BOLDER™
SURGICAL

CoolSeal™ REVEAL

An Open Sealer, Divider, and Dissector

REF CSL-RV105-10, Reveal Sealer/Divider/Dissector, 12 mm jaw length, 10 cm shaft length

Compatible with:

REF CSL-200-50, CoolSeal™ Generator SW v1.1.0 or later

en - Instructions for Use

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REF CSL-200-50, CoolSeal™ Generator SW v1.1.0 or later

Caution
Read all warnings, cautions, and instructions provided with this instrument before use.
Read the warnings, cautions, and instructions provided with the compatible generator before system use. Specific warnings, cautions, and instructions for the generator use are not included in this manual.
Federal (USA) law restricts this device to sale by or on the order of a physician.
This device is intended for medical professional use only.

Symbols

STERILE EO	Sterilized Using Ethylene Oxide
REF	Catalog, Reorder or Reference Number
	Consult Instructions for Use
	Single Use Only
	Manufacturer of Record
	Do Not Resterilize
	Use-by Date
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

	Do Not Use if Package is Opened or Damaged
	Attention, Consult Accompanying Documents
0°C 28°C	Store in Temperatures Between 0°C – 28°C
LATEX	Not Made with Natural Rubber Latex
MD	Medical Device
	Keep Dry
LOT	Lot Number

The CoolSeal™ Reveal, an Open Sealer, Divider, and Dissector is designed for use with the CoolSeal™ Generator or any generator with the CoolSeal™ technology. Please refer to the cover page for details on compatible generator models. The Reveal creates seals by application of radiofrequency (RF) electrosurgical energy to vascular structures (vessels and lymphatics) or tissue bundles interposed between its jaws. A blade within the instrument is surgeon-actuated to divide tissue. The double action jaws have been designed to dissect tissue, which includes separating tissue planes and widening openings as necessary for the surgical procedure. Maximum rated voltage: 190 V_{peak}

Indications for Use

The CoolSeal™ Reveal is a bipolar electrosurgical instrument intended for use in open surgical procedures in adults and pediatrics where ligation and division of vessels, tissue bundles, and lymphatics is desired. The CoolSeal™ Reveal can be used on vessels (arteries and veins) up to and including 6 mm in diameter. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedures may include but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis.

The CoolSeal™ Reveal is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, and parotidectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands.

The CoolSeal™ Reveal has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the CoolSeal™ Reveal for these procedures.

General Warnings

Warning
This product is intended for single use only; it cannot be adequately cleaned or resterilized for safe reuse. Attempts to clean or sterilize may result in bio-incompatibility, infection, or product failure risks to the patient.

These instruments are intended for use only with generators with the CoolSeal™ technology. Use of these instruments with other generators may not result in the desired tissue effect, may result in injury to patient or surgical team, or may cause damage to the instrument.

Do not use the CoolSeal™ system unless properly trained. Use of this equipment without proper training may result in serious unintended injury to the patient or surgical team.

Do not use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

When using the CoolSeal™ Reveal device for ENT procedures, particular care should be taken near thermally sensitive proximal tissues such as nerves and parathyroid glands as the thermal safety margin for this device may exceed 2-3 mm. Adjunctive use of a nerve monitoring device is recommended during nerve-sparing procedures.

Caution

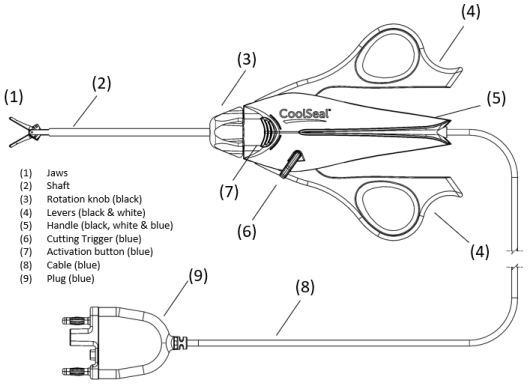
Use caution during surgical cases in which patients exhibit certain types of vascular pathology (atherosclerosis, aneurismal vessels, etc.). For best results, apply the seal to unaffected vasculature.

The performance of this single-use device has been tested according to the expected conditions of a single surgical procedure. Subjecting the device to process steps, tools, and/or chemicals commonly used by third-party re-processors may negatively affect its performance.

Important

Please refer to the Guidance and Manufacturer's Declaration in the Technical Specifications section of the CoolSeal™ Generator User's Guide for information related to Electrical Safety and Electromagnetic Compatibility.

Getting Started



1. Remove instrument from tray by firmly pulling on the handle (5). Do not pull on the instrument's jaws (1), shaft (2), or cable (8).
2. Insert the plug (9) into the receptacle on the generator. Follow the instructions in the generator user's guide to complete the setup procedure.

Warning

Electric Shock Hazard: Do not connect wet accessories to the CoolSeal™ Generator.

Do not wrap the instrument cords around metal objects. This may induce stray currents that could lead to injury to the patient or surgical team.

Examine all instruments and connections to the system before using. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

Inspect the instrument, instrument cords and generator cable for breaks, cracks, nicks, or other damage before use. Failure to observe this warning may result in injury or electrical shock to the patient or surgical team or cause damage to the instrument. If damaged, do not use.

Do not use in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or in close proximity to volatile solvents (such as methanol or alcohol), as explosion may occur.

Because of concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plume and aerosols), protective eye wear, filtration masks, and effective smoke-evacuation equipment should be used in both open and minimally invasive procedures.

Caution

Inspect sterile barrier packaging for damage. If damaged, do not use.

Using the CoolSeal™ Reveal

Warning

Avoid placing fingers between the levers, handle, trigger, or in the jaws. Injury to the user may result.

Place the vessel or vascular bundle in the center of the jaws. To avoid incomplete sealing, do not grasp structure beyond the electrode surface; do not place tissue in the jaw hinge.

Contact between the active instrument electrode and any metal object (hemostats, staples, clips retractors, etc.) may increase current flow and can result in unintended surgical effects such as an effect at an unintended site or insufficient energy deposition.

Do not activate the CoolSeal™ Reveal until the instrument jaws have been fully closed. Activating the generator before this is done may result in improper sealing and may increase thermal spread to tissue outside the intended surgical site.

If the instrument shaft is visibly bent, discard and replace the instrument. A bent shaft may prevent the instrument from functioning properly.

Activate the CoolSeal™ Reveal only when the instrument is in direct contact with the target tissue to reduce the possibility of unintended burns.

During a seal cycle, energy is applied to the area between the instrument jaws. This energy may convert water into steam, and this steam may cause unintended injury in close proximity to the jaws. Take care in surgical procedures occurring in confined spaces in anticipation of this possibility.

Keep the cord free from the jaw and levers of the instrument.

Do not place instruments near or in contact with flammable materials (such as gauze, surgical drapes, of flammable gases.) Instruments that are activated or hot from use may cause a fire. When not using instruments, place them in a clean, dry highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

Avoid the accumulation of naturally occurring flammable gases that may accumulate in body cavities such as the bowel.

Aspirate fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.

Notice:

Do not overfill the jaws of the instrument with tissue, as this may reduce device performance.

Tissue Manipulation and Dissection

Warning

Use caution when handling the instrument between uses to avoid accidental activation of the CoolSeal™ system. Do not place the instrument on the patient or drapes when not in use.

Do not apply excessive force when performing tissue manipulation and dissection so as not to cause unintended tissue damage.

The instrument can be used to manipulate and dissect tissue with the jaws either opened or closed.

Knob Rotation

Turn the black rotation knob (3) on the handpiece until the jaws are in the required position.

Grasping

To grasp tissue with the device, place the tissue in the jaws and close the levers.

Sealing

Warning

Do not use this instrument on vessels larger than 6 mm in diameter.

Eliminate tension on tissue when sealing and cutting to ensure proper function.
Do not attempt to seal over clips or staples or contact metal objects (e.g., retractors). Contact between an active electrode and any metal objects may result in alternate site burns or incomplete seals.

Notice:
Verification testing of the CoolSeal™ Reveal has been conducted to confirm device performance for up to 70 sealing cycles.
The surgeon may inspect the seal before cutting the vessel or tissue. After inspecting the seal, the surgeon may create a second seal adjacent to the first seal before cutting, as described below.

1. Open the jaws by widening the movable levers (4).
2. Grasp the intended vessel or vascular bundle in the center of the jaws.
3. Close the movable levers until fully closed.
4. To activate the instrument, press and hold one of the blue activation buttons (7). A continuous tone sounds to indicate that the vessel or vascular bundle is being sealed. When the activation cycle is complete, three-pulsed "complete seal" tone sequence sounds and RF output ceases.
5. Release the seal activation button on the instrument when the seal cycle is complete and the tone sounds.
6. Open the jaws to release tissue by widening the movable levers.
7. To seal adjacent tissue, overlap the edge of the existing seal. The second seal should be distal to the first seal to increase seal margin.

Cutting

Caution
Energy based devices such as electrosurgical pencils or ultrasonic scalpels that are associated with thermal spread must not be used to transect seals.

Notice:
Do not engage the cutting mechanism over clips, staples, or other metal objects as damage to the cutter may occur.

To activate the cutting mechanism:

1. Grasp the intended tissue in the center of jaws.
2. Close the movable levers until fully closed.
3. Pull back on the blue cutting trigger (6) to deploy the knife.
4. Release the blue cutting trigger to retract the cutting blade.
5. Open the jaws by widening the movable levers.

Cleaning the Instrument During Use

Warning
Do not activate the instrument or cutting trigger while cleaning the jaws. Injury to the operating room personnel may result.
Inspect the instrument jaws prior to cleaning to ensure the blade is not deployed.

Caution
Keep the instrument jaws clean. Buildup of eschar may reduce the seal effectiveness. Wipe the jaw surfaces and edges with a wet gauze pad as needed. Do not clean instrument jaws with a scratch pad or scalpel blade.
Do not use excessive force (torque or bend the instrument jaws) during use or cleaning. Damage to the device may occur. If damaged, do not use.

Wipe jaw surfaces and edges with wet gauze pad as needed.

Troubleshooting

The following is a list of troubleshooting suggestions for situations encountered when using the instrument with a compatible CoolSeal™ Generator. For details on specific situations, refer to the corresponding generator user's guide. If any incidents occur while using the CoolSeal™ system, users should report these issues directly to Bolder Surgical by phone (866.683.1743) or by email (complaints@boldsurg.com) and to your local competent authority.

Alert Conditions:

When an alert condition occurs, energy delivery stops. After the alert condition has been corrected, energy delivery will be immediately available.

Seal Complete
Indicated By: • A **three** sequential tone alert • RF energy delivery stops • Activation display brightens **blue** for a half (0.5) second
Causes: • Successful vessel seal
To Resolve: • None, normal operation

Reactivate / Incomplete Seal
Indicated By: • A **three-pulsed** alert tone • RF energy delivery stops • Activation display brightens **amber** for one (1) second
Causes: • Seal time exceeds five (5) seconds OR • User either opened the instrument jaws or released the activation button, which causes the seal cycle to be interrupted before seal was completed OR • Current stays at the maximum current limit for longer than four (4) seconds, which indicates an electrical short between the jaws has occurred OR • The instrument has been activated in open air
To Resolve: 1. Release the activation button 2. Press the activation button to reactivate the seal cycle without repositioning the instrument 3. Open the instrument jaws and inspect for a successful seal 4. If possible, reposition the instrument and regrasp tissue in another location, then reactivate the seal cycle 5. Visually inspect seal before cutting
Possible use conditions include:

Grasping thin tissue or activating in open air	Open the jaws and confirm that a sufficient amount of tissue is inside the jaws If necessary, increase the amount of tissue and repeat the procedure
Grasping too much tissue between the jaws	Open the jaws and reduce the amount of tissue which is grasped, and reactivate the seal cycle
Grasping a metal object	Avoid grasping objects, such as staples, clips or encapsulated sutures in the jaws of the instrument
Activating in excess pooled fluids around the instrument tip	Minimize or remove excess fluids Reactivate the seal cycle without repositioning the instrument
Excessive tissue eschar on electrode tips	Use a wet gauze pad to clean surfaces and edges of instrument jaws

Instrument Error
Indicated By: • A **three-pulsed** alert tone • Instrument receptacle display illuminates **amber** and flashes continuously • Generator will not allow RF energy delivery
Causes: • Generator is receiving an activation request from the instrument
To Resolve: 1. Disconnect instrument from the generator 2. Ensure instrument activation button is not being pressed 3. Reconnect instrument to the generator 4. Confirm the instrument receptacle display illuminates green If the instrument error reoccurs: • Do not use the instrument • Use a different CoolSeal™ instrument
Possible use conditions include:

Inadvertent depression of the instrument activation button during instrument connection	Remove anything depressing the instrument activation button and reconnect instrument
The instrument switch is malfunctioning	Replace the instrument

Invalid Instrument	
Indicated By: • A **single-pulse** alert tone • Instrument receptacle display illuminates and remains **red** • Generator will not allow RF energy delivery	
Causes: • An unusable instrument has been connected	
To Resolve: 1. Disconnect instrument from the generator 2. Ensure instrument is CoolSeal™ compatible 3. Reconnect instrument to the generator 4. Confirm the instrument receptacle display illuminates green If the instrument error reoccurs: • Do not use the instrument • Use a different CoolSeal™ instrument	
Possible use conditions include:	
Instrument connected is not CoolSeal™ technology compatible	Confirm CoolSeal™ technology compatibility of the instrument from the instrument instructions for use
Instrument connected has been used previously	Discard instrument
Instrument is not usable with software version	Confirm the software version required by the instrument is not greater than the software version labelled on the bottom of the CoolSeal™ Generator For a software upgrade refer to the Software Upgrade section of the CoolSeal™ Generator User Guide

After Surgery

Warning

Do not reuse or resterilize the CoolSeal™ Reveal.

Discard the instrument after use according to the facility's policy for biohazards and sharps.

Pre-Clinical Study

Caution

There is no animal data qualified to predict the effectiveness of this device in sealing vessels containing atherosclerotic plaque.

Product performance of the device was established in a chronic in-vivo porcine model. The results showed that no animals studied experienced any hemostatic complications related to the device during the 21-day survival period. A variety of tissue types and vessels were evaluated to demonstrate effective sealing in arteries and veins up to and including 6 mm.

The United States FDA clearance of this device was not based on human clinical testing.

Vessel Type	Tissue/Vessel Name	Vessel Size Range
A/V Bundle	Mesentary	≤ 2.0 mm
	Gastrosplenic	2.0 mm – 6.0 mm
	Short Gastric	3.5 mm – 6.0 mm
	Ovarian Pedicle	3.0 mm – 6.0 mm
	Broad Ligament	2.0 mm – 5.0 mm
	Thyroid	2.0 mm – 6.0 mm
Artery	Renal	1.0 mm – 6.0 mm
	Splenic	1.0 mm – 6.0 mm
Vein	Renal	1.0 mm – 6.0 mm
	Splenic	1.0 mm – 6.0 mm

CoolSeal™
REVEAL

BOLDER™ SURGICAL

Bolder Surgical
Made in USA.

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Patent Information
www.BolderSurgical.com/patents

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