Masterpiece™

Bipolare Pinzetten / Bipolar Forceps

REF:
787000 – 789999

FIG. 1

TAB 1		REF
A		701775-01 → n=1 701775-02 → n=2 701775-05 → n=5 701775-10 → n=10

English EN

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.
Notwithstanding these instructions, reading the instructions for use provided with the electrosurgery device and other accessories being used is mandatory. For further information about electrical safety, we recommend IEC TR 61289 or DIN EN 60601-2-2 supplement 1.

⚠ **Not sterile.** Clean and sterilize prior to initial use and prior to each subsequent use.

Intended purpose:
Dissection and bipolar coagulation of soft tissue. For connection on the bipolar output of the electrosurgery device used with a suitable bipolar cable.

Service life:
A minimum of 20 reconditioning cycles can be expected with proper use.

Before use:
⚠ Before each use, check the product for cleanliness, mechanical function and possible damage.

⚠ Only use sterilized products that are in flawless condition!
A certain discoloration of instrument tips is normal and harmless.
Only connect forceps and cable to the electrosurgery device when it is switched off or in standby mode. Failure to comply with this instruction can result in burns and electric shocks!

Electrosurgery cables:
The Sutter Masterpiece bipolar forceps are intended for use with bipolar silicone cables with a European flat connector from the manufacturer Sutter Medizintechnik GmbH.

During use:
⚠ Always work with the lowest output setting for the desired surgical effect.
⚠ Masterpiece forceps are uninsulated precision forceps that do not comply with Sections 201.8.8.3.103 and 201.8.8.3.104 of IEC 60601-2-2:2017.
⚠ For proper use only activate the instrument, when the tissue to be coagulated is securely located between the tips of the forceps.
⚠ Failure to comply with this instruction can result in unintended electrical effects!
⚠ Maximum permissible voltage 500 Vp
⚠ Regularly wipe off blood and tissue residues from the tips.
⚠ Tips of the forceps can cause injuries!
⚠ After use, the tips of the forceps can be so hot that they cause burns!
⚠ Never set down the instrument on the patient or in the immediate vicinity of the patient! Lay out 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.
⚠ Due to the effectiveness and reproducibility, mechanical cleaning / disinfection should always be preferred!
⚠ Do not place in (H_2O_2) hydrogen peroxide!
⚠ Do not bend open the forceps! **(FIG1)**!
To protect the instruments from mechanical damage, Sutter Medizintechnik GmbH recommends the use of storage trays **(TAB1:A)** for mechanical cleaning and subsequent sterilization

Pre-cleaning:
- Do not allow blood and tissue residues to dry on the instrument; rinse thoroughly with cold water after max. 1 hour! Use a soft brush if needed (do not use a wire brush or similar item)
- Movable parts must be moved back and forth several times during pre-cleaning.

- Remove blood and tissue residues with a soft cloth or brush!
- Do not use aggressive / abrasive cleaning agents!

Manual cleaning and disinfection:

Cleaning step	Description
Pre-cleaning	Rinse for 5 minutes under cold water, while activating moving parts. Brush off the instrument with a soft brush (e.g. MED100.33 Medisafe GmbH) until visual inspection confirms that all residues have been removed.
Ultrasound and disinfection	Ultrasound bath 35 kHz at room temperature, 10 minutes, cleaning or disinfectant solution 2% Bomix® plus (Bode Chemie).
Secondary cleaning	Rinse hard to reach areas for 20 seconds with a spray nozzle as needed, then rinse-off the entire instrument for 30 seconds with demineralized water.

Machine cleaning and disinfection:

In selecting the cleaning and disinfection device (CDD), note that the effectiveness of the CDD must have been tested (DGHM ("Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V.", German Association for Hygiene and Microbiology) or have FDA approval for instance, or the CE marking according to EN ISO 15883).

- Load instruments into the CDD. In doing so, make sure the instruments do not touch each other and are securely supported.
- To protect the instruments from mechanical damage, Sutter Medizintechnik GmbH recommends the use of storage trays **(TAB1:A)** for mechanical cleaning and subsequent sterilization.

Program steps	Parameter
Pre-rinse	10±2 °C, 1 minute
Clean 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

- Please note: The preceding instructions contain validated minimum times for successful cleaning with the prescribed program steps. Deviating process parameters (longer cleaning time and higher cleaning temperatures up to 95 °C) do not damage the instruments and are permitted according to the A_0 concept, comparable A_0 value > 3000. If a different cleaning agent is used, only use products with properties comparable to the properties of deconex® 28 ALKA ONE-x (Borer Chemie), for instance regarding the pH value and compatibility with plastics. If in doubt, contact the responsible supplier or hygiene officer.

Inspection:
Prior to sterilization, visually inspect the instrument and check for intact insulation, cleanliness, and integrity.

Maintenance:
None

Packaging:
Package cleaned and disinfected instruments in disposable sterilization packaging (single or double packaging), or wrap the instrument or tray with the cleaned and disinfected instruments in a cotton cloth and store them together in suitable sterilization containers that meet the following requirements:
- EN ISO/ANSI AAMI ISO 11607
- Suitable for steam sterilization (resistant to temperatures up to at least 141 °C sufficient vapor permeability)
- Sufficient protection of the instruments or sterilization packaging against mechanical damage

Sterilization:
Only sterilize cleaned and disinfected products.
- Steam sterilization, steam sterilizer according to EN 13060 or EN 285 and validated according to EN ISO 17665

Program steps	Parameters
Process	Fractionated vacuum (dynamic evacuation)
Sterilization temperature	132 °C (max. 138 °C plus tolerance according to EN ISO 17665)
Sterilization time (holding time at sterilization temperature)	at least 3 minutes
Drying time	at least 30 minutes

⚠ Sterilization at high temperatures and longer sterilization time shortens the service life of the instrument.
⚠ Ensure adequate drying!
⚠ 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 equipment, 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 modification of the product or deviation from these instructions for use will result in exclusion of any liability on the part of Sutter Medizintechnik GmbH.

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