ENSEAL® X1 Large Jaw Tissue Sealer

Optimized Device Performance

ENSEAL® X1 Large Jaw Tissue Sealer instrument is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. It is a bipolar instrument for use with the Ethicon Generator G11 (GEN 11).

ENSEAL® X1 Technology:

- Cuts and seals 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

**38 mm Curved Jaw Length**

**Curved Jaw**
- Curved jaws can be partially or fully closed by squeezing the closing handle
- Grasps and holds targeted tissue when clamped

**360° Single Hand Rotation**
- Continuous 360° rotation

**Separate Seal and Cut Controls**

**Sealing**
- Press the SEAL button or MIN foot pedal to deliver bipolar energy to coagulate targeted tissue

**Cutting**
- Press the CUT button to advance the knife the length of the jaws to transect targeted tissue

<table>
<thead>
<tr>
<th>Tone</th>
<th>Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activation Tone</td>
<td>Continuous steady beeping</td>
<td>Generator On. Device is active</td>
</tr>
<tr>
<td>End Tone</td>
<td>One short beep</td>
<td>End of Cycle. Energy is stopped</td>
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</tbody>
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Optimal 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.

2. **Close the Jaws**
   Squeeze closing handle until it latches (and a click is heard) to clamp targeted tissue between the jaws.

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

3a. **Seal (Activation - Tone 1)**
   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) as energy is delivered to the clamped tissue.

   **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.

3b. **Seal (End Tone - Tone 2)**
   Continue to depress the blue SEAL button or MIN foot pedal until the activation cycle is complete, and a second tone (End Tone) is heard, indicating energy has been stopped.

   **Caution:**
   Do not press the CUT button until the End Tone is heard. If the knife is advanced prior to the End Tone, this may result in an incomplete seal prior to transecting tissue and lack of hemostasis.

4. **Cut**
   Fully press the CUT button against the grip housing. The knife will advance to the cut line.

   **Warning:**
   To reduce the possibility of an inadvertent activation of the cutting mechanism prior to sealing, do not place your finger on the CUT button until activation is complete and transection is intended.

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 electrosurgical 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.

Generator Troubleshooting

Reposition Jaws and Reactivate

Description: “Short Detected” screen exits.
Troubleshooting: Reposition device and reactivate the SEAL button.

Replace Instrument

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

Cleaning the Device

Clean the Device
For optimal 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.

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 clamp arm, use forceps to remove residue, taking care not to actuate the instrument.