It is recommended to carry out disassembly immediately after the application in the operating theater.

To separate the tubular shaft from the handle, it must not be locked. The jaw part of the tubular shaft must be open!

NOTICE

The use must be documented in the patient file (if a sterile blade is used) by entering the item description as well as the REF and LOT numbers. Only this way can clear traceability be ensured.

6 Cleaning, Disinfection and Sterilization

⚠WARNING

Possible danger to life of the patient in case of non-sterile handling!

Products supplied in non-sterile condition must be cleaned, disinfected and sterilized before the first and any further use.

- In case of patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible CJD variants, processing of the products must be carried out according to the applicable national regulations.
- The operator/processor is responsible for cleaning, disinfecting and sterilizing the products used. It is essential that national regulations, including restrictions, be observed.

The processing procedure must be validated prior to use of the medical device. The operator/processor is responsible for this.

Products delivered in sterile condition (blade in sterile packaging) are marked with the corresponding symbol. They may be removed from the packaging only immediately before use. The expiration date and the intactness of the sterile packaging must always be checked before use.

Because of potentially inadequate labeling on the product, products that have been removed from their sterile packaging but have not been used and are not contaminated cannot be considered equivalent to products that have been obtained as non-sterile products. In this case, the operator/processor is responsible for use including labeling, cleaning, disinfection and sterilization.

The specific information for each reference number for the following section is available at:

www.klsmartin.com/processing

6.1 Limitations and Restrictions on Cleaning, Disinfection and Sterilization

⚠WARNING

Possible danger to life of the patient from cleaning, disinfection and sterilization of contaminated single-use products!

Single-use products that have not been used but have come into contact with bodily fluids, blood, tissue and/or similar are to be considered used and must be discarded.

Cleaning, disinfection, sterilization and use can increase the risk of contamination, e.g. by carryover of germs.

⚠CAUTION

Danger of injury from an excessive number of processing cycles!

With each application, the wear of the instrument progresses.The manfuacturer guarantees reliable functioning for a maximum of 50 cycles, provided the instrument is cleaned and processed according to the information in the Instructions for Use and subjected only to loads typical for the respective indication. The manufacturer recommends discontinuing use after this time and replacing the marSeal5 plus to ensure risk-free and safe operation.

- Use the cycle counter to mark the processing cycles already performed.

Product lifetime is usually determined by wear and damage during instrument use. Possible damage includes: Loss of insulation on the cable, dirt on the jaw part that cannot be removed, damaged or scratched contact surfaces with tissue adhesion, deterioration of function due to decreasing compressive force in the jaw part, loosening or wear of components, bent tubular shaft.

- At the end of the product lifetime, dispose of the marSeal5 plus in accordance with national regulations, see section 9.3, “Disposal”, page 92.

6.2 Pre-Treatment at the Application Location prior to Cleaning

NOTICE

It is recommended to carry out disassembly immediately after the application in the operating theater.

To separate the tubular shaft from the handle, it must not be locked. The jaw part of the tubular shaft must be open!

Conduct the cleaning and disinfecting of contaminated instruments as soon as possible after use.

The following generally applies:

The sooner the inner lumina are cleaned, the better the result will be. Should it not be possible to comply with this time due to the length of the application or due to organizational aspects, it is the user's own responsibility to specify and validate measures in order to prevent drying of the contaminants, or to ensure success of the cleaning despite drying, respectively.

We generally recommend dry return transport in a closed transport container without addition of liquids, cleaning agents or disinfectants.

6.3 Preparation before Cleaning

6.3.1 Disassembly of the Instrument

- Clean the marSeal5 plus in disassembled state.

The instrument must always be cleaned manually and mechanically.

NOTICE

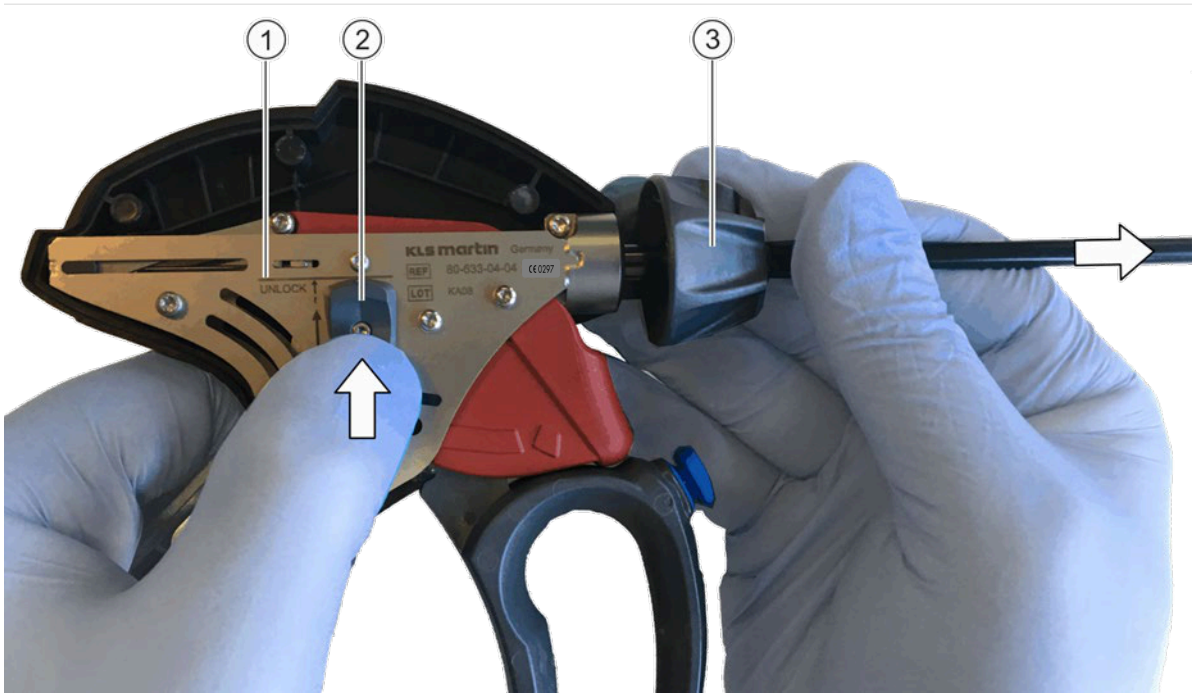
It is recommended to carry out disassembly immediately after the application in the operating theater.

To separate the tubular shaft from the handle, it must not be locked. The jaw part of the tubular shaft must be open!

6.3.2 Disassembly into Handle, Tubular Shaft and Blade Holder

- To remove the tubular shaft, open the handle by pushing apart the handle plates.

Handle disassembled into 2 handle plates



- Push the slider (2) up to the marking (1).
- Pull the tubular shaft (3) off the handle.

6.3.3 Removal of the Blade Holder

- Unscrew the knurled nut (1).

- Pull the blade holder (2) out of the tubular shaft.

6.3.4 Disposal of the Blade Holder

⚠WARNING

Danger of infection and risk of damage in case of improper processing!

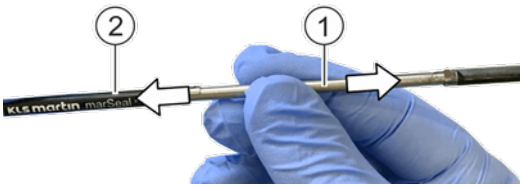
Non-sterile application can cause severe health risks for the patient!

- Sterile and non-sterile blade holders are single-use products and must be disposed of after use in accordance with the applicable regulations!
- Never process and/or reuse blade holders! Processing the blade holder can damage the instrument!

After application and after the product has exceeded its lifetime, we recommend disposing of the blade holders in a germ-proof and puncture-proof container, see section 6.6 “Packaging”, page 81.

6.3.5 Disassembly of the Tubular Shaft into Inner and Outer Tube

- Press the button on the rotary wheel (marked in white in the illustration) and slide the inner tube to the front.



- Keep the button on the rotary wheel pressed, pull out the inner tube (1) from the outer tube (2).

The following figures show the inner and the outer tube after disassembly (the shaft length varies depending on the model)

Inner tube with jaw part

Outer tube

NOTICE

The outer tube and the inner tube are marked with a continuous serial number.

- Ensure that the two tubes stay together during the cleaning procedure and further use.

⚠CAUTION

Possible danger of injury to the patient from residues on the medical device!

Particles from cloths and brushes may get stuck on products with rough surfaces, threads, sharp edges, narrow gaps or the like.

- Use only soft, clean and lint-free cloths for drying.
- The brushes for ducts must be a little bit bigger than the inner diameter of the duct, and the shaft of the brush must be at least as long as the duct.

6.4 Cleaning and Disinfection

6.4.1 Manual Cleaning and Disinfection

Recommendations for manual cleaning: Validated cleaning and disinfection procedure acc. to DIN EN ISO 15883. Deviating cleaning procedures, validated acc. to DIN ISO 15883, are possible.

Manual pre-cleaning serves as preparation for machine cleaning.

6.4.2 Cleaning the Jaw Part

NOTICE

Risk of damaging the jaw part!

The supplied cleaning tool is used to clean the blade guide in the jaw part and the joint area. It must not be used for scraping off sealing residues on the electrodes, as the polished electrode surface could be scratched!

- To protect the electrode surface, use soft brushes, damp swabs or paint brushes.

- Clean the blade guide in the jaw part and the joint area using the cleaning tool.
- Clean the jaw part using nylon brushes, swabs and/or paint brushes until the coarse contamination has been removed.

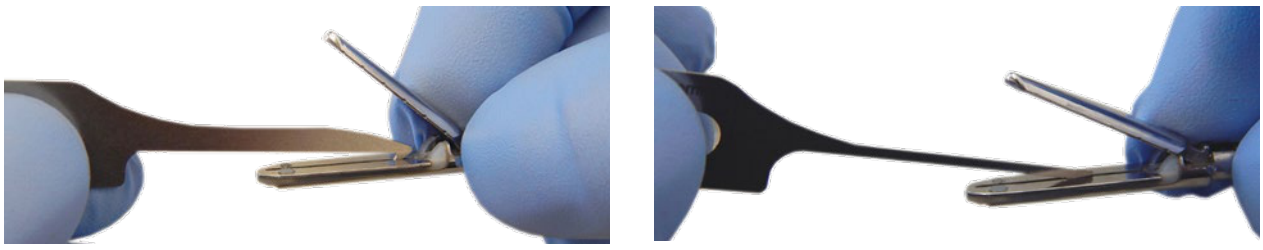


Fig. 6-1: Cleaning of the jaw part using the cleaning tool

6.4.3 Flushing the Tubular Shaft

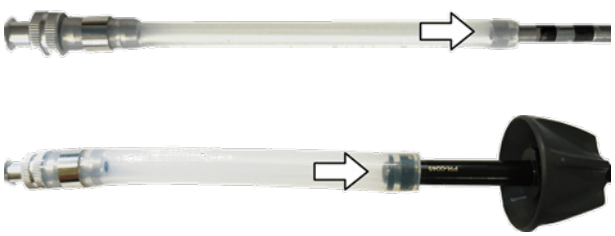
⚠CAUTION

Danger of injury from flushing water!

During the flushing of the inner and outer tubes with the flushing adapters provided for this purpose, there is risk of splashing!

- Perform the flushing process carefully.
- Protect eye area!

To ensure thorough and reliable internal cleaning of the inner and outer tubes, use the respective flushing adapter provided.



- Plug the silicone hose of the flushing adapter onto the inner tube.
- Plug the silicone hose of the flushing adapter onto the outer tube.

- Use the water jet gun to clean the inner and outer tubes via the Luer lock connection of the corresponding flushing adapter for at least 5 s in a pulsating manner.

- Alternatively, the inner and outer tubes can be cleaned directly with the water jet gun.

- Clean in ultrasonicator with e.g. neodisher® MediClean forte, working solution 0.5 % at max. 40 °C (104 °F) for 5 min.
- Flush the inner and outer tubes using the water jet gun for at least 5 s in a pulsating manner.
- Check parts, especially the jaw part, for cleanliness.
- Check for patency of the tubes.
- Repeat the cleaning process if required.

Use of hydrogen peroxide can lead to premature wear of the instrument and thus reduce its lifetime.

6.4.4 Machine Cleaning and Disinfection

Recommendations for machine cleaning: Validation acc. to DIN EN ISO 15883 and information to be provided acc. to DIN EN ISO 17664. Cleaning with other process parameters, validated according to DIN EN ISO 15883, is possible.

- Before connecting the accesses of the flushing adapter to the flushing system of the washer-disinfector (WD), check for patency.
- Place the handle and disassembled tubular shaft (inner and outer tube) e.g. into the tray basket and insert them into the WD load carrier.
- Position both handle plates with open side facing downwards.
- Connect inner tube to the Luer lock connector of the load carrier via the flushing adapter.
- Connect outer tube to the Luer lock connector of the load carrier via the flushing adapter.

6.4.5 Phases of the Machine Cleaning Process

Phase	Step	Temperature	Time	Water quality	Chemical agent
1	Precleaning	Cold water max. 40 °C (104 °F)	2 min	Drinking water	--
2	Cleaning	55 °C (131 °F) max. 65 °C (149 °F)	5 min	Fully demineralized water if possible	pH-neutral to alkaline, e.g. neodisher® MediClean forte working solution 0.5 %
3	Neutralization	Cold water max. 40 °C (104 °F)	3 min	Fully demineralized water if possible	--
4	Interim rinsing	Cold water max. 40 °C (104 °F)	2 min	Fully demineralized water if possible	--
5	Thermal disinfection	e.g. 90 °C (194 °F) A0 3000, see DIN EN ISO 15883	5 min	Fully demineralized water if possible	--
6	Drying	--	Acc. to program	--	--

After the procedure, check all parts for visible contamination. If any residual contamination is present, repeat the process.

6.4.6 Drying

NOTICE

Ensure reliable drying!

Reliable drying is crucial for the success of subsequent sterilization.

6.5 Inspection, Functional Check, Maintenance

6.5.1 Inspection and Functional Check

NOTICE

Further use is confirmed by the successful inspection of the product. The inspection release and packing into a sterile barrier system releases the product for the next application.

- The products must be macroscopically clean, i.e. free from visible contamination, after each cleaning process.
- Stained instruments must be discarded immediately and fed into special treatment.
- All moving parts must be inspected with particular care.
- In case of defects or damage, discard the instruments immediately.
- After each cleaning procedure, treat the marSeal5 plus with a physiologically harmless instrument oil or instrument care spray in the area of the jaw part as well as on the joints and sliding guides of the handles.
  Instrument care agents or surface tension reducing agents may be added as long as they are approved for the medical instruments and validated in the process.
- After the inspection, store the marSeal5 plus in a specially designed tray basket to avoid transport damage, and protect it against damage using suitable devices.

6.5.2 Maintenance

“Maintenance” refers to the application of instrument oil or instrument milk (emulsion of white oil in water). The joints of the instruments must be treated with steam-sterilizable care agents based on paraffin oil.

LubriPen®, REF 55-997-01-04 for the maintenance of surgical instruments.

6.6 Packaging

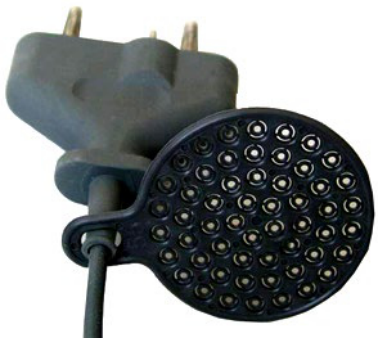
Approved sterilization packaging (e.g. conforming to EN 868, ISO 11607) must be used for sterilization, subsequent transportation and storage.

6.7 Sterilization

6.7.1 Before Sterilization

6.7.1.1 Cycle Counter

A cycle counter with 55 indicators is located on the device-side connector of the instruments. The cycle counter makes it possible to easily mark the number of applications already completed.



A spare instrument must be ordered well before the guaranteed applications have been completed, in order to ensure continuous usability of the bipolar vessel sealing instrument.

One indicator must be broken out of the cycle counter after each application and before re-sterilization. Use a ballpoint pen or a similar object to remove it. By pressing the indicator slightly, it is broken out.

Prior to each sterilization, the instruments must undergo a complete visual inspection and functional check for damage and wear, see section 6.5.1 “Inspection and Functional Check”, page 80.

Damaged instruments or their components must be immediately appraised by the manufacturer or an authorized partner and repaired or replaced, respectively.

Repeat the cleaning if a visual check reveals tissue residues on the instrument, or if the blade is still in the instrument, see section 6.4 “Cleaning and Disinfection”, page 77.

The maximum number of allowed reprocessing cycles must not be exceeded, see also section 6.1 “Limitations and Restrictions on Cleaning, Disinfection and Sterilization”, page 72.

⚠WARNING

Risk of infection in case of non-sterile handling!

Improper sterilization and non-sterile application can lead to serious health hazards to patients.

The operator/user is responsible for cleaning, sterilizing and re-sterilizing the instrument. It is essential that national regulations, including restrictions, be observed.

Sterilization must be carried out according to a validated steam sterilization process, for example in a sterilizer complying with DIN EN 285:2009 and validated in accordance with DIN EN ISO 17665-1:2006.

- Approved sterilization packaging (e.g. acc. to DIN EN 868, ISO 11607) must be used for sterilization, subsequent transportation and storage.
- Sterilization packaging must comply with the applicable standards and norms.

⚠WARNING

Danger of infection and risk of damage in case of improper processing!

Non-sterile handling can cause severe health risks for the patient.

- After each use, remove and dispose of the blade holder according to the applicable regulations!
- Never reprocess and/or reuse blade holders! Processing can damage the instrument! Processing the blade holders can damage the instrument!

- The instruments to be sterilized must be carefully subjected to steam, including on their internal surfaces.
- The **non-sterile blade holder** REF 80-633-11-04 for shaft length 370 mm, REF 80-633-14-04 for shaft length 230 mm, REF 80-633-16-04 for shaft length 450 mm) must be sterilized before application. In this case, assembly and functional check of the mechanical components, locking function and blade feed of the marSeal5 plus can also be carried out before sterilization. The instrument can be sterilized when fully assembled. Sterilization in opened state: movable handle not locked, jaw part opened.
- The **sterile blade holder** (REF 80-633-09-04 for shaft length 370 mm, REF 80-633-10-04 for shaft length 230 mm, REF 80-633-15-04 for shaft length 450 mm) is mounted into the sterile marSeal5 plus exclusively in the sterile operating area.
  The subsequent functional check of the mechanical components, locking function and blade feed are carried out **only** after the sterile blade holder has been inserted into the sterile operating area.

NOTICE

- Do not sterilize with hot air or with so-called flash autoclave procedures!
- Do not use plasma sterilization procedures (LTP sterilization)!

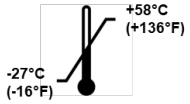
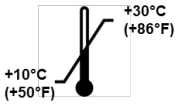
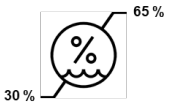
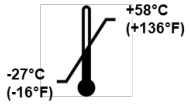
The temperature in the autoclave must not exceed 138 °C (280 °F) and a holding time of 18 min, otherwise insulation and other plastic parts may be damaged.

Steam sterilization with fractionated pre-vacuum	
Minimum requirement	3 min at 132 °C (270 °F)
Maximum sterilization temperature	138 °C (280 °F)
Maximum sterilization time	18 min
Drying time	according to validation/program

- Other times and temperatures can also be used, as long as they are within the appropriate range. The operator must ensure that sterility is maintained after the sterilization process.
- Follow the handling and loading recommendations by the manufacturer of the sterilization device!

6.8 Storage and Transportation

Information regarding the environmental conditions for storage and transport:

Non-sterile product components und accessories:	
Minimum and maximum temperature for storage and transportation	
Store in a dry place	
Keep away from sunlight	
Sterile accessories:	
Minimum and maximum temperature for storage	
Minimum and maximum humidity for storage	
Minimum and maximum temperature for transportation	
Minimum and maximum humidity for transportation	
Store in a dry place	
Keep away from sunlight	

- Protect instruments from mechanical damage.
- Store and transport instruments in safe containers/packing. Appropriately approved sterilization packaging (e.g. according to DIN EN 868, ISO 11607) or sterilization containers must be used for this purpose.
- Handle instruments with great care. Do not drop or throw.

6.9 Environmental Conditions for Operation

See IFU HF generator maxium.

6.10 Blade Holder

6.10.1 Inserting the Non-Sterile Blade Holder

⚠WARNING

Danger of infection from improper handling!

Improper sterilization and non-sterile handling can lead to serious health hazards to patients.

- Sterilize non-sterile blade holder before each application.

The instrument with the inserted non-sterile blade holder can be sterilized when fully assembled.

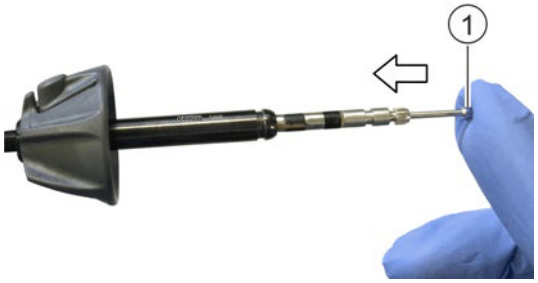
⚠CAUTION

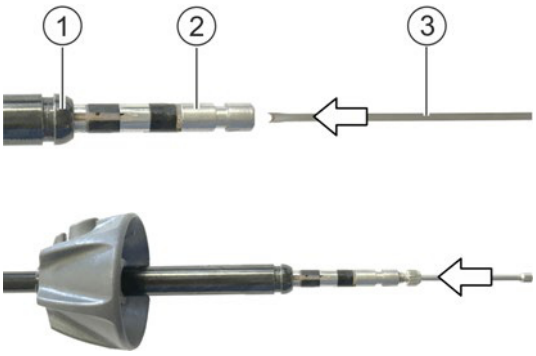
Danger of infection and injury from sharp blades!

When the tubular shaft is dismantled, the integrated blade (2) can be pushed through the tubular shaft and out of the open jaw part by accidentally pressing on the rear end of the blade holder (1).

- Avoid contact with the sharp blade (2)!

The working method must at all times be carried in such a manner that no contamination of the sterile surgical gloves and the sterile blade holder occurs.





1 Outer tube

2 Inner tube

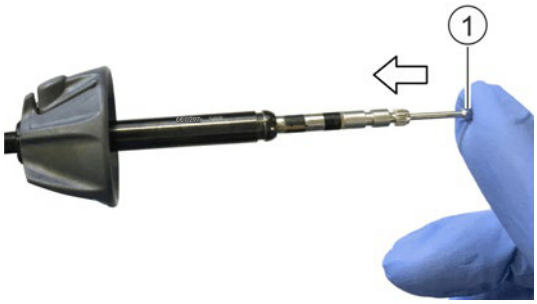
3 Blade Holder

- Slide the blade holder (3) into the inner tube (2) from the rear.
- If necessary, turn the blade holder slightly in the last third until it can be pushed into the jaw part.

- Tighten the knurled nut (1).

The blade holder in non-sterile packaging is secured.

6.10.2 Checking the Blade Feed



- To check the blade feed, press against the rear of the blade holder (1).

6.11 Inserting a Sterile Blade Holder

NOTICE

The sterile blade holder can be inserted directly from the sterile packaging into the tubular shaft without further pre-treatment.

- Do not use the sterile blade holder until **after** sterilization of the instrument and only in the **sterile operating area**.

⚠WARNING

Danger of infection from damaged sterile packaging!

The sterile blade holder is a single-use product and **STERILE** on delivery.

A sterile blade holder removed from damaged or opened sterile packaging and from packaging with an expired use-by date must be considered non-sterile.

- Do not use! The sterility of the blade holder can be ensured only if the packaging is undamaged.

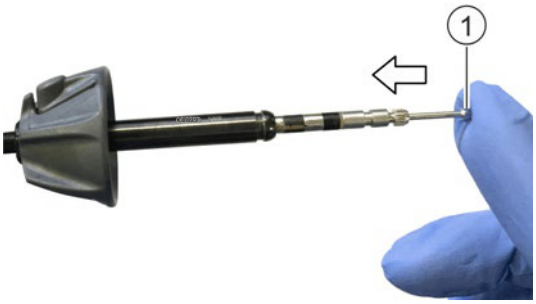
⚠CAUTION

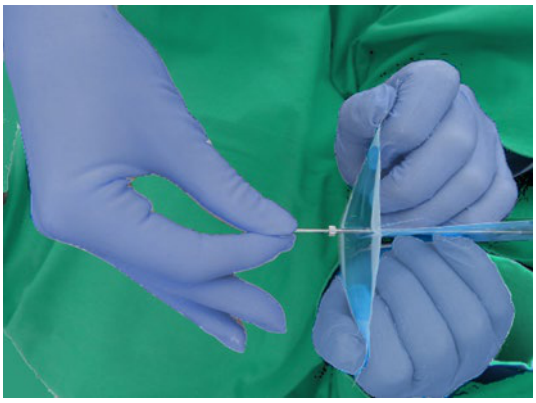
Danger of infection and injury from sharp blades!

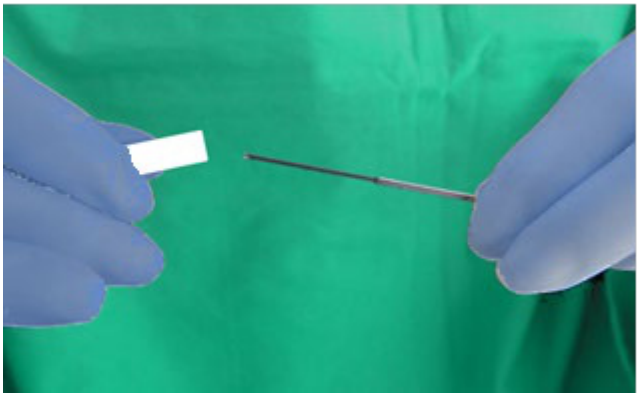
When the tubular shaft is dismantled, the integrated blade (2) can be pushed through the tubular shaft and out of the open jaw part by accidentally pressing on the rear end of the blade holder (1).

- Avoid contact with the sharp blade (2)!

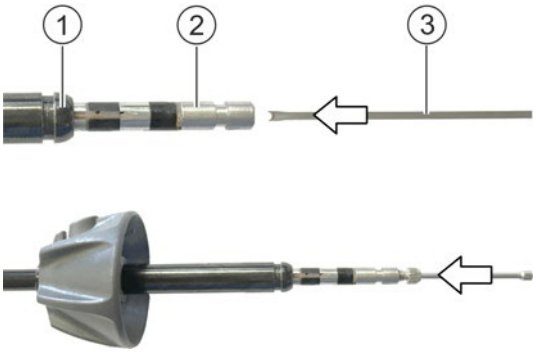
The working method must at all times be carried in such a manner that no contamination of the sterile surgical gloves and the sterile blade holder occurs.







- Remove the sterile blade holder from the sterile packaging (on the side of the knurled nut).
- Remove protective cap.



1 Outer tube

2 Inner tube

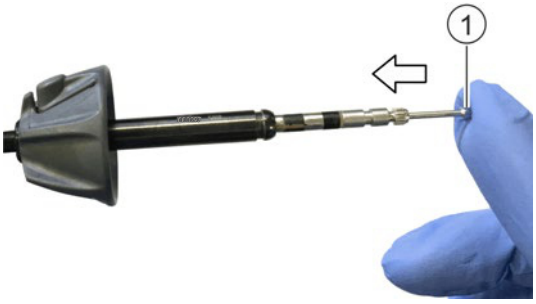
3 Blade Holder

- Slide the blade holder (3) into the inner tube (2) from the rear.
- If necessary, turn the blade holder slightly in the last third until it can be pushed into the jaw part.

- Tighten the knurled nut.

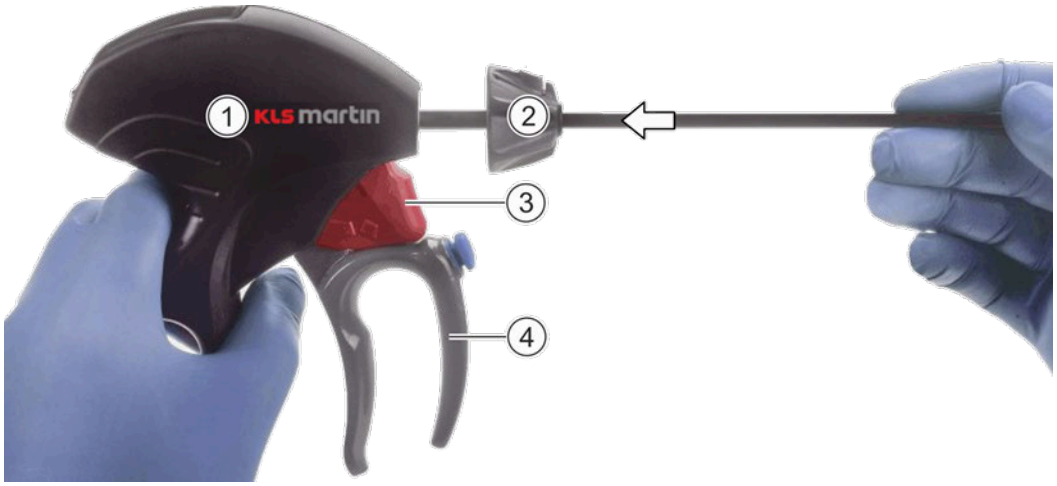
The blade holder in sterile packaging is secured.

6.11.1 Checking the Blade Feed



- To check the blade feed, press against the rear of the blade holder (1).

7 Assembling the Handle with Tubular Shaft



1 Handle

2 Tubular shaft

3 Blade trigger (red pushbutton)

4 Movable handle

- Insert the assembled tubular shaft (2) with the inserted blade holder straight into the handle (1) down to the end stop. Close the jaw part.

7.1 Functional Check

⚠CAUTION

Danger of injury from uninspected instruments or components!

Non-functional or defective instruments and components can endanger the patient or user, as well as affect the intended function of the marSeal5 plus in combination with the current type SealSafe® IQ.

- Always keep electrosurgical instruments and their components in flawless working order.
- Never use electrosurgical instruments and their components if they are damaged due to improper handling or transport.
- If the device does not work properly and/or cannot be operated safely, it must be marked as non-operational and put out of operation.
- Use of components or accessories by other manufacturers may constitute a source of danger. In case of doubt, please contact the manufacturer.

To prevent injury or damage, contact the Martin Service Center immediately if any damage or malfunction is detected.

NOTICE

Risk of fracture or blunting of the blade!

- Ensure that the blade never touches hard objects.

Carry out the following functional checks before each application:

Mechanical function check

- Visual check for potential damage (check for cracks, fractures or deformation)
  - Handle (1)
  - Rotating wheel (2)
  - Tubular shaft (3)
  - Insulation of the connection cable (7)
- Check for mechanical function and easy movement, especially for:
  - Jaw part (8) of the tubular shaft
  - Blade holder (9)
  - Rotating wheel (2) of the tubular shaft, rotatable by 360°
- **Test the mechanical function before starting the surgery**
  - Opening, closing, locking and unlocking of the jaw part (8) using the movable handle (6).
  - Movement of the integrated blade (9) using the red pushbutton of the blade trigger (4).
- **Test the electrical function in fully assembled condition at the operating table**
  - Activation of the sealing current (5) e.g. on a sterile swab soaked in NaCl solution.

7.2 Consumables

Illustration	Designation	REF
	Sterile blade holder 370 mm, single-use, sales unit = 10 pcs	80-633-09-04
	Non-sterile blade holder 370 mm, single-use, sales unit = 10 pcs	80-633-11-04
	Sterile blade holder 230 mm, single-use, sales unit = 10 pcs	80-633-10-04
	Non-sterile blade holder 230 mm, single-use, sales unit = 10 pcs	80-633-14-04
	Sterile blade holder 450 mm, single-use, sales unit = 10 pcs	80-633-15-04
	Non-sterile blade holder 450 mm, single-use, sales unit = 10 pcs	80-633-16-04

8 Maintenance

8.1 General Notes

The product may be repaired only by the manfuacturer or a qualified person or firm expressly authorized by the manufacturer to perform such work.

Modification of the product can lead to unforeseeable risks and is therefore not permitted.

If the repair is carried out by a person or firm specially authorized by the manufacturer, the operator of the product is required to obtain from the repairer a certificate with details about the nature and scope of the repair work done. This certificate must show the date of the repair and the details of the person or firm carrying out the work and must be signed.

In all cases where a party other than the manfuacturer performed the work, repaired products must be additionally marked with the repairer's ID label.

Improper interventions or alterations performed by third parties during the period of limitation shall void any and all warranty claims. Unauthorized actions performed on the product are never allowed and shall void any claims of liability against the manufacturer.

9 Environment Information/Disposal

9.1 Packaging

The manufacturer will take back the full packaging upon request. Whenever possible, parts of the packaging will be reused.

If this option is not used, the packaging can be disposed in the general paper and household waste.

9.2 Consumables

Dispose of single-use products in the problematic waste.

Infected sharp parts of single-use products must be handled like any other “sharps” (cannulas, needles and scalpels) in accordance with valid regulations (disposal via microbiologically tight and puncture-proof containers).

9.3 Disposal

In designing the product, we tried to avoid using composite materials wherever possible. This allows a high degree of recycling. We therefore offer to take the product back for proper disposal and recycling.

9.4 National Regulations

The national regulations and disposal provisions must be observed for all disposal measures.