双极镊 Bipolar Forceps

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Sutter

Classic / Classic Micro
SELECTAL™
SuperGliss® / SuperGliss® ELP
SuperGliss® TEO / SuperGliss® zhora
Irrigation/Suction

REF:
700150 – 700399 - incl. S, SV, SV1, SV2, F
700700 – 700799 - incl. S, SV
700800 – 700899 - incl. S, SV
702100 – 702299 - incl. S, SV
780130 – 786999 - incl. SG, SGS, SGSV, SGSSV, SL, SLS, SGZ, SGSZ

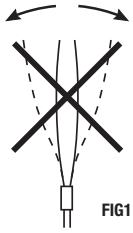
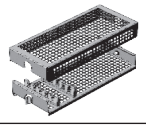


FIG1

TAB1		REF
A		992901012 → 290 mm, Ø 1.2 mm 992901018 → 290 mm, Ø 1.8 mm 993801018 → 380 mm, Ø 1.8 mm
B		701724, 701725 → n=2 701764, 701765 → n=5 701766, 701767 → n=10

Registration Number / 注册证编号: 20153010208
Technical requirement Number / 技术要求编号: 20153010208

代理人名称：泰世德（北京）医药科技有限公司
地址：北京市朝阳区红军营南路15号院5号楼6层602室
联系方式：86-10-64187881

售后服务代理
代理人名称：广州侨德医疗科技有限公司
地址：广东省广州市荔湾区花湾路638-680号A1、A2栋3层332房
联系方式：020-81516821

Sutter Medizintechnik GmbH
苏特医疗科技有限公司
Alfred-Walz-Str. 22, 79312 Emmendingen/Germany
Tel: +49 (0) 7641 962560
Fax: +49 (0) 7641 9625630
E-Mail: info@sutter-med.de.
www.sutter-med.de

CE 0297

REF 899000_CN

中國 ZH

产品 / 用户 / 废弃处理：
仅允许专业医疗人员使用该电外科配件，并对其进行废弃处理！
尽管提供了本说明书，但仍然要阅读所使用电外科装置和其他配件的使用说明书。
⚠ **未消毒。**首次使用和每次再次使用前，要对其进行清洁和消毒。

按规定使用：
Sutter SuperGliss®, SuperGliss® ELP, SuperGliss® TEO, SuperGliss® zhora, Classic, Classic Micro
和 Selectal™ 双极镊用于选定组织的电凝。
Sutter 双极吸引镊用于在电外科作业中电凝组织和吸液。
Sutter 双极冲洗镊用于在电外科作业中选定组织的电凝和液体输送。

使用寿命：
如果正确使用，则至少可以重复使用 20 次。

在使用之前：
⚠ 在每次使用之前，检查产品的清洁度、机械功能和绝缘完好性。
我们建议，需使用恰当的检测设备检查绝缘情况。
⚠ 只能使用无缺陷、经过消毒的产品！
非粘性仪器尖端出现一定变色是正常的，无需担心。
镊子和电缆只能连接至已关闭的电外科装置上，或者在待机模式下进行连接。违反这些规定可能导致烫
伤和触电！
对于电气安全方面的其他信息，我们建议查阅 DIN EN 60601-2-2 标准附页 1。

电外科电缆：
Sutter 双极镊指定利用硅胶线配备美标电插头或欧标扁平接口使用，其制造商是 Sutter Medizintechnik GmbH。

在使用期间：
⚠ 必须始终以能够达到所需外科效果的最低的功率设置进行工作。
⚠ 最高许可电压为 500 Vp
⚠ 定期清除仪器尖端上残留的血液和组织。
⚠ 镊尖可能造成人员受伤！
⚠ 使用完以后，镊尖的高温会导致烫伤！
⚠ 绝对不得将仪器置于患者身上，或者患者附近！和患者绝缘铺设电缆，并隔离存放不使用的器械。
⚠ 不能在现场使用可燃物质或爆炸物质！

再处理：

一般提示：
遵守国家准则和规定！
断开仪器的电缆！
整个再处理包括预清洗、清洗 / 消毒和灭菌。
⚠ 基于有效性和可再现性，始终优先采用机械清洁 / 消毒！
⚠ 始终以机械方式再处理冲洗镊和吸引镊！
⚠ 勿要放入双氧水 (H_2O_2)！
⚠ 勿要向两侧掰弯镊子！**(FIG1)**

预清洗：
- 血液和组织残留物不得干燥，而是在最长 1 个小时之后使用冷水冲洗！ 必要时使用软刷 （不使用钢丝刷等）。
- 在彻底冲洗冲洗镊和吸引镊之前，请保证开口畅通。必要时使用通管针 / 刷子 **(TAB1:A)**。 使用一次性注射器（最低容量 50 ml）以及当前路厄氏锁定的直接接口冲洗器械内腔五次。
- 移动部件在预清洗时来回移动多次。

手工清洁和消毒：

清洁步骤	说明
预清洗	冷水冲洗 5 分钟，期间处理移动部件。 并使用软刷（例如 MED100.33 Medisafe GmbH）清洁器械，直至看不到任何残留物。
超声和消毒	室温下的 35 kHz 超声波电解液池 ，10 分钟，2 % 的 Bomix® plus 清洁和消毒溶液 (Bode Chemie)。
后清洗	如果有必要，使用清洁喷枪冲洗不易清洁的部位 20 秒钟， 然后使用去矿物质水冲洗整个器械 30 秒钟。

仪器对于手动清洁和消毒的基本适用性验证由一家独立的认证测试实验室进行，验证时使用了浓度为 2% 的仪器消毒剂 Bomix® plus（Bode Chemie），测试报告编号为 0 7015-2，2015.11.24。

机器清洁和消毒：
在选择清洗消毒器 (WD) 时注意，WD 的效果必须经过检测（比如 DGHM 或 FDA 许可证或者符合 EN ISO 15883 标准的 CE 标识）。
- 将仪器放到 WD 中。这时注意，不能触摸仪器，并且要稳定地放置。
- 可选装的存放托盘 **(TAB1:B)** 可以保障安全存放。

为了改善清洁效果，可以用现有的路厄氏锁定接口将冲洗镊和吸引镊的内腔与 WD 的冲洗接口相连。

程序步骤	参数
预冲洗	10±2 °C，1 分钟
使用浓度为 0.5 %（5 ml/升）的 deconex® 28 ALKA ONE-x 清洁剂清洗	70±2 °C，5 分钟
后冲洗	10±2 °C，1 分钟
热消毒	90±2 °C，5 分钟

仪器有效机械清洗和消毒的基本适用性验证是由一家独立的认证测试实验室进行的，验证时使用了消毒器 Miele G7836 CD（高温消毒，Miele & Cie.有限两合公司，Gütersloh）和浓度为 0.5 % 的清洁剂 deconex® 28 ALKAONE-x（Borer 化学股份公司，瑞士 Zuchwil），测试报告编号为 111738-10， 2011.05.11。

- 注意：上述信息是以所述程序步骤成功进行清洁的最低时间说明，该信息均已经过验证。过程参数 存在偏差（更长的清洁持续时间以及更高的清洁温度，最高可达到 95 °C）并不会损坏仪器，而且根据 A0-方案是允许的存在一定偏差的，（参比 A0 值 > 3000）。 如果使用其他清洁剂， 则只能使用具有与清洁剂 deconex® 28 ALKA-ONE-x（Borer 化学公司）相同性能（比如 pH 值以及与塑料的相容性） 的清洁剂。如果存在疑问，请联系负责的供应商或卫生专员。

检查：
在进行消毒前，目视检查仪器绝缘完好性、清洁度和完整性。

保养：
无

包装：
使用一次性消毒包装对经过清洁和消毒的仪器进行包装（单层或双层包装），将仪器或盛有经过清洁和
消毒仪器的存放托盘包入棉布，并放到消毒器皿中，消毒器皿需满足以下要求：
- EN ISO/ANSI AAMI ISO 11607
- 适于蒸汽消毒（可以耐抗至少 141 °C 的温度，蒸汽渗透性充足）
- 充分防止仪器或消毒包装受到机械损坏

消毒：
仅消毒经过清洁和无菌的产品。
• 蒸汽消毒，根据 EN 13060 或 EN 285 和 EN ISO 17665 标准进行验证的蒸汽消毒器

程序步骤	参数
工艺	分馏真空（动态抽真空）
消毒温度	132 °C （最高 138 °C，包括符合 EN ISO 17665 标准的公差）
消毒时间（消毒温度下的保温时间）	最短 3 分钟
干燥时间	30 分钟

仪器对于有效蒸汽消毒的基本适用性验证 是由一家独立的认证测试实验室进行的，测试报告编号为 111739-10，2011.06.07。期间考虑了诊所和医生诊室内的典型条件以及上述工艺。

⚠ 不能在高温空气中消毒！
⚠ 不能在 STERRAD® 中消毒！
⚠ 如果仪器可能与蛋白酶传染性因子发生了接触，则要将仪器（CJD 感染危险） 销毁， 不得回收再用

存放 / 运输：
干燥存放。防止阳光直射。使用稳固的箱子 / 包装存放和运输。 退运时，只能使用消毒包装递送经过清洁和消毒的产品。

特别提示：
如果对产品进行了任何改动，或者未遵守本使用说明书中的规定，则 Sutter Med 医疗技术公司不承担责任。

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English EN

Product / User / Disposal:
Electrosurgery accessories may only be used and disposed of by qualified medical personnel! 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 use:
Sutter SuperGliss®, SuperGliss® ELP, SuperGliss® TEO, SuperGliss® zhora, Classic, Classic Micro and Selectal™ bipolar forceps for coagulation of the selected tissue. Sutter bipolar suction forceps for use in electrosurgery for the coagulation of tissue and suctioning fluids. Sutter bipolar irrigation forceps for use in electrosurgery for coagulation and to supply fluid to select tissue.

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 forceps and cables, the electrosurgery device must be turned off or in standby mode. Failure to comply may lead to burns and electric shocks!
For further information about electrical safety, we recommend DIN EN 60601-2-2 supplement 1.

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

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.
⚠ Tips of the forceps may cause injuries!
⚠ After application, the tips of the forceps may be so hot they cause burns!
⚠ Never lay down instruments on or in the immediate vicinity of the patient! Lay 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.
⚠ Machine cleaning / disinfection is preferred due to effectiveness and reproducibility!
⚠ Irrigation and suction forceps must always be reconditioned by machine!
⚠ Do not immerse in hydrogen peroxide (H_2O_2)!
⚠ Do not bend open the forceps! **(FIG1)**

Pre-cleaning:
• Do not allow blood and tissue residues to dry up; rinse thoroughly with cold water after max. 1 hour! Use a soft brush if needed (no wire brush or similar).
• On irrigation and suction forceps, verify that openings are unobstructed prior to flushing. Use a cleaning wire / brush if needed **(TAB1:A)**. Flush the lumina of the instruments five times with a disposable syringe (minimum volume 50 ml) and direct connection to the existing Luer-Lock.
• Moveable parts must be moved back and forth several times during pre-cleaning.

Manual cleaning and disinfection:

Cleaning step	Description
Pre-cleaning	Flush for 5 minutes under cold water, operating moving parts. Clean the instrument with a soft brush (such as MED100.33 from Medisafe GmbH) until no more residues are visible.
Ultrasound and disinfection	Ultrasound bath 35 kHz at room temperature, 10 minutes, cleaning / disinfection solution 2 % Bomix® plus (Bode Chemie).
Secondary cleaning	Rinse hard to reach areas for 20 seconds with a spray nozzle as needed, then rinse the entire instrument for 30 seconds with demineralized water.

Proof of fundamental suitability of the instruments for manual cleaning and disinfection was provided for a worst-case product by an independent, accredited test laboratory using the instrument disinfectant Bomix® plus (Bode Chemie) with a concentration of 2 %, test report no. 07015-2 dated 24.11.2015.

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).
• Load instruments into the CDD. In doing so, make sure the instruments do not touch each other and are securely supported.
• The optionally available storage trays **(TAB1:B)** ensures secure support.
• For improved cleaning results, the lumina of the irrigation and suction forceps can be connected to the flushing connection of the CDD using the existing Luer-Lock connections.

Program steps	Parameters
Pre-rinse	10±2 °C, 1 minute
Cleaning 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

Proof of fundamental suitability of the instruments for effective machine cleaning and disinfection was provided by an independent, accredited test laboratory using the Miele G7836 CD disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany) and the cleaning agent deconex® 28 ALKA ONE-x with a concentration of 0.5 % (Borer Chemie AG, Zuchwil, Switzerland) (test report no. 111738-10 dated 11.05.2011).

• 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 A0 concept,comparable A0 value > 3000. If a different cleaning agent is used, only use products with properties comparablecomparable to deconex® 28 ALKA ONE-x (Borer Chemie), for instance regarding the pH value and compatibility with plastics. Contact the responsible supplier or hygiene officer in case of doubt.

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 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.
• Steam sterilization, steam sterilizer according to EN 13060 and/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)	min. 3 minutes
Drying time	30 minutes

Proof of fundamental suitability of the instruments for effective steam sterilization was provided by an independent, accredited test laboratory, test report no. 111739-10 dated 07.06.2011. Typical conditions in clinics and medical practices as well as the process described above were taken into account.

⚠ 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:
Any change to the product or deviation from these instructions for use waives the liability of Sutter Medizintechnik GmbH.
Changes reserved.

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