To-BiTE™
双极电凝钳
Bipolar Coagulation Forceps

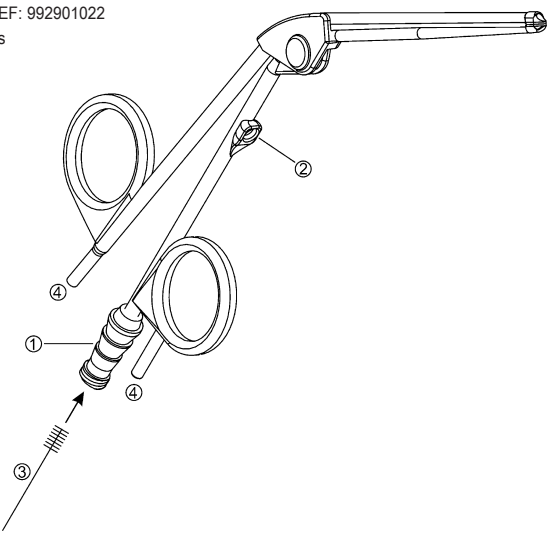
To-BiTE™
双极电凝钳
Bipolar Coagulation Forceps

Sutter

**REF:**
700960SG

① 吸引管厄氏接口 ZH
② 吸引管断路器
③ 清洁刷 REF : 992901022
④ 电缆接头

① Luer connection suction tube EN
② Suction tube interrupt
③ Cleaning brush REF: 992901022
④ Cable connections




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 899022_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 :**
双极电凝软组织。根据具体仪器功能范围 , 还可用于外科手术过程中的吸液。

**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。
仪器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 !

**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。
⚠ 仪器尖端可能造成人员受伤 !
⚠ 使用完以后 , 仪器尖端的高温会导致烫伤 !
⚠ 绝对不得将仪器置于患者身上 , 或者患者附近 !
⚠ 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 !
血液和组织残留物不得干燥 !
请使用软布或软刷清除血液和组织残留物 !
勿要使用尖锐 / 研磨性辅助工具 !
⚠ 勿要放入双氧水 ($H_2O_2$) !

**手工清洁和消毒 :**
⚠ 始终以机械方式再处理仪器 – 不能进行手工清洁 !
根据 DGSV ( 德国消毒产品供应公司 ) 的建议 , To-BiTE™ 被划分为 B 类风险组。 此类产品原则上要求以机械方式进行清洁。
*根据 DGSV 用于分级 2013 年度医疗产品的流程图进行该分级 , 其基于德国联邦健康文件 KRINKO/
BfArM 建议 2012; 55:1244-1310

**手工预清洁 :**
- 在使用完以后立即 ( 在最多 1 小时内 ) 用冷水彻底清洗仪器 , 直至完全清除了所有可见污染物。请仅使用软刷手动清除杂质。切勿使用烈性或腐蚀性清洁剂、钢丝棉或金属刷。期间请尤其注意仪器的尖端、路厄氏接口 [1] 以及吸引管的内腔。
- 使用清洁喷枪彻底冲洗吸引通道至少 10 秒钟。这时用一根手指封闭吸引管断路器 [2]。
- 使用恰当的清洁刷 [3] 在流动水下清洁受到污染的吸引管 , 同时需确保末端的开口畅通。 清洁刷的尖部必须探出吸引管末端。
- 使用清洁喷枪彻底冲洗吸引管至少 10 秒钟。这时用一根手指封闭吸引管断路器 [2]。
- 然后在超声波中清洁仪器 : 40 °C , 15 分钟 , 浓度为 0.5 % 的弱碱性清洁剂， deconex® 28 ALKA ONE-x ( Borer 化学公司 )。

仪器对于手动预清洁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 0704041002 , 2004.04.02。

**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 )。在 WD 中必须有用于冲洗仪器的接口。
程序 :
- 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。

用现有的路厄氏锁定接口将仪器的内腔与 WD 的冲洗接口相连。

| 程序步骤 | To-BiTE™ |
|---|---|
| 使用低温自来水预冲洗 | 4 分钟 |
| 使用 0.5 % 的 deconex® 28 ALKA ONE-x 在 70 °C 下清洁 | 6 分钟 |
| 使用高温自来水 (40-45 °C) 中和 | 3 分钟 |
| 使用高温自来水 (40-45 °C) 中间冲洗或补充冲洗 | 2 分钟 |
| 使用去离子水冲洗 | – |

*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 Vario TD / Miele G7735 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 ALKA ONE-x （Borer 化学股份公司 , 瑞士 Zuchwil ) , 测试报告编号为 0704041002 , 2004.04.02。*

- 请注意 : 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 $A_0$ 方案是允许的存在一定偏差的 , 比如在 90 °C 下高温消毒 5 分钟 ( 参比 $A_0$ 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。如有疑问， 请联系您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。利用放大镜检查路厄氏接口 [1] 的清洁度。如果有必要 , 再次手动预清洗 , 然后机械清洗和消毒。

**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 ) , 或将仪器存放到合适的 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。

**只能使用下列消毒工艺消毒 :**
- 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

| 程序参数 | To-BiTE™ |
|---|---|
| 工艺 | 3 重分馏预真空工艺 |
| 消毒温度 | 132 °C |

| 程序参数 | To-BiTE™ |
|---|---|
| 消毒时间 ( 消毒温度下的保温时间 ) | 3.5 分钟 |
| 最高消毒温度 , 包括符合 EN ISO 17665 标准的公差 | 138 °C |
| 干燥时间 | 10 分钟 |

*仪器有效蒸汽消毒的基本适用性验证 由一家独立的认证测试实验室利用同类产品进行， 验证时使用了消毒器 Autoclave 6-6-6 Selectomat HP， 测试报告编号为 2105021003 , 2005.03.23。*

⚠ 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 :**
低温、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 医疗技术公司不承担责任。
保留变更的权利。



## 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:**
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 to 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 the recommendations of the DGSV ("Deutsche Gesellschaft für Sterilgutversorgung", German Association for Sterile Goods Supply), To-BiTE™ is 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:**
- Promptly after use (within 1 hour at most), thoroughly clean the instrument with cold water until all visible contaminants have been removed. Use only a soft brush for manually removing contaminants. Never use aggressive or abrasive cleaners, steel wool or metal brushes. Pay special attention to the instrument tip, the Luer connections [1], and the inner lumen of the suction channel.
- Thoroughly flush the suction channel with a spray nozzle for at least 10 seconds. While doing so, hold the suction interrupt [2] closed with a finger.
- Clean the contaminated suction channel with a suitable cleaning brush [3] 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.
- Thorougly flush the suction channel with a spray nozzle for at least 10 seconds. While doing so, hold the suction interrupt [2] closed with a finger.
- Then 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).

Proof of fundamental suitability of the instruments for manual pre-cleaning was provided by an independent, accredited test laboratory, test report no. 0704041002 dated 02.04.2004.

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

| Program steps | To-BiTE™ |
|---|---|
| Pre-rinse with cold tap water | 4 minutes |
| Clean with 0.5 % deconex® 28 ALKA ONE-x at 70 °C | 6 minutes |
| Neutralize with warm tap water (40-45 °C) | 3 minutes |
| Mid-cycle and/or final rinse with warm tap water (40-45 °C) | 2 minutes |
| Rinse with deionized water | - |

*Proof of fundamental suitability of the instruments for effective machine cleaning and disinfection was provided by an independent, accredited test laboratory using the Vario TD / Miele G7735 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. 0704041002 dated 02.04.2004.*

- 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 $A_0$ 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.
Inspect the Luer connections [1] with a magnifying glass to verify they are clean. If necessary, perform manual pre-cleaning with subsequent machine cleaning and disinfection again.

**Maintenance:**
None

**Packaging:**
Package cleaned and disinfected instruments in disposable sterilization packaging (single or double packaging), or store the instrument in 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 | To-BiTE™ |
|---|---|
| Process | 3x fractionated vacuum process |
| Sterilization temperature | 132 °C |
| Sterilization time (holding time at sterilization temperature) | 3.5 minutes |
| Max. sterilization temperature plus tolerance according to EN ISO 17665 | 138 °C |
| Drying time | 10 minutes |

*Proof of fundamental suitability of the instruments for effective steam sterilization was provided by an independent, accredited test laboratory using a comparable product and the steam sterilizer Autoclave 6-6-6 Selectomat HP, test report no. 2105021003 dated 23.03.2005.*

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