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Disposable Ultrasonic Shears			
Instructions			
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[SOUND REACH Open Shears]

en Disposable Ultrasonic Shears Instructions

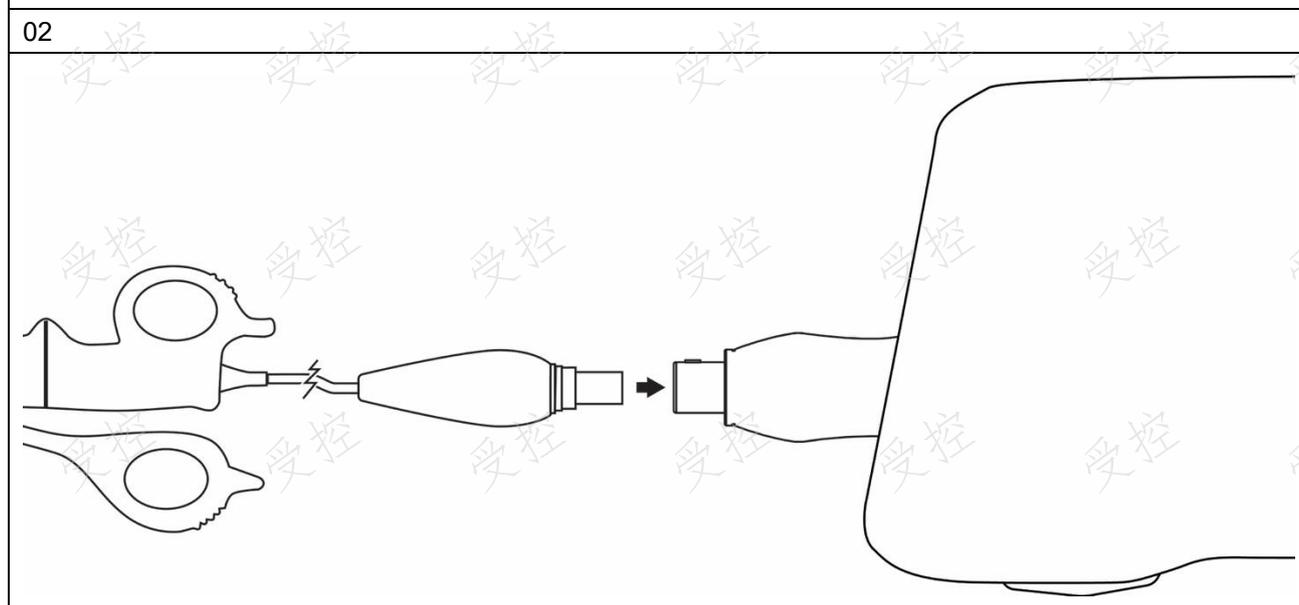
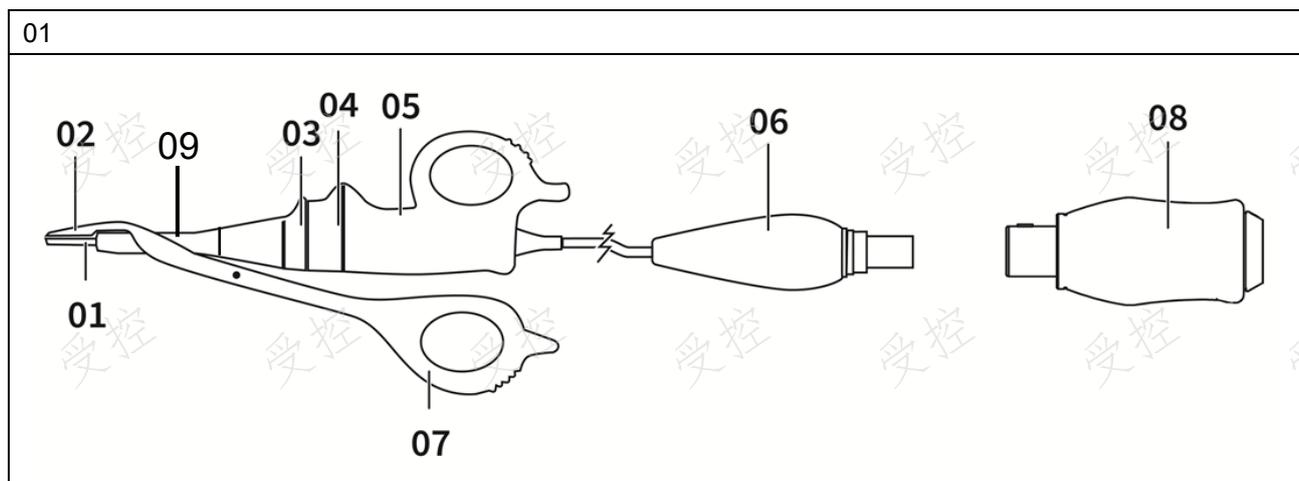


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Illustrations



en/English

Before using the instrument, please read the following contents carefully.

This document is designed to assist in using this Instrument. It is not a reference for surgical techniques.

This Instrument is designed, inspected, and manufactured for single use only. Do not reuse, reprocess or re-sterilize this Instrument. Reusing or reprocessing may result in Instrument failure or patient injury.

Standard Conventions Used: Warning, Caution, and Note statements

Information relative to the completion of a task in a safe and thorough manner will be supplied in the form of a Caution, Warning, or Note statement. These statements are found throughout the documentation. These statements should be read before continuing to the next step in a procedure.

Warning: indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.

Caution: alerts the user of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the instrument and the care necessary to avoid damage to the instrument that may occur because of use or misuse.

Note: indicates an operating, practice, or condition that is necessary to execute a task efficiently.

Description

The Disposable Ultrasonic Shears (hereinafter referred to as the Instrument) are sterile, single patient use Instrument used for dissection, grasping, coagulation, and cutting between the Blade and Clamp Arm. The energy output is controlled by two buttons (Min Button for minimum power level and Max Button for maximum power level).

Min button: user can adjust power levels from 1-5.

Max button: Output power level 5; user cannot adjust.

The instrument consists of curved Blade, Clamp Arm, Handle, and Connector. The Blade has multiple functions. The Blunt Side can implement the best hemostasis effect with tissue incision function, while the Sharp Side can implement rapid tissue incision and separation.

The instrument is designed to be connected to compatible generator via Ultrasonic Converter: USC. Verify compatibility the software version of the generator before use. The CSUS8000 generator's software version should be V01.01 or later, and OP9 generator's software version V01.01 or later. Refer to the instructions of the generators for information about checking the software versions.

Open procedures involving the use of the device should be performed only by healthcare professionals having adequate training and familiarity with open procedures and the use of ultrasonic devices.

Nomenclature (Illustration 01)

[01] Blade	[02] Clamp Arm and Tissue Pad
[03] Max Button	[04] Min Button
[05] Handle	[06] Connector
[07] Movable Finger Ring	[08] Converter (not included in the package)
[09] Tube	

Chart 01 - Instrument Product Codes

Product Code	Length (cm)
SFA9	9 ± 2
SFA17	17 ± 2

Product Name	Product Code
Ultrasonic Converter	USC

Intended Use

This instrument is used to dissect soft tissue for cutting and/or coagulating tissues.

Indications

The instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric and urologic procedures.

Intended User

This instrument is intended for use by healthcare professionals for surgical applications.

Intended Use Environment

This instrument is intended to be used in a hospital.

Intended patient population

Patients aged 3 and older who need surgery in which soft tissue incisions with bleeding control and minimal thermal injury are required.

Clinical Benefits

The instrument can be used safely and effectively in soft tissue incision when bleeding control and minimal thermal injury are desired.

Contraindications

- The Instrument is not indicated for incising bone.
- The Instrument is not intended for contraceptive tubal occlusion.

Undesirable Side Effects / Residual Risks

Undesirable side effects and risks associated with ultrasonic devices include the potential for bleeding, tissue injury via mechanical or thermal damage, introduction of non-sterile surfaces or pathogen transfer, inflammatory or unintended tissue reaction, electrical shock, foreign body or magnetic resonance incompatibility, and property or environmental damage.

In addition, unintended harm, extended surgery, or altered surgical approach may result from issues related to device activation, damaged devices, electromagnetic interference, or an attempt to alter the device.

Instructions for Use

Preparation

Using sterile technique, remove the Instrument from the package. To avoid damaging the Instrument, do not drop the Instrument onto the sterile field, or flip the Instrument into the sterile field. Do not use if the package is damaged.

Using the Instrument

1. The Converter must be in a clean state prior to use. The cleaning method for the Converter is as follows:
 - Sani-Cloth Plus
 - 70% Isopropyl Alcohol
 - 6% Sodium Hypochlorite (Bleach)
 - 10% Hydrogen Peroxide
 - 1% Phenyl Phenol (Sporicidin)
2. Connect the Converter to the generator. And then connect the Connector to the Converter and turn on the generator. (Illustration 02)
3. Select the desired power level using the INCREASE and DECREASE buttons on the generator's touchscreen (Illustration 03).
 - Minimum starting power level defaults to power level 3 (Illustration 03). The power level for the Min button can be adjusted from 1 to 5. For greater tissue cutting speed, use a higher power level. For greater coagulation, use a lower power level. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.
 - MAX power is set at power level 5 and cannot be adjusted

4. The instrument may be operated with either the foot switch or hand control. For foot switch or hand control function, refer to a compatible Generator User Manual for further detail and setup and operation instructions.
5. For optimal performance, clean the instrument blade and Clamp Arm throughout the procedure by activating the instrument tip in sterile saline. The instrument can be wiped with a sterile moist gauze sponge to remove tissue, if necessary.

Warning: Do not touch the instrument to metal while activated. See Warnings and Precautions.

6. If tissue is still visible in the Clamp Arm, use hemostats to remove residue
7. The blade is ultrasonically energized when either the foot switch pedal is depressed or one of the hand controls is depressed.
 - Pressing either the left foot pedal of the foot switch or the proximal hand control (MIN) on the instrument activates the selected minimum power level.
 - Pressing either the right foot pedal of the foot switch or distal hand control (MAX) on the instrument activates the maximum power level.
 - The generator provides an audible tone to indicate when the instrument blade is active.
 - The generator changes to a second audible tone as Tissue Sense function which regulates the delivery of energy.
 - Thermal influences such as fluids or minimal to no tissue in the jaws may affect the presence or timing of the tone change.
 - The tone change does not provide confirmation of tissue effect. When the second tone is heard, the situation should be assessed and the intended surgical action completed, such as gradual application of tension to facilitate transection.
 - The secondary activation tone change is not a substitute for surgical experience.
8. Close the clamps and insert the instrument through the incision. Use the instrument for dissection, grasping, coagulation, and cutting between the blade and Clamp Arm. Use the top of the blade with the Clamp Arm open if using for back cutting.

Caution: Keep the Clamp open when back cutting or while the Blade is active without tissue between the Blade and Clamp Arm to avoid damage to the Tissue Pad and increased Blade and Clamp Arm temperatures.

Warning: Avoid contact with all metal or plastic Instruments or objects when the Instrument is activated.

Contact with staples, clips or other Instruments while the Instrument is activated may result in scratches on the blade, cracked or broken blades and premature blade failure.

Caution: Tissue Pad damage may occur if Instrument is activated without tissue in the closed jaws. Activation without tissue between the jaws will cause Tissue Pad degradation.

Caution: Prolonged blade activation with the Clamps closed (with or without tissue between the Blade and Clamp Arm) may cause Tissue Pad damage. If the tissue is hard to transect, try to relocate or Clamp Arm less tissue.

Note: To avoid overheating the Blade, cleaning the Blade off residual tissues with wet gauze.

9. Close the clamps and remove the instrument from the body cavity.
10. Turn off the power switch of the generator and disconnect the instrument.
11. Dispose of devices and cables in appropriate containers. No disassembly required.

Post procedure

Dispose of the Instrument and its accessories into appropriate containers. Do not reuse Instrument. Internal components of the instrument contain lead (PZT zirconium titanate pliers). Processing should follow local rules and requirements.

Warnings and Precautions

- The Instrument allow for the coagulation of vessels up to and including 5 mm in diameter. Do not attempt to seal vessels more than 5 mm in diameter.
- If you fail to observe hemostasis situation at operative site, do not use The Instrument.
- The Instrument is sterile, and single use only. Discard it after use. Do not sterilize or reuse.
- During and after incision, hemostasis should be checked; slight hemorrhage may, if any, be manually stitched for hemostasis.
- Place tissue to be cut between the jaws and be sure that there are no other obstacles between the jaws.
- After incision is finished, the generator should stop driving at the same time, and the Blade should avoid contacting other tissues as possible.
- Do not touch the instrument to metal while activated
- Keep the Clamp Arm open when back cutting or while the Blade is active without tissue between the Blade and Clamp Arm to avoid damage to the Tissue Pad and increased Blade and Clamp Arm temperatures.
- Avoid contact with metal or plastic Instruments or objects when the Instrument is activated. Contact with staples, clips or other Instruments while the Instrument is activated may result in scratches on the blade, cracked or broken blades and premature blade failure.
- Before surgical operation, doctors should consult related literatures to understand surgical technology, complication and risks.
- This instrument is supplied sterile. It is sterilized with EO. Do not use if sterile package is damaged.
- Used instruments should be placed in a specified recycle bin or refuse container. Do not litter to avoid environmental pollution. At the end of the service life, the instrument should not be discarded at will. It should be disposed of by professionals in a timely manner in strict accordance with the state and local regulations on the disposal of medical waste to avoid infection and environmental pollution.
- This instrument is applicable for the general population.
- Vibration of mechanical force and heat are generated on the Tip during cutting and hemostasis. 1mm to 2 mm thermal damage may occur around the application site. The heat may accumulate near the tip of the outer tube. Therefore, contact with and clamping of normal tissues should be minimized.
- When the generator alarms, the instrument stops vibration, and it is required to check whether the instrument touches foreign objects and other abnormal use, and to find the abnormal situation of connected equipment based on the system tips.
- When a high-frequency noise is made by the instrument or transducer, it indicates that the instrument or transducer does not function properly, that the instrument is not properly connected or that the transducer is out of service life, which may cause the instrument temperature to abnormally rise to the extent that it can cause harm to the doctor and the patient.
- If Instruments and accessories other than this system are used in a single procedure, the compatibility

between the Instruments should be confirmed and insulation and grounding are not compromised.

- Do not use the Instrument beyond its expiration date.
- A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to Reach Surgical, Inc. through Reachquality@reachsurgical.com and the competent authority of the Member State in which the user and/or patient is established.

Environmental Conditions for Transport and Storage

Temperature: -10 °C ~ 55 °C

Relative Humidity: ≤ 80 %

Air Pressure: 860 hPa ~ 1060 hPa

Expiration Date

The Instrument is sterilized by Ethylene Oxide. The expiration date is labeled on the package. The period of validity is 3 years from sterilization date. Do not use this Instrument beyond its expiration date.

How Supplied

This Instrument is supplied sterile for single patient use. Discard after use.

	en Medical device
	en Sterilization batch
	en Peel Here
	en HDPE recyclable
	en Recyclable
	en Authorized Representative
	en Do not use if package is damaged and consult instructions for use
	en Do not resterilize
	en Manufacturer
	en Date of manufacture
	en Country of manufacture
	en Serial number
	en Batch code
	en Use-by date
	en Fragile, handle with care
	en Keep dry
	en Keep away from sunlight

	en Up
	en Do not re-use
	en Caution
	en Catalogue number
	en Temperature limit
	en Humidity limitation
	en Atmospheric pressure limitation
	en Single sterile barrier system
	en Unique device identifier
	en Refer to instruction manual
	en Sterilized using ethylene oxide