REACH SURGICAL, INC.

SOUND REACH **SR7 Shears**

Disposable Ultrasonic Shears Instructions

Rev. A.0

CE 0197

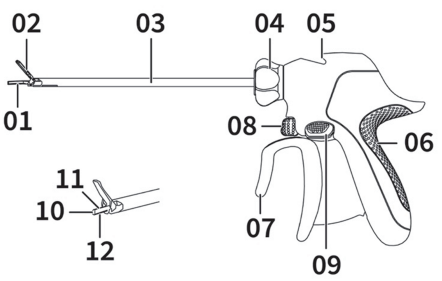
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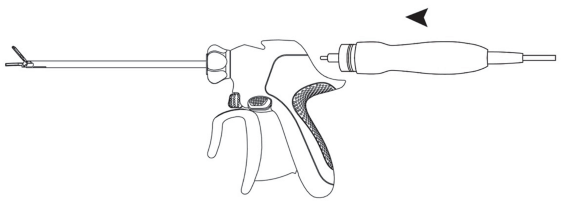
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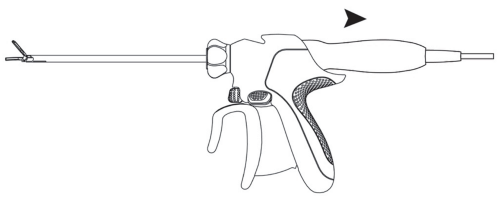
Illustrations

01

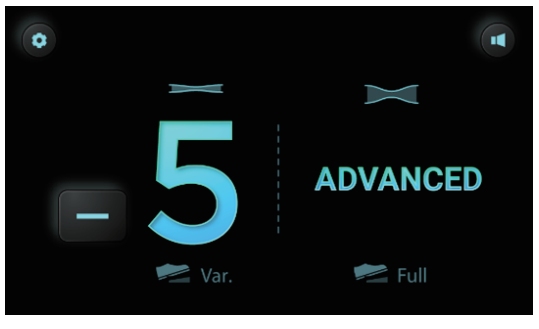


02





03



Before using this 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.

Standard Conventions Used: Caution, Warning, 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: A WARNING statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.

Caution: A Caution statement 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 a Instrument that may occur as a result of use or misuse.

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

Descripción

Disposable Ultrasonic Shears (hereinafter referred to as the Instrument) are available in various sizes. Available sizes are: 14cm,23cm, 36cm and 45cm. It is designed to be attached to an ultrasound surgical equipment and contact with a patient during vibration at high frequency in order to fragment soft-tissue cells for cutting and/or coagulating of soft tissue in open surgeries and endoscopic surgeries. The instruments are sterile, single patient use for dissection, grasping, coagulation, and cutting between the blade and clamp.
The energy output is controlled by two buttons.
Energy button: user can adjust power levels from 1 to 5.
Energy button with Advanced Homeostasis: for large vessel sealing; user cannot adjust.
Shear consists of Shaft and Handle. The Blade has multiple functions. Blunt side of the blade is used for hemostasis at power lever 3 or lower, or incision at power lever 4 or higher. Sharp side of the blade is intended for incision at all power levels. Tip of the blade is intended for spot hemostasis

Nomenclature (Illustration 01)

[01] Blade	[02] Clamp
[03] Shaft	[04] Rotation Knob
[05] Groove	[06] Handle
[07] Trigger	[08] Energy Button
[09] Energy Button with Advanced Hemostasis	[10] Tip
[11] Blunt Side	[12] Sharp Side

Chart 01 - Instrument Product Codes

Product Code	Shaft Length (cm)	Diameter(mm)
SRB14	14±0.5	Φ5.5±0.1
SRB23	23±0.5	Φ5.5±0.1
SRB36	36±0.5	Φ5.5±0.1
SRB45	45±0.5	Φ5.5±0.1

Intended Use

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

Indications

This instrument is designed to be attached to an ultrasound surgical equipment and contact with a patient during vibration at high frequency in order to dissect soft-tissue for cutting and/or coagulating tissue in open surgeries or endoscopic surgeries. In general, pediatric, gynecologic, urologic, thoracic, and sealing and transection of lymphatic vessels.

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

• Shorter operative time;

• Less intraoperative bleeding;

• Less thermal injury.

Contraindications

• The Instrument is not indicated for incising bone.

• The Instrument is not intended for contraceptive tubal occlusion.

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.

Assembly and Unloading

1.The jaws are open by default, do not try to close it by hand. Do not apply too much pressure on the Trigger.
2.To assemble the Instrument with the Transducer, align the screwed end of transducer with threaded hole in the handle (Illustration 02), hold Transducer with one hand and the rotation knob with the other. Turn clockwise till two click sounds are heard.
3.To disassemble, hold the transducer with one hand while holding the rotation knob with the other. Turn counterclockwise to release the Transducer from the Instrument.

Using the Instrument

1.To close the clamp, pull the Trigger.
2.To rotate the Shaft, spin the Rotation Knob.
3.Insert the Instrument through incision or trocar.
Caution: The clamp must be closed when the Instrument is inserting through or removing from the incision or trocar. Once the Instrument is inserted through the incision or trocar, release the Trigger and open the clamp.
Caution: The diameter of the Shaft is 5.5±0.1 mm. Verify the compatibility of the Shaft and the trocar before insertion.
4.Select the desired power level using the INCREASE and DECREASE buttons on the generator's touchscreen (Illustration 03). The power level for the Energy button can be adjusted from 1 to 5. The system default 5. For greater tissue cutting speed, use a higher power level. For greater coagulation, use a lower power level.
5.Place targeted tissue between Clamp and the Blade, and ensure there are no other objects in the clamp. The desired length of transection should not exceed the Tip. Tissue with long transection length may need several activations.
Note: Do not place excessive tissue between the Clamp and the Blade as it may lead to overheating.
Caution: Keep the Clamp open when back-cutting or while the Blade is active without tissue between the Blade and Clamp to avoid damage to the tissue pad and increased Blade, Clamp and distal shaft temperatures.
6.Squeeze the trigger until it stops against the plastic handle (and a click is heard) to close the jaws.
• To achieve complete sealing, the trigger should be fully closed, and the vessel fully contained between the Clamp and the Blade. An audible and tactile "click" indicates full trigger closure. To achieve full closure of the jaws, squeeze the Trigger until you feel it stop against the plastic handle (plastic to plastic). Grip force needs to be maintained throughout the transection to keep trigger closed.
• When you close the jaws with tissue and hear a 'click' from the Handle, it means the jaws have acted uniform pressure on tissue. DO NOT strongly hold the handle and trigger and try to give more tension to tissue to increase the cutting speed. Do not hold the trigger too tight when the blood vessels are closed.
7.To activate the Blade, press one of the foot pedal switches or one of the Energy Buttons on the Instrument.
• Pressing the left foot pedal of the footswitch or the Energy button on the Instrument activates the selected power level (1-5). The Energy button allows for sealing vessels up to 5 mm in diameter with full trigger closure and can enable other soft tissue applications **(back-cutting, scoring, drilling, ostomy creation, and others)**, where full trigger closure is not needed

• Pressing the right foot pedal of the footswitch or Energy button with Advanced Hemostasis on the Instrument activates Advanced Hemostasis. When using the Energy button with Advanced Hemostasis, energy is not delivered unless the jaws are completely closed. This button activates an algorithm in the generator that, in conjunction with full trigger closure, allows for sealing larger vessels (up to 7 mm in diameter).

Foot Pedal	Button	Generator
Left Var	Energy Button	Left power level
Right Full	Energy Button with Advanced Hemostasis	Right Advanced Hemostasis

• The generator emits one of the audible tones listed in the table below to indicate when the Blade is first activated.

Tone	Button	Action
Repeating single tone	Energy Button	Generator On: Instrument is active
3 repeating, ascending tones	Energy Button with Advanced Hemostasis	Generator On: Instrument is active and in Advanced Hemostasis mode

The generator will switch to another audible tone when ATT function is in effect. The ATT function regulates energy and prevents excessive energy output. 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 audible tone change is not a substitute for surgical experience.

Tone	Button	Action
High pitched, repeating single tone	Energy Button	Adaptive Tissue Technology is active

WARNING: Avoid contact with any and 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 Clamp closed (with or without tissue between the Blade and Clamp) may cause tissue pad damage. If the tissue is hard to transect, try to relocate or clamp less tissue.
Note: To avoid overheating the blade, cleaning the Blade off residual tissues with wet gauze.
8.When activation is completed, release the Trigger to open the Clamp. Remove the Instrument from the tissue carefully. Check hemostasis at site of application. If there is any haemorrhage, manually suture or legate.
9.Close the Clamp by pulling the trigger, and remove the Instrument from trocar or incision.

Post procedure

Dispose of the Instrument and its accessories into appropriate containers. Do not reuse Instrument.

Warnings and Precautions

• The Instrument allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis. Do not attempt to seal vessels in excess of 7 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.

• The Instrument uses 5mm trocar. Before shear is inserted into or taken out of sleeve of trocar, its clamp should be kept closed.

• During and after incision, hemostasis should be checked; slight haemorrhage may, if any, be manually stitched for hemostasis.

• Tissue placed beyond exposed length of blade or too much force applied may cause apparatus failure and abnormal incision.

• Place tissue to be cut between the jaws and be sure that there are no other obstacles between the jaws.

• Verify compatibility with generators. Use Instrument only with Generator (CSUS8000) software version V01.01 or later. Software revision can be found under "System Information" in the Generator (CSUS8000). Refer to the Ultrasound Surgical Equipment Operation Manual for more information.

• 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 use the Energy Button with Advanced Hemostasis when energy application is desired prior to full closure of the jaws. Using the Energy button with Advanced Hemostasis without full trigger closure may result in lack of hemostasis.

• If activation is unintentionally stopped while sealing, maintain jaw closure and reactivate. Releasing the trigger while sealing may result in lack of hemostasis.

• Keep the Clamp open when back-cutting or while the blade is active without tissue between the blade and the Clamp to avoid damage to the tissue pad and increased temperatures of the Blade, the Clamp and distal Shaft.

• During benchtop testing of vessels > 5 mm, the strongest vessel seals were achieved by allowing the Advanced Hemostasis mode to completely transect the targeted vessel.

• Prolonged use of Advanced Hemostasis mode may damage the tissue pad. Pressing the VAR pedal of footswitch activates power level, Pressing the Full pedal of footswitch activates Advanced Hemostasis.

• During the separation of the gallbladder and liver tissue, the liver and gallbladder should be reliably protected, to avoid the tip of the shear mistakenly in contact with the tissue and avoid bleeding and other injuries.

• Minimally invasive surgery can only be performed by doctors with rich experience and familiarity with minimally invasive surgery. Before surgical operation, doctors should consult related literatures so as to understand surgical technology, complication and risks.

• This Instrument is supplied sterile, EO sterilized. If sterile package is damaged, DO NOT use.

• 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 shear 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 shear stops vibration, and it is required to check whether the shear 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 shear or transducer, it indicates that the shear or transducer does not function properly, that the shear is not properly connected or that the transducer is out of service life, which may cause the shear 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 5 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.

EO Batch	Sterilization batch
	Peel Here
02 PE-HD	HDPE recyclable
	Recyclable
	Electrical and Electronic equipment, separate collection
	Refer to instruction manual
EC REP	Authorized Representative in the European Community
	Do not use if package is damaged
2 STERILIZE	Do not resterilize
	Manufacturer
	Date of manufacture
SN	Serial number
LOT	Batch code
	Use-by date
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Up
	Do not re-use
	Caution
REF	Catalogue number
	Storage temperature limit
	Storage humidity limitation
	Storage atmospheric pressure limitation
	Single sterile barrier system
CN	Country of manufacture
MD	Medical device
UDI	Unique device identifier

STERILE EO	Sterilized by Ethylene Oxide
www.int.reachsurgical.com/support	Consult instructions for use or consult electronic instructions for use

REACH SURGICAL INC.