

Gun Type InSeal Sealer/Divider (EG) Instruction

Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences.

Important: This package insert is designed to provide instructions for use of the Innolcon Gun Type InSeal Sealer/Divider. Prior to use please refer to E21 system and other E21 components instructions for use to get the complete information and important warnings and notes. It is not a reference to surgical techniques.

Before using the instrument for the first time, the user needs to be trained by Innolcon's authorized service personnel in order to use the equipment correctly.

Declaration

Innolcon had applied trademark of InowaSeal for company's InSeal Sealer/Divider and relative electro-surgical instrument/system, wherein InSeal just represents InSeal mode adaptive tissue algorithm for ligation and division of vessels, tissue bundles and lymphatic.

Illustration and Nomenclature

EG2145、EG2138、EG2124、EG2145-C、EG2138-C、EG2124-C InSeal Sealer/Divider

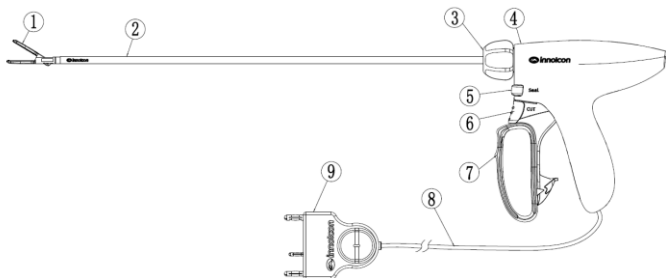


Fig.1 Appearance structure diagram of Gun Type Curved Jaw InSeal Sealer/Divider(closed handle)

EG2145-F、EG2138-F、EG2124-F、EG2145-CF、EG2138-CF、EG2124-CF InSeal Sealer/Divider

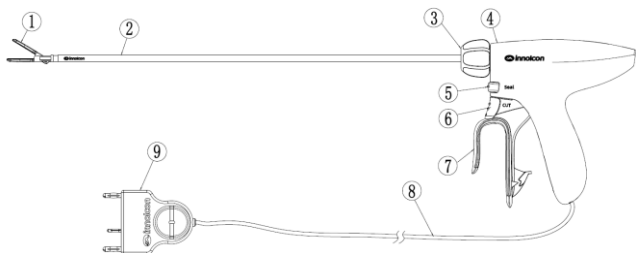


Fig.2 Appearance structure diagram of Gun Type Curved Jaw InSeal Sealer/Divider(open handle)

EG1145、EG1138、EG1124、EG1145-C、EG1138-C、EG1124-C InSeal Sealer/Divider

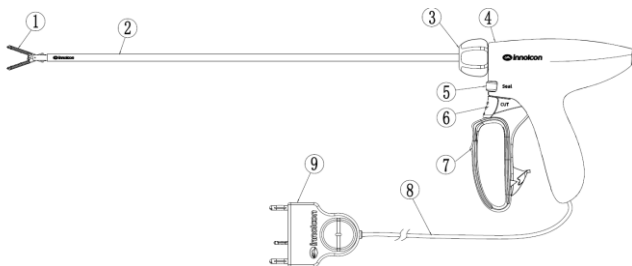


Fig.3 Appearance structure diagram of Gun Type Blunt Jaw InSeal Sealer/Divider(closed handle)

EG1145-F、EG1138-F、EG1124-F、EG1145-CF、EG1138-CF、EG1124-CF InSeal Sealer/Divider

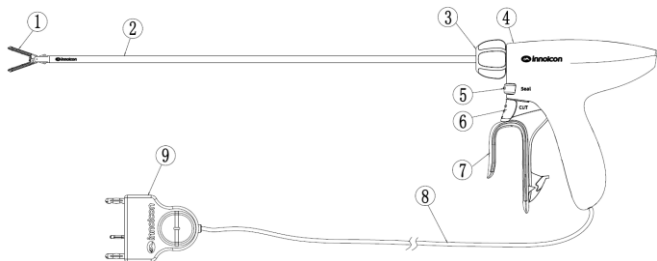


Fig.4 Appearance structure diagram of Gun Type Blunt Jaw InSeal Sealer/Divider(open handle)

EG3122, EG3122-C InSeal Sealer/Divider

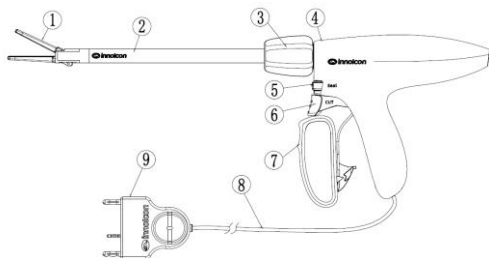


Fig.5 Appearance structure diagram of Gun Type Large jaw InSeal Sealer/Divider

No.	Name	Fuction
1	Jaw component	It is used to grasp the tissue and transmit electric energy to the tissue.
2	Tube assembly	It is used to connect handle and jaw component
3	Tube knob	When the handle of jaw is released, it can be operated to rotate tube assembly to any angle.
4	Shell	Shell of the operation handle
5	Seal button	It is used to control the on-off of the electric power.
6	Cut button	It is used to activate the built-in blade into the jaw to cut tissue.

7	Handle of jaw	It is used to open or close the jaw for clamping.
8	Cable	It is used to transfer electric energy from the generator to the instrument.
9	Plug	It is used to connect to the generator to transmit electric energy.

Device Description

- The gun type InSeal sealer/dividers are sterile, disposable instruments for high frequency surgical equipment.
- The gun type InSeal sealer/dividers includes an ergonomic hand-held device with manual controlled button (The SEAL indicates vessel sealing function and the CUT indicates tissue dividing function). A handle self-locking mechanism is designed in the device. When the handle of jaw is fully pressed, the jaw is fully closed, and there is a prompt sound. Then, loosen the handle of jaw, the jaw keeps closed and clamped. The handle self-locking mechanism can reduce the operation burden. Press the handle of jaw fully and loosen it after hearing the prompt sound, and the handle of jaw can automatically return to the initial state.
- The tube assembly of the gun type InSeal sealer/divider can rotate 360°, which is convenient for observation and easy to enter the target tissue.
- Each InSeal sealer/divider is equipped with a plug, which is used to connect the InSeal interface of the generator to transmit energy.
- The InSeal sealer/dividers include jaw, shaft, handle, cable and plug, involving metal material such as stainless steel, nickel plated copper, and non-metallic materials such as ceramics, PPA, PVDF, TPE, PC, ABS, PVC.
- Maximum rated voltage: 280V_{peak}

Model

Model of Gun Type Curved Jaw InSeal sealer/divider:

EG2145、EG2138、EG2124、
EG2145-C、EG2138-C、EG2124-C、
EG2145-F、EG2138-F、EG2124-F、
EG2145-CF、EG2138-CF、EG2124-CF.

Model of Gun Type Blunt Jaw InSeal sealer/divider:

EG1145、EG1138、EG1124、
EG1145-C、EG1138-C、EG1124-C、
EG1145-F、EG1138-F、EG1124-F、
EG1145-CF、EG1138-CF、EG1124-CF.

Model of Gun Type Large jaw InSeal sealer/divider:

EG3122、EG3122-C.

Intended Use/Indications

The Gun Type InSeal Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures when ligation and division of vessels, tissue bundles and lymphatic is desired. The InSeal Sealer/Divider can be used on vessels (arteries and veins) up to and including 7mm. It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic and gynecologic. These may include, but are not limited to, such procedures as Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.

Contraindications

The InSeal Sealer/Divider has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the InSeal Sealer/Divider for these procedures.

Patient populations

Adult patients (>18 years old) and adolescent with no genetic or gender restrictions. This device is suitable for patients in general surgery and such surgical specialties as urologic, vascular, thoracic and gynecologic. These may include, but are not limited to, such procedures as Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.

Complications

Thermal injury
Bleeding
Infection
Tissue trauma

Intended user

The device is only for use by medical professionals trained.

General Warnings

Warning

- This product cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices without appropriate regulatory authorization may result in bio-incompatibility, infection, or product failure risks to the patient.
- These instruments are intended for use ONLY with the innolcon E21 and E21-A Generator. Use of this instrument with other generators may not result in the desired tissue effect, may result in injury to the patient or surgical team, or may cause damage to the instrument.
- Do not use the InSeal system unless properly trained to use it in the specific procedure being undertaken. Use of this equipment without such training may result in serious unintended patient injury.
- Use the system with caution 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 permanently damage the device. Consult the device manufacturer or responsible hospital department for further information when use is planned in patients with implanted medical devices.
- When this instrument is used 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.
- In minimally invasive surgery, inspect the outer surfaces of the instrument before insertion through the cannula to ensure there are no rough or sharp edges to damage tissue.
- Contact between an active instrument electrode and any metal objects (hemostats, staples, clips, retractors, etc.) may increase current flow and may result in unintended surgical effects or insufficient energy deposition.
- The safe and effective use of RF energy depends on many factors solely under the control of the operator. There is no substitute for properly trained and vigilant personnel. It is important that the operating instructions supplied with this or any other medical equipment be read, understood, and followed.

Precaution

- Use caution during surgical procedures in which patients exhibit certain types of vascular pathology (atherosclerosis, aneurysmal 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. These have the potential to degrade the InSeal nano-coating technology on the sealing surfaces, which may lead to increased tissue adhesion.

Operation

Setup

Warning

- Electric Shock Hazard-Do not connect wet accessories to the InSeal system.
- Position instrument cords to avoid contact with the patient or other cords. Do not wrap cords around metal objects. This may induce currents that could lead to shock, fire, or injury to the patient or surgical team.
- Examine all InSeal system and instrument connections before using. Improper connection may 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. If damaged, do not use.
- Confirm proper InSeal system settings before proceeding with surgery.
- Do not use in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide (N₂O) and oxygen, or in close proximity to volatile solvents (such as ether or alcohol) as an 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.
- Connect adaptors and accessories to the electrosurgical unit only when the unit is off or in standby mode. Failure to do so may result in injury or electrical shock to the patient or operating personnel.

Precaution

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

Operation Steps

1. Remove instrument from tray by firmly pulling on the shell (4). Do not pull on the instrument's jaws (1) or cable (8).
2. Insert the connector (9) into the receptacle on the generator. Follow the instructions in the generator user's guide to complete the setup procedure.

During Surgery

Tissue Manipulation and Dissection

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

Warning

- Avoid placing fingers between the shell and the handle of jaw, or between the handle of jaw and the cut button, or in the jaws. Injury to the user may result.
- Use caution when handling the instrument between uses to avoid accidental activation of the InSeal system. Do not place the instrument on the patient or drapes when not in use.
- Keep the cord free from the jaw and shell of the instrument.
- **Fire Hazard**-Do not place instruments near or in contact with flammable materials (such as gauze, surgical drapes, or 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.
- For minimally invasive procedures, be alert to these potential hazards:
 - Do not use hybrid trocars that are comprised of both metal and plastic components. Capacitive coupling of RF current may cause unintended burns.
 - Use the appropriately sized trocar to allow for 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 jaws using device handle of jaw before insertion/extraction in the trocar.

Rotating the Instrument Jaws

Turn the tube knob on the instrument until the jaws are in the required position.

Notice: Do not turn the tube knob (3) when the handle of jaw fully depressed. Product damage may occur.

Grasping and Manipulating Tissue

- To grasp tissue with the device, place the tissue in the jaws and fully press the handle of jaw.
- The click indicates the end of the grasp zone and the jaw keeps closed and clamped. The handle self-locking mechanism can reduce the operation burden.
 - Press the handle of jaw fully again and loosen it after hearing the prompt sound, and the handle of jaw can automatically return to the initial state.

Sealing Vessels and Tissue Bundles

Warning

- Do not use this instrument on vessels larger than 7 mm in diameter.
- If the instrument shaft is visibly bent, discard and replace the instrument. A bent shaft may prevent the instrument from sealing or cutting properly.
- Do not place the vessel and/or tissue in the jaw hinge. Place the vessel and/or tissue in the center of the jaws.
- Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to the instrument may carry electrical current or heat, which may cause unintended burns to the patient. Aspirate fluid from around the instrument jaws before activating the instrument.
- Keep the external surface of the instrument jaws away from adjacent tissue while activating the InSeal system or unintended injury may result.
- During a seal cycle, energy is applied to the tissue between the instrument jaws. This energy may cause water to be converted into steam. The thermal energy of steam may cause unintended injury to tissues in close proximity to the jaws. Care should be taken in surgical procedures occurring in confined spaces in anticipation of this possibility.
- Eliminate tension on the tissue when sealing and cutting to ensure proper function.
- Use caution when grasping, manipulating, sealing, and dividing large tissue bundles.
- Do not bend instrument shaft.
- Do not attempt to seal or cut over clips or staples as incomplete seals will be formed.
- 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.
- Inadvertent activation or movement of the activated instrument outside of the field of vision may result in injury to the patient or surgical team.
- Do not activate the InSeal system in an open-circuit condition. Activate the system only when the instrument is in direct contact with the target tissue to lessen the possibility of unintended burns.
- Do not activate the instrument while instrument jaws are in contact with, or in close proximity to, other instruments including metal cannulas, as localized burns to the patient or physician may occur.
- If the system prompts "seal timeout", do not cut the tissue and reactivate the instrument until the system prompts seal successful before continuing with subsequent operations. If the system continues to prompt "seal timeout", please remove excess liquid from the surrounding area or replace the device.
- Pay attention to the difference between the seal button and the cut button, and do not press the cut button when sealing.

Precaution

- Do not overfill the jaws of the instrument with tissue, as this may reduce device performance.
- Keep the instrument jaws clean. Build-up of eschar may reduce the seal and/or cutting effectiveness. Wipe jaw surfaces and edges with a wet gauze pad as needed.

Sealing with Hand-activation

1. Ensure hand-activation is enabled on the appropriate receptacle. Refer to the generator user's guide if needed.
2. Open the jaws by pushing forward on the handle of jaw.
3. Squeeze the handle of jaw to grasp the intended vessel and/or tissue in the center of the jaws. The click indicates the user has reached the end of the grasp zone.
4. Press the seal button and energy is delivered. Continue to hold the seal button pressed until the seal cycle is complete.
5. A continuous tone sounds to indicate the activation of RF energy. When the activation cycle is complete, a two-pulsed Seal-Cycle-Complete tone sounds and RF output ceases.

Precaution: The seal button must be continually pressed until the seal cycle is complete.

Notice: The surgeon may inspect the seal before cutting the vessel or tissue. After inspecting the seal, the surgeon should create a second seal adjacent to the first seal before cutting, as described below.

A tone with multiple pulses indicates that the seal cycle was not completed. Refer to the Troubleshooting section for possible causes and corrective actions. Do not cut tissue until you have verified that there is an adequate seal.

6. Press the handle of jaw fully again and loosen it after hearing the prompt sound, and the handle of jaw can automatically return to the initial state, and the jaws is opened to release tissue.
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.

Notice: Keep the activation button dry and clean.

Sealing with Footswitch Activation

A footswitch can be used instead of the activation button. Ensure that the footswitch is connected to the footswitch receptacle that corresponds to the instrument in use.

Warning: Activating energy delivery with a footswitch when the handle of jaw is not fully depressed may result in improper sealing and increase thermal spread to tissue outside the surgical site. Proper pressure is being applied to the tissue when the handle of jaw is locked.

1. Ensure hand-activation is disabled on the appropriate port.
2. Squeeze the handle of jaw to grasp the intended vessel and/or tissue in the center of the jaws. The click will indicate the end of the grasp zone has been reached.
3. Press and hold the footswitch pedal to activate energy until the seal cycle is complete.
4. A continuous tone sounds to indicate the activation of RF energy. When the activation cycle is complete, a two-pulsed Seal-Cycle-Complete tone sounds and RF output ceases.

Notice: The surgeon may inspect the seal before cutting the vessel or tissue. After inspecting the seal, the surgeon should create a second seal adjacent to the first seal before cutting, as described below.

A tone with multiple pulses indicates that the seal cycle was not completed. Refer to the Troubleshooting section for possible causes and corrective actions. Do not cut tissue until you have verified that there is an adequate seal.

5. 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.

Notice: Keep the activation button dry and clean.

Cutting Tissue

Warning

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

Notice

- Do not engage the cutting mechanism over clips, staples, bone or other metal/hard objects as damage to the cutter may occur.
- The cut button can only be used when the handle of jaw is pressed. When the jaws are open, the cut button is locked, and forcibly operating the cut button will lead to instrument damage.

Operation Steps

1. To activate the cutting mechanism:
 - . Grasp the tissue firmly in the jaws by press the handle of jaw.
 - . Pull the cut button (6).
 - . Release the cut button to retract the cutting blade.

Precaution: If the cut button does not automatically return to position, open the handle of jaw manually return the cut button.

2. Open the jaws by pressing the handle of jaw fully again and loosen it to release tissue.

Notice: Keep the activation button dry and clean.

Cleaning the Instrument during Use

Warning

- Inspect the instrument jaws prior to cleaning to ensure the blade is not deployed.
- Do not activate the instrument or cut button while cleaning the jaws. Injury to operating room personnel may result.
- Wipe jaw surfaces and edges with a wet gauze pad as needed.
 - If the instrument cannot operate properly, clean the accumulated tissue or eschar at the jaws. If it still cannot operate, replace the instrument.

Notice

- Do not attempt to clean the instrument jaws by activating the instrument on wet gauze. Product damage may occur.

- Remove any embedded tissue from blade track and jaw hinge area.
- Do not clean the instrument jaws with a scratch pad or other abrasives.

After Surgery

- Discard the instrument after use according to the facility's policy for biohazards and sharps.
- Do not resterilize.

Disassembly

Turn the generator OFF at the power switch.

Dispose of the instrument in an appropriate container.

Transport Conditions

Temperature: -22°C to 60°C

Relative Humidity: 10-80%

Storage Conditions

Temperature: -22°C to 30°C

Relative Humidity: 20-70%

Operation Conditions

Temperature: 10°C to 40°C

Atmospheric pressure: 700hPa to 1060hpa

Relative humidity: 30% to 75%, non-condensing

Preheating time: If the handling or storage temperature is outside the working temperature range, it should be left for 1 hour before use to bring the temperature of InSeal Sealer/Dividers to room temperature.

Troubleshooting

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. After the alert condition has been corrected, energy delivery will be immediately available.

Troubleshooting steps:

1. Release the footswitch pedal or seal button, if still engaged.
2. Open the instrument jaws and inspect for a successful seal.
3. According to the error message displayed on the generator screen, implement the recommended corrective action in the manual.
4. If possible, reposition the instrument and regrasp tissue in a location that overlaps the previous seal, then reactivate the seal cycle.

Possible causes of an error message:

1. Short circuit - Too little tissue between the jaws, activation on metal objects, soiled jaws, excess fluid at the surgical site
2. Open circuit - There is too much tissue between the jaws and the jaws are dirty
3. Seal interrupted - Release the start switch before the closing completion sound
4. Seal timeout - The maximum closure cycle time has been reached

Recommended corrective action

1. Too little tissue between the jaws-The user is grasping thin tissue or not enough tissue; open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the thickness of tissue that is grasped and reactivate the seal cycle.
2. Too much tissue between the jaws-The user is grasping too much tissue; open the jaws, reduce the amount of tissue that is grasped, and reactivate the seal cycle.
3. Activating on a metal object - Avoid grasping objects, such as staples, clips, or encapsulated sutures in the jaws of the instrument.
4. Dirty jaws - Use a wet gauze pad to clean surfaces and edges of instrument jaws.
5. Excess Fluids in the Surgical Field - Minimize or remove excess fluids from around the instrument jaws.

6. Activation switch released before seal complete tone – Release the footswitch or seal button after the seal cycle was complete.
7. Maximum seal cycle time has been reached – The system needs more time and energy to complete the seal cycle. Reposition the instrument and regrasp tissue in a location that overlaps the previous seal, then reactivate the seal cycle.
















How Supplied

The InSeal Sealer/Dividers are supplied for single patient use. Each instrument is shipped with on sterile, single use. Discard the instrument after use.

Validity period

Production date and expiration date can be found on the product label.

Validity period: 3 years

	Sterilized using Ethylene Oxide		Authorized representative in the European Community		Lot Number
	Use-by Date		Humidity limitation		Date of Manufacture
	Refer to instruction manual		Temperature limit		Manufacturer
	Do not re-use		Do not re-sterilize		Do not use if package is damaged
	To sale by or on the order of a physician.		Medical device		Serial number



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