REF 899016_LB 1 | 03/2021 © Sutter Medizintechnik GmbH

Calvian® / Calvian endo-pen®

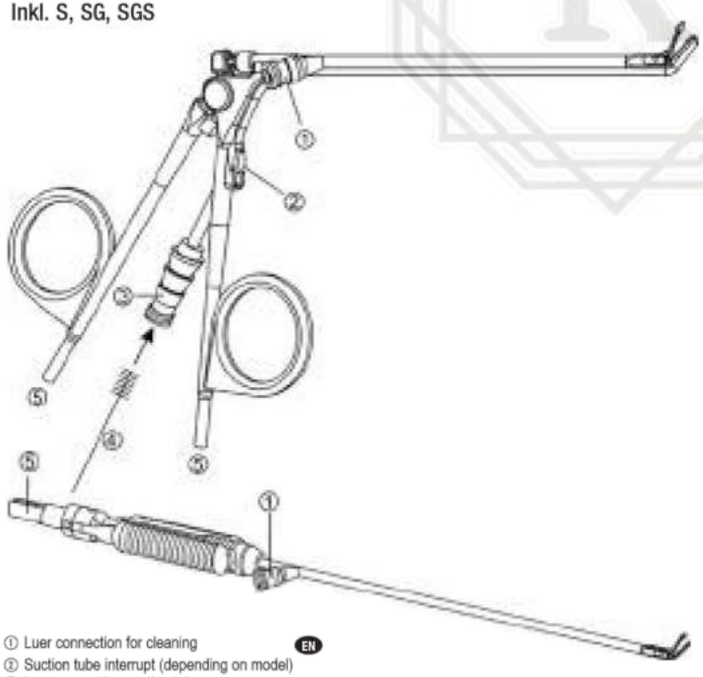
- DE Bipolare Koagulationszangen
- EN Bipolar Coagulation Forceps
- FR Pinces de Coagulation Bipolaires

Calvian® / Calvian endo-pen®

- ES Pinzas de Coagulación Bipolares
- IT Pinze di Coagulazione Bipolari
- NL Bipolaire Coagulatietangen

Sutter

REF:
700900 – 700959
700961 – 700994
Inkl. S, SG, SGS



① Luer connection for cleaning EN
② Suction tube interrupt (depending on model)
③ Luer connection suction tube
④ Cleaning brush REF: 992901018 (290 mm, Ø 1.8 mm), 993801018 (l380 mm, Ø 1.8 mm)
⑤ Cable connections

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.

⚠ **Not sterile.** Must be cleaned and sterilized prior to initial and each subsequent use.

Intended purpose:
Bipolar coagulation of soft tissue. Depending on the instrument's scope of functionality, also for suctioning fluids during surgical procedures.

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

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 instrument 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.
⚠ Instrument tips may cause injuries!
⚠ After application, instrument tips may be so hot they cause burns!
⚠ Never lay down instruments on or in the immediate vicinity of 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!
Do not allow blood and tissue residues dry up!
Remove blood and tissue residues with a soft cloth or brush!
Do not use sharp tools / scouring agents!
⚠ Do not immerse in hydrogen peroxide (H_2O_2)!

Manual cleaning and disinfection:
⚠ The instrument must always be reconditioned by machine – no manual cleaning!
According to recommendations of the DGSV ("Deutsche Gesellschaft für Sterilgutversorgung", German Association for Sterile Goods Supply), the Calvian® and Calvian endo-pen® are assigned to risk group B*. Machine cleaning is required for such products.
**This classification was assigned according to the DGSV 2013 flow chart for the classification of medical devices based on the recommendations of the KRINKO ("Krankenhaushygiene und Infektionsprävention Kommision", Hospital Hygiene and Infection Prevention Commission)/BfArM ("Bundesinstitut für Arzneimittel und Medizinprodukte", Federal Institute for Drugs and Medical Devices), Bundesgesundheitsblatt (Federal Health Bulletin) 2012; 55:1244-1310*

Manual pre-cleaning:
⚠ Manual pre-cleaning is an important prerequisite for successful machine cleaning and therefore part of the overall reconditioning process!

Calvian®	Calvian endo-pen®
Promptly after use (within 1 hour at most), thoroughly rinse the instrument with cold water.	Promptly after use (within 1 hour at most), immerse the instrument in cold water for at least 5 minutes, filling the lumen (channel) with water.
Clean the instrument (especially the instrument tip) with a soft brush until no residual contamination is visible (use a magnifying glass!).	Clean the instrument (especially the instrument tip) with a soft brush until no residual contamination is visible (use a magnifying glass!).
Thoroughly flush both lumina (channels) with a spray nozzle for at 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.	Rinse the lumen (channel) for at least 20 seconds in pulses (4 surges) with the spray nozzle. Flush the instrument tip with a water spray gun for 10 seconds (2 pulses of 5 seconds, static water pressure of 2 bars).
Clean the instrument in an ultrasound bath: 40 °C, 15 minutes, mildly alkaline cleaner with a concentration of 0.5 %, deconex® 28 ALKA ONE-x (Borer Chemie).	–

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 FDA clearance for instance, or the CE marking according to EN ISO 15883). The CDD must have connections for flushing the instruments.

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). The lumina of the instruments must be connected to the flushing connection of the CDD using the Luer-Lock connections provided.

Program steps	Parameters
Pre-rinse with cold tap water	3 minutes
Clean with 0.5 % deconex® 28 ALKA ONE-x at 70 °C	5 minutes
Neutralize with warm tap water (40-45 °C)	–
Mid-cycle and/or final rinse with warm tap water (40-45 °C)	1 minute
Rinse with deionized water	1 minute

- 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 instrument and are permitted according to the A_0 concept, for instance thermal disinfection at 90 °C, 5 minutes, comparable A_0-value>3000. If a different cleaning agent is used, only use products with properties comparable to deconex® 28 ALKA ONE-x (Borer Chemie), for instance regarding the pH value and compatibility with plastics. Please contact your supplier or hygiene officer in case of questions.

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

Maintenance:
None

Packaging:
Package cleaned and disinfected storage trays in disposable sterilization packaging (single or double packaging), or place the instrument or tray with the cleaned and disinfected instruments into a suitable sterilization container 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.
Use **only** the sterilization process described in the following:

- Steam sterilization, steam sterilizer according to EN 13060 and/or EN 285 and validated according to EN ISO 17665

Program parameters	Parameters
Process	3x fractionated vacuum process
Sterilization temperature	132 °C
Sterilization time (holding time at sterilization temperature)	3 minutes
Max. sterilization temperature plus tolerance according to EN ISO 17665	138 °C
Drying time	Min. 10 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 cool, 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 change to the product or deviation from these instructions for use waives the liability of Sutter Medizintechnik GmbH.

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