BIPOLAR FORCEPS INSTRUCTION FOR USE

Product / User / Disposal:

- Electrosurgery accessories may only be used and disposed of by qualified medical personnel! Dispose of the instrument according to internal hospital guidelines for sharp, biologically contaminated items.
- Not sterile. Must be cleaned and sterilized prior to initial and each subsequent use.

Intended purpose:

- Sutter SuperGliss®, SuperGliss®ELP, SuperGliss®TEO, SuperGliss®zhora, Classic, Classic Micro and Selectal™ bipolar forceps for coagulation of the selected tissue.
- Sutter bipolar suction forceps for use in electrosurgery for the coagulation of tissue and suctioning fluids.
- Sutter bipolar irrigation forceps for use in electrosurgery for coagulation and to supply fluid to select tissue.

Before using:

- Inspect the product for cleanliness, mechanical function, and intact insulation before each use. We recommend checking the insulation with a suitable test device.
- Only use sterilized products that are in flawless condition!
- A certain discoloration of the non-stick instrument tip is normal and harmless.
- To connect the forceps and cables, the electrosurgery device must be turned off or in standby mode. Failure to comply may lead to burns and electric shocks!

During use:

- Always work with the lowest output setting for the desired surgical effect.
- Maximum allowable voltage 500 Vp.
- Regularly wipe blood and tissue residue from the tips.
- Tips of the forceps may cause injuries!
- After application, the tips of the forceps may be so hot they cause burns!
- Never lay down instruments on or in the immediate vicinity of the patient! Lay cables and store unused instruments so they are isolated from the patient.
- Not for use in the presence of combustible or explosive substances!

Reconditioning:

General information:

Observe national guidelines and regulations! Disconnect the instrument from the cable!

The overall reconditioning process encompasses pre-cleaning, cleaning / disinfection, and sterilization.

- Machine cleaning / disinfection is preferred due to effectiveness and reproducibility!
- Irrigation and suction forceps must always be reconditioned by machine!
- Do not immerse in hydrogen peroxide (H_2O_2)!
- Do not bend open the forceps!

Manual cleaning and disinfection:

Cleaning step	Description
Pre-cleaning	Flush for 5 minutes under cold water, operating moving parts. Clean the instrument with a soft brush (such as MED100.33 from Medisafe GmbH) until no more residues are visible.
Ultrasound and disinfection	Ultrasound bath 35 kHz at room temperature, 10 minutes, cleaning / disinfection solution 2 % Bomix® plus (Bode Chemie).
Secondary cleaning	Rinse hard to reach areas for 20 seconds with a spray nozzle as needed, then rinse the entire instrument for 30 seconds with demi- neralized water.

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Machine cleaning and disinfection:

- Load instruments into the CDD. In doing so, make sure the instruments do not touch each other and are securely supported.
- The optionally available storage trays (TAB1:B) ensures secure support.
- For improved cleaning results, the lumina of the irrigation and suction forceps can be connected to the flushing connection of the CDD using the existing Luer-Lock connections.

Program steps	Parameters
Pre-rinse	10±2 °C, 1 minute
Cleaning with 0.5 % (5 ml/liter) deconex® 28 ALKA ONE-x	70±2 °C, 5 minutes
Final rinse	10±2 °C, 1 minute
Thermal disinfection	90±2 °C, 5 minutes

Packaging:

Package cleaned and disinfected instruments in disposable sterilization packaging (single or double packa- ging), or wrap the instrument or tray with the cleaned and disinfected instruments in a cotton cloth and store them together in suitable sterilization containers meeting the following requirements:

- EN ISO/ANSI AAMI ISO 11607
- Suitable for steam sterilization (resistant to temperatures up to min. 141 °C, adequate vapor permeability)
- Sufficient protection of the instruments and/or sterilization packaging against mechanical damage

Sterilization:

- Products must be cleaned and disinfected prior to sterilization.
- Steam sterilization, steam sterilizer according to EN 13060 and/or EN 285 and validated according to EN ISO 17665

Program steps	Parameters
Process	Fractionated vacuum (dynamic evacuation)
Sterilization temperature	134 °C (max. 138 °C plus tolerance according to EN ISO 17665)
Sterilization time (holding time at sterilization temperature)	min. 3 minutes
Drying time	min. 30 minutes

- Do not sterilize in hot air!
- Do not sterilize in STERRAD®!
- In case of potential contact with prions (CJD – risk of contamination), destroy the instrument and do not use it again.

Storage / Transportation:

- Store in a dry place. Protect from sunlight. Store and transport in secure containers / packaging. For returns, products must be cleaned, disinfected, and packed in sterile packaging.

Please note:

- The instructions listed above have been validated by the manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reconditioner to ensure that actual reconditioning with the equip- ment, materials, and personnel used in the reconditioning facility achieves the desired result.
- Any serious-incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- The product may only be repaired by the manufacturer or an agent expressly authorized by the manufacturer. Otherwise the warranty and any possible additional liability claims against the manufacturer are voided. Any change to the product or deviation from these instructions for use waives the liability of Sutter Medizin- technik GmbH.
- STERRAD® is a trademark of Johnson & Johnson, Inc.