**Bipolar Forceps – Masterpiece**

**REF:**
78 70 00 – 78 99 99 - incl. S

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**Product/User/Disposal:**
Electrosurgical accessories may only be used and disposed of by trained medical staff! These instructions do not substitute the instructions for the electrosurgical and other accessories used. After successful cleaning and disinfection, defective and obsolete instruments must be properly disposed of in accordance with national regulations.

**Non-Sterile.** Clean, disinfect and sterilise before first and subsequent uses.

**Intended Use:**
Dissection and bipolar coagulation of soft tissue. Use an appropriate cable to connect to the bipolar outlet of the electrosurgical unit used.

**Product life:**
The life cycle of the product depends on the use and treatment it gets.

**Prior to use:**

- Examine the integrity of the insulation as well as the cleanliness and integrity of the forceps.
- Only use safe and sterilized products.

A certain discolouring of the tips of non-stick instruments is normal and harmless. Before connecting forceps and cables to an electrosurgical unit, make sure that the unit has been switched off or is in standby mode. Disregarding these instructions may lead to burns and electrical shock.

**During use:**
Always use the lowest power setting available to achieve the desired surgical effect.

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**PLEASE NOTE:**
Masterpiece forceps are uninsulated precision instruments that do not comply with sections 201.8.8.3 103 and 201.8.8.3 104 of IEC 60601-2-2:2010-01. The functional safety of the connector is designed for a maximum voltage of up to 1000Vpp. It is only safe to activate the instrument after the tissue of the area to be treated has been securely grasped between the tips of the forceps.

**DISREGARDING THIS INSTRUCTION MAY LEAD TO UNDESIRED ELECTRICAL EFFECTS.**

- Frequently clean the tips from blood and debris.
- The tips of forceps may cause injuries.
- The tips of forceps may be hot after use and cause burns. Never place forceps on or close to the patient. Do not use with flammable or explosive substances.

**Reprocessing:**
Observe nationally applicable regulations and guidelines. Disconnect cable from forceps. Do not allow blood and debris to dry on forceps. Use a soft cloth or brush to remove blood and debris. Do not use aggressive/abrasive cleaners. Rinse thoroughly with clean tap water before cleaning.

- Do not put in hydrogen peroxide (H2O2)!

We generally recommend machine cleaning and thermal disinfection. Protect instruments against mechanical damage. For machine cleaning and subsequent sterilization, Sutter recommends the use of sterilization trays, REF 70 17 75 (TAB1:A), to protect instruments against mechanical damage.
**Manual cleaning and disinfection:**

We recommend cleaners suitable for plastic materials, e.g. Sekusept aktiv (Ecolab). Observe the manufacturer’s instructions.

**Manual cleaning and disinfection:**

Thermal disinfection at >90 °C (194 °F), minimum 5 minutes. Sutter recommends cleaners suitable for plastic materials, e.g. deconex 28 ALKA ONE (Borer Chemie AG, CH). Follow the manufacturer’s instructions for dosage and the program run.

Use distilled water or fully desalinated water for the final rinsing circle.

=> Perform visual control prior to sterilization and verify the cleanliness and integrity of the entire instrument.

**Sterilization:**

Only sterilize clean/disinfected instruments. Use paper/foil wrapping or appropriate sterilization containers.

Steam sterilize in the autoclave.

Fractioned pre-vacuum: 134 °C (273 °F), minimum 3 minutes, maximum temperature 138 °C (280 °F), maximum sterilization time 20 minutes.

=> Sterilization at high temperatures and long sterilization times shorten the life cycle of the instrument.

Ensure that the instrument is dry after sterilization.

⚠️ Do not sterilize in hot air!

⚠️ Do not sterilize in STERRAD®!

⚠️ Destroy instruments that might have been contaminated with prions (CJD). – Do not reuse!

**Storage and transport:**

Store in a cool and dry place. Protect from direct sunlight. Store and transport in safe containers/packaging.

⚠️ Sutter Medizintechnik cannot be held liable for changes to the product after purchase or for deviations from these instructions.

Subject to change.

For updates see www.sutter-med.de.

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Testing instructions QM-PA 10/01
Electrical testing of bipolar forceps and bipolar dissection clamps (and nasal clamps)

1. Connector testing at 1000V (pole against pole)
   - Connect both of the insulated “pistol” handpieces to the testing units. (Usually they are already permanently connected to the rear panel of the testing unit).
   - Switch on the testing unit by turning the key and pressing the green button twice. The red signal lamp must come on.
   - Adjust the required testing voltage of 1000V by turning the large knob while observing the digital display.
   - Test the testing unit by bringing the tips of the metal pencils together: If the unit functions properly, error control will be activated, i.e. the red warning light will come on and the alarm signal sound.
   - Test connector by touching the connector surface of the forceps with each metal pencil at the same time. For dissection clamps touch the drill hole for the connector cable or alternatively some electrically conductive blank metal surfaces of the jaws of the dissection clamps. No error signal is permitted. If an error signal occurs, mark the pieces accordingly and have them reworked (by production facilities, QM).
   - Turn off the unit after testing (turn the key) or put it in stand-by mode (green signal).

2. High-port insulation testing at 800V/660V/430V (pole against insulated material)
   - Use handpiece 1 "sponge" (cropped sponge) and connect it to the testing unit (usually at the front end of the casing).
   - Wet the sponge well with saline solution NaCl 0,9% (it should not be dripping).
   - Insert forceps into handpiece 2. For dissection clamps use a matching adapter cable and create a contact at both poles, and then connect to handpiece 2 and to the testing unit.
   - Switch on the testing unit and adjust voltage according to the memo on electrical testing attached to the wall.
   - Test the testing unit by touching the blank tips of the forceps with the sponge. If the unit functions properly, error control will be activated (red light and warning signal).
   - Test the entire insulation by moving the sponge slowly over the insulated surfaces up to about 10mm off the polished tips of the forceps or dissection clamps. Pay special attention to the following areas:
     o The end of the connector, glue spots, parallel guide (contactivity through the teflon piece to the guide screw is acceptable when the forceps are closed).
     o No error signal, successful rework = test passed.
     o If an error signal occurs = test not passed, mark the pieces accordingly and have them tested (production facilities, QM).
   - Switch off unit after use.

PLEASE NOTE:
- According to the memo “Electrical testing site” (filename: Elektroprüfplatz Wandschild 1) posted on the wall, there are models of forceps for which high-port testing will be done at 800V or at 430V according to the customers’ wishes.
- Forceps and dissection clamps which have been reworked have to be tested again.
- Immediately put aside forceps and dissection clamps which have caused the activation of error control and mark them with a yellow dot.
- Make sure that you fill in the testing protocol carefully. Contact your department manager in case of questions or if an unusual number of errors occurs.