REACH SURGICAL | ENER REACH

ENER REACH Enerseal

EN Electrosurgery Handpieces
Instructions

Rev.A.0

CE 0197

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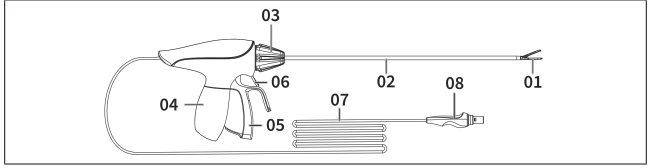
Illustrations

01



EN/English

Overview

Please read the following information carefully before using this instrument. It provides important instructions regarding proper operation, potential risks, and potential damage to the product or individuals. In the event of any abnormal situation, follow the specified instructions to prevent harm to yourself or damage to the equipment. Failure to follow these instructions may result in compromised safety, performance, warranty, or maintenance, for which the manufacturer cannot be held liable.
This document is designed to assist in using this instrument. It is not a reference for surgical techniques.

Nomenclature (Illustration 01)

[01] Jaws	[02] Shaft
[03] Rotation Knob	[04] Handle
[05] Lever	[06] Cutting Trigger
[07] Cable	[08] Connector

Standard Conventions Used: Caution, WARNING, and Note Statements

Please note the following statements, categorized as CAUTION, WARNING, or NOTE, which provide essential guidance for completing tasks safely and thoroughly. These statements can be found throughout the documentation and should be read before proceeding to the next step in a procedure.
WARNING: This statement highlights an operating or maintenance procedure, practice, or condition that, if not strictly followed, could lead to personal injury or loss of life.
CAUTION: This statement alerts the user to a potentially hazardous situation that, if not avoided, may result in minor or moderate injury to the user or patient, as well as damage to the equipment or other property. It may also serve as a warning against unsafe practices. This includes the necessary precautions for the safe and effective use of the Instrument and the care required to prevent damage resulting from proper or improper use.
NOTE: This statement indicates an operating practice or condition that is essential for executing a task efficiently.

Description

The ENER REACH Enerseal Electrosurgery Handpieces (hereinafter referred to as the **instrument**) are designed for use with the ENER REACH Optimus Electrosurgical Instruments OP9 generator, which includes vessel sealing capability. For more detailed information, refer to the generator's instructions or contact the relevant department at Reach Surgical, Inc.
These instructions assume that the operator possesses knowledge and proficiency in correctly setting up and operating the associated Reach Surgical, Inc. generator. For setup instructions and additional warnings and precautions, please consult the user's guide of the generator.
The instrument functions by utilizing radiofrequency (RF) electrosurgical energy to create a seal on vascular structures such as vessels and lymphatics, as well as tissue bundles positioned between the instrument's jaws. The surgeon can activate a blade within the instrument to divide tissue as needed. Shorter shaft lengths are typically used for open procedures, while longer shaft lengths are typically employed for laparoscopic procedures.

Instrument Product Codes

Product Code	Shaft Length (cm)	Diameter (mm)
OSA23	23	Φ5
OSA37	37	Φ5
OSA44	44	Φ5

Intended Use
The instrument is used in medical institutions for cutting and coagulation of tissues during surgery.

Indications
The instrument is used in medical institutions for cutting and coagulation of tissues during open surgeries or laparoscopic surgeries in general, pediatric, gynecologic, urologic, thoracic surgery. It can be used to close arteriovenous vessels and lymphatic vessels with a diameter of no more than 7mm and tissue bundles suitable for the size of instrument jaws.

Contraindications
The instrument is contraindicated for bone incisions, contraceptive tubal occlusion, and coagulation procedures. It is also not intended for use in neurosurgery.

Intended User
The instrument is intended for use by healthcare professionals for surgical applications.

Intended Use Environment
The instrument is intended to be used in a hospital.

Intended Patient Population and medical condition to be treated
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 ligation and division of vessels, tissue bundles, and lymphatics.

Instructions for use

Unpacking and connection
- Remove instrument from tray by firmly pulling on the Handle. Do not pull on the instrument's Jaws or Cable.
- Insert the Connector into the Electrosurgical socket on the generator. Follow the instructions in the generator user's guide to complete the setup procedure.

Tissue Manipulation and Dissection
- The instrument can be used to manipulate and dissect tissue with the jaws either open or closed.

Rotating the jaws
- Spin the Rotation Knob to rotate the jaws.

CAUTION: Do not turn the Rotation Knob when the Lever is fully pulled as this may damage the instrument

Closing and opening the jaws
- To close the jaws, place the tissue between the jaws and pull the Lever. The first click indicates the jaws are fully closed.
- To open the jaws, release the Lever.

CAUTION: Do not turn the Rotation Knob when the Lever is fully pulled as this may damage the instrument.
CAUTION: Continue pulling the Lever after the first click will activate energy and start sealing.

Sealing and cutting with Hand Activation
- After the jaws are fully closed and the first click heard, pull the Lever further until a second click heard, this will activate energy delivery, hold until the seal cycle is complete.
- Open the jaws to release tissue or use the Cutting Trigger to cut the tissue.

NOTE: To use this mode, ensure hand-activation is enabled on the generator before use.
NOTE: The user should inspect the seal before cutting the vessel or tissue.
NOTE: To apply a double seal, clamp overlap the edge of the existing seal. The second seal should be distal to the first seal to increase seal margin.
NOTE: A tone with multiple pulses indicates that the seal cycle was not completed. Refer to the Troubleshooting section possible causes and corrective actions. Do not cut tissue until you have verified that there is an adequate seal.
CAUTION: Pull the Lever firmly until the sealing is complete. The Lever does not latch onto the activation position.
CAUTION: A continuous tone sounds to indicate the activation of RF energy. When the activation cycle is complete, there will be a two-pulsed Seal-Cycle-Complete tone sounds to indicate RF output stops.

Sealing with Footswitch Activation
- After the jaws are fully closed and the first click heard.
- Pull the Lever further until a second click is heard, while keep pulling the Lever, press and hold the footswitch pedal to activate energy delivery until the seal cycle is complete.
- Release from the footswitch, and release the Lever to open jaws, or use the Cutting Trigger to cut the tissue.

NOTE: To use this mode, ensure hand-activation is disabled on the generator before use.
NOTE: The user should inspect the seal before cutting the vessel or tissue.
NOTE: To apply a double seal, clamp overlap the edge of the existing seal. The second seal should be distal to the first seal to increase seal margin.
NOTE: A tone with multiple pulses indicates that the seal cycle was not completed. Refer to the Troubleshooting section possible causes and corrective actions. Do not cut tissue until you have verified that there is an adequate seal.
CAUTION: Pull the Lever firmly until the sealing is complete. The Lever does not latch onto the activation position.
CAUTION: A continuous tone sounds to indicate the activation of RF energy. When the activation cycle is complete, there will be a two-pulsed Seal-Cycle-Complete tone sounds to indicate RF output stops.
WARNING: Activating energy delivery with a footswitch with jaws not fully closed may result in improper sealing and increase thermal spread to tissue outside the application site. Make sure the jaws are fully closed during energy delivery.

Cutting Tissue
- To cut the tissue, first pull the Lever, make sure the first click heard and the jaws are fully closed.
- Pull the Cutting Trigger activate the cutting mechanism.
- Release the Cutting Trigger to retract the blade.
- Release the Lever to open jaws.

WARNING: Energy-based devices, such as electrosurgical pencils or ultrasonic scalpels which generates thermal spread should not be used to transect tissues sealed by this instrument.

WARNING: Make sure the seal cycle is completed before cutting.
CAUTION: Do not use the cutting mechanism if clips, staples, or other metal objects are located between the jaws, as this could damage the blade.
CAUTION: Using excessive force to pull the Lever can result in inadvertently activate of energy delivery.
CAUTION: If the cutting trigger does not automatically retract to its original position, push the cutting trigger to reset it.

Cleaning the instrument

- The jaws should be kept clean for optimum performance. Build-up of eschar may impact the seal and/or cutting effectiveness. Wipe jaw surfaces and edges with a wet gauze pad and remove any residue tissue from blade track and jaw hinge area.

WARNING: Inspect the jaws prior to cleaning, make sure that the blade is not deployed.
WARNING: Do not pull the Lever or the Cutting Trigger while cleaning the jaws, as this may cause injury to the user.
CAUTION: Do not pull the Lever with gauze between the jaws as this may damage the instrument.
CAUTION: Do not clean the instrument scratch pad or other abrasives.
Post procedure

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

Warnings and Precautions

- The instrument is sterile, and single use only. Discard it after use. Do not sterilize or reuse. Attempts to clean sterilize these devices without appropriate regulatory authorization may result in bio-incompatibility, infection, or product failure risks to the patient.
- This instrument is intended for use ONLY with the compatible generators from Reach Surgical. Use of this instrument with other generators may not result in the desired tissue effect, may result in injury to the patient or the user, or may cause damage to the instrument.
- Do not use this instrument unless properly trained to use it in the specific procedure being performed. Use of this equipment without such training may result in serious unintended patient injury.
- Exercise caution when using the system in the presence of internal or external pacemakers or other implanted devices. Interference produced by electrosurgical equipment can cause a pacemaker or other device to enter an unsafe mode or sustain permanent damage. Consult the device manufacturer or the responsible hospital department for further information when planning to use the instrument in patients with implanted medical devices.
- When using this instrument with an energized endoscope, the leakage current from the instrument and the endoscope are additive. The patient may be exposed to unexpected levels of leakage current if this instrument is used with an energized endoscope that is not a type CF applied part.
- Before inserting the instrument through the cannula, inspect its outer surfaces to ensure there are no rough or sharp edges that could damage tissue.
- Contact between an active instrument electrode and any metal objects (hemostats, staples, clips, retractors, etc.) may increase current flow and result in unintended surgical effects or insufficient energy deposition.
- The safe and effective use of RF energy depends on various factors solely under the control of the operator. It is important to read, understand, and follow the operating instructions provided.
- This Instrument is supplied sterile, EO sterilized. If sterile package is damaged, DO NOT use.
- Verify the instrument model is correct before the procedure.
- Electric Shock Hazard - Do not connect a wet instrument to the generator.
- Position instrument cords to prevent contact with the patient or other cords. Avoid wrapping cords around metal objects, as this can cause currents that may lead to shock, fire, or injury to the patient or surgical team.
- Carefully inspect all connections between the instrument and generator before use. Improper connections can result in arcing, sparks, accessory malfunction, or unintended surgical effects.
- Inspect the instrument and cords for breaks, cracks, nicks, or other damage before use. Failure to observe this caution may result in injury or electrical shock to the patient or surgical team, or cause damage to the instrument. Do not use a damaged instrument.
- Avoid using the instrument in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide (N20) and oxygen, or in close proximity to volatile solvents (e.g., ether or alcohol) to prevent the risk of explosion.
- Due to concerns regarding the potential carcinogenic and infectious nature of electrosurgical by-products (such as tissue smoke plume and aerosols), it is advisable to use protective eye wear, filtration masks, and effective smoke-evacuation equipment during both open and minimally invasive procedures.
- Connect adaptors and accessories to the electrosurgical unit only when the unit is turned off or in standby mode. Failure to adhere to this instruction may result in injury or electrical shock to the patient or operating personnel.
- Avoid placing fingers between the Lever and the Handle, or between the jaws. It may result in injury to the user.
- Avoid placing cable between the Lever and the Handle, or between the jaws.
- Use caution when handling the instrument between uses to prevent accidental activation. Do not place the instrument on the patient or on the drape when not in use.
- **Fire Hazard**: Avoid placing the instrument near or in contact with flammable materials such as gauze, surgical drapes, or flammable gases. Activating or hot instruments may cause a fire. When not in use, store the instruments in a clean, dry, highly visible area that is not in contact with the patient. Accidental contact with the patient may result in burns.
- For minimally invasive procedures, do not use hybrid trocars that have both metal and plastic components. Capacitive coupling of RF current may cause unintended burns.
- For minimally invasive procedures, verify the combability of the trocar size before use to easy insertion and extraction of the instrument. Carefully insert and withdraw the instrument through the cannula to avoid damage to the device and/or injury to the patient.
- Close the jaws before insertion/extraction through the access point.
- Do not use the instrument to ligate vessels larger than **7 mm** in diameter.
- Do not bend the shaft. If the instrument shaft is visibly bent, do not use it. Discard it, and replace it with a new instrument.
- Do not place the vessel and/or tissue near the jaw hinge. Always place the vessel and/or tissue at the center part of the jaws.
- Conductive fluids (e.g., blood or saline) in direct contact with or near the instrument may carry electrical current or heat, which can cause unintended burns to the patient. Aspirate fluid near the instrument jaws before activating the instrument.
- Keep the external surface of the instrument jaws away from adjacent tissue while activating the electrosurgical instrument system to avoid unintended injury.
- During a seal cycle, energy is applied to the tissue between the jaws. This generates heat and can cause water to convert into steam, which may result in unintended injury to tissues near the jaws. Exercise caution during surgical procedures in confined spaces.
- Release tension on the tissue when sealing and cutting to ensure proper function.
- Use caution when grasping, manipulating, sealing, and dividing large tissues.
- Do not attempt to seal or cut over clips or staples, as this may compromise seals. Contact between an active electrode and any metal objects may result in alternate site burns or incomplete seals.
- The surfaces of the jaws may remain hot enough to cause burns after the RF current is deactivated.
- Avoid using the instrument in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide (N20) and oxygen, or near volatile solvents (such as ether or alcohol) to prevent the risk of explosion.
- Due to concerns regarding the potential carcinogenic and infectious nature of electrosurgical by-products, such as tissue smoke plume and aerosols, it is recommended to use protective eyewear, filtration masks, and effective smoke-evacuation equipment in both open and minimally invasive procedures.
- Do not activate the instrument while the instrument jaws are in contact with or near other instruments, including metal cannulas, as localized burns to the patient or physician may occur.
- Exercise caution during surgical procedures involving patients with certain types of vascular pathology (such as atherosclerosis or aneurysmal vessels). For optimal outcomes, apply the seal to unaffected vasculature.
- Do not close the jaws if there's excessive tissue between the jaws.

Environmental Conditions for Transport and Storage

Temperature: -10°C ~ 55°C
Relative Humidity: ≤ 80 %
Air Pressure: 800 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.

Troubleshooting

The following is a list of troubleshooting suggestions for situations encountered when using the instrument with compatible Reach Surgical generators. For details on specific situations, refer to generator instructions for reference.

Alerts

When an alert occurs, energy delivery stops. After the alert condition has been corrected, energy delivery will be immediately available. When an alert condition occurs, energy delivery stops, the generator produces a sequence of pulsed tones, and an alert will be displayed on the generator. Do Not Cut the Vessel The user should inspect the seal site and instrument before proceeding.

Troubleshooting steps

- Stop activation by releasing the Lever or Footswitch pedal.
- Open the jaws and inspect if the seal is complete.
- Follow the suggested corrective actions on the generator screen, the generator quick reference card, or in the generator user's guide.
- If possible, reposition the instrument and regrasp tissue in a location that overlaps the previous seal, then reactivate the seal.

Possible reasons and solutions

Inadequate tissue between the jaws: Open the jaws and grasp more tissues. Close the jaws and reactivate the seal.
Excessive tissue between the jaws: Open the jaws, reduce the amount of tissue grasped. Close the jaws and reactivate the seal.
Activating on a metal object: Avoid grasping objects, such as staples, clips, or encapsulated sutures in the jaws of the instrument.
Dirty jaws: Use a wet gauze pad to clean surfaces and edges of instrument jaws.
Excess Fluids in the Surgical Field: Reduce or remove excess fluids from around the instrument jaws.
Activation switch released before seal complete tone: The footswitch pedal or Lever was released before the seal cycle was complete.
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.

Symbols

EO Batch	**EN** Sterilization batch		**EN** Peel Here
02 PE-HD	**EN** HDPE recyclable		**EN** Recyclable
	en Electrical and Electronic equipment, separate collection		**EN** Refer to instruction manual
EC REP	**EN** Authorized Representative in the European Community		**EN** Do not use if package is damaged.
	EN Do not resterilize		**EN** Manufacturer
	EN Date of manufacture	SN	**EN** Serial number
LOT	**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
REF	**EN** Catalogue number		**EN** Storage temperature limit
	EN Storage humidity limitation		**EN** Storage atmospheric pressure limitation
	EN Single sterile barrier system	CN	**EN** Country of manufacture
MD	**EN** Medical device	UDI	**EN** Unique device identifier
STERILE EO	**EN** Sterilized by Ethylene Oxide.		
	www.int.reachsurgical.com/support		**EN** Consult instructions for use or consult electronic instructions for use