Technique Guide

VENTRALEX™ ST Hernia Patch
VENTRALEX™ Hernia Patch

Ventral, Incisional, Umbilical, Epigastric Herniorrhaphy, and Trocar Closure
The technique presented herein is for informational purposes only. The decision of which technique to use in a surgical application lies with the surgeon based on patient profile and previous surgical experience. This technique applies to both VENTRALEX™ ST Hernia Patch and VENTRALEX™ Hernia Patch products.

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**VENTRALEX™ ST / VENTRALEX™ Hernia Patch Overview**

Both the **VENTRALEX™ ST** and **VENTRALEX™ Hernia Patches** are designed for the intraabdominal repair of umbilical and small ventral hernias. Intraabdominal placement has the potential to eliminate or reduce the lateral dissection required for preperitoneal placement, which may help minimize post-op pain. The monofilament polypropylene pocket and strap design helps facilitate placement, positioning and lateral fixation. Monofilament polypropylene mesh allows for rapid and complete tissue ingrowth and incorporation in the abdominal wall while the ePTFE and Sepra Technology barriers helps reduce or prevent adhesions from the viscera to the mesh.

Both technologies are available in 3 sizes. See back cover for ordering information.

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**VENTRALEX™ ST Hernia Patch for an absorbable barrier**

- Incorporates SEPRAMESH™ IP Composite which is based on Sepra® Technology, with over 15 years of proven clinical success. The unique hydrogel bioresorbable coating resorbs within 30 days.

- Absorbable SORBAFLEX™ Memory Technology allows the patch to “spring open,” lay flat to maintain shape with absorption essentially complete in 24-32 weeks.*

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**VENTRALEX™ Hernia Patch for a permanent barrier**

- Submicronic ePTFE barrier with over 15 years of proven clinical success.

- SORBAFLEX™ Memory Technology allows the patch to “spring open,” lay flat to maintain shape and then fully absorbs over time.

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* Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.
### Ventralex™ ST Hernia Patch

#### Open Repair

1. Small incision over the hernia.
2. Dissect and divide the hernia sac.
3. Reduce contents of the hernia sac and excise the redundant hernia sac.
4. Insert patch into the defect without touching the skin.
5. Pull up gently on the looped positioning strap to flatten the patch against the abdominal wall.
6. Sweep around the patch with your index finger to make sure that it is lying flat.
7. Pull the looped positioning strap apart to create two straps and insert one finger into the positioning pocket.
8. Utilizing the anterior mesh straps and pocket, place interrupted U-stitches in two quadrants for the small patch (4.3 cm) and in four quadrants for the medium (6.4 cm) and large (8.0 cm) patches. Care should be taken to ensure the sutures secure the fascia to the anterior polypropylene pocket only. For the appropriate amount of sutures follow your surgical judgement and adjust to specific patient needs.
9. Secure the patch by suturing the positioning straps to the margins of the defect and/or the anterior layer of the polypropylene to the fascia.
10. Cut off and discard excess positioning strap material above the fixation line and at the level of the fascia.
11. Reapproximate the fascia and then close the subcutaneous tissues. Lastly, reapproximate the wound.

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**Special thanks to:**
Guy Voeller, MD, FACS, Professor of Surgery, University of Tennessee Health Science Center
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Dissect and divide the hernia sac.

3

Reduce the contents of the sac into the abdomen and excise the redundant hernia sac.
4 Insert a finger or peanut sponge into the defect to clear the underside of the peritoneum of adhesions or bowel. Clear enough space around the defect to place a patch twice the size of the hernia defect.

5 Completely immerse the VENTRALEX™ ST Hernia Patch (in sterile saline for 1-3 seconds) immediately prior to placement in order to maximize the flexibility of the prosthesis.
Insert a small retractor into the defect and pull anterior and cephalad to make room for the patch. Choose either the small, medium or large patch to insert into the defect. The chosen patch size should be approximately twice the size of the hernia defect. Gently fold or roll the patch parallel to the opening between the strap with the barrier side facing out carefully avoiding any sharp folding or kinking that might compromise the memory ring. Care should also be taken not to cut or nick the memory recoil ring. Gently insert the patch all the way through the defect and into the intraabdominal space, using an atraumatic clamp. Prevent the patch from touching the patient’s skin.

Remove the clamp and the small retractor. The memory recoil ring will allow the patch to “pop open.” Gently pull up on the looped positioning strap until the patch rests against the abdominal wall without pulling harder than necessary. This allows the patch to evenly rest tension-free against the abdominal wall in all four quadrants.
While gently pulling up on the looped positioning strap, use a retractor to peer in between the anterior portion of the patch and the peritoneum to ensure that no tissue such as a bowel or omentum is caught between the patch and the abdominal wall.

Gently separate the two straps to allow access to the inner positioning pocket to ensure that the patch is lying flat in the intraabdominal space, against the anterior abdominal wall.
Utilizing the anterior mesh straps and pocket, place interrupted U-stitches in a minimum of two quadrants for the small patch (4.3 cm) and in four quadrants for the medium (6.4 cm) and large (8.0 cm) patches. Care should be taken to ensure the sutures secure the fascia to the anterior polypropylene pocket only. For the appropriate amount of sutures follow your surgical judgement and adjust to specific patient needs.

Use nonabsorbable sutures to secure the patch by suturing the positioning straps to the margins of the defect. Cut off the excess positioning straps and discard. The patch recoil technology and abdominal pressure will ensure that the patch lies flat.
Reapproximate the fascia and then close the subcutaneous tissues. Lastly, reapproximate the wound.

**Ventralex™ ST Hernia Patch**

**Trocar Site Closure**

Laparoscopic surgery offers patients many advantages including the potential for reduced pain and a shorter recovery. However, the technique can have complications. Literature suggests that herniation into a trocar site occurs in 1%-6% of abdominal laparoscopic procedures.†

If small bowel becomes trapped in a trocar defect, a Richter’s hernia may occur. 
Preperitoneal trocar site and Richter’s hernias may occur even if the anterior fascia above the defect has been closed.

The patch allows for an intraabdominal tension-free repair that does not require transfascial suturing. The patch relies on fibroblastic tissue ingrowth of the abdominal wall into the polypropylene mesh side of the patch to seal off and repair the defect.

**Ventrelex™ ST Hernia Patch**

**Basic Steps for Laparoscopic Trocar Site Closure**

1. Gently fold or roll the small-size patch in half with the barrier side out, and place onto a 5 mm grasper.
2. Deploy the patch down the trocar and into the intraabdominal space while holding the mesh strap.
3. Gently pull the patch up to the distal end of the trocar.
4. Take out the trocar (slide over mesh strap).
5. Gently pull the patch up to the abdominal wall.
6. Verify correct patch position and tension if laparoscopic camera is still in place.
7. Suture mesh strap to the fascia. Cut off excess mesh strap above the suture.
8. Close wound.

10–12 mm trocar site.
2 For Ventralex™ ST Hernia Patch

Completely immerse the Ventralex™ ST Hernia Patch (in sterile saline for 1-3 seconds) immediately prior to placement to maximize the flexibility of the prosthesis.

3

Gently fold or roll the small-size prosthesis in half, barrier side out. Grab the middle of the prosthesis with a 5 mm atramautic grasper. Care should be taken to avoid any sharp folding or kinking that might compromise the memory ring.
Insert the prosthesis down (10-12 mm) trocar. For regular length trocars the depth marker (blue line), identifies the point at which the patch is all the way through a standard trocar.

Deploy the prosthesis through the trocar and into the intraabdominal space.
6

Release the prosthesis from the grasper when the depth marker reaches the proximal end of the trocar. The memory recoil ring allows the patch to “pop open” and lay flat in the intraabdominal space.

7

Under laparoscopic visualization and control, gently pull up on the positioning strap to hoist the prosthesis up to the distal end of the trocar.
While gently pulling out the trocar, pull up on the positioning strap, hoisting the prosthesis firmly but gently against the abdominal wall. Slide the trocar off of the positioning straps.

Gently pull up firmly on the positioning strap to make sure that the prosthesis is completely covering the defect. Ensure that no tissue is trapped between the abdominal wall and the prosthesis and that the prosthesis is neither loose nor warped.
Indications:
The Ventralex™ ST Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, including repair of hernias and deficiencies caused by trocars.

Contraindications:
1. Do not use the Ventralex™ ST Hernia Patch in infants or children, whereby future growth will be compromised by use of such mesh material.
2. Do not use the Ventralex™ 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. Product should be used once exterior foil pouch has been opened. Do not store for later use. Unused portions of this prosthesis should be discarded.
3. Do not cut or reshape any portion of the Ventralex™ ST Hernia Patch (as this could impact its effectiveness), except for the polypropylene positioning strap. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament. If the SorbaFlex™ PDO monofilament is cut or damaged during insertion or fixation, 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 potentially 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 side against the bowel. There may be a possibility for adhesion formation when the mesh (including strap) is placed in direct contact with the bowel or viscera.

While gently pulling up on the positioning strap with your suture, close the anterior fascia, catching the positioning strap between the margins of the fascia. Cut off positioning strap at the level of the fascia to eliminate all the excess strap material. Close the subcutaneous tissues and reapproximate the wound.
6. To ensure a strong repair, the prosthesis should be secured with tacks or sutures through the polypropylene mesh straps or positioning pocket.

7. Excess positioning strap material above the fixation line must be cut off and discarded to eliminate excess material from remaining in the body.

8. When used to repair deficiencies caused by trocars, the device should be used under endoscopic guidance or direct visualization.

9. 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.

10. 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.

11. 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 techniques should use this prosthesis.
3. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament during fixation.
4. The safety and effectiveness of Ventralex™ ST has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity.

Adverse Reactions:
Possible complications include seroma, adhesions, hematoma, 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.

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 Bard® Ventralex™ Hernia Patch.
3. Do not cut or reshape any portion of the Bard® Ventralex™ Hernia Patch (as this could affect its effectiveness), except for the monofilament polypropylene positioning strap. Care should be taken not to cut or nick the SorbaFlex™ PDO Monofilament. If the recoil ring is cut or damaged during insertion or fixation, additional complications may include bowel or skin perforation and infection.
4. Follow proper rolling techniques for all patches as described in these instructions for use as other rolling techniques may potentially compromise the SorbaFlex™ PDO Monofilament.
5. Ensure proper orientation; the solid white surface (ePTFE) must be oriented against the bowel or sensitive organs. Do not place the mesh surface against the bowel. There is a possibility for adhesion formation when mesh (including strap) 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 straps and/or positioning pocket. Suturing or tacking on the sealed edge of mesh alone is not recommended.

7. Excess positioning strap material above the fixation line and at the level of the fascia must be cut off and discarded to eliminate excess material from remaining in the body.

8. When used to repair deficiencies caused by trocars, the device should be used under endoscopic guidance or direct visualization.

9. 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.

10. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the patch. An unresolved infection may require removal of the device.

11. 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 techniques and use of this device should use this prosthesis.
3. Care should be taken not to cut or nick the SorbaFlex™ PDO Monofilament or the knitted polypropylene mesh tube during fixation.
4. The safety and effectiveness of Bard® Ventralex™ 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, hematoma, 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.

PK3793271
VENTRALEX™ ST Hernia Patch featuring Sepra® Technology

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<td>Small Circle with Strap</td>
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<td>3.2” x 3.2” (8.0 cm x 8.0 cm)</td>
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VENTRALEX™ Hernia Patch

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Order Form

☐ Please add the VENTRALEX™ ST Hernia Patch to my preference card.

☐ I would like to have the VENTRALEX™ ST Hernia Patch in stock.

☐ I would like to trial the VENTRALEX™ ST Hernia Patch.

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

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