

VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System

Catalog Number	Shape	Mesh Size	
5955680	Ellipse	6" x 8" (15.2 cm x 20.3 cm)	<input type="checkbox"/>
5955610	Oval	6" x 10" (15.2 cm x 25.4 cm)	<input type="checkbox"/>
5955790	Ellipse	7" x 9" (17.8 cm x 22.9 cm)	<input type="checkbox"/>
5955810	Ellipse	8" x 10" (20.3 cm x 25.4 cm)	<input type="checkbox"/>
5955113	Ellipse	10" x 13" (25.4 cm x 33.0 cm)	<input type="checkbox"/>
5955124	Rectangle	12" x 14" (30.5 cm x 35.6 cm)	<input type="checkbox"/>

- Please add the VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System to my preference card.
- I would like to have the VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System in stock.
- I would like to trial the VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System.

COMPOSIX™ L/P Mesh with ECHO PS™ Positioning System

Catalog Number	Shape	Mesh Size	
0144680	Ellipse	6.2" x 8.2" (15.9 cm x 21.0 cm)	<input type="checkbox"/>
0144610	Oval	6.2" x 10.2" (15.9 cm x 26.1 cm)	<input type="checkbox"/>
0144790	Ellipse	7.2" x 9.2" (18.4 cm x 23.5 cm)	<input type="checkbox"/>
0144810	Ellipse	8.2" x 10.2" (21.0 cm x 26.1 cm)	<input type="checkbox"/>
0144113	Ellipse	10.2" x 13.2" (26.1 cm x 33.7 cm)	<input type="checkbox"/>
0144114	Rectangle	10.2" x 14.2" (26.1 cm x 36.2 cm)	<input type="checkbox"/>

- Please add the COMPOSIX™ L/P Mesh with ECHO PS™ Positioning System to my preference card.
- I would like to have the COMPOSIX™ L/P Mesh with ECHO PS™ Positioning System in stock.
- I would like to trial the COMPOSIX™ L/P Mesh with ECHO PS™ Positioning System.

Surgeon's Signature _____

Purchase Order Number _____

Catalog Number _____

Date _____ Quantity _____

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Warwick, RI 02886 • 1.800.556.6275 • www.davol.com
Medical Services & Support 1.800.562.0027

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.

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BARD

DAVOL INC.

ECHO PS™ Positioning System

with VENTRALIGHT™ ST Mesh or COMPOSIX™ L/P Mesh



Technique Guide

BARD

DAVOL INC.

TECHNOLOGY
TECHNIQUE
TRAINING
TRUST



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ABSORBABLE BARRIER VENTRALIGHT™ ST MESH

Featuring an absorbable barrier based on proven Sepra® Technology on one side of the mesh...

- Based on the technology used in Seprafilm®
- Minimizes tissue attachment to the visceral side of the mesh



...and a low profile design with a lightweight monofilament polypropylene mesh on the other.

- Insertion through trocar and mechanical fixation made easier
- Allows for rapid and complete tissue ingrowth
- Approximately 50% lighter than traditional polypropylene mesh

PERMANENT BARRIER COMPOSIX™ L/P MESH

Featuring a permanent ePTFE barrier on one side of the mesh...

- Minimizes tissue attachment to the prosthesis
- Submicronic ePTFE used in general surgery for many years with demonstrated clinical success



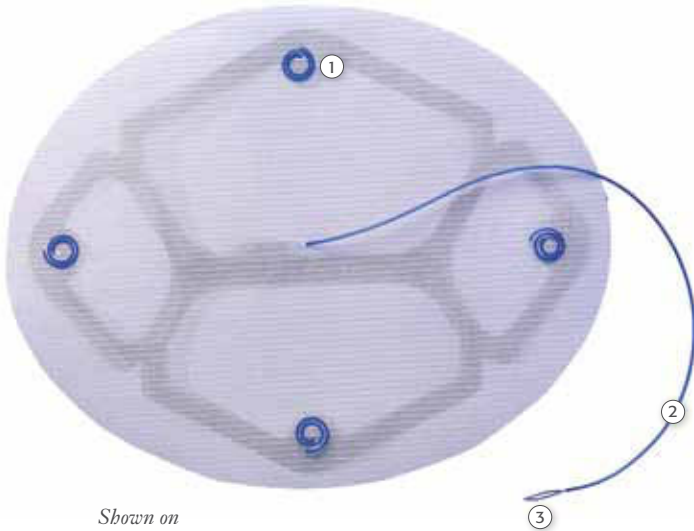
...and a low profile design with lightweight monofilament polypropylene mesh on the other

- Easy handling and laparoscopic insertion
- Allows for rapid and complete tissue ingrowth
- Approximately 60% lighter than traditional polypropylene mesh

ECHO PS™ POSITIONING SYSTEM

The ECHO PS™ Positioning System comes pre-attached to VENTRALIGHT™ ST or COMPOSIX™ L/P Mesh, requiring no assembly or specialty instruments.

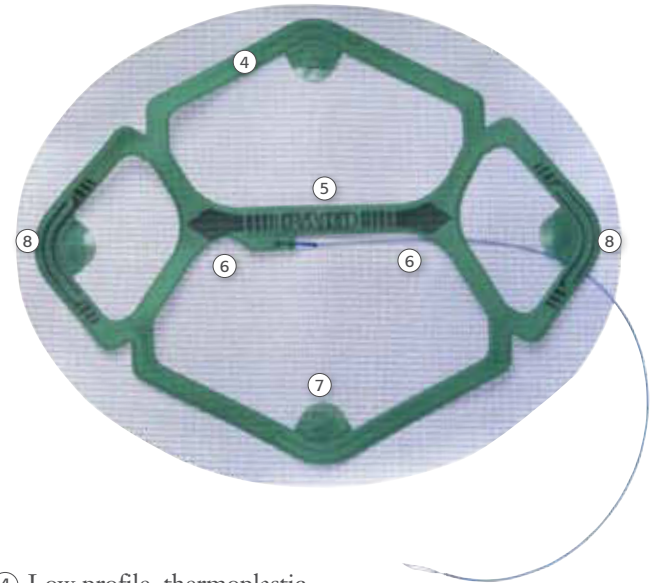
Anterior Side:



*Shown on
VENTRALIGHT™ ST Mesh*

- ① Connectors keep the Echo PS™ Positioning System attached to the mesh, but are simultaneously removed from the body with the positioning system
- ② Inflation tube
- ③ Retrieval loop

Posterior Side:



- ④ Low profile, thermoplastic polyurethane (TPU) coated nylon balloon
- ⑤ Logo identifies long axis
- ⑥ Removal points marked by arrows
- ⑦ Tabs clearly identify the connector locations
- ⑧ Marked center of proximal ends represent the midline of the mesh

Also Included

Pre-packaged inflation assembly inflates balloon



Introducer Tool facilitates rolling and insertion of mesh



TROCAR SIZE RECOMMENDATIONS

VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System

Catalog Number	Shape	Mesh Size	# of Mesh Connectors	Recommended Minimum Trocar/Incision Size*
5955680	Ellipse	6" x 8" (15.2 cm x 20.3 cm)	4	12 mm
5955610	Oval	6" x 10" (15.2 cm x 25.4 cm)	4	12 mm
5955790	Ellipse	7" x 9" (17.8 cm x 22.9 cm)	4	12 mm
5955810	Ellipse	8" x 10" (20.3 cm x 25.4 cm)	4	12 mm
5955113	Ellipse	10" x 13" (25.4 cm x 33.0 cm)	8	15 mm
5955124**	Rectangle	12" x 14" (30.5 cm x 35.6 cm)	8	12 mm trocar incision site

COMPOX™ L/P Mesh with ECHO PS™ Positioning System

Catalog Number	Shape	Mesh Size	# of Mesh Connectors	Recommended Minimum Trocar/Incision Size*
0144680	Ellipse	6.2" x 8.2" (15.9 cm x 21.0 cm)	4	12 mm
0144610	Oval	6.2" x 10.2" (15.9 cm x 26.1 cm)	4	12 mm
0144790	Ellipse	7.2" x 9.2" (18.4 cm x 23.5 cm)	4	12 mm
0144810	Ellipse	8.2" x 10.2" (21.0 cm x 26.1 cm)	4	12 mm
0144113	Ellipse	10.2" x 13.2" (26.1 cm x 33.7 cm)	8	15 mm
0144114	Rectangle	10.2" x 14.2" (26.1 cm x 36.2 cm)	8	15 mm

*If a proximal cap is available on the trocar, removing the proximal cap can help facilitate deployment. Deployment capability may vary depending on rolled patch size and graspers/trocars used.

**12" x 14" (30.5 cm x 35.6 cm) VENTRALIGHT™ ST Mesh (Cat # 5955124) does not include an Introducer Tool.

NOTE ON TRANSFASCIAL SUTURES



The ECHO PS™ Positioning System eliminates the need for transfascial orientation sutures.

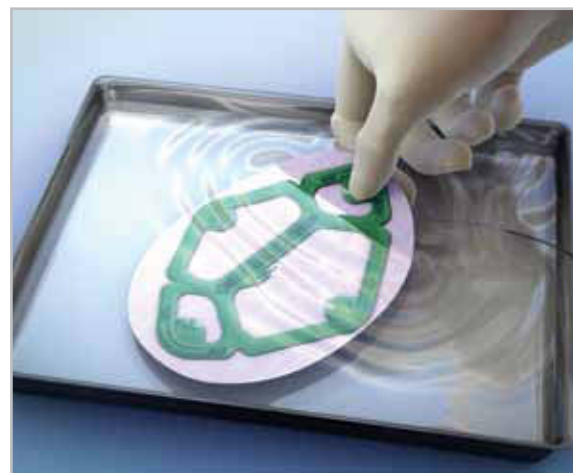
If transfascial sutures are to be used for fixation, place sutures after removing the ECHO PS™ Positioning System and after completing all mechanical fixation.



1 Device Preparation

Remove mesh with ECHO PS™ Positioning System (the device*) and included Introducer Tool from the sterile pouch. Set inflation assembly pouch aside.

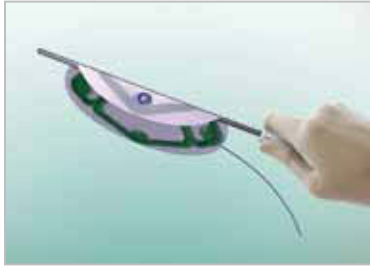
*“The device” refers to either “VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System” or “COMPOSIX™ L/P Mesh with ECHO PS™ Positioning System.”



2 Device Hydration

For VENTRALIGHT™ ST Mesh Only:

Hydrate the device for no more than 1-3 seconds just prior to rolling.



2a

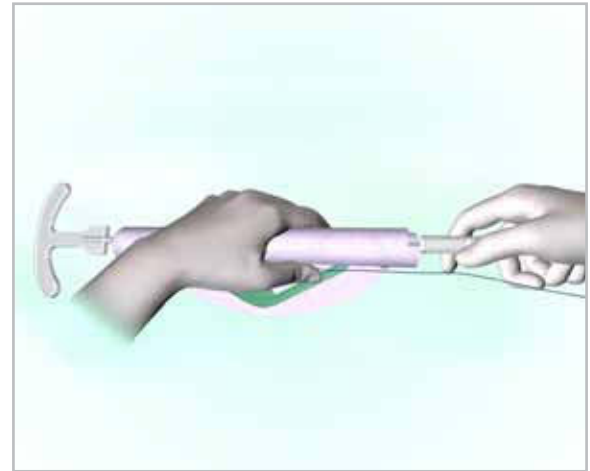
Device Insertion with Introducer Tool*

Place the device lengthwise between the metal tines approximately 2.5 to 5 cm from the long edge of the device (The BARD® logo and dark shaded areas on the device represent the long axis).

Ensure that the device is centered on the tines and that the inflation tube is laying flat and facing the proximal end of the tool in parallel to the rolling tines.

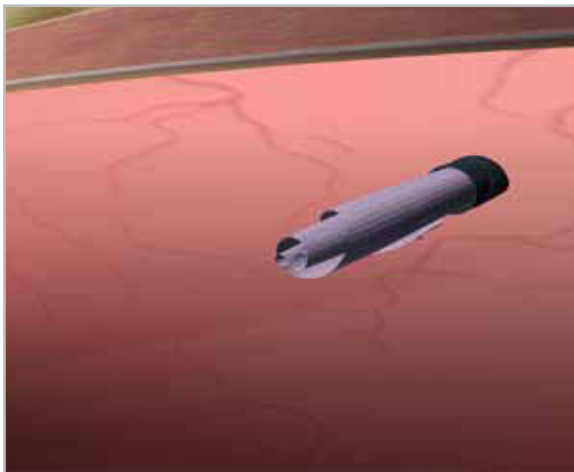
Place T-cap on the end of the tines.

* 12" x 14" (30.5 cm x 35.6 cm) VENTRALIGHT™ ST Mesh (CAT# 5955124) does not include an Introducer Tool. Please refer to Device Insertion with Grasper step 2b, on page 14.



Grasp the center of the device/tines to provide counter pressure against the device/tines. With one hand roll the device, polypropylene side out and bioresorbable coated side with ECHO PS™ Positioning System on the inside, by turning the handle until the device is completely wrapped around the tines. Ensure the inflation tube is not wrapped around the mesh.

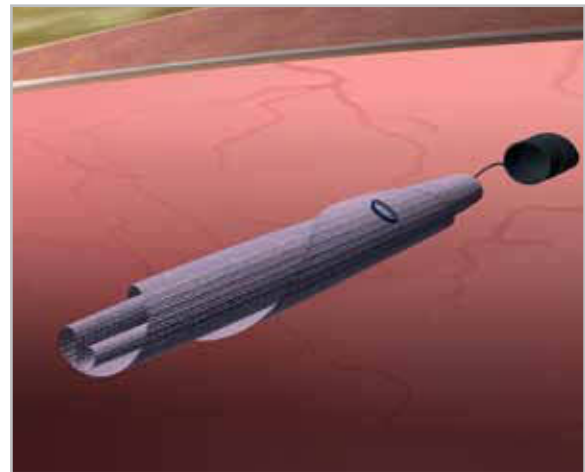
Remove the T-cap. Ensure the device is positioned such that at least 1/2 cm of the tines extends beyond the mesh edge.



Deliver the device through the trocar under sufficient visualization of the device and the surrounding anatomy.

As the device is being deployed through the trocar, rotate the handle in the direction that the device was rolled. This will keep the device tight around the tines, thus facilitating deployment.

To release the device from the Introducer Tool, rotate the handle approximately $\frac{1}{2}$ turn in the opposite direction the device was rolled and partially slide the tines out of the device. Do not completely remove the tines from the device until the device has passed through the trocar entirely.



Note: If the tines are removed from the device before it is completely deployed through the trocar, use the laparoscope to push the mesh through the trocar, or use a grasper from an opposing trocar location to pull the mesh into the abdomen.

Under visualization, continue to advance the device and the tines through the trocar. Repeat the previous steps and rotate the handle in the direction the device was rolled to completely deploy the patch through the trocar.

After the device has cleared the trocar, remove the Introducer Tool from the trocar and discard appropriately.



*Grasper technique to be used with
12" x 14" VENTRALIGHT™ ST Mesh only*

2b

Device Insertion with Grasper –
for 12" x 14" VENTRALIGHT™ ST Mesh (CAT# 5955124) Only

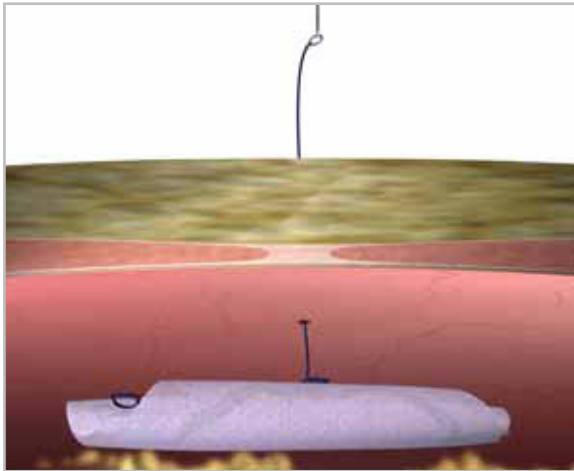
Roll the device tightly on itself starting at the long outside edge (The BARD® logo and dark shaded areas of the device represent the long axis). Continue across with the polypropylene side on the outside and bioresorbable coated side with the Echo PS™ Positioning System on the inside.



*Grasper technique to be used with
12" x 14" VENTRALIGHT™ ST Mesh only*

While holding the rolled device, grasp the leading edge with the grasper as shown. Ensure that the inflation tube is laying flat and facing the proximal end of the grasper. Place through the trocar incision site.

Note: If the grasper slips from the device before the device is completely deployed through the trocar incision site, use a grasper from an opposing trocar location to pull the mesh into the abdomen.

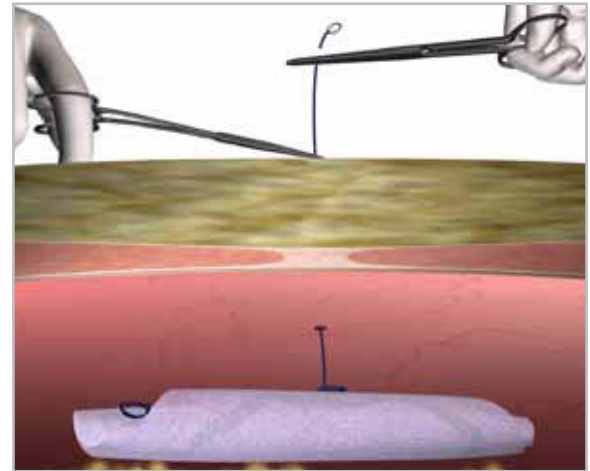


3

Balloon Inflation

Once the device is inserted into the abdomen, use a grasper to locate the blue retrieval loop on the inflation tube, ensuring that the blue inflation tube is not wrapped around the mesh and is clearly visible.

Pass a suture passer device through healthy skin at the center of the hernia defect (avoid going directly through the umbilicus). Grasp the blue retrieval loop and pull the retrieval loop and inflation tube out of the abdominal cavity.



Place an atraumatic clamp or hemostat on the inflation tube at the level of the skin to temporarily hold the device in place. Cut the inflation tube 1-2 cm below the retrieval loop with surgical scissors to ensure the tube is unobstructed. Discard the retrieval loop.



Remove the inflation assembly from the sterile pouch and screw the inflation adapter tightly to the syringe. Connect the inflation tube and inflation assembly as follows:

- a. Ensure the clear cap of the adapter is pushed downward to open the inflation tube channel
- b. Insert the inflation tube at least 5 cm into the cap opening
- c. Push the clear cap of the adapter upward to lock in place

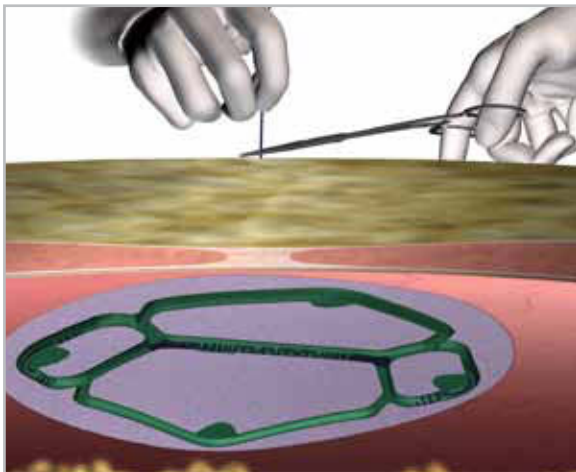


To inflate the device, release the clamp or hemostat and pull the inflation tube upward to lift the mesh off the viscera.

Be sure to always grab and pull the tube directly. Do not lift up using the inflation adapter/assembly.

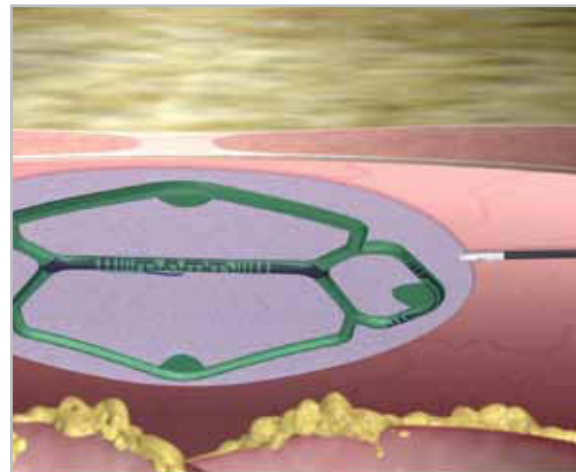
Inflate the device by pumping the syringe until the balloon is fully inflated. One to three pumps will be required to fully inflate the device depending on the size of the mesh. A slight high pitch sound may occur; this is normal and indicates the inflation assembly is working properly. A fully inflated balloon will not accept more air.

Once the device is inflated, if desired, remove the syringe by unscrewing from the adapter setting aside.



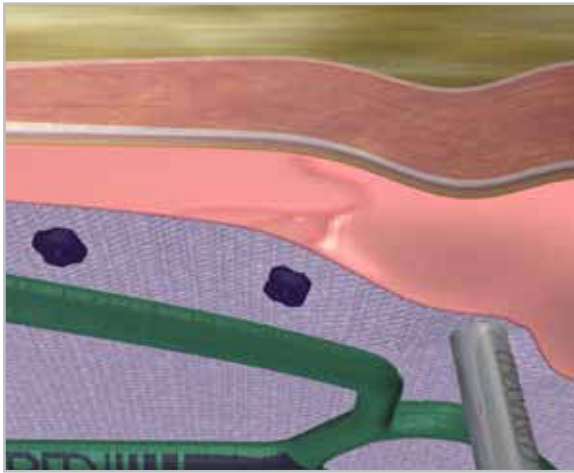
4 Mesh Positioning

Raise the inflation tube to properly adjust the mesh to the desired position. Clamp the inflation tube to hold the device in place.



Use a grasper to orient the mesh in relation to the defect.

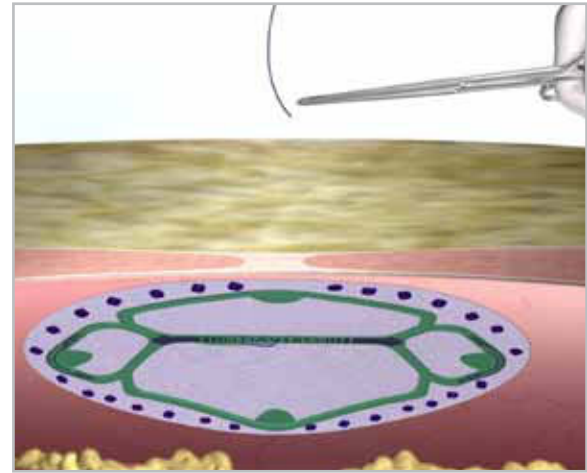
The BARD® logo and dark shaded areas on the device represent the long axis. The two marked areas at both ends of the long axis indicate the midline of the mesh.



5

Initial Mesh Fixation

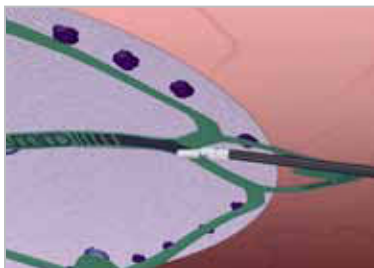
Once the device has been properly positioned and before the Echo PS™ Positioning System is deflated, ensure that no tissue is entrapped between the device and the abdominal wall and then fixate around the entire perimeter of the mesh with fasteners placed 1-2 cm apart. For COMPOSIX™ L/P, fasteners must be placed at least 1/2 cm inside the outermost row of stitches. Ensure that no fasteners are placed through the Echo PS™ Positioning System.



6

Balloon Deflation

To deflate the Echo PS™ Positioning System, release the clamp on the inflation tube, cut the tube as close to the skin as possible, and then discard.

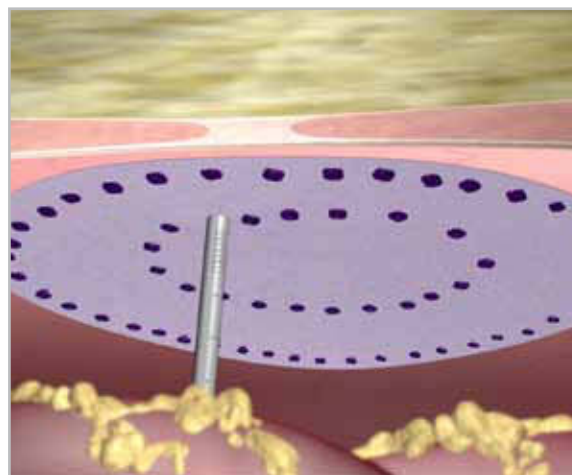


7 Balloon Removal

Begin removal of the ECHO PS™ Positioning System by grasping one of the two removal points marked by the dark arrows adjacent to the BARD® logo and pulling the positioning system off the mesh in one smooth motion.

Continue removing the ECHO PS™ Positioning System by pulling it up to the tip of the trocar. **Remove both the ECHO PS™ Positioning System and trocar simultaneously.** Verify that the device is fully intact after removal.* Discard the ECHO PS™ Positioning System appropriately.

* Refer to the chart on page 6 for the number of connectors for each catalog number.



8 Final Mesh Fixation

Reinsert the trocar, apply final fixation, 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.

VENTRALIGHT™ ST MESH WITH ECHO PS™ POSITIONING SYSTEM

INDICATIONS:

VENTRALIGHT™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

The ECHO PS™ Positioning System is intended to be used to facilitate the delivery of soft tissue prostheses during laparoscopic hernia repair.


CONTRAINDICATIONS:

1. Do not use the VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System in infants or children whereby future growth will be compromised by use of such material.
2. Do not use VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System 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. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.
2. This device has been designed for single use only. Reuse, resterilization, reprocessing and/or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user.

3. If unused prosthesis 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 infections.
4. Ensure proper orientation; the coated side of VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There is a possibility for adhesion formation when the polypropylene side is placed in direct contact with the bowel or viscera.
5. The use of any permanent mesh or patch in a contaminated or infected wound could lead to infection, fistula formation and/or extrusion of the prosthesis.
6. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the prosthesis. An unresolved infection may require removal of the prosthesis.
7. To prevent recurrences when repairing hernias, it is recommended that the prosthesis be large enough to extend at least 3 to 5 cm beyond the margins of the defect.
8. Do not apply sharp, heat emitting, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the ECHO PS™ Positioning System.
9. The ECHO PS™ Positioning System should not be used with any other hernia prosthesis aside from those with which it comes pre-attached/packaged.
10. VENTRALIGHT™ ST Mesh is the only permanent implant component of the device. The inflation adapter and syringe are to be kept external to the patient and discarded after use. The ECHO PS™ Positioning System (including the balloon, all connectors, and inflation tube) is to be removed from the patient and appropriately discarded as it is not part of the permanent implant.

11.  Discard Introducer Tool and all components of the ECHO PS™ Positioning System (including the inflation adapter and syringe) after use. This product 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. Please read all instructions prior to use.
2. Only physicians qualified in the appropriate surgical techniques should use this device.
3. The safety and effectiveness of VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System has not been evaluated in clinical studies for the presence of malignancies in the abdominopelvic cavity.
4. Visualization should be maintained throughout the course of the entire procedure. Additionally, laparoscopic removal of the ECHO PS™ Positioning System must be performed under sufficient visualization of the entire device and surrounding anatomy, to ensure proper removal.
5. Do not trim the mesh. This will affect the interface between the mesh and positioning system.

FIXATION:

BARD® fixation devices or nonabsorbable monofilament sutures are recommended to properly secure VENTRALIGHT™ ST Mesh. If other fixation devices are used, they must be indicated for use in hernia repair. If transfascial sutures are to be used for fixation, place sutures after removing the ECHO PS™ Positioning System from the body and after completing all mechanical fixation. Care should be taken to ensure that the patch is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be placed.

PK3796633 115R

COMPOSIX™ L/P MESH WITH ECHO PS™ POSITIONING SYSTEM

INDICATIONS:

COMPOSIX™ L/P Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects.

The ECHO PS™ Positioning System is intended to be used to facilitate the delivery of soft tissue prostheses during laparoscopic hernia repair.


CONTRAINDICATIONS:

1. Literature reports there is a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.
2. Do not use the COMPOSIX™ L/P Mesh with ECHO PS™ Positioning System in infants or children whereby future growth will be compromised by use of such material.
3. Do not use COMPOSIX™ L/P Mesh with ECHO PS™ Positioning System for the reconstruction of cardiovascular defects.

WARNINGS:

1. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.
2. This device has been designed for single use only. Reuse, resterilization, reprocessing and/or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user.

3. Ensure proper orientation; the solid white surface (ePTFE) of COMPOSIX™ L/P Mesh with Echo PS™ Positioning System must be oriented against the bowel or sensitive organs. Do not place the polypropylene mesh surface against the bowel. There is a possibility for adhesion formation when polypropylene mesh is placed in direct contact with the bowel or viscera.
4. The use of any permanent mesh or patch in a contaminated or infected wound could lead to infection, fistula formation and/or extrusion of the prosthesis. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the prosthesis. An unresolved infection may require removal of the prosthesis.
5. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the prosthesis. An unresolved infection may require removal of the prosthesis.
6. To prevent recurrences when repairing hernias, it is recommended that the prosthesis be large enough to extend at least 3 to 5 cm beyond the margins of the defect.
7. Do not apply sharp, heat emitting, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the Echo PS™ Positioning System.
8. The Echo PS™ Positioning System should not be used with any other hernia prosthesis aside from those with which it comes pre-attached/packaged.
9. COMPOSIX™ L/P Mesh is the only permanent implant component of the device. The inflation adapter and syringe are to be kept external to the patient and discarded after use. The Echo PS™ Positioning System (including the balloon, all connectors, and inflation tube) is to be removed from the patient and appropriately discarded as it is not part of the permanent implant.

10.  Discard Introducer Tool and all components of the Echo PS™ Positioning System (including the inflation adapter and syringe) after use. This product 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. Please read all instructions prior to use.
2. Only physicians qualified in the appropriate surgical techniques should use this device.
3. Visualization should be maintained throughout the course of the entire procedure. Additionally, laparoscopic removal of the balloon device must be performed under sufficient visualization of the device and surrounding anatomy, to ensure proper device removal.
4. Do not trim the mesh. This will affect the interface between the mesh and positioning system.

FIXATION:

BARD® fixation devices or nonabsorbable monofilament sutures are recommended to properly secure COMPOSIX™ L/P Mesh. If other fixation devices are used, they must be indicated for use in hernia repair. If transfascial sutures are to be used for fixation, place sutures after removing the Echo PS™ 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.



NOTES:



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