单极电极 Monopolar Electrodes

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Sutter

Standard
ARROWtip™
Arthro
Micro

REF:
360320 – 360379
360342SV1
360440 – 360463
360500 – 360529
360531
360535
360540 – 360549
360800 – 360818
360830 – 360859

TAB1	REF	Max. Vp	Ø [mm]	Ø [mm]
	360320 – 360379 360342 SV1	3000	2,4 (3/32")	2,4 (3/32")
	360500 – 360521	1000	1,6	1,6
	360531 / 360535	900	1,6	1,6 Sutter-REF 360215
	360540 – 360549	2000	1,6	1,6
	360800 – 360818	2000	2,4 (3/32")	2,4 (3/32")
	360830 – 360859	500	2,4 (3/32")	2,4 (3/32")
	360885 – 360893	2000	2,4 (3/32")	2,4 (3/32")

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

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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：
单极电极用于外科手术中软组织的电切和电凝。

使用寿命：
根据应用类型，使用寿命可能会出现不同程度地缩短。最晚在使用 20 次后更换电极。
ARROWtip™ 型号拥有两层绝缘。如果上方的黑色绝缘层受损，并可以看到下层的黄色绝缘层，则出于安全原因需要报废处理电极！

在使用之前：
⚠ 在每次使用之前，检查产品的清洁度、绝缘完好性和是否受损。
对于长电极，我们建议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！
将电极接口完整且按规定插入指定的电外科手柄。
只能将电极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！
注意正确放置中性电极！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。

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。
⚠ 注意最高电压规格和插头提示 **(TAB1)**。
⚠ 电极尖端可能造成人员受伤！
⚠ 使用完以后，电极尖端的高温会导致烫伤！
⚠ 绝对不得将电极或手柄置于患者身上，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！
如果同时使用配备冲洗仪器的电极，则请尽量使用非导电性冲洗液！

再处理：
遵守国家准则和规定！
电极 / 转接器 / 手柄 / 电缆彼此分离。
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！
⚠ 勿要放入双氧水 (H_2O_2)！

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)。

手工清洁和消毒：

清洁步骤	说明
预清洗	冷水冲洗 5 分钟，并使用软刷 (例如 MED100.33 Medisafe GmbH) 清除，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针对最差状态 (worst-case) 的产品进行，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 07015-2，2015.11.24。可转移性通过编号为 V277 和 V279 的内部验证证明。

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。

程序步骤	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由一家独立的认证测试实验室针对最差状态 (worst-case) 的产品进行，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 ALKA ONE-x (Borer 化学股份公司，瑞士 Zuchwil)，测试报告编号为 111738-10，2011.05.11。可转移性通过编号为 V268 的内部验证证明。

• 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，(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。如果存在疑问，请联系负责的供应商或卫生专员。

检查：
在进行后续消毒前，目视检查仪器的绝缘完好性、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，酌情注意尖锐的仪器尖端)，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。
• 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	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	15 分钟

仪器对于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针对最差状态 (worst-case) 的产品进行，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。可转移性通过编号为 V268 和 V280 的内部验证证明。

⚠ 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 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:
Monopolar electrode for cutting and coagulating soft tissue during surgical procedures.

Service life:
The service life may be non-specifically shortened depending on the type of application. Replace the electrode after no more than 20 applications.
ARROWtip™ models feature dual-layer insulation. If the outer, black insulation is damaged and the inner, yellow insulation is visible, dispose of the electrode for safety reasons!

Before using:
⚠ Inspect the product for cleanliness, intact insulation, and damage before each use.
For long electrodes, we recommend checking the insulation with a suitable test device.
⚠ Only use sterilized products that are in flawless condition!
Insert the electrode connection fully and properly into the electrosurgery handle intended for the purpose.
To connect the electrode, the electrosurgery device must be turned off or in standby mode.
⚠ Failure to comply may lead to burns and electric shocks!
Verify that the neutral electrode is applied correctly! For further information about electrical safety, we recommend DIN EN 60601-2-2 supplement 1.

During use:
⚠ Always work with the lowest output setting for the desired surgical effect.
⚠ Note the maximum voltages and connection information **(TAB1)**.
⚠ Electrode tips may cause injuries!
⚠ After application, electrode tips may be so hot they cause burns!
⚠ Never lay down the electrode and/or handle 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!
When flushing instruments are used simultaneously with the electrode, use non-conductive flushing fluid if possible!

Reconditioning:
Observe national guidelines and regulations!
Disconnect the electrode / adapter / handle / cable from each other.
The overall reconditioning process encompasses pre-cleaning, cleaning / disinfection, and sterilization.
⚠ Machine cleaning / disinfection is preferred due to effectiveness and reproducibility!
⚠ Do not immerse in hydrogen peroxide (H_2O_2)!

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).

Manual cleaning and disinfection:

Cleaning step	Description
Pre-cleaning	Rinse for 5 minutes under cold water and clean 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. Transferability was proven by the internal validations no. V277 and V279.

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.

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 for a worst-case product 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. Transferability was proven by the internal validation no. V268.

• 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, 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. 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 – note sharp instrument tips!), 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.
• 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	15 minutes

Proof of fundamental suitability of the instruments for effective steam sterilization was provided for a worst-case product 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. Transferability was proven by the internal validations no. V268 and V280.

⚠ 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.