单极吸引管 Monopolar Suction Tubes

单极吸引管 Monopolar Suction Tubes

Sutter

REF:
715000 – 715019

TAB 1			REF
A		Sutter (BM-780 II), Martin, Berchtold, Aesculap, Erbe (T-Serie)	360185
B		Erbe ACC / IC / ViO, Karl Storz	360186
C		Sutter CURIS®, Valleylab, Conmed, Bovie, Bowa	360187
D		290 mm, Ø 3.2 mm --> (REF 715010)	992901032
E		290 mm, Ø 2.2 mm --> (REF 715015)	992901022
F		380 mm, Ø 2.2 mm --> (REF 715017)	993801022
G		290 mm, Ø 3.2 mm --> (REF 715018)	992901032
H		290 mm, Ø 3.2 mm --> (REF 715019)	992901032

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 899010_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：
单极吸引管用于在外科手术时吸出烟雾和液体，以及软组织的电凝。

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、绝缘完好性和完整性。
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。
如果电绝缘出现损坏、存在可见腐蚀，或产品出现缺口、凹陷、碎裂或裂纹，则不要使用。在这种情况下，请按规定报废处理产品。
⚠ 仅利用 Sutter 的合适连接线使用仪器。(参见 **TAB1:A-C**) 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！
⚠ 单极器械如果未配备中性电极，切勿使用！注意正确放置中性电极。
⚠ 尽管提供了本说明书，但仍然要阅读所应用电外科装置和所使用配件的使用说明书。 对于所使用的电外科装置，请仔细遵从制造商的指导， 并阅读所有告警和安全提示。

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。
仅在电凝模式下以最大 40 瓦特的功率运行。尽可能选择较短的脉冲激活。避免持续激活 > 15 秒。
勿要在喷射 / 电灼模式下使用！
避免形成电火花！
⚠ 使用完以后，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！
⚠ 安置电缆时，注意不可以接触患者和其他导线。
⚠ 对于不使用的器械，和患者暂时隔离存放。
⚠ 不能使用或邻近可燃物质或爆炸物质！
⚠ 如果同时使用冲洗仪器，则请尽量使用非导电性冲洗液！
⚠ 最高许可电压为 3000 Vp。

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*，单极吸引管被划分为 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：
为了简化接下来的清洁过程，请在使用时避免组织残留和血液干燥。
在使用后立即 (最长 1 个小时以内) 清除器械上的粗颗粒杂质。为此请使用流动的水或消毒剂溶液。
消毒剂必须不含醛 (避免血液粒子附着)，有效性经过验证 (例如经过 VAH/DGHM 认证、具有 CE 标志)，并适用器械的消毒 (参见“材料耐抗性”)。
为了手动清除杂质，请务必使用软刷或干净的软布——切勿使用金属刷、钢丝棉、 研磨海绵或其他研磨性清洁工具。
使用一次性注射器 (最低容量 20 ml) 以及当前路厄氏锁定接口冲洗吸引管， 这时用一根手指封闭吸引管断路器。
使用恰当的清洁刷 (参见 **TAB1:D-H**) 在流动水下清洁吸引管，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。
然后重新使用一次性注射器 (最低容量 20 ml) 以及当前路厄氏锁定接口冲洗吸引管， 这时用一根手指封闭吸引管断路器。

机器清洁和消毒：
在选择消毒器时注意，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)。
- 所使用的程序适用器械，并拥有充分的冲洗循环，
- 后冲洗仅能使用无菌或低细菌 (最多 10 个细菌/ml) 以及低内毒素 (最多 0.25 内毒素单位/ml) 的水 (纯净水 / 高纯度水)。
- 用于干燥的空气经过过滤，且
- 定期保养和检测消毒器。

在选择清洁剂系统时，请注意：
- 其适用于清洁金属和塑料材质的器械，
- 使用有效性经过验证的合适消毒剂 (例如 VAH/DGHM 或 FDA 认证或 CE 标志)， 且兼容所使用的清洁剂，
- 所使用的化学品和器械兼容 (参见“材料耐抗性”)。

⚠ 务必遵守清洁剂和消毒剂制造商注明的浓度、作用时间、冲洗量等。

程序：
1. 将器械放到消毒器中。 这时注意，不能触摸器械。 用现有的路厄氏锁定接口将吸引管与消毒器的冲洗接口相连。 在彻底冲洗之前，请保证开口畅通。 必要时使用通管针 / 刷子 (参见 **TAB1:D-H**)。
2. 启动程序。请遵守下方为清洁 / 消毒循环列出的验证参数。
3. 在程序结束之后断开器械接口，并从消毒器上移除。
4. 移除后尽快检查器械，如要有必要，结束又一次后干燥循环之后在一个干净的位置包装 (参见“检查”)。

程序步骤	参数
预冲洗	10±2 °C，1 分钟
使用浓度为 0.5 %(3 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 G 7836 CD(高温消毒，Miele & Cie.有限两合公司，Gütersloh) 和清洁剂 deconex® 28 ALKA ONE-x (Borer 化学股份公司，瑞士 Zuchwil)。测试报告编号为 121627-10, 2012.04.25。

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器械进行包装 (单层或双层包装)，或将器械放入消毒器皿，消毒器皿需满足以下要求：
- DIN 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
- 按照消毒器皿的制造商说明定期保养

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 STERRAD® 中消毒 !
⚠ 不能在高温空气中消毒 !
⚠ 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。

材料耐抗性:
保证下方列出的物质不是清洁剂或消毒剂的成分 :
• 有机酸、无机酸、氧化性酸 (允许的最低 pH 值为 5.5)
• 强碱 (允许的最大 pH 值卫 12)
• 有机溶剂 (例如丙酮、乙醚、酒精、汽油)
• 氧化剂 (例如过氧化物)
• 卤素 (氯、碘、溴)
• 芳香烃、卤代烃
勿要使用金属刷、钢丝棉、研磨海绵或其他研磨性清洁工具清洁器械、消毒盘和消毒器皿 !
勿要让器械、消毒盘和消毒器皿承受 141 °C 以上的高温。

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 医疗技术公司不承担责任。
保留变更的权利。

STERRAD® is a trademark of Johnson & Johnson, Inc.

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:
Monopolar suction tube for suctioning smoke and fluids and for coagulating soft tissue during surgical procedures.

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

Before using:
⚠ Inspect the product for cleanliness, intact insulation, and integrity 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 tips on non-stick instruments is normal and harmless.
Do not use in case of discernible damage to the electrical insulation, visible corrosion, or if the product exhibits nicks, dents, chipping, or cracks. Properly dispose of the product in such cases.
⚠ Only use the instrument with a suitable connection cable from Sutter! (see **TAB1:A-C**).
To connect the product, the electrosurgery device must be turned off or in standby mode. Failure to comply may lead to burns and electric shocks!
⚠ Never use monopolar instruments without a neutral electrode! Verify that the neutral electrode is applied correctly.
⚠ Notwithstanding these instructions, reading the instructions for use provided with the electrosurgery device and other accessories being used is mandatory. Carefully follow the instructions provided by the manufacturer of the electrosurgery device being used, and read all warnings and safety notices.

During use:
⚠ Always work with the lowest output setting for the desired surgical effect.
Operation only in COAG mode with max. 40 watts. Brief, pulse-like activation if possible. Avoid continuous activation > 15 seconds.
Do not use in spray / fulugration mode!
Avoid spark formation!
⚠ After application, the tips may be so hot they cause burns!
⚠ Never lay down instruments on or in the immediate vicinity of the patient!
⚠ Position cables so the possibility of contact with the patient and other electrical lines is excluded.
⚠ When instruments are temporarily unused, store them so they are isolated from the patient.
⚠ Not for use with or in the vicinity of combustible or explosive substances!
⚠ When flushing instruments are used simultaneously, use non-conductive flushing fluid if possible!
⚠ Maximum allowable voltage 3000 Vp.

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), monopolar suction tubes 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:
To make subsequent cleaning easier, do not allow tissue residue and blood to dry on during use.
Clean the instruments to remove major contamination directly after use (within 1 hour at most). Use running water or a disinfectant solution. The disinfectant must be aldehyde-free (to prevent fixing blood particles) with proven effectiveness (for instance VAH ("Verbund für Angewandte Hygiene e.V", Applied Hygiene Association)/DGHM ("Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V.", German Association for Hygiene and Microbiology) approval, CE marking) and be suitable for disinfecting the instruments (see "Material resistance").
Only use a soft brush or soft, clean cloth to manually remove contaminants – no metal brushes, steel wool, scouring sponges, or abrasive cleaning agents.
Flush the suction tube five times with a disposable syringe (minimum volume 20 ml) connected to the existing Luer-Lock while keeping the three suction interrupts closed with a finger.
Clean the suction channel with a suitable cleaning brush (see **TAB1:D-H**) 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.
Flush the suction tube again five times with a disposable syringe (minimum volume 20 ml) connected to the existing Luer-Lock while keeping the three suction interrupts closed with a finger.

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).
• Ensure that the selected program is suitable for the instruments and includes sufficient flushing cycles,
• that only sterile or low-germ (max. 1 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (for instance purified water / highly purified water) is used for the final rinse,
• the air used for drying is filtered, and
• the disinfector is inspected and maintained regularly.
In selecting the cleaning agent system to be used, ensure that
• it is suitable for cleaning instruments made of metals and plastics,
• a suitable disinfectant with proven effectiveness (for instance VAH ("Verbund für Angewandte Hygiene e.V", Applied Hygiene Association)/DGHM ("Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V.", German Association for Hygiene and Microbiology) approval, CE marking) is used and this is compatible with the chosen cleaning agent, and
• the chemicals being used are compatible with the instruments (see "Material resistance").
⚠ Complying with the concentrations, exposure times, flushing instructions and so on provided by the manufacturer of the cleaning agent or disinfectant is mandatory.
Process:
1. Load the instruments into the disinfector. In doing so, make sure the instruments do not touch each other. Using the Luer-Lock connection provided, connect the suction tube to the flushing connection of the disinfector. Verify that openings are unobstructed prior to flushing. Use a cleaning wire / brush if needed (see **TAB1:D-H**).
2. Start the program. Note the validation parameters for the cleaning / disinfection cycle listed below.
3. After the program ends, disconnect the instruments from the connections and take them out of the disinfector.
4. Inspect the instruments as soon as possible after removal and, if required, package them after a subsequent drying cycle in a clean place (also see "Inspection").

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 minutes
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 G 7836 CD disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany) and the cleaning agent deconex® 28 ALKA ONE-x (Borer Chemie AG, Zuchwil, Switzerland). Test report no. 121627-10 dated 25.04.2012.

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 store in a suitable sterilization container meeting the following requirements:
• DIN 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
• Regular maintenance according to the information provided by the sterilization container manufacturer

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 STERRAD®!
⚠ Do not sterilize in hot air!
⚠ In case of potential contact with prions (CJD – risk of contamination), destroy the instrument and do not use it again.

Material resistance:
Make sure that the substances listed below are not part of the cleaning agent or disinfectant:
• Organic acids, mineral acids, oxidizing acids (minimum allowable pH value 5.5)
• Strong lye (maximum allowable pH value 12)
• Organic solvents (such as acetone, ether, alcohol, gasoline)
• Oxidants (such as peroxide)
• Halogens (such as chlorine, iodine, bromine)
• Aromatic halogenated hydrocarbons
Do not use metal brushes, steel wool, scouring sponges or abrasive cleaning agents to clean instruments or sterilization trays and containers!
Do not expose instruments or sterilization trays and containers to temperatures in excess of 141 °C!

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.

STERRAD® is a trademark of Johnson & Johnson, Inc.