English

Bipolar Sealing System marClamp® CUT IQ

Instructions for Use

CE 0297

REF 90-017-52-11
Revision 03
Date of Release: 2023-11

www.klsmartin.com

Explanation of Symbols

The following symbols are either part of these Instructions for Use and/or of the product label.

	**Safety alert symbol** CAUTION — Indicates a situation which, if not avoided, could result in minor or moderate injury WARNING — Indicates a situation which, if not avoided, could result in death or serious injury. DANGER — Indicates a situation which, if not avoided, will result in death or serious injury.
medical device	Medical device
	Instructions for Use
	Follow Instructions for Use
	Catalogue number
	Health Industry Barcode for globally unique product labeling using the global standard for industry & healthcare
	Batch code
	Do not re-use
	Do not resterilize
	Not sterile
	Sterilized using steam or dry heat
	Keep away from sunlight
	Store in a dry place

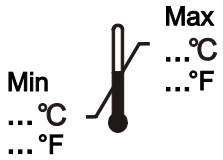
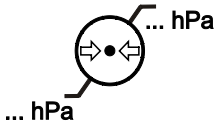
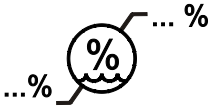
	Information on minimum and maximum temperature for storage and transportation
	Information on minimum and maximum atmospheric pressure for storage and transportation.
	Information on minimum and maximum humidity for storage and transportation
	Manufacturing date
	Manufacturer
	Do not use if package is damaged
	Use by
	Latex-free
CE 0297	CE marking

Table of Contents

1 General

1.1 Manufacturer

Thank you for choosing a KLS Martin product.

This product has the CE mark, which means that it is compliant with the essential safety and performance requirements for medical devices pursuant to 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
Phone +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com ·www.klsmartin.com

1.2 Hotline

If you have questions about how to use this device or product or questions about clinical applications, please contact the product management team:

Tel: +49 7461 706-0

Email: info@klsmartin.com

If you have technical questions or questions about maintenance contracts and training, please contact the Martin Service Center:

Tel: +49 7461 706-343

Fax: +49 7461 706-484

Email: service@klsmartin.com

NOTICE

All packaging, and in some cases also the product itself, is marked with a batch number (LOT) and a catalogue number (REF). When making a product complaint, please include the LOT and REF.

1.3 Adverse incident reporting requirement

All serious adverse incidents related to this product must be reported to the manufacturer and to the competent authorities immediately.

1.4 About this document

⚠WARNING

Could result in the death of or serious injury to the patient, user or a third party if these instructions are not followed!

Read and observe the Instructions for Use completely. In particular, take all precautionary measures and heed all warnings.

This text refers to male, female and non-binary individuals equally, but not all pronouns have been used, solely for reasons of readability.

The electronic version of these instructions for use can be downloaded from www.klsmartin.com.

1.5 Abbreviations and Terms

Name	Description
B1, B2	Bipolar outputs of the electrosurgical unit
CJD	Creutzfeldt-Jakob disease
G1 – G5	Graduation levels for power setting
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)

1.6 Validity of this document

The marClamp Cut IQ 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 marClamp® CUT IQ.

1.7 Accompanying Documents

- Processing instructions for marClamp® CUT IQ (REF 90-016-51-10)

2 Scope of delivery

Figure	Description	REF
	marClamp® CUT IQ, 18 cm, with integrated connection cable	80-632-18-04
	Cleaning tool	80-630-58-04
	Cleaning brushes (3 pieces)	80-632-01-04
	Instructions for Use Reprocessing instructions	
	**Must be ordered separately** Blade (single-use item, **sterile**), sales unit = 10 pieces	80-632-00-04

2.1 Inspection of the delivery for completeness and correctness

Immediately after receiving the delivery, check that it is complete and in good condition.

Report any damage that occurs during transit promptly.

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 system marClamp® CUT IQ is intended for permanent occlusion of veins, arteries and tissue bundles, with subsequent dissection of the sealed tissue using the same instrument. It is designed for use in open surgery applications.

3.2 Indications

The indications result from the intended purpose.

3.3 Contraindications

- Note that tubal ligatures with the marClamp® CUT IQ cannot be considered a reliable method 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

There are no known product-specific adverse effects when used as intended. The user is responsible for informing the patient about possible adverse effects and complications associated with the surgical intervention.

3.6 Residual risks

The user is responsible for informing patients about the residual risks associated 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 Environmental conditions during use

Use only in ORs under conditions appropriate for surgery or in medical facilities designed for this.

3.10 Restrictions on use

⚠WARNING

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

Safe use of the marClamp® CUT IQ 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!

Note that tubal ligatures with the marClamp® CUT IQ cannot be considered a reliable method 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!

Never use flammable anesthetics or oxidizing gases when working with the marClamp® CUT IQ bipolar sealing system.

- 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.

- 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!

⚠CAUTION

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 marClamp® CUT IQ before each use, see section 9, "Processing, cleaning, disinfection, and sterilization", page 24.
- Use the bipolar sealing system only for its intended purpose, see section 9, "Processing, cleaning, disinfection, and sterilization", page 24.
- For the functional check, see section 9, "Processing, cleaning, disinfection, and sterilization", page 24, 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

Shipping contaminated products could result in the death of or serious injury to third parties!

When returning products, send only cleaned and disinfected products in sterile packaging.

4 Operation/Use/Application

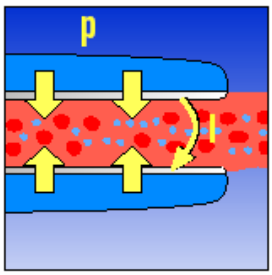
4.1 Description of the components

Figure	Description
Product components	
	marClamp® CUT IQ, 18 cm, with integrated connection cable
Accessory components for the instrument	
	Blade (single-use item, **sterile**), sales unit = 10 pieces
	Instructions for Use Reprocessing instructions
Accessory Components for Cleaning	
	Cleaning tool
	Cleaning brushes (3 pieces)

The blade for tissue separation is a consumable. It is available as a sterile product. It is not included in the scope of delivery of the instrument and must be ordered separately, see section 4.2, “Consumables”, page 15.

4.1.1 Structure, Functionality and Performance Characteristics

The bipolar sealing instrument marClamp® CUT IQ is intended exclusively for use with the maxium® electrosurgical unit (type ME 402) from hardware version HW 06 and software version V3.412 or new developments by KLS Martin. It is connected to the corresponding bipolar outlet using its own connection cable. The current type “SealSafe® IQ” is selected automatically. It can be used exclusively with these 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. Placing two seals side by side is recommended for larger vessels. The integrated blade can then be used to cut in the middle between these seals. The maximum sealing length of the instrument is 18 mm, of which approx. 16 mm are cut.

- The maxium® electrosurgical unit provides a bipolar sealing current type that is adapted to the sealing of tissue and tissue layers and specifically designed for use with the sealing instruments: current type SealSafe® IQ for marClamp® CUT IQ instruments.

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.

For control, the instrument is equipped with a cycle counter, see section 3.10, “Restrictions on use”, page 10, 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 maximum permissible HF voltage is 300 Vp.

⚠WARNING

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

Safe use of the marClamp® CUT IQ 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!

NOTICE

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

⚠CAUTION

Danger of injury from improper application and abuse or misuse!

Note that tubal ligatures with the marClamp® CUT IQ cannot be considered a reliable method for contraception!

4.1.2 Combination products and accessories

NOTICE

The bipolar sealing instrument marClamp® CUT IQ 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 V3.412, or new developments by KLS Martin. The IQ connector of the marClamp® CUT IQ can be connected to the bipolar socket B1 or B2 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 connection cable of the marClamp® CUT IQ 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.

The power setting is adjusted in graduation levels (G grades). It can be varied from G1 to G5. Here, with increasing G grade the switch-off impedance is increased and the sealing time extended. If a foot switch is required for activation of the sealing current, it must be selected separately.

4.2 Consumables

Figure	Name	REF
	Blade (single-use item, **sterile**), sales unit = 10 pieces	80-632-00-04

5 Maintenance

5.1 General Notes

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

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 manufacturer 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.

5.2 Storage and transport

Information on minimum and maximum temperature for storage and transportation:

Name	marSeal 5 plus	
Environmental conditions for storage	Ambient temperature Relative humidity (no condensing moisture!)	+4.4 °C up to +49 °C 10 –70 %
Environmental conditions for transport	Ambient temperature Relative humidity (no condensing moisture!)	–27 °C up to +58 °C 35 –80 %

- Store the instruments in a clean, cool and 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.
- Do not store or transport the cable together with cutting instruments.
- Protect sterile-packaged blades from direct sunlight. It is recommended to keep the product in its original packaging until it is used for the first time.

5.3 Environmental conditions for operation

See IFU HF generator maxium.

6 About this document

⚠WARNING

Failure to comply with the safety warnings in this document may result in serious injury to the patient or user!

Improper handling and care as well as use other than intended can lead to premature wear and/or pose a risk for patients and users!

It is the operator’s responsibility to ensure that all personnel handling the product have understood and do observe the notes and instructions in this document.

- Every user is required to read this document completely and follow it carefully.
- In particular, be sure to heed all cautions, warnings and danger notices.
- Keep this document accessible to users at all times.
- The application instructions provided in this document do not replace the instructions for use of the maxium® electrosurgical unit. The safety instructions in particular must be observed and followed under all circumstances!
- The present document refers to all genders alike. Reference to individual genders is waived solely for reasons of improved readability.

6.1 Symbols used in this document

Important information such as general or safety-related information is highlighted in this document with the following symbols and signal words:

⚠WARNING

Peril to life or danger of serious physical injury!

Failure to comply with these instructions may result in death or serious injury!

⚠CAUTION

Danger of injury!

Failure to comply with these instructions may result in serious injury!

NOTICE

Risk of material damage!

Failure to comply with these instructions may result in property damage (time loss, data loss, machine errors, etc.)!

7 Safety precautions

⚠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!

Never use flammable anesthetics or oxidizing gases when working with the marClamp® CUT IQ bipolar sealing system.

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

⚠WARNING

Contact between the electrodes and metallic parts may result in burns!

Shunts for the HF current or concentrated leakage current paths can form upon contact of the electrodes with metallic parts. These can cause burns.

- Do not touch any other metallic 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 unintentional contact with the patient's tissue!

Unintentional HF activation, e.g. via the foot switch, can lead to burns and electric shocks if the electrosurgical instrument is placed on the patient and thereby 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 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 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

Non-sterile use can lead to infection!

- Remove the blade following each application and discard the used blade.
- Never reprocess and / or reuse blades!

⚠CAUTION

Risk of injury when inserting the blade!

- Avoid touching the cutting edge!

⚠CAUTION

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 marClamp® CUT IQ before each use, see section 9, “Processing, cleaning, disinfection, and sterilization”, page 24.

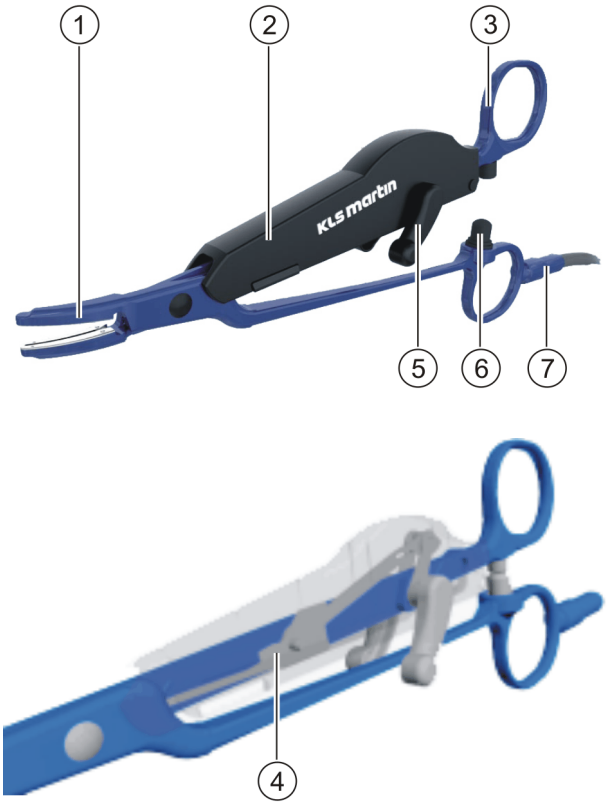
A functional check must be carried out before each use, see section 9.9, “Inspection, functional check, maintenance”, page 33!

- Route the connection cable so that it touches neither the patient nor other cables. Protect the connection cable from mechanical damage (running over, crushing, bending)!
- Use of high-frequency devices can interfere with other devices!

8 Application

- Observe the safety notes, see section 7, “Safety precautions”, page 17.
- Sterilize the marClamp® CUT IQ before the first use, see section 9, “Processing, cleaning, disinfection, and sterilization”, page 24!
- Products in sterile packaging can be applied directly from their sterile packaging without further pre-treatment.
- A functional check must be carried out before each use, see section 9.9, “Inspection, functional check, maintenance”, page 33!

8.1 Overview



1	Jaw Part
2	Protective case
3	Handle
4	Blade
5	Blade trigger
6	Switch
7	Connection cable

8.2 Connection to the Electrosurgical Unit maxium®

NOTICE

The bipolar sealing instrument marClamp® CUT IQ with sterile blades is intended exclusively for use with the maxium® electrosurgical unit (type ME 402) hardware version HW 06 and software version from V3.412 or new developments by KLS Martin. It is connected to the corresponding bipolar outlet using its own connection cable. The current type “SealSafe® IQ” is selected automatically.

NOTICE

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

The maximum permissible HF voltage is 300 Vp.

8.2.1 Procedure using SealSafe® IQ current type

After plugging in the instrument plug, the maxium® electrosurgical unit automatically supplies the required current type SealSafe® IQ with a factory default setting G3. Either of the two bipolar output sockets on the maxium® may be used for this purpose.

The power setting is adjusted in graduation levels (G grades G1–G5). Here, with increasing G grade the switch-off impedance is increased and the sealing time extended.

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

8.3 Sealing

- Place the jaw part (1) in an ergonomically optimal position.
- Then grasp the tissue to be treated with the jaw part (1), only grasping enough tissue so that it does not protrude proximally over the electrodes.
- Close the handle (2) until the sealing current is triggered by the switch integrated into the handle.
- The maxium® finishes the sealing process automatically and confirms this acoustically. This shuts down the current automatically before carbonization of the tissue can occur.

⚠WARNING

Risk of infection in case of non-sterile handling!

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

- The sterility of the blades can be ensured only if the packaging is undamaged and the packaging seal is intact.
- Do not use after the expiration date indicated on the packaging.
- Remove the blades following each application.
- Discard used blades!
- Never reprocess and / or reuse blades!

- By moving the blade trigger (3), the blade is pushed through the joint of the handle and the jaw part (1) of the marClamp® CUT IQ, thereby cutting the sealed tissue, see also section 8.1, “Overview“, page 20.

⚠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.!
- Vessels up to a maximum diameter of 7 mm can be permanently sealed. Placing two seals side by side is recommended for larger vessels. The integrated blade can then be used to cut in the middle between these seals. The maximum sealing length of the instrument is 18 mm, of which approx. 16 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

The high concentration of current may pose a risk of burns!

- Start at a low power setting and increase the power as needed.
- If the sealing effect is inadequate or absent, first attempt to identify the error. Do not increase the power setting to the maximum level without prior inspection!

⚠WARNING

Danger of bleeding in case of improper application!

- Never press the blade trigger during vessel sealing! The blade must be retracted into the marClamp® CUT IQ; 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 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 jamming). Use the supplied cleaning tool, a brush or swab and sterile water to clean the instrument.

⚠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!

9 Processing, cleaning, disinfection, and sterilization

9.1 General Notes

NOTICE

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

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

Processing information according to DIN EN ISO 17664 is enclosed in an appendix sheet for posting in the instrument processing department.

The parameters for cleaning and disinfecting the product are to be determined by the operator/ user, e.g. as part of the hygiene plan. The treatment agents must be compatible with the component materials and their hygienic and microbiological effectiveness must be guaranteed. A thorough final rinse must be performed to ensure that no cleaning or care product residues are left on any of the individual components after reprocessing.

NOTICE

- Observe all applicable national regulations in regard to reprocessing of the products in case of patients suffering from Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of the disease.
- Note that successful reprocessing of this medical product can be guaranteed only after prior validation of the reprocessing process. The operator/processor is responsible for this.
- In the interest of process safety and better and more reliable cleaning results, machine reprocessing should always be preferred to manual cleaning unless it is necessary to combine the two.
- Due to process tolerance, the data provided by the manufacturer serve only as reference values for the evaluation of reprocessing processes carried out by the operator/reprocessor.

NOTICE

- Dried or fixated operation residues may corrode the surface of the products.
  - Ensure short disposal times.
  - Do not use fixating pre-cleaning, nor fixating disinfecting agents.
- The product can be damaged by unsuitable cleaning agents or excessive temperatures.
  - Only use cleaning and disinfecting agents that are approved for use with plastics and stainless steel.
  - Only use cleaning and disinfecting agents according to the manufacturer's instructions
  - Observe the information regarding concentration, temperature and exposure time.
- The use of hydrogen peroxide can lead to premature wear of the instrument and thus reduce its lifetime.
- Additional reprocessing instructions can be found at http://kls-martin.com/phnet/

Products delivered in sterile condition (blade in sterile packaging) are marked with the corresponding symbol. They should not be removed from the packaging until immediately before use. Always check the use by date and that the packaging is not damaged 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

9.2 Limitations and restrictions on cleaning, disinfection, and sterilization

⚠WARNING

Cleaning, disinfecting and sterilizing contaminated single-use products could result in the death of or serious injury to the patient!

Unused single-use products that have come into contact with bodily fluids, blood, tissue and/or the like should be considered used and must be discarded.

Cleaning, disinfection, sterilization, and use can increase the risk of contamination, e.g., through bacterial transmission.

⚠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.

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.

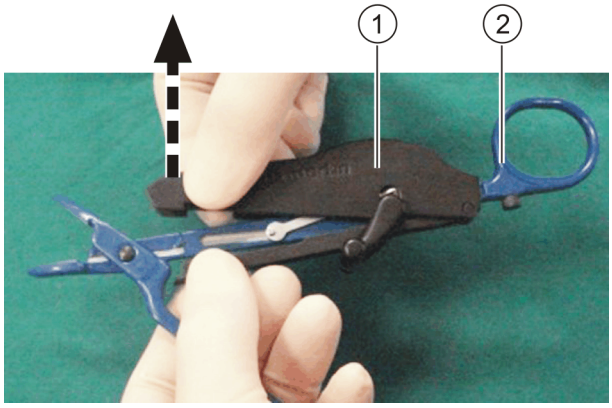
- At the end of the product lifetime, dispose of the marClamp® CUT IQ in accordance with national regulations, see section 10.3, “Disposal”, page 35.

9.3 Preparation for cleaning

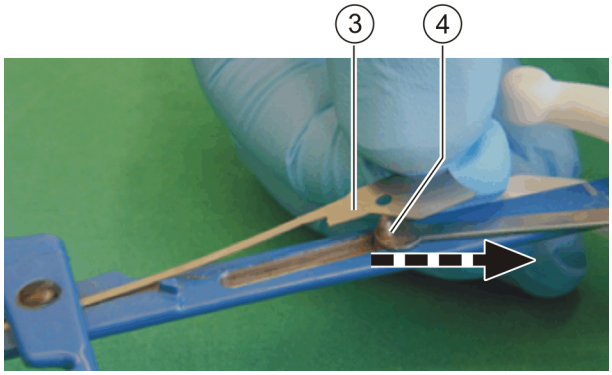
The marClamp® CUT IQ must be cleaned with the protective case open.

The instrument must always be cleaned manually and mechanically.

- Open the handles (2) on the instrument wide.
- Hold the upper section of the protective case (1) in one hand and grasp the lower section with the other hand.
- Now pull the upper and lower sections apart.



- Lift the blade (3) out of the pin (4) by bending it slightly and pull it back out of the instrument.



NOTICE

Risk of damaging the marClamp® CUT IQ!

- When assembling the system, take care to ensure that the sections of the protective housing latch together securely and as intended!
- Avoid using excessive force, as the plastic parts may break!

⚠WARNING

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

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

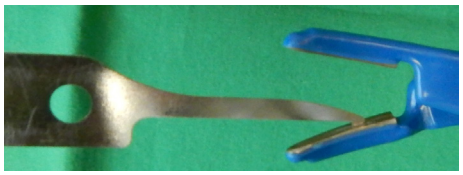
- Remove the blade following each application!
- Never reprocess and / or reuse blades! Processing the blades can damage the marClamp® CUT IQ!
- Discard used blades according to applicable regulations!

9.4 Manual precleaning of the jaw part

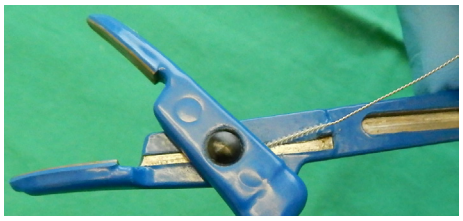
NOTICE

The supplied cleaning tools are used to clean the blade guide in the jaw 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.



- Remove the blade (if not already removed in the operating room).
- Soak in cold water for 5 min.
- Clean the slit in the jaw part using the hook on the cleaning tool.
- Clean the electrodes and the jaw area using a suitable soft brush.
- Move all moving parts.
- Wipe away any tissue residues using a moist fiber cloth.



- Insert the supplied cleaning brush through the blade guide in the clamp joint and move back and forth several times.
- Wash for 5 min at 40°C in an ultrasound bath using a 0.5% alkaline cleaning agent ready-to-use solution.

9.5 Automated cleaning

- Place the marClamp® CUT IQ in the W/D load carrier.
- Always place the instrument onto the carrier with the protective case in the open position.

Recommendations for machine cleaning (for example, validation acc. to DIN EN ISO 15883 and information to be provided acc. to DIN EN ISO 17664). Alternative cleaning parameters are possible when validated acc. to DIN ISO 15883:

Phase	Step	Temperature (°C/°F)	T (min)	Water quality	Chemical agent
1	Pre-cleaning	Cold water max. 40	2	Drinking water	–
2	Cleaning	55 max. 65	5	Fully demineralized water if possible	pH-neutral to alkaline, e.g. neodisher® MediClean forte working solution 0.5%
3	Neutralization	Cold water	3	Fully demineralized water if possible	–
4	Interim rinsing	> 10	2	Fully demineralized water if possible	–
5	Thermal disinfection	e.g. 90 AO 3000, see DIN EN ISO 15883	5	Fully demineralized water if possible	–
6	Drying	–	According to program	–	–

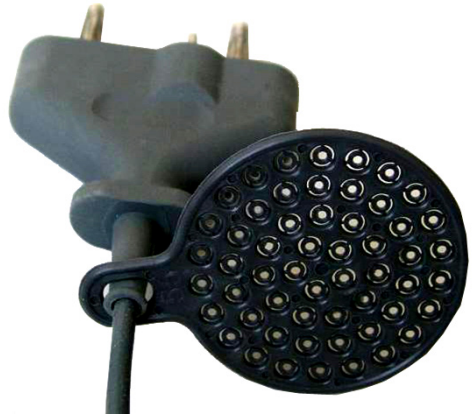
Agents to protect the instrument or reduce surface tension may be used as long as they are approved for use with medical instruments and are part of the validated program.

After this procedure, all parts should be checked for visible dirt. If any residual contamination is present, repeat the process.

After each use, one indicator must be removed from the cycle counter before re-sterilization, see section 9.6, “Cycle counter”, page 29.

9.6 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 50 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.

9.7 Sterilization

⚠WARNING

Risk of infection in case of non-sterile handling!

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

Sterilization must be carried out according to a validated steam sterilization process, for example in a sterilizer complying with DIN EN 285 and ANSI/AAMI ST79 and validated in accordance with DIN EN ISO 17665.

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

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

Prior to each sterilization, the instruments must undergo a complete visual inspection and functional check for damage and wear, see section 9.9, “Inspection, functional check, maintenance”, page 33.

Repeat the cleaning if a visual check reveals tissue residues on the instrument, or if the blade is still in the instrument.

⚠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 discard the blade according to the applicable regulations!
- Never reprocess and/or reuse blades! Reprocessing the blades can damage the instrument!

- Do not sterilize with hot air or with so-called flash autoclave procedures!
- Do not use plasma sterilization procedures (LTP sterilization)!
- The instruments to be sterilized must be carefully subjected to steam, including on their internal surfaces.
- The instrument can be sterilized with the case closed.
- Due to the use of the sterile-supplied blades, blade insertion and the subsequent test of the mechanical components and blade feed are only carried out after the blade has been inserted.
- The temperature in the autoclave must not exceed 138 °C 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
Maximum sterilization temperature	138 °C
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!

9.8 Inserting the Sterile Blade

NOTICE

The sterile-packaged blade can be inserted directly from its sterile packaging into the handle without further pre-treatment.

⚠WARNING

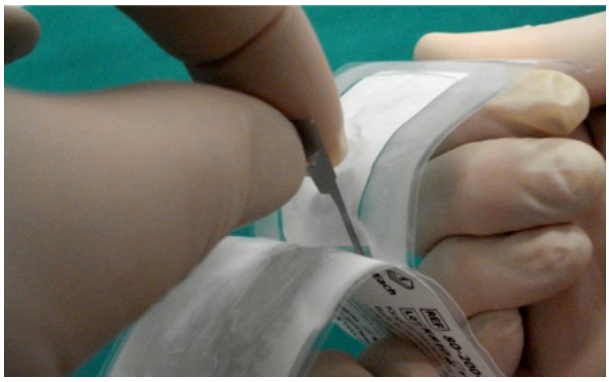
Danger of infection from damaged sterile packaging!

- The blade is a single-use item and is **STERILE** at delivery. The sterility of the blade can be ensured only if the packaging is undamaged and the packaging seal is intact.
- Do not use after the expiration date indicated on the packaging.

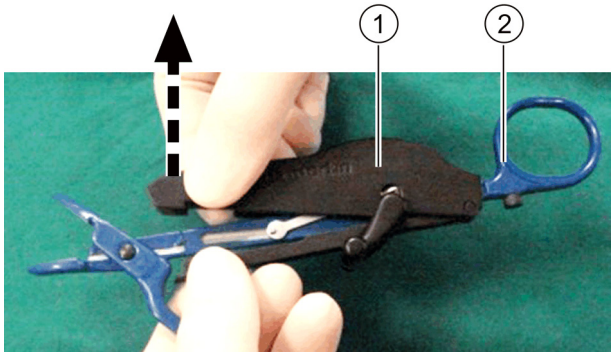
NOTICE

Risk of damage to the blade!

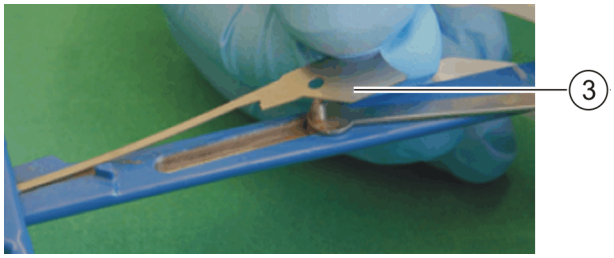
- Use caution when inserting the blade into the handle and avoid bumping.
- Ensure that the blade never touches hard objects.



- Remove the sterile blade from the sterile packaging.

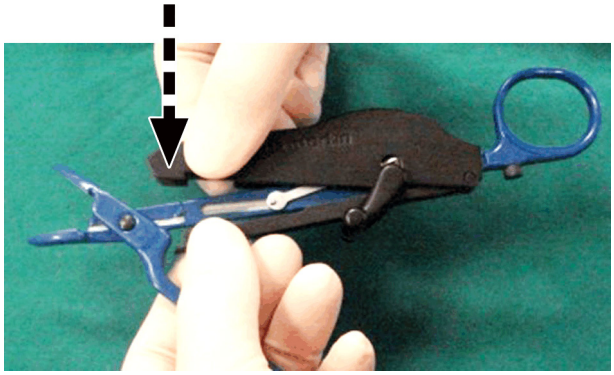


- Open the handles (2) on the instrument wide.
- Hold the upper section of the protective case (1) in one hand and grasp the lower section with the other hand.
- Now pull the upper and lower sections apart.



- Insert the sterile blade (3) into the slit in the joint section of the handle carefully and without bumping it.

- Bend the blade up slightly and allow the bore hole to latch into the pin (4).



- Close the protective case and the handle.
- Take care to ensure that the upper and lower sections of the protective case latch together securely!

9.9 Inspection, functional check, maintenance

9.9.1 Inspection and functional check

NOTICE

Whether or not the product can be used any further shall be confirmed by 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 marClamp® CUT IQ 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 marClamp® CUT IQ in a specially designed tray basket to avoid transport damage, and protect it against damage using suitable devices.

⚠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 marClamp® CUT IQ 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. Dispose of immediately in case of damage.
- Use of components or accessories by other manufacturers may constitute a source of danger. In case of doubt, please contact the manufacturer.

NOTICE

Risk of cracking or blunting of the blade!

- Ensure that the blade never touches hard objects.

9.9.2 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.

9.10 Packaging

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

Perform the following functional checks before use:

- Visual check for potential damage (check for cracks, fractures or deformation):
  - Handle (3)
  - Insulation of the connection cable (7)
  - Protective case (2)
- No corroded or loose parts
- Handles are attached securely
- Check that all components can be moved with ease, especially:
  - Jaw part (1)
  - Blade trigger (5)
- Test the mechanical function before starting the surgery:
  - Opening and closing of the jaw part (1) using the handle (3)
  - Movement of the blade using the blade trigger (5)
- Test the electrical function before starting the surgery:
  - e.g. on a sterile swab soaked in NaCl solution

⚠CAUTION

Danger of injury due to prohibited accessories!

Use of components or accessories by other manufacturers may constitute a source of danger. In case of doubt, contact the manufacturer.

10 Environmental information/disposal

10.1 Packaging

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

If this is not an option, the packaging can be disposed of with paper/household waste.

10.2 Consumables

Dispose of single-use products with hazardous waste.

Infected sharp parts on single-use products are treated like other sharps (cannulas, needles and scalpels) in accordance with the applicable regulations (disposal in leak-proof and puncture-resistant containers).

10.3 Disposal

The product was designed to use as few composite materials as possible. This design approach ensures that it can be recycled to a large degree. This is why we offer to take back the product and to dispose of it properly.

10.4 National regulations

Follow national waste management regulations and guidelines for all disposal activities

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