

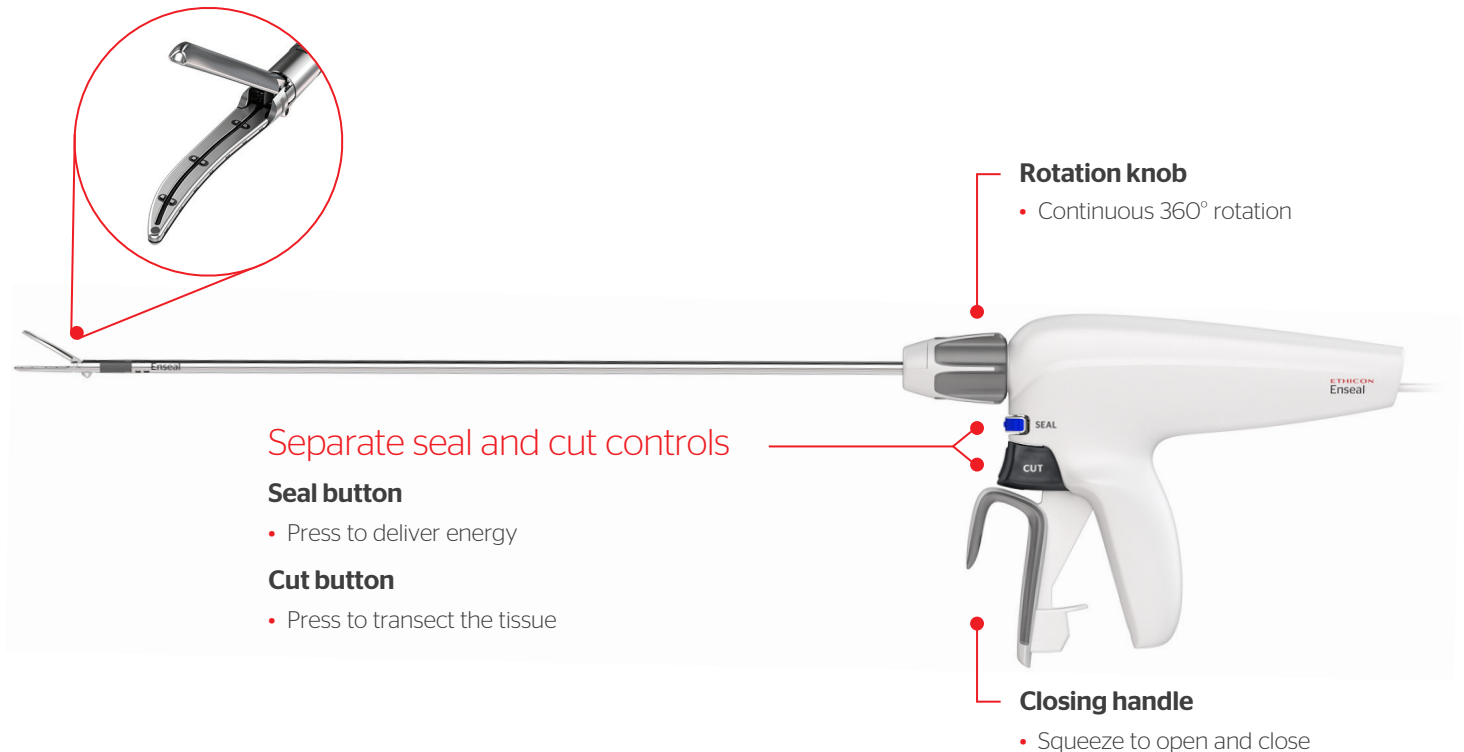
ENSEAL® X1 Tissue Sealer

Optimized Device Performance

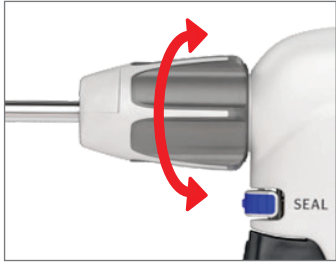
ENSEAL® X1 Tissue Sealer instruments are bipolar electro-surgical instruments intended for use in open and laparoscopic surgical procedures where ligation and division of vessels is desired. They are designed for use exclusively with the Ethicon Generator G11 (GEN 11).

ENSEAL® X1 technology:

- Seals and cuts vessels or cuts, grasps, and dissects tissue independently during surgery
- Coagulates and transects vessels, tissue, or vascular bundles up to and including 7 mm in diameter



Optimized usage

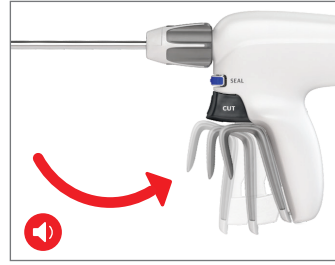


1. Rotate knob

Turn the rotation knob to move the shaft around to the desired position. Position the vessel or tissue in the center of the jaws.

Warning:

To reduce the possibility of an inadvertent activation of the sealing mechanism, do not place your finger on the blue SEAL button until the jaws are in the desired position and activation is intended.



2. Close the jaws

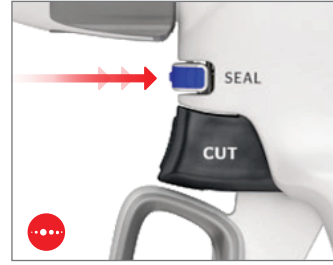
Squeeze closing handle until it latches to clamp targeted tissue between the jaws. Relax grip on closing handle once it is latched. Once the handle is latched, it will remain latched until it is squeezed again.

Warning:

If the closing handle is not fully latched, this may result in improper sealing and thermal spread.

Warning:

Prior to squeezing the closing handle, check for objects such as surgical drapes, gowns, and/or patient tissue that could get caught between the closing handle and the grip housing of the device. Failure to do so may result in patient injury, loss of sterility, and/or impaired device functionality.

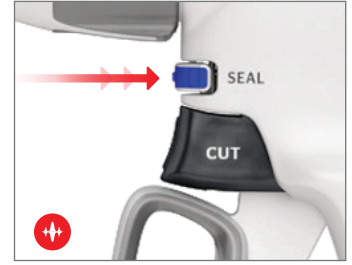


3a. Seal (activation tone)

Press the blue SEAL button or MIN foot pedal to energize the jaws and begin coagulation of the targeted tissue. The generator gives audible feedback (Activation Tone - continuous steady beeping), which indicates the device is active and energy is being delivered to the clamped tissue.

Warning:

Avoid placing tension on the tissue when sealing or cutting to ensure adequate hemostasis.

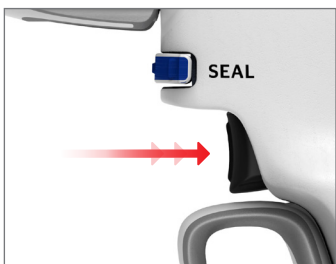


3b. Seal (end tone)

Continue to depress the blue SEAL button or MIN foot pedal until the activation cycle is complete, and a second tone (End Tone - one short beep) is heard, indicating energy has been stopped.

Warning:

If transection of tissue is desired after sealing, wait for the End Tone before pressing the CUT button and transecting the tissue. If the knife is advanced prior to hearing the end tone, this may result in incomplete sealing and lack of hemostasis.

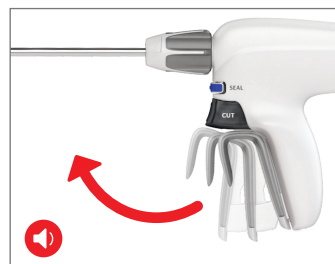


4. Cut

Fully press the CUT button against the grip housing. The knife will advance to the end of the knife slot.

Warning:

Prior to cutting, inspect the vessel or tissue to ensure proper sealing.



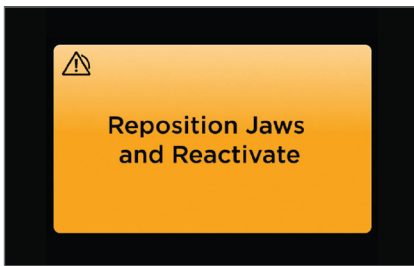
5. Open jaws

After the transection cycle is complete, squeeze the closing handle until it unlocks.

Additional warnings & cautions

- 1 Use caution during surgical cases in which patients have connective tissue disorder or exhibit certain types of pathology (e.g., Atherosclerosis, Crohn's, etc.). For best results, apply the seal to unaffected vasculature.
- 2 Do not use energy-based devices to transect seals, such as electrocautery pencils or ultrasonic scalpels.
- 3 Do not use this device on vessels in excess of 7 mm in diameter. This may lead to improper sealing and hemostasis.
- 4 Pools of conductive fluids (e.g. blood, saline) in direct contact with the instrument jaws may affect device performance. Remove pooled fluid from around the instrument jaws before activating the instrument.
- 5 For complete indications, contraindications, warnings and precautions, please reference the full package insert.

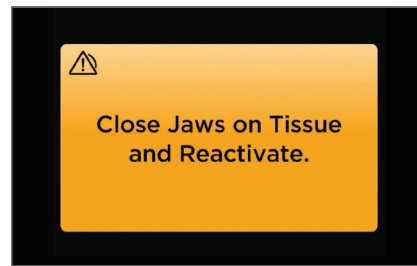
Generator troubleshooting



Reposition jaws and reactivate

Description: A short is detected. A short can occur when the instrument comes in contact with metal, such as a staple, during activation.

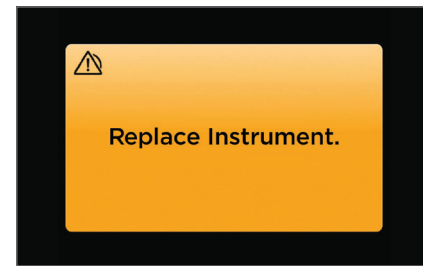
Troubleshooting: Reposition device and reactivate the SEAL button.



Close jaws on tissue and reactivate

Description: An open circuit is detected. If an open circuit is detected three consecutive times, there may be an issue in the instrument and the user is prompted to replace the instrument.

Troubleshooting: Close jaws on targeted tissue and reactivate.



Replace instrument

Description: The same alarm has triggered multiple times in a row. There may be an issue in the instrument.

Troubleshooting: Replace the instrument.

Cleaning the device



Clean the device

For optimized performance and to avoid tissue sticking, clean the instrument jaws and distal end of the shaft with a sterile, moist gauze sponge throughout the procedure. If possible, support the end of the shaft with one hand while cleaning to help prevent inadvertent damage to the end effector.



Do not immerse

Do not immerse distal tip in liquid, including saline solution, to clean. This may result in damage to the instrument.



Do not clean instrument with abrasives

If tissue is still visible in the jaws, use forceps to remove residue, taking care not to actuate the instrument.

Caution:

Do not activate the instrument while cleaning to avoid inadvertent user injury.