VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System
Permanent Mesh with Bioresorbable Coating and Positioning System for Laparoscopic Ventral Hernia Repair

Instructions for Use

- Single Use
- Do not Resterilize
- Partially Absorbable
- 2°C (36°F) Temperature Limit
- 25°C (77°F) Temperature Limit
- STERILE EO
- Rx only
The VENTRALIGHT™ ST Mesh with Echo™ 2™ Positioning System (the device) is a low profile, biocompatible coated, permanent mesh, with a preattached removable positioning system, designed for the reconstruction of soft tissue deficiencies during laparoscopic ventral hernia repair.

**Indications**

1. VENTRALIGHT™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.
2. The Echo™ 2™ Positioning System is intended to facilitate the delivery and positioning of the soft tissue prosthesis during laparoscopic hernia repair.

**Contraindications**

1. Do not use the device in infants, children or pregnant women, whereby future growth will be compromised by use of such material.
2. Do not use for the reconstruction of cardiovascular defects.
3. Literature reports there is a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.

**Warnings**

1. The use of any synthetic mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh and is not recommended.
2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. Unresolved infection may require removal of the mesh.
3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections.
4. To prevent recurrences when repairing hernias, the mesh must be large enough to provide adequate overlap and must be placed in contact with the visceral structures. Careful attention to mesh fixation, placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue.
5. Ensure proper orientation; the coated side of VENTRALIGHT™ ST Mesh must be oriented against the bowel or sensitive organs. Do not place the uncoupled mesh against the bowel as there is risk for adhesion formation when the uncoated mesh is placed in direct contact with the bowel or viscera (see Section 2, “Surface Orientation”).
6. VENTRALIGHT™ ST Mesh is the only permanent implant component of the device. The Echo™ 2™ Positioning System (which includes deployment frame, center hoisting suture and all connectors) must be removed from the patient and appropriately discarded. It is not part of the permanent implant.
7. Do not apply sharp, pointed, cautery devices, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the Echo™ 2™ Positioning System frame.
8. The device contains superelastic nitinol wire; do not cut and avoid direct contact with active surgical electrodes.
9. The device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.
10. The device is designed for single use only. Do not reuse or resterilize any portion of the device.
11. Product must be used once the exterior foil pouch has been opened. Do not store for later use. Unused portions of the device must be discarded.
12. The Echo™ 2™ Positioning System should not be used with any other hernia mesh. The biocompatible covered side of the mesh must be placed against the bowel and after completing all other fixation.
13. Discard the Echo™ 2™ Positioning System (including the frame, center hoisting suture, all connectors and Mesh introducer) after use. These may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

**Precautions**

1. Only physicians qualified and trained in the appropriate surgical techniques should use this prosthesis.
2. Please read all instructions prior to use. The safety and effectiveness of the device has not been evaluated in clinical studies for the presence of malignancies in the abdominal cavity. Use this prosthesis.
3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of infection.
4. Visualization must be maintained throughout the course of the entire surgical procedure. Additionally, laparoscopic removal of the Echo™ 2™ Positioning System frame must be performed under sufficient visualization of the entire device and surrounding anatomy, to ensure proper removal.

**INSTRUCTIONS FOR USE**

**Note on Transfascial Sutures:** The Echo™ 2™ Positioning System eliminates the need for transfascial orientation and positioning sutures. If transfascial sutures are used for fixation, place sutures after removing the Echo™ 2™ Positioning System frame from the body and after completing all other fixation.

**1) Preparation**

VENTRALIGHT™ ST Mesh with Echo™ 2™ Positioning System should be hydrated for no more than 1-3 seconds and must be rolled immediately after hydration to maximize the flexibility of the prosthesis. The safety and effectiveness of VENTRALIGHT™ ST Mesh with Echo™ 2™ Positioning System in combination with solutions other than sterile saline have not been tested.

**2) Surface Orientation**

It is extremely important that this product is oriented correctly to function as intended. The biocompatible coated side of the VENTRALIGHT™ ST Mesh (which contains the Echo™ 2™ Positioning System frame) must always be positioned towards those surfaces where minimal tissue attachment is desired, i.e., bowel or other visceral structures. The biocompatible coated surface is designed to temporarily separate tissue surfaces and minimize tissue attachment to the mesh. The uncoated polypropylene mesh side must face the surface where tissue ingrowth is desired, and must never be placed against the bowel or other visceral structures.
3) Trocar Size Recommendations
Insert into the abdomen through the recommended minimum trocar or trocar incision site. Never force the device through the trocar. If the device will not easily deploy down the trocar, remove the trocar and insert the next largest available size trocar or through the trocar incision site and reinsert trocar. See Table 1 in “Product Description” section for recommended minimum trocar size.

4) Inserting with Graspers
**Note:** This section is only applicable to REF 5990011, REF 5991015 and REF 5993035, which do not include the Mesh Introducer.
1. Remove the VentraLight™ ST Mesh with Echo 2™ Positioning System from the sterile pouch.
2. Hydrate the device for no more than 1-3 seconds, in a sterile saline solution (Fig. 4).
3. Lay the device frame side up, on a flat, sterile surface, as shown, with the long axis pointing left to right, indicated by the black arrows in the middle and outer edges of the frame. Lay the center hoisting suture to the side so it is not in the way (Fig. 5).
4. Start at the bottom and roll the device tightly with the polypropylene side on the outside and bioresorbable barrier and Echo 2™ Positioning System frame on the inside (Fig. 6). Follow the Nitinol frame outward as the mesh is rolled, indicated by the arrows in Figure 6. Take care not to let the hoisting suture become rolled up with the mesh.
5. Hold the tightly rolled frame and grasp the leading edge of the device with an atraumatic grasper or grasping tool. Take care to grasp both mesh and frame material at approximately a 45 degree angle (Fig. 7). A black line indicates the suggested location to grasp the mesh.
6. With the grasper, insert the leading edge of the rolled device into the trocar or incision site. Do not let the rolled mesh bend as it is inserted into the trocar. In one continuous movement, deploy the device into the abdomen (Fig. 8). Maintain visualization of the device via laparoscope, as it is deployed into the abdomen.
**Note:** If the grasper slips from the device before it is completely deployed through the trocar or incision site, use a grasper from an opposing trocar location to pull the device into the abdomen. Ensure that the barrier is not damaged during insertion.

5) Inserting with Mesh Introducer
**Note:** This section is only applicable to REF 5990015, REF 5991520, REF 5991525, REF 5991623, REF 5992025 and REF 5992533, which include the Mesh Introducer.
1. Remove the VentraLight™ ST Mesh with Echo 2™ Positioning System from the sterile pouch.
2. Hydrate the device for no more than 1-3 seconds, in a sterile saline solution (Fig. 4).
3. Lay the device frame side up, on a flat, sterile surface. Insert the device between the lines of the Mesh Introducer, parallel to the long axis of the device. Ensure the tines are positioned 2 cm past the edge of the mesh and are on to the edge of the frame, as shown (Fig. 9). To secure the tines together, place the white “T” cap on the distal end of the Mesh Introducer (Fig. 10).
4. Begin rolling by rotating the handle of the Mesh Introducer towards the center of the mesh (Fig. 11). Ensure the hoisting suture is facing the proximal end of the Mesh Introducer so it does not get wrapped in the mesh. Place opposing hand under the mesh, to aid in rolling. Continue rolling until the entire device is wrapped around the Mesh Introducer (Fig. 12).
5. Remove the white “T” cap from the end of the Mesh Introducer and take care not to let the mesh unroll. Ensure the device is positioned such that the distal end of the Mesh Introducer extends at least ¾ cm beyond the mesh edge (Fig. 13).
6. Insert the distal end of the Mesh Introducer into the trocar, while simultaneously rotating the handle of the Mesh Introducer in the direction that the device was rolled (Fig. 11), and deliver the device through the trocar. The rotating motion of the device will help keep it rolled around the tines, facilitating insertion. Continue this motion until the handle of the Mesh Introducer is near the cap of the trocar. The mesh may not be completely in the abdomen at this point (Fig. 14).

7) Removal of Echo 2™ Positioning System Frame
1. Remove the atraumatic clamp or hemostat from the hoisting suture and, external to the patient, cut the center hoisting suture close to the skin to temporarily hold the device in place (Fig. 19).
2. Use the visual markings on the frame (Fig. 1) to identify the long and short axes of the mesh. Intraabdominally, use an atraumatic grasper to orient and position the Echo 2™ Positioning System appropriately, in relation to the defect.
4. Once properly positioned, ensure that no bowel or any other tissue is entrapped between the device and the abdominal wall. Fixate around the entire perimeter of VentraLight™ ST Mesh with fasteners placed 1-2 cm apart (Fig. 20). Ensure that no fasteners are placed through the echo 2™ Positioning System frame.

8. To complete deployment, rotate the handle in the original direction it was rolled in Step 4 of the section “Inserting with Mesh Introducer” (Fig. 11). Continue to simultaneously rotate the handle of the Mesh Introducer and deploy the mesh through the trocar until it is all the way in the abdomen (Fig. 17).
**Note:** If the Mesh Introducer is removed from the device before it is completely deployed through the trocar, use an atraumatic grasping tool to push the mesh through the trocar, or pull the device into the abdomen from an opposing trocar location.

9. After the mesh is deployed into the abdomen, remove and appropriately discard the Mesh Introducer.

6) Hoisting, Positioning, Fixating and Removal of Device
1. Once the Echo 2™ Positioning System is deployed into the abdomen, locate the center hoisting suture. With a suture passer, retrieve the hoisting suture through the center of the hernia defect (Fig. 18). Avoid going through the umbilicus. To prevent potential contamination, ensure suture does not slip back into the abdominal cavity.
2. Raise the center hoisting suture to hoist the device to the desired position, and then place an atraumatic clamp or hemostat on the center hoisting suture at the level of the skin to permanently hold the device in place (Fig. 19).
3. Maintain constant visualization and ensure no fasteners are placed through the mesh will detach one-by-one from the mesh. Maintain constant visualization and ensure no tissue or organs are caught while removing the frame through the trocar. Never remove the device from the center frame struts.

**Note:** The Echo 2™ Positioning System frame is designed to separate into one strand when removed. It is recommended that the frame is removed from the same size trocar from which it was inserted.
3. Continue to remove the Echo 2™ Positioning System frame by pulling it through the trocar (Fig. 23) and out of the abdomen (Fig. 24).
4. Verify that the Echo 2™ Positioning System frame is fully intact after removal, including all components listed in Table 2 and discard appropriately (Fig. 25).

![Echo 2™ Positioning System Frame](image)

**Table 2**

<table>
<thead>
<tr>
<th>REF</th>
<th>Device Size</th>
<th>Number of Connectors</th>
<th>Hoisting Suture</th>
</tr>
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<tbody>
<tr>
<td>5990011</td>
<td>11 cm (4.5&quot;)</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>5991015</td>
<td>10 cm x 15 cm (4&quot; x 6&quot;)</td>
<td>5</td>
<td>1</td>
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<tr>
<td>5990015</td>
<td>15 cm (6&quot;)</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>5991520</td>
<td>15 cm x 20 cm (6&quot; x 8&quot;)</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>5991525</td>
<td>15 cm x 25 cm (6&quot; x 10&quot;)</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>5991823</td>
<td>18 cm x 23 cm (7&quot; x 9&quot;)</td>
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<td>5993035</td>
<td>30 cm x 36 cm (12&quot; x 14&quot;)</td>
<td>6</td>
<td>1</td>
</tr>
</tbody>
</table>

5. Place any additional fixation as needed and complete the procedure. Care should be taken to ensure that the mesh is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be placed. Follow established surgical principles.

**Fixation**

Bard® fixation devices or monofilament sutures are recommended to properly secure the VentraLight™ ST Mesh. If other fixation devices are used, they must be indicated for use in hernia repair. If trans fascial sutures are used for fixation, place sutures after removing the Echo 2™ Positioning System from the body and after completing all mechanical fixation. Care should be taken to ensure that the mesh is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be placed.

**Adverse Reactions**

Possible complications may include, but are not limited to, seroma, adhesion, hematoma, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction and recurrence of the hernia or soft tissue defect.

**Traceability**

A traceability label which identifies the type, size, expiration date, and lot number of the device is attached to every package. This label should be affixed to the patient’s permanent medical record to clearly identify the device which was implanted. If you experience a product failure, please contact Davol Inc. at 1-800-556-6275 for instructions on returning the product.

**Storage**

Ventralight™ ST Mesh with Echo 2™ Positioning System should be stored in a clean, dry area until ready for use.

**Radioopaque**

Non-clinical testing performed in accordance with ASTM F640-12, section 6.3.1 demonstrated the frame of the Echo 2™ Positioning System is visible through the body mimic.

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