Bipolar Forceps – Calvian® / Calvian endo-pen®

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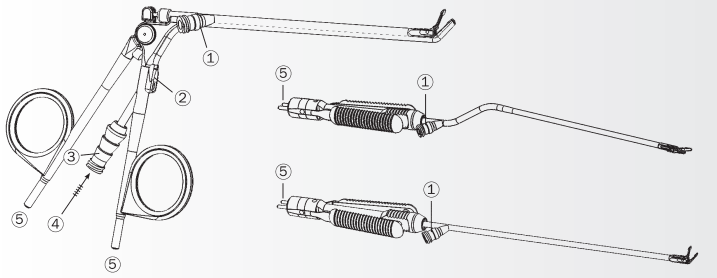

FIG. 1	Structure
1	Luer connector for cleaning
2	Suction interruptor (depending on model)
3	Luer connector suction tube
4	Cleaning brush REF 992901018 (short), 993801018 (long)
5	Cable connectors

1. EXPLANATION OF SYMBOLS AND ABBREVIATIONS

Symbol	Meaning
	Manufacturer
	Date of manufacture
	See instructions for use
	Protect against moisture
	Protect against sunlight
REF	Article Number
LOT	Batch Number
Rx only	Caution: Federal law in the U.S.A. restricts this device to sale by or on the order of a physician.
CE 0297	Designed, manufactured, and controlled according to DIN EN ISO 13485: Medical devices – Quality management systems – Requirements for regulatory purposes.

2. PRODUCT DESCRIPTION

These instructions for use apply to the following product line:

Calvian®/ Calvian endo-pen®
Sutter Bipolar Forceps
REF: 70 09 00 – 70 09 59
70 09 61 – 70 09 94
incl. S, SG, SGS

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Rx only CE 0297

REF 899027_US
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3. INTENDED USE

The electrosurgical instruments are intended to remove tissue and control bleeding.

4. ELECTROSURGICAL CABLES

Sutter Bipolar Forceps are intended to be used with Sutter Bipolar Silicone Cables for 2 x 2 mm Connector, 2-Pin Connector or Flat Connector manufactured by Sutter Medizintechnik GmbH or any compatible bipolar cable that is legally marketed within the USA

5. BEFORE USE

- **Caution:** This instrument 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 and the mechanical function 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 10: 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 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:** Do not activate the bipolar power unless the instrument is touching the target tissue.
- **Caution:** Forceps tips can cause injuries to patient and user.
- **Caution:** 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 (manual pre-cleaning / automated main cleaning)

This instrument 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. Use in the USA legally marketed equipment and accessories for medical devices only.

- **Warning:** To prevent fixation of blood and protein residue, do not use hot water, alcohol, disinfectants containing aldehyde or antiseptics.
- **Warning:** Do not use metal brushes or steel wool to clean instruments.
- **Warning:** Do not place instruments in hydrogen peroxide (H_2O_2).

AFTER USE
Manual pre-cleaning (First reprocessing step)

Calvian®	Calvian endo-pen®
Promptly after use (within 1 hour at most), immerse the instrument in cold water for at least 5 minutes, filling the lumen (channels) with water.	Immediately after use, disconnect the cable from the instrument and prepare for cleaning and sterilization within a maximum time of 1 hour after use. Never allow blood and/or other contaminants, such as body fluids, tissue, debris or saline solution, to dry on the instruments.

Calvian®	Calvian endo-pen®
Clean the instrument (especially the instrument tip) with a soft brush until no residual contamination is visible (use a magnifying glass!).	Immerse instrument in cold tap water to remove visible impurities. Use a soft brush for the manual removal of coarse impurities. Wipe coarse impurities off the instrument with a clean disposable soft tissue and rinse thoroughly with running cold tap water at 14–18 °C (58–64 °F) for min. 5 minutes.
Thoroughly flush both lumina (channels) with a spray nozzle for least 10 seconds. While doing so, hold the suction interrupt [2] closed with a finger, clean the contaminated channels with a suitable cleaning brush [4] under running water, making sure that the openings at the ends are unobstructed. The tip of the cleaning brush must come out the end of the suction channel. Thoroughly flush both channels again with a spray nozzle for at least 10 seconds. While doing so, hold the suction interrupt [2] closed again with a finger.	Flush the channel with a water spray gun for min. 20 seconds (4 pulses of 5 seconds, static water pressure 2 bar). Rinse the tips of the instrument with a water spray gun min. 10 seconds (2 pulses of 5 seconds, static water pressure of 2 bar).
Place the instrument in an ultrasonic bath for 5 minutes, 40°C filled with 0,5% deconex® 28 ALKA ONE-x[1]. Afterwards flush both channels again with a spray nozzle for at least 10 seconds. While doing so, hold the suction interrupt [2] closed again with a finger.	–
Rinse the tips twice with a spray nozzle for at least 10 seconds.	–

After rinsing, place the instrument in a transportation container and make sure it is maintained moist inside the container. The instrument may be transported in an instrument tray within the transportation container.

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

Automated main cleaning (Second reprocessing step)

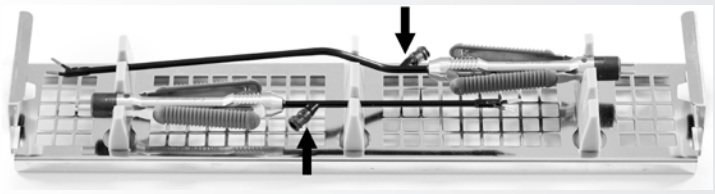
Recommended equipment and detergent:

- Cleaning and disinfection device (CDD) with approved efficiency (e.g. FDA clearance or CE mark according to ISO 15883 series), properly installed, qualified and regularly subjected to maintenance and testing. The CDD must have connections for flushing the instruments.
- CDD must have a validated thermal disinfection program. Deviating from the validated process parameters (longer cleaning time and higher cleaning temperatures up to 95 °C (203 °F)) do not damage the instrument and are permitted according to the A_0 concept, for instance thermal disinfection at 90 °C (194 °F), 5 minutes, comparable A_0-value>3000.
- Select detergent intended for cleaning and/or disinfection of medical devices made of metals and plastics, and with approved efficiency (e.g. FDA approval or CE mark). [1]For the validation deconex® 28 ALKA ONE-x (Borer Chemie) was used. Any selected detergent must have comparable properties regarding pH value (alkaline, pH = 10-13) and compatibility with plastics, please contact your supplier or hygiene officer in case of questions.

Process:

Load instruments into the CDD. In doing so, make sure the instruments do not touch each other and are securely supported. The Calvian endo-pen® should be placed into the storage trays included or available as accessories (REF 701778-01, 701778-02, 701778-05 and 701778-10). Pay attention to insert correctly with Luer-Lock connections positioned on sides of instrument trays for one/two or on top for instrument trays for five/ten.

Exemplary illustration showing instrument tray for two with Luer-Lock connections on sides:

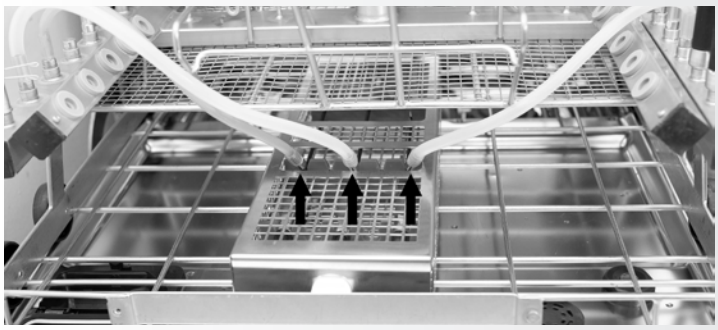


The lumina of the instruments [1, 3] must be connected to the flushing connection of the CDD using the Luer-Lock connections provided.

See exemplary illustrations for Calvian endo-pen®:

- Instrument tray for one or two, with connection for the rinsing port on left/right sides.

- Instrument tray for five or ten, with connection for the rinsing port on top.



Program steps	Calvian®	Calvian endo–pen®
Pre-rinse with cold tap water	3 minutes	3 minutes
Clean with 0.5 % deconex® 28 ALKA ONE-x at 70 °C (158 °F), or equivalent	5 minutes	5 minutes
Mid-cycle and/or final rinse with warm tap water (40–45 °C) (104–113 °F)	1 minute	1 minute
Rinse with cold deionized water	1 minute	1 minute

Inspection:

After cleaning, visually inspect the instrument and check for intact insulation, cleanliness, and integrity.

8. STERILIZATION (Third reprocessing step)

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

Type of Cycle	Temperature	Exposure Time	Drying Time
Dynamic Air Removal	min. 132 °C (270 °F)	4 minutes	min. 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. Place instrument alone or within an appropriate instrument tray into individual sterilization pouches (i.e. Chex-All II Instant Sealing pouch 12”x18” by Propper Manufacturing Company Inc., USA, reorder number 02401800) and seal according to recommendation of manufacturer. **Packaging used for sterilization must comply with ISO 11607 and ANSI/AAMI ST 79.**
2. Load the pouches into the sterilizer and perform sterilization. If you use trays, do not stack trays during sterilization.
3. Check whether the wrapped instruments are dry after sterilization. Items with wet packaging are considered contaminated. Repackage and sterilize any instruments with wet packaging.

9. STORAGE

Storage of non-sterile instruments that have 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 instruments with care to prevent damaging the sterile barrier. Excessive handling of wrapped instruments 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.

10. END OF LIFE INDICATORS AND INSPECTIONS

According to the performed reprocessing validation, a minimum of 20 reconditioning cycles can be expected with proper use.

Inspection of the surgical instrument under magnification before use for visible damage and wear should be performed. Pay particular attention to locations where soil may become trapped such as mating surfaces and recessed features such as holes.

Do not use the instrument 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 instrument according to approved hospital procedures.

The reprocessing facility should track the number of reprocessing cycles by using an instrument traceability management system (e.g. T-DOC Instrument Traceability Management System from GETINGE GROUP, ORLocate from Haldor advanced technology Ltd.).

11. RETURNING FOR REPAIR

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

For any questions on this matter please contact the manufacturer.

12. WARRANTY

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