BARD® CAPSURE™
Permanent Fixation System

Technique Guide
Laparoscopic Inguinal, Open and Laparoscopic Ventral Hernia Repair
The opinions and techniques presented herein are for informational purposes only and the decision of which technique to use in a particular surgical application should be made by the surgeon based on the individual facts and circumstances of the patient and previous surgical experience.

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Introduction

Bard has redefined permanent fixation. The CapSure™ Permanent Fixation System is designed to address the traditional challenges of permanent fixation by providing surgeons strong and reliable fixation in an easy to use delivery system.

CapSure™ is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

The CapSure™ Permanent Fixation System is available in 15 or 30 fastener configurations and features a comfort grip handle that is designed to fit a wide range of surgeon hand sizes, a low resistance ergonomic trigger with an audible click to provide surgeons with an indication that the fastener is fully deployed, a 37 cm shaft providing improved access across a wide range of patient sizes and a fastener level indicator that keeps track of the fastener level.

The CapSure™ fastener is a stainless steel helical coil designed with a smooth polyetheretherketone (PEEK) cap to eliminate the exposed metal tip.

The PEEK cap is low profile, atraumatic and provides a smooth visceral surface.

At 4 weeks post implantation, CapSure™ fasteners show rapid reperitonealization and incorporation into the tissue.*

Benefits of the CapSure™ Permanent Fixation System

Covered

- Smooth polyetheretherketone (PEEK) cap eliminates exposed metal tip

Strong

- Fixates into Cooper’s ligament and underlying structures, similar to ProTack™

Reliable

- Comfortable handle and easy to deploy trigger
- Consistent fastener deployment and depth of tissue purchase
- Reliable, secure fixation regardless of mesh pore size
- Improved fixation with large pore meshes due to larger cap surface area of fastener, versus ProTack™

* Preclinical data on file. Results may not correlate to performance in humans.
Laparoscopic Ventral Hernia Repair Using VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System

After the implant has been positioned with the use of ECHO PS™, you should insert the CAPSURE™ Permanent Fixation System in a quadrant of the body that should be 180 degrees away from the area where the mesh is being attached. Bring the prosthesis (mesh) or tissue into position. Place the tip of the CAPSURE™ Permanent Fixation System at the desired location on the mesh. Prior to fixating reduce the pneumoperitoneum appropriately to achieve optimal depth of penetration and better abdominal wall compliance. Apply adequate pressure, assuming individual patient circumstances and anatomy permitting.

Ensure optimal contact between the fixation device tip and the underlying mesh and tissue is achieved by palpating the abdominal wall with your hand. Ideally, the abdominal wall should be cupped around the tip of the device, forming a 90° angle.

Compress handpiece actuation lever in a single, complete and uninterrupted stroke to drive a permanent fastener through the mesh into the tissue. Keep consistent pressure on the distal tip of the device through the entire stroke. Release the actuation lever allowing it to return completely to its resting position. After each deployment, each fastener should be visually assessed for proper placement against the mesh or tissue.

The fasteners should be placed around the edge of the patch to set the location (1-4). Then, fixate the VENTRALIGHT™ ST Mesh or other hernia mesh into place around the perimeter of the mesh.
Several fasteners are placed around the margins of the defect to hold the mesh to the abdominal wall. Fasteners should be placed 1-2 cm apart.

For mesh selection, reference the mesh instructions for use.

Note: Echo PS™ has been removed at this point in the procedure.

For fixation, counter pressure should be applied on the skin of the abdominal wall. Use counter pressure to allow the abdominal wall to be pushed down perpendicular to the fixation device thus securing the mesh to the abdominal wall.

Care should be taken in the application of external counter pressure to avoid tissue compression between the end of the device and the location of counter-pressure of less than 4.2 mm.

Avoid placing hand or finger directly over the area where the fastener is being deployed to prevent potential injury.
Release pneumoperitoneum under visualization. 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 used. The fasteners should be visually assessed for proper placement against the mesh and tissue.

Desufflating the abdomen under visual control helps the surgeon confirm the mesh remains flat against the abdominal wall and has not rolled or curled, thus completing the repair.

The number of fasteners presented here is for informational purposes only and the decision of fastener numbers to use in a particular surgical application should be made by the surgeon based on the individual facts and circumstances of the patient and previous surgical experience.

The fasteners should be placed entirely into the tissue and the head of the fastener should be flush against the mesh or tissue in order to achieve the best fixation performance. If the fastener head is not flush in mesh or tissue, it is recommended to use a Maryland grasper, or similar atraumatic surgical grasping device, and place the tip of one jaw on the inside of the fastener head and the tip of the other jaw on the outer diameter of the head. To fully seat the fastener, turn the grasper clockwise. If the fastener still does not fully seat, use a Maryland grasper in the same manner to remove the fastener by turning the grasper counter clockwise. Place another fastener in the same vicinity as the removed fastener.
Open Ventral Hernia Repair Using the Ventrio™ ST Hernia Patch

The patch should be fixated in a way that:

- Keeps the patch flat and from buckling around the edges.
- Allows for a minimal tension repair.

If the margins of the defect are to be reapproximated, it is important to ensure that the patch lies completely flat in the intra-abdominal space. To accomplish this, the healthy tissue around the defect should be appropriately pretensioned prior to fixation. Pretensioning can be accomplished by grasping one side of the defect at a time with two pairs of Allis or other atraumatic clamps.

Initially fixate the patch in positions (A) and then (B), to ensure the patch is centered. Then, while pretensioning each side of the defect, fixate positions (C) and then (D). Place a minimum of three fasteners approximately 1 cm apart in each of these four locations.

Then, while pretensioning each side of the defect, fixate the remaining perimeter of the patch, placing additional fasteners approximately 1 cm apart.

(See next page for more fixation instructions)
To fixate:

- Place the fixation device through the incision and into the outer positioning pocket (in between the two layers of mesh).
- Make sure that the tip of the device is as far lateral in the positioning pocket as possible, then back the tip up 1-2 mm and tilt it upward toward the abdominal wall and away from the SorbaFlex™ or Posiflex™ Memory Technology to achieve a 90° position for optimal fastener deployment.
- Ensure optimal contact between the fixation device tip and the underlying mesh and tissue is achieved by palpating the abdominal wall with your hand. Ideally, the abdominal wall should be cupped around the tip of the device, forming a 90° angle.
- Lift the edge of the incision enough to visualize and ensure that the bowel has not slipped between the abdominal wall and the mesh.
- Using a low opposition force, actuate the fixation device, placing fasteners approximately 1 cm apart.
- 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 used.
In laparoscopic inguinal hernia repair procedures, CAPSURE™ Permanent fasteners may be used to fixate mesh, such as 3DMax™ Light Mesh. Fasteners may be deployed in soft tissue as well as Cooper’s Ligament and underlying structures. To prevent patient injury, stay clear of bone, vessels, nerves, bowel and viscera when entering the surgical site, manipulating tissue and fixating mesh.

The CAPSURE™ Permanent Fixation System may also be used for the reapproximation of soft tissue in a TAPP repair. Use counter pressure to allow the abdominal wall to be pushed down perpendicular to the fixation device. Use a grasper to reapproximate the peritoneum, do not stretch the peritoneum. Fixate from lateral to medial in a uniform motion.
**CapSure™ Permanent Fixation System**

**INDICATIONS:**
The CapSure™ Permanent Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

**CONTRAINDICATIONS:**
1. Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as bone, nerves, vessels, and viscera. Use of the CapSure™ Permanent Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener below the fastener head is 3.2 mm, the fastener head is another 1 mm (total 4.2 mm).

**PRECAUTIONS:**
1. Adequate counter pressure should be applied on the target area. Avoid placing hand or finger directly over the area where fastener is being deployed to prevent injury.
2. Use caution when applying the CapSure™ fastener over or in proximity to underlying bone, vessels, nerves, or viscera. The intended fixation site should be assessed to ensure that while the tissue is compressed the total distance from the surface of the tissue to any underlying structures is greater than the length of the CapSure™ fastener.

**ADVERSE REACTIONS:**
Adverse reactions and potential complications associated with fixation devices such as the CapSure™ Permanent Fixation System may include, but are not limited to the following: hemorrhage, pain, edema and erythema at wound site; septicemia/infection; hernia recurrence/wound dehiscence, erosion and allergic response in patients with known sensitivities to PEEK and metals contained in 316L stainless steel, including chromium, nickel, copper, and iron.

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**3DMax™ Light Mesh**

**INDICATIONS:**
The 3DMax™ Light Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in the repair of inguinal hernias.

**CONTRAINDICATIONS:**
1. Literature reports that there may be a possibility for adhesion formation when polypropylene mesh is placed in direct contact with the bowel or viscera.
2. Do not use polypropylene mesh in infants and children, whereby future growth will be compromised by use of such material.

**WARNINGS:**
1. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.
2. This device is for single use only. Do not resterilize or reuse any portion of the 3DMax™ Light Mesh.
3. This device has been designed for single use only. Reuse, reprocessing, resterilization 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.
4. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the prosthesis.
5. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the device.
6. To prevent recurrences when repairing hernias, the prosthesis should be large enough to extend beyond the margins of the defect.
7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves and vessels.
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 viral 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.

ADVERSE REACTIONS:
Possible complications include seromas, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

PRECAUTIONS:
1. Please read all instructions prior to use.
2. Only physicians qualified in appropriate surgical techniques should use this prosthesis.
3. Do not cut or reshape the 3DMax™ Light Mesh as this may affect its effectiveness.
4. Use an appropriate sized trocar to allow mesh to slide down the trocar with minimal force.
5. If fixation is used, Bard® permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the device. If other fixation devices are used, they must be indicated for use in hernia repair.
6. If fixation is used, 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 used.

ADVERSE REACTIONS:
Possible complications include seromas, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

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 viral 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.

ADVERSE REACTIONS:
Possible complications include seromas, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.
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.

ADVERSE REACTIONS:
Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation, infection, allergic reaction, and recurrence of the hernia or soft tissue defect.

**Vентрио™ ST Hernia Patch**

**INDICATIONS:**
The Vентрио™ ST Hernia Patch is indicated for use in the reconstruction of tissue deficiencies, such as for the repair of hernias.

**CONTRAINDICATIONS:**
1. Do not use the Vентрио™ ST Hernia Patch in infants or children, whereby future growth will be compromised by the use of such mesh material.
2. Do not use the Vентрио™ ST Hernia Patch for the reconstruction of cardiovascular defects.
3. Literature reports that there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera.

**WARNINGS:**
1. The device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.
2. This device is for single use only. Do not resterilize or reuse any portion of the Vентрио™ ST Hernia Patch. Product should be used once exterior foil pouch has been opened. Do not store for later use.
3. Do not cut or reshape the Vентрио™ ST Hernia Patch, as this could impact its effectiveness. Care should be taken not to cut or nick the SorbaFLEX™ PDO monofilament during insertion or fixation. If the SorbaFLEX™ PDO monofilament is cut or damaged, additional complications may include bowel or skin perforation and infection.
4. Follow proper folding techniques for all patches as described in these Instructions for Use as other folding techniques may compromise the SorbaFLEX™ PDO monofilament.
5. Ensure proper orientation, the bioresorbable coated side of the prosthesis should be oriented against the bowel or sensitive organs. Do not place the polypropylene mesh side against the bowel. There may be a possibility for adhesion formation when the mesh is placed in direct contact with the bowel or viscera.
6. To ensure a strong repair, the prosthesis should be secured with tacks or sutures through the polypropylene mesh structure or full device. Suturing or tacking on edge of mesh alone is not recommended.
7. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the prosthesis.
8. 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.

9. To prevent recurrences when repairing hernias, the prosthesis should be large enough to extend beyond the margins of the defect.

**PRECAUTIONS:**
1. Please read all instructions prior to use.
2. Only physicians qualified in the appropriate surgical technique should use this device.
3. Care should be taken not to cut or nick the SORBAFLEX™ PDO monofilament during fixation.
4. The safety and effectiveness of VENTRIO™ ST Hernia Patch has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity.

**ADVERSE REACTIONS:**
Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation, infection, allergic reaction, and recurrence of the hernia or soft tissue defect. If the SORBAFLEX™ PDO monofilament is cut or damaged during insertion or fixation, additional complications may include bowel or skin perforation and infection.
CapSure™ Permanent Fixation System

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Order Form

☐ Please add the CapSure™ Permanent Fixation System to my preference card.

☐ I would like to have the CapSure™ Permanent Fixation System in stock.

☐ I would like to trial the CapSure™ Permanent Fixation System.

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