

Non-Sterile Bipolar Forceps SuperGliss®

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1. EXPLANATION OF SYMBOLS

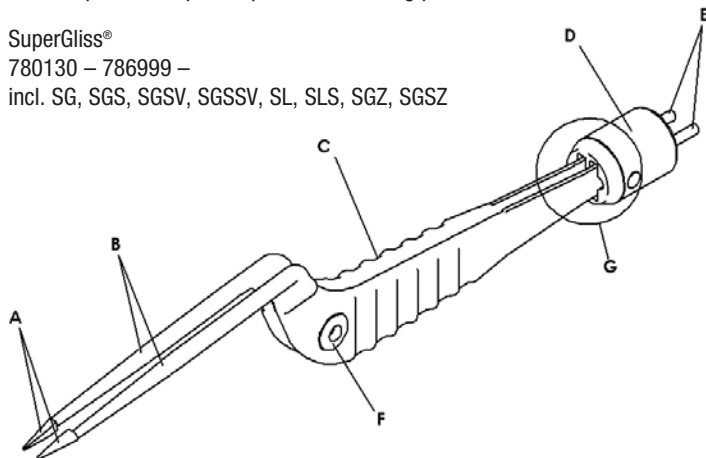
Symbol	Meaning
	Manufacturer
	Date of manufacture
	See instructions for use
	Protect against moisture
	Protect against sunlight
	Article Number

Symbol	Meaning
	Batch Number
	Caution: Federal law in the U.S.A. restricts this device to sale by or on the order of a physician.
	Designed, manufactured, and controlled according to DIN EN ISO 13485: Medical devices – Quality management systems – Requirements for regulatory purposes.

2. PRODUCT DESCRIPTION

Sutter Bipolar Forceps comprise the following product line:

SuperGliss®
780130 – 786999 –
incl. SG, SGS, SGSSV, SGSSV, SL, SLS, SGZ, SGSZ



- A Tips
- B Tines
- C Handle
- D Connector plug
- E Connector Pin
- F Guide Stop (only selected models): difficult to reach area for cleaning
- G Between Springs: difficult to reach area for cleaning

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Rx only

REF 89 90 17
2023-02-21
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3. INDICATIONS FOR USE

Intended Use: Sutter Bipolar Forceps SuperGliss® are designed to grasp, manipulate and coagulate selected tissue. They are to be connected to the bipolar output of an electrosurgical generator with an appropriate bipolar cable and must only be used with parameters for bipolar coagulation.

Indications: General surgery, Orthopaedic coagulation, Thoracic coagulation, Neurosurgical coagulation, Gynaecological coagulation (except for use in female sterilisation), Urological coagulation, Ear-, Nose- and Throat coagulation.

Contraindications: Sutter Bipolar Forceps SuperGliss® have not been shown to be effective for tubal sterilisation or tubal coagulation for sterilisation procedures and should not be used for this purpose.

4. ELECTROSURGICAL CABLES

Sutter Bipolar Forceps are intended to be used with Sutter Bipolar Silicone Cables for 2-Pin Connector or Flat Connector manufactured by Sutter Medizintechnik GmbH.

5. BEFORE USE

- **Caution:** This device is delivered non-sterile. It must be cleaned and sterilized by the user before first use and after each use. Use sterilized products only.
- **Warning:** Examine the integrity of the electrical insulation as well as the cleanness and integrity of the forceps under magnification to prevent unintended burns or malfunction. Inspect the instruments as described in Chapter End of Life Indicators and do not use any damaged instrument.
- **Warning:** Before connecting forceps and cables to an electrosurgical generator, make sure that the generator has been switched off or is in standby mode. Disregarding these instructions may lead to burns and electrical shock.
- **Warning:** The device delivers bipolar energy. Double check that you did not accidentally mismatch the connector with a monopolar input.
- **Caution:** These instructions do not substitute the instructions for the electrosurgical generator and other accessories used. Follow the instructions supplied by the manufacturer of your electrosurgical generator carefully, making sure to read all warnings and precautions.

- **Caution:** Electrosurgical accessories may only be used and disposed of by trained medical staff.

6. DURING SURGICAL USE

- **Warning:** Do not exceed a maximum voltage output of the generator of 500 Vp. The device is not intended for fulguration and arcing coagulation procedures.
- **Warning:** For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the

pacemaker may occur, or the pacemaker may be damaged. Bipolar electrosurgery should be used at least 1 cm away from implants. In case of doubt, approved qualified advice should be obtained.

- **Warning:** Please do not activate the bipolar power unless the instrument is touching the target tissue.
- **Caution:** Forceps tips can cause injuries to patient and user.
- **Warning:** Store temporarily unused forceps in a location that is isolated from the patient.
- **Warning:** Position cables in such a way that contact with the patient and with other leads is avoided.
- **Warning:** Do not use in the vicinity of inflammable or explosive substances.
- **Warning:** Coagulation should only be performed if the contact surfaces are visible.

7. REPROCESSING INSTRUCTIONS

This product is delivered non-sterile. It must be thoroughly cleaned and sterilized by the user according to the following processing instructions before first use and after each use. Reprocessing is to be done with the validated parameters as described below together with in the US for use on medical devices legally marketed equipment and accessories.

A. FIRST REPROCESSING STEP AFTER SURGICAL USE

Immediately after surgical use, disconnect the cable from the forceps and prepare for cleaning and sterilization within a maximum time of 2 hours after surgical use. Never allow blood and/or other contaminants, such as body fluids, tissue, debris or saline solution, to dry on the instruments.

Wipe coarse impurities off the forceps with a clean disposable soft tissue and rinse thoroughly with one to two liters running warm tap water at 35°-40°C (95°F-105°F) for two minutes.

After rinsing, place the forceps in a transportation container and make sure they are maintained moist inside the container.

Cover the container and transport to the dedicated cleaning area. Immediately proceed to the main cleaning step, as described below.

B. PREPARATION OF MAIN CLEANING

Detergents

The validated cleaning was performed with 15.6 mL/L of ENZOL® Enzymatic Detergent supplied by ASP Advanced Sterilization Products.

Read, understand and follow the indications, instructions and warning information supplied with the detergent for correct handling and use of the product. Prepare the detergent solutions according to the manufacturer's recommendations.

Always provide personal protective equipment (PPE) for processing personnel according to the instructions and material safety data sheets (MSDS) supplied with the detergent.

Water Quality

Use filtered water for diluting detergents and for rinsing the equipment. Mineral residues from hard water can stain the equipment and/or prevent effective cleaning. Always follow the water quality requirements per AAMI TIR 34.

C. MANUAL MAIN CLEANING (Second reprocessing step)

Thoroughly clean the product before sterilization. Minimize or eliminate time delays between the cleaning and sterilization steps. Delays may create conditions favorable to microbial growth or colonization and increase the challenge to each subsequent step.

Warnings

- Make sure that impurities are completely removed from the instruments. Insufficient cleaning may result in the accumulation and coagulation of protein residue on the instruments and subsequently interfere with sterilization.
- Do not apply instrument oils after cleaning!

Recommended Equipment

- Non-abrasive, soft, flexible, nylon-bristle brushes
- Syringe
- PPE as recommended by the detergent supplier (minimum: overalls, gloves, face/eye shield)
- Absorbent wipes
- Soft, lint-free cloth
- Warm water with an optimum temperature range of 35°-40°C (95°F-105°F).
- Medical-grade compressed air, < 140 kPa (< 20 psi).

Recommended Procedure to Clean Forceps

1. Prepare a cleaning bath with 15.6 mL/L of ENZOL® prepared according to the manufacturer's instructions.
2. Place the product in the cleaning bath, so that the surfaces are entirely wetted and the product does not come in contact with any other parts in the bath. Using ENZOL® the immersion time is 25 minutes at room temperature.
3. Prepare an ultrasonic bath with 15.6 mL/L of ENZOL® prepared according to the manufacturer's instructions.
4. Place the product in the ultrasonic bath large enough to allow complete immersion of the instrument, frequency 25 to 50 kHz. Using ENZOL® the immersion time is 5 minutes at room temperature.
5. Remove all gross soil from the equipment using absorbent wipes or a soft, lint-free cloth moistened with the prepared detergent solution.
6. Using suitable, soft bristled toothbrushes that will not damage the tips, clean the equipment thoroughly. Pay particular attention to rough surfaces, crevices, and difficult-to-reach areas where soil may be shielded from brushing, such as details around a guide stop or con-

ductor. Flush difficult-to-reach areas [FIG. 1: F, G] with a syringe filled with the detergent solution for a minimum of 1 minute per area.

7. Actuate all moving parts of the equipment to clean hidden surfaces.
8. Rinse the equipment in warm running water for at least 4 minutes or until all traces of detergent solution are removed. Pay particular attention to rough surfaces and joints between mating parts. Actuate all moving parts to remove any remaining detergent solution.
9. Visually inspect the equipment for any remaining soil or detergent solution. If soil remains, repeat the complete manual main cleaning procedure using fresh detergent solution.
10. Dry the equipment with a soft, lint-free cloth or medical-grade compressed air.
11. After cleaning, check the product for corrosion and damages as described in the Chapter about End of Life Indicators and follow instructions for damaged product. Otherwise proceed immediately to sterilization.

D. STERILIZATION (Third reprocessing step)

Steam sterilization is recommended to be done via dynamic-air-removal (pre-vacuum) cycles for wrapped product using the following validated parameters:

Type of Cycle	Dynamic Air Removal
Temperature	132°C (270°F)
Exposure	4 minutes
Time Drying	20 minutes

Caution: Make sure your FDA-cleared sterilizer is properly installed, qualified and regularly subjected to maintenance and testing. Sterilization wraps and any accessories must be cleared by FDA for use with the dynamic-air-removal steam sterilization cycle described in these Instructions for use, i.e. be compliant with the sterilization requirements specified in AAMI ANSI ST 79, ISO 11607 and ISO 17665-1.

Recommended Procedure to Sterilize Forceps

1. If you use sterilization pouches, protect the tips from damage by using Tip Guards as for example manufactured by Aspen Surgical, MI 49316 USA. Sutter Medizintechnik GmbH is selling the article under Article No. 990051.
2. Place product into sterilization equipment and seal according to recommendation of corresponding manufacturer.
3. Load wrapped product into the sterilizer and perform sterilization. If you use trays, do not stack trays during sterilization.
4. Check whether the wrapped product is dry after sterilization. Items with wet packaging are considered contaminated. Repackage and sterilize any product with wet packaging

5. After sterilization, allow the wrapped product to cool to room temperature prior use. Failure to comply may result in burned patient tissue or healthcare staff, and/or damage to the instrument.

Caution: The Tip Guards [TAB1: A] are intended for single use only. Do not re-use, reprocess, or repackage Tip Guards. Failure to comply may lead to infection or cross infection and result in patient and/or healthcare staff injury.

8. STORAGE

Storage of non-sterile product that has not been used so far is recommended to be done within the original packaging. Do not expose to direct sunlight.

After sterilization, always transport wrapped product with care to prevent damaging the sterile barrier. Excessive handling of wrapped product will increase the likelihood of damaging the sterile barrier and may lead to contamination.

See the instructions for use supplied with the sterilization wrap for maximum shelf-life information.

9. END OF LIFE INDICATORS AND INSPECTIONS

Due to the product design, the raw materials used and the intended purpose it is not possible to determine a precise end of life depending on the maximum possible number of reprocessing cycles. Moreover, the actual product lifetime depends on the use and treatment the instruments receive. To avoid damage please pay particular attention to the following:

Warnings regarding Cleaning Instruction:

Failure to observe these warnings may result in insufficient cleaning success or may shorten the life span of the product.

- To prevent fixation of blood and protein residue, do not use hot water at temperatures above 40°C (104°F), alcohol, disinfectants containing aldehyde or antiseptics.

- Do not use metal brushes or steel wool to clean the product.
- Do not place the product in hydrogen peroxide (H₂O₂)!
- Do not bend the forceps tines apart [FIG.1: B].

Warnings regarding Surgical use instruction:

Failure to observe these warnings may result in insulation breakdown during surgery or may shorten the life span of the instrument.

- Do not exceed a maximum voltage output of the generator of 500 Vp.

Routine and careful inspection is the best method for determining the serviceable live span of the product.

It is very important to check each surgical product under magnification before use for visible damage and wear. Pay particular attention to locations where soil may become trapped such as mating surfaces and recessed features such as holes.

Caution: Do not use the product if you observe any of the following indicators:

- Visible damage to the electrical insulation
- Corrosion
- Visible nicks, dents, chips or cracks
- Any other sign of damage

If any of the above indicators appear, discard the product according to approved hospital procedures.

Caution: A certain discoloring of the tips of Sutter Bipolar Forceps SuperGliss® is normal and harmless.

From the reprocessing validation performed, the end-of-life point of the Sutter Bipolar Forceps SuperGliss® is twenty uses.

Caution: To determine if the product is fit for use, perform a routine and careful inspection as described above.

10. RETURNING FOR REPAIR

Defect products must pass the complete reprocessing process before being returned for repair.

For any questions on this matter please contact the manufacturer.

11. WARRANTY

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