Ventral Hernia Repair

VENTRIO[™] ST Hernia Patch VENTRIO[™] Hernia Patch



Technique Guide

Open and Laparoscopic Ventral Hernia Repair



This Technique Guide contains the opinions of and personal surgical techniques practiced by Dr. David Iannitti and Dr. Stephen Wohlgemuth. They are both paid consultants to BARD.

These techniques apply to either VENTRIO™ ST, and/or VENTRIO™.

The opinions and techniques presented herein are for informational purposes only. The decision regarding which technique to use in a particular surgical application should be made by the surgeon and should be based on the facts and circumstances regarding the individual patient and the surgeon's previous surgical experience.

Ventral Hernia Repair

VENTRIO[™] ST Hernia Patch VENTRIO[™] Hernia Patch



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Introduction

The Ventrio™ ST and Ventrio™ Hernia Patches are designed to provide the benefits of a laparoscopic repair through an open anterior incision. Both products incorporate the unique SorbaFlex™ Memory Technology which allows the patches to "spring open," lay flat to maintain shape and then fully absorbs over time. This feature plus the monofilament polypropylene positioning pocket design aid in proper intraabdominal placement and positioning, while also allowing the use of mechanical fixation for an easy and efficient repair.



Overview

VENTRIO™ ST Hernia Patch

for an Absorbable Barrier Repair

- Incorporates Sepra® Technology (ST) which has over 10 publications and used clinical use since 2007.
- The unique hydrogel barrier swells to minimize tissue attachment to the visceral side of the mesh.
- Bioresorbable PGA fibers reinforce the integrity of the hydrogel barrier by binding it to the polpropylene mesh.
- The hydrogel barrier resorbs within 30 days.

VENTRIO™ Hernia Patch

for a Permanent Barrier Repair

- Incorporates an expanded polytetrafluoroethylene (ePTFE) barrier with submicronic porosity which has over 15 years of proven clinical success.
- Minimizes tissue attachment to the prosthesis and provides long-term protection against complications such as bowel obstruction and fistulas.

Sterile Technique Guidelines¹ for Open Intraabdominal Ventral Herniorrhaphy

David Iannitti, MD, FACS, Carolinas Medical Center, recommends the following steps to minimize the risk of mesh infection.

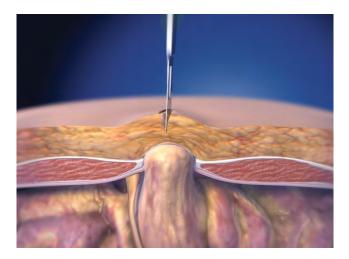
- Prophylactic preoperative antibiotics should be administered within one hour before making the surgical incision (not after). Antibiotics may be continued postoperatively in selected high-risk patients.
- Hair should be removed from the surgical site immediately before the procedure with clippers, rather than shaving. Shaving (especially the day before surgery) can cause microabrasions in the skin where bacteria can proliferate and contaminate the patient's tissues during the operation.
- Patients should not be allowed to become hypoxic, hypothermic, or hyperglycemic perioperatively.
 These factors raise the incidence of postoperative complications.

- Prepare the site with betadine or chlorhexidine (Hibiclense) SCRUB first, followed by betadine paint.
- Some surgeons choose to cover the abdomen
 with a drape such as the 3M™ loban® Antimicrobial
 Incise drape. The longer the skin is exposed to air,
 the higher the bacterial count may become.
- Dissection: Do not raise/dissect large subcutaneous flaps laterally (some surgeons have been trained to dissect the subcutaneous tissues laterally for suture placement).

Special thanks to David Iannitti, MD, FACS, Carolinas Medical Center, for open ventral hernia repair technique insights.

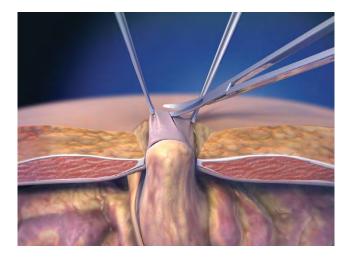
¹ Refer to www.cdc.gov for full guidelines issued by the Centers for Disease Control.

Open Intraabdominal Technique



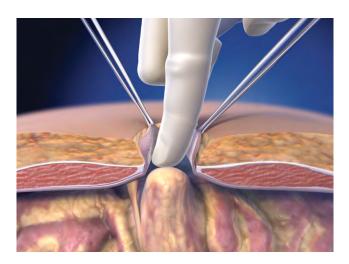
1

Make an incision the size of the defect.

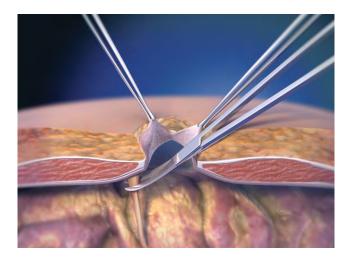


2

Identify and open the hernia sac. No additional subcutaneous dissection is necessary.

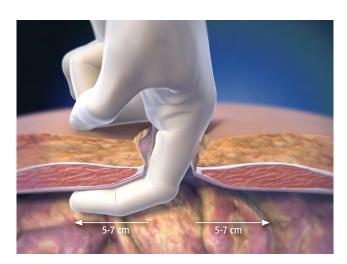


Reduce the hernia sac contents back into the abdominal cavity. Leave the opened hernia sac intact.

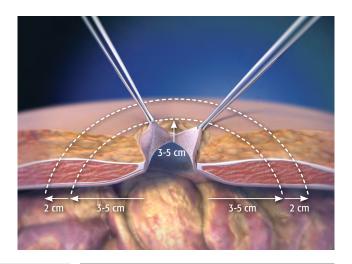


4

Lyse all intraabdominal adhesions under direct vision.



Check for multiple defects and clear out an intraabdominal plane 5-7 cm around the total defect perimeter.



6

Add 3-5 cm to the size of the total defect area to determine the proper patch size. For larger defects, at least 5 cm should be added to the perimeter. An additional 2 cm should be added to clear space for patch placement.

11

Prosthetic Preparation

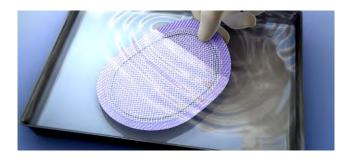
The prosthetic should be opened immediately before implantation, minimizing contact with the patient's skin and instrument table. This decreases the possibility of inadvertent contamination of the graft.

Surgeons may consider changing gloves before handling the mesh to further minimize the risk of mesh contamination.

7

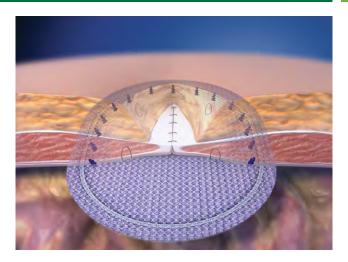
For Ventrio™ ST Hernia Patch

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



For suture technique, proceed to page 26

Open Intraabdominal Mechanical Fixation Technique



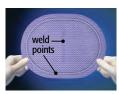
Open Intraabdominal Mechanical Fixation Technique



8

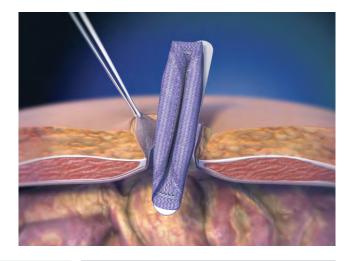
Smaller patches can be rolled around the surgeon's fingers for insertion into the abdominal cavity.

For easier insertion of larger patches into the abdominal space, roll the patch into thirds along the long axis, barrier side out. To prevent kinking of the memory technology monofilament, avoid sharp creases or crimps, particularly on the weld points (see illustration at right), when folding the patch.



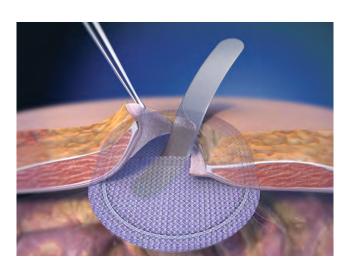




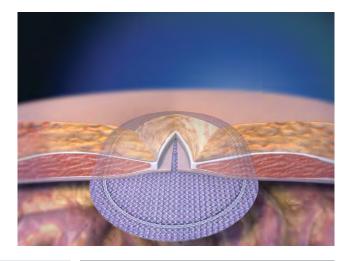


9

Insert the patch into the intraabdominal space. Avoid skin contact during insertion.

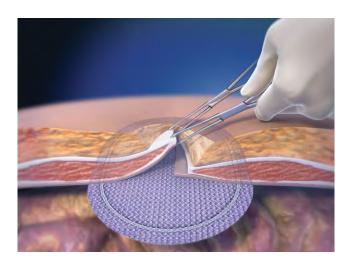


A malleable or ribbon retractor may be used in the positioning pocket to facilitate placement and to help flatten out the patch.



11

The patch should lay completely flat in the intraabdominal space. Do not retract heavily on the incision. This may cause the bowel to push up laterally around the edges of the patch.

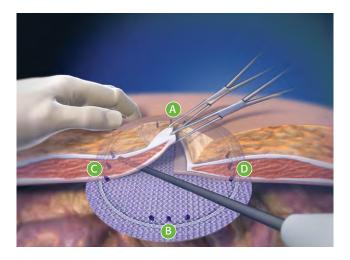


12A

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 re-approximated, it is important to ensure that the patch lies completely flat in the intraabdominal space. To accomplish this, the defect should be pre-tensioned prior to fixation. Pre-tensioning can be accomplished by grasping one side of the defect at a time with two pairs of Allis clamps.

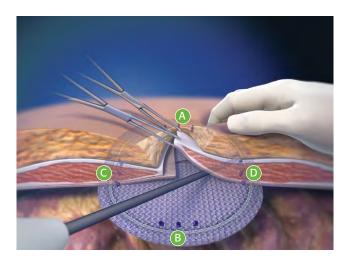


12B

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

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

(Continued next page)



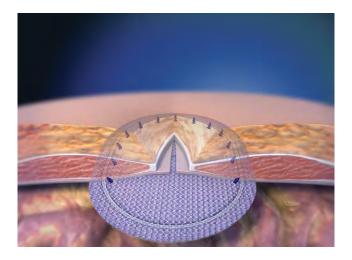
12B

(Continued from previous page)

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™ memory technology.

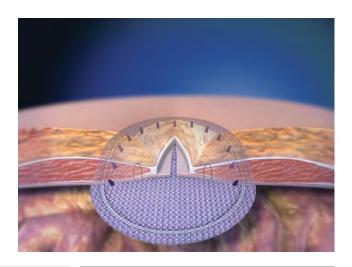


12C

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.

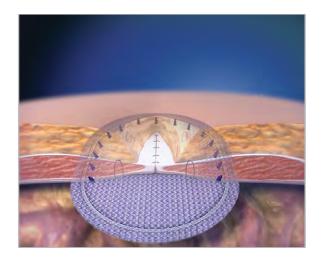
Lift the edge of the incision just enough to visualize that bowel has not slipped between the abdominal wall and the edge of the mesh.

Using a low opposition force, activate the fixation device, placing fasteners approximately 1 cm apart.



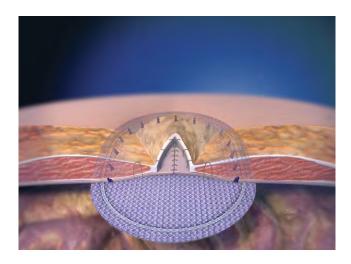
Completely fixate the perimeter of the patch into place. For larger size patches, additional fasteners may be placed into the inner positioning pocket. A series of sutures can also be placed around the peripheral aspect of the graft where it is most comfortable for the surgeon. The patch is now secured into place allowing for the polypropylene mesh side to incorporate into the abdominal wall.

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.



14

Reapproximate the fascia as much as possible without placing excessive tension on the repair. The margins of the defect are secured to the anterior layer of the mesh. If the fascia can be closed with minimal tension, place sutures through the closed fascia and the anterior layer of polypropylene mesh and excise the remaining hernia sac.

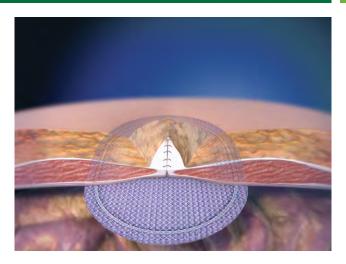


If the fascia cannot be closed without excessive tension, secure the margins of the defect to the anterior layer of the mesh. Use the remaining hernia sac to cover anyexposed mesh and close the sac with absorbable suture. For this approach, pre-tensioning of the defect is not required.

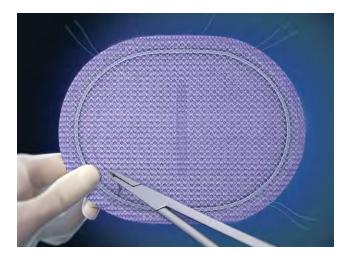
NOTE: Some surgeons use drains. If you do place drains, use a closed wound suction drain in the subcutaneous space and not in contact with the mesh. Do not use passive drains such as Penrose or cigarette drains.

Surgeons may also choose to place an abdominal binder or other compressive garment on the patient for 2-6 weeks postoperatively.

Open Intraabdominal Suture Technique



Open Intraabdominal Suture Technique



8

After completing steps 1-7 on pages 6-12, continue with the suture technique.

Prior to introduction, place monofilament sutures along the perimeter of the patch, around the memory technology ring. Clamp sutures outside the body.

Continued from page 12



9

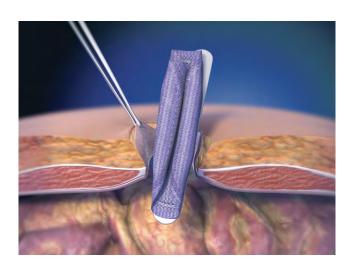
Smaller patches can be rolled around the surgeon's fingers for insertion into the abdominal cavity.

For easier insertion of larger patches into the abdominal space, roll the patch into thirds along the long axis, barrier side out. To prevent kinking of the memory technology monofilament, avoid sharp creases or crimps, particularly on the weld points (see illustration at right), when folding the patch.



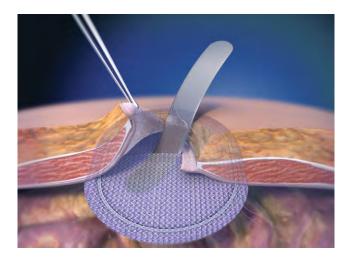






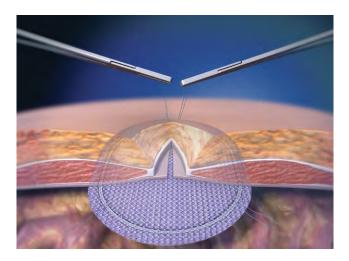
10A

Insert the patch into the intraabdominal space. Avoid skin contact during insertion.

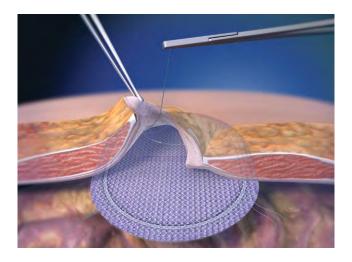


10B

A malleable or ribbon retractor may be used in the positioning pocket to facilitate placement and to help flatten out the patch.



The patch should lay completely flat in the intraabdominal space. Do not retract heavily on the incision. This may cause the bowel to push up laterally around the edges of the patch.

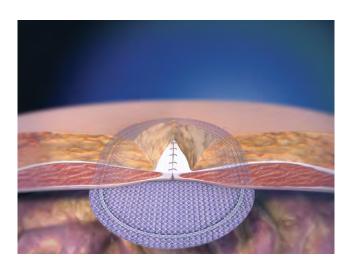


12

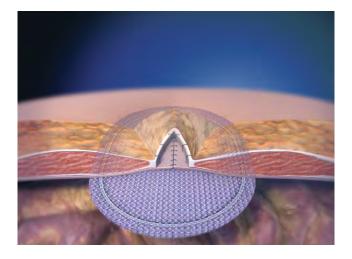
Pass the sutures through the peritoneum and posterior rectus sheath. They are then tied, securing the patch and memory technology to the fascia and peritoneum. For larger size patches, additional sutures may be required.

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.

31



Reapproximate the fascia as much as possible without placing excessive tension on the repair. The margins of the defect are secured to the anterior layer of the mesh. If the fascia can be closed with minimal tension, place sutures through the closed fascia and the anterior layer of polypropylene mesh and excise the remaining hernia sac.



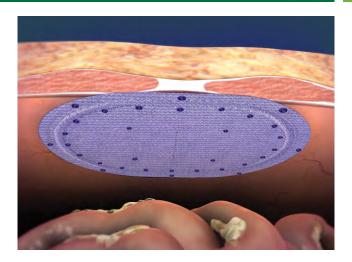
14

If the fascia cannot be closed without excessive tension, secure the margins of the defect to the anterior layer of the mesh. Use the remaining hernia sac to cover any exposed mesh and close the sac with absorbable suture.

NOTE: Some surgeons use drains. If you do place drains, use a closed wound suction drain in the subcutaneous space and not in contact with the mesh. Do not use passive drains such as Penrose or cigarette drains.

Surgeons may also choose to place an abdominal binder or other compressive garment on the patient for 2-6 weeks postoperatively.

Laparoscopic Ventral Hernia Repair Technique



Special thanks to Stephen Wohlgemuth, MD, FACS, Sentara Medical Group, VA for laparoscopic ventral hernia repair technique insights.

Laparoscopic Ventral Hernia Repair Technique

Port Placement Options



Standard Placement

A camera port is placed laterally in the upper left or right quadrant of the abdomen in order to allow complete vision internally. This is done so the ports can be placed on both sides and no opposition of view is encountered. The additional ports are then placed as far lateral as possible in the remaining three quadrants. This allows one to reach up to the abdominal wall and to be able to work all sides of the mesh.

Additional ports can be added as needed to accommodate larger defects or more complex adhesiolysis.





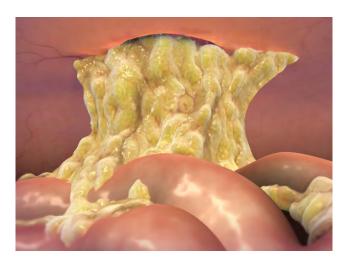
Midline Hernia

Left Epigastric Hernia

Prosthesis Size	Trocar Site (minimum)
5.4" x 7.0" (13.8 cm x 17.8 cm) or smaller	12 mm
6.1" x 10.1" (15.5 cm x 25.7 cm) or greater	Not Tested / Not Recommended

The self-expanding property of the patch with Memory Technology allows it to unfold without the need for multiple instruments or multiple sutures to splay it out against the abdominal wall.

For laparoscopic procedures, after hydration for 1-3 seconds, patches indicated in the table above should be inserted through a minimum trocar site of 12 mm. If the patch is hydrated for longer than 3 seconds and/or does not easily deploy through the trocar site, a larger trocar site may be required.



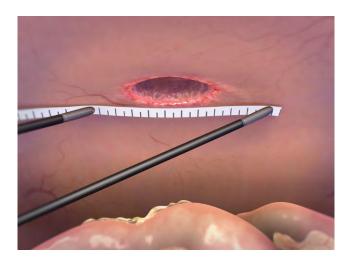
Reduce the contents of the hernia sac and lyse all adhesions to the area of the defect.



2

Once all of the contents of the hernia sac have been reduced, it is critical that the surgeon evaluate what has been removed to ensure:

- That there is no evidence of bowel injury.
- That all adhesions that could be lysed have been lysed.



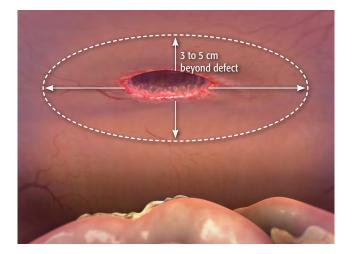
Measuring the Defect

Internally

This can be done by cutting a non-paper ruler to a small size and deploying it down the 5 mm trocar or by using an instrument to measure.

Externally

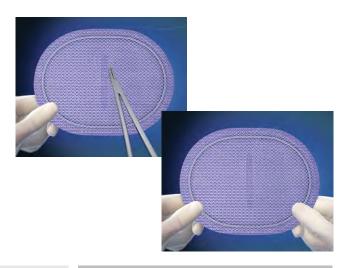
This can be done with a needle by going around the outside of the defect and making marks on the abdominal wall to correspond with the internal opening or the internal facial ring. Once this is complete, there is an outline on the abdominal wall of the defect.



4

Determining the Patch Size

The patch should overlap the defects 3-5 cm on all sides. For larger defects, the overlap should be at least 5 cm.



Place a stitch through the middle of the patch.

Prosthetic Preparation

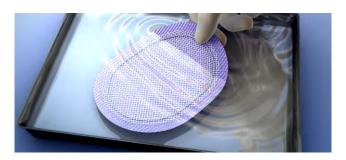
The prosthetic should be opened immediately before implantation, minimizing contact with the patient's skin and instrument table. This decreases the possibility of inadvertent contamination of the graft.

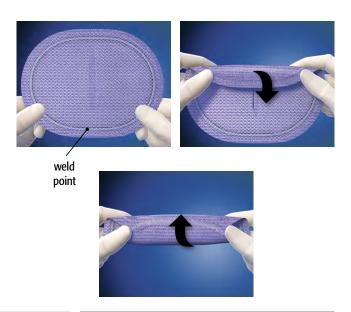
Surgeons may consider changing gloves before handling the mesh to further minimize the risk of mesh contamination.

6

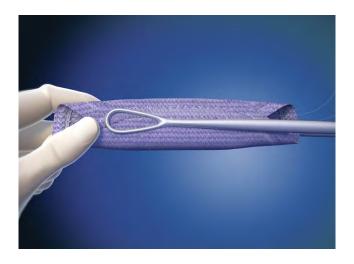
For Ventrio™ ST Hernia Patch

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





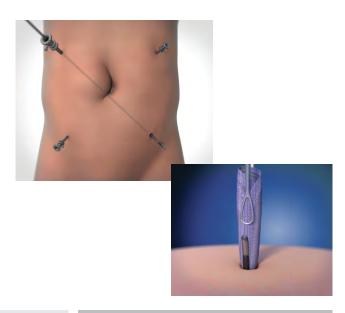
Roll the patch into thirds (two folds) along the long axis, barrier side out. To prevent kinking of the memory technology avoid sharp creases or crimps, particularly on the weld points (see first illustration above), when rolling the patch.



8

Inserting the Mesh

Put the rolled patch onto a sponge holder.



9A

Place a grasper through the proximal trocar, pass it intraabdominally through the distal trocar. Then remove the distal port from the abdomen, leaving the grasper in place to hold open the tissue planes. Grasp the rolled mesh externally with the graspers and pull the mesh into the abdominal cavity as you guide it with the sponge clamp, minimizing skin contact.

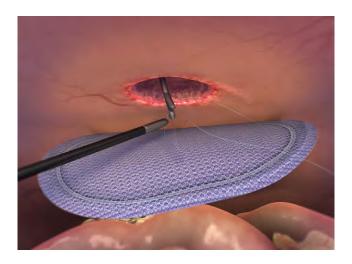




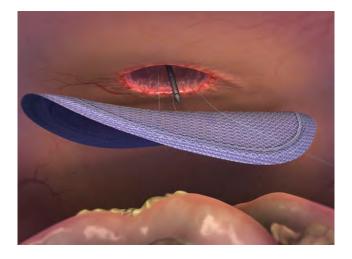
9B

Another option for insertion of the mesh is to take out the trocar and insert finger into opening. Space should be large enough to accommodate the index finger.

Remove finger and insert patch. After the patch has been deployed, reinsert the trocar, minimizing skin contact.

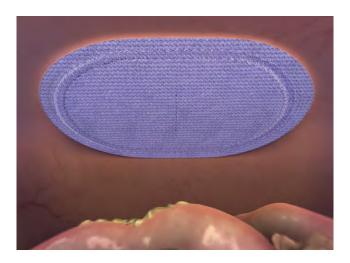


After insertion of the mesh into the intraabdominal space, position the patch below the hernia defect. Guide a suture-grasping device through the skin in the middle of the hernia defect.

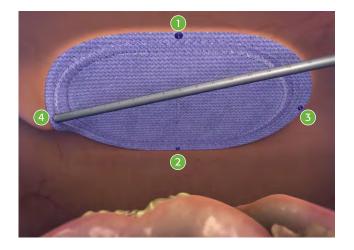


11

Use a suture-grasping device to grasp the suture. This makes pulling the mesh to the abdominal wall simple. The needle-passing device is driven through the direct center of the hernia or hernias if there are multiple defects. This is then used to pull the mesh up to the abdominal wall and to center it on the defect.

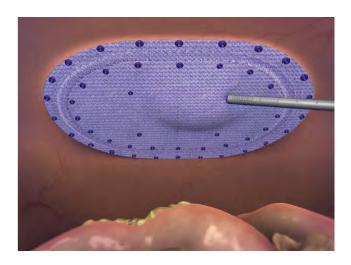


Hoist the patch against the abdominal wall. The self-expanding property of the patch with memory technology not only makes it much easier to place, but also keeps the mesh taut against the abdominal wall. Grasp the edges and maneuver the patch until the central portion of the mesh is over the central defect, allowing for adequate overlap beyond the margins of the defect.



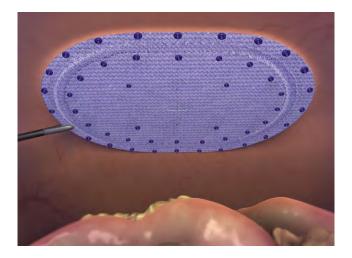
13

The trocar in which you are inserting the fixation device should be in the quadrant of the body 180 degrees away from the area the mesh is being attached. First place fasteners around the edge of the patch to set the location (1-4). Then fixate the patch into place around the perimeter of the patch, outside of the memory technology. 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. Avoid fixating through the memory technology when fixating the mesh.



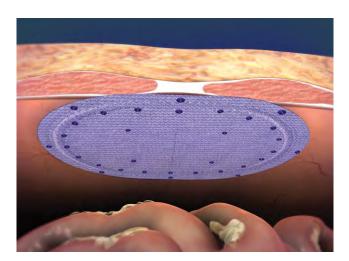
Additional fasteners should be placed on the inside perimeter of the memory technology. Care should be used to secure fasteners outside of the stitch lines.

Several fasteners are placed around the margins of the defect to hold it to the abdominal wall. Fasteners should be placed 1-2 cm apart. The central suture can either be cut or sewn in place.



15

Release pneumoperitoneum. Once the patch is secured, pull on the edge of the mesh with a grasper. This shows that the patch is secure, and when adequately secured in this technique, pulling on the patch will actually move the entire abdominal wall. This can be visualized from outside the abdomen. Desufflating the abdomen with the mesh under direct visualization shows that the mesh does not roll or curl and remains flat to the abdominal wall, thus completing the hernia repair.



Patch fixated into place for a laparoscopic ventral hernia repair.

VENTRIO™ ST Hernia Patch

INDICATIONS:

The VENTRIO™ ST Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as for the repair of hernias.

CONTRAINDICATIONS:

- Do not use the Ventrio™ ST Hernia Patch in infants or children, whereby future growth will be compromised by use of such mesh material.
- Do not use the Ventrio™ 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 VENTRIO™ 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 VENTRIO™ 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.
- 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.
- 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.
- Only physicians qualified in the appropriate surgical techniques should use this prosthesis.
- Care should be taken not to cut or nick the SORBAFLEX™ PDO monofilament during fixation.
- 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.

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

VENTRIO™ Hernia Patch

INDICATIONS:

The VENTRIO™ Hernia Patch is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

CONTRAINDICATIONS:

- Do not use the Ventrio™ Hernia Patch in infants or children, whereby future growth will be compromised by use of such mesh material.
- Do not use the VENTRIO™ Hernia Patch for the reconstruction of cardiovascular defects.
- Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera.

WARNINGS:

- 1. Do not cut or reshape the VENTRIO™ Hernia Patch, as this could affect its effectiveness. 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.
- Follow proper folding techniques for all patches as described in these Instructions for Use as other folding techniques may break the SORBAFLEX™ PDO monofilament.
- The device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.
- This device is for single use only. Do not resterilize or reuse any portion of the VENTRIO™ Hernia Patch.
- 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 may be a possibility for adhesion formation when mesh is placed in direct contact with the bowel or viscera.
- 6. Careful attention to the Ventrio™ Hernia Patch handling, fixation, and suture technique is most important in the presence of known or suspected wound contamination or infection.
- If an infection develops, treat the infection aggressively. The prosthesis may not have to be removed. An unresolved infection, however, may require removal of the prosthesis.

- 8. To prevent recurrences when repairing hernias, the prosthesis should be large enough to extend beyond the margins of the defect.
- To ensure a strong repair, the prosthesis should be secured through the polypropylene mesh structure. Suturing or tacking on sealed edge of mesh alone is not recommended.
- The use of any permanent mesh or patch on a contaminated or infected wound could lead to fistula formation and/or extrusion of the prosthesis.

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. Davol permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the prosthesis. If other fixation devices are used, they must be indicated for use in hernia repair.

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

Notes

Notes Notes

VENTRIO™ ST Hernia Patch

ENTRIO SI	Hernia Pat	ch		
Catalog #	Quantity	Shape	Size	
5950030	1/cs.	Small Oval	3.1" x 4.7" (8.0 cm x 12.0 cm)	
5950040	1/cs.	Medium Oval	4.3" x 5.5" (11.0 cm x 14.0 cm)	
5950050	1/cs.	Large Oval	5.4" x 7.0" (13.8 cm x 17.8 cm)	
5950010	1/cs.	Small Circle	3.0" (7.6 cm) diameter	
5950020	1/cs.	Large Circle	4.5" (11.4 cm) diameter	
5950070	1/cs.	Extra Large Oval	7.7" x 9.7" (19.6 cm x 24.6 cm)	
5950080	1/cs.	Extra Large Oval	8.7" x 10.7" (22.1 cm x 27.1 cm)	
5950090	1/cs.	Extra Large Oval	10.8" x 13.7" (27.4 cm x 34.9 cm)	
5950060	1/cs.	Midline	6.1" x 10.1" (15.5 cm x 25.7 cm)	
entrio™ He	rnia Patch			
Catalog #	Quantity	Shape	Size	
0010211	1/cs.	Small Oval with ePTFE	3.1" x 4.7" (8.0 cm x 12.0 cm)	
0010215	1/cs.	Medium Oval with ePTFE	4.3" x 5.5" (11.0 cm x 14.0 cm)	
0010212	1/cs.	Large Oval with ePTFE	5.4" x 7.0" (13.8 cm x 17.8 cm)	
0010213	1/cs.	Small Circle with ePTFE	3.0" (7.6 cm) diameter	
0010214	1/cs.	Large Circle with ePTFE	4.5" (11.4 cm) diameter	
0010216	1/cs.	Extra Large Oval with ePTFE	8.7" x 10.7" (22.1 cm x 27.1 cm)	
0010217	1/cs.	Extra Large Oval with ePTFE	10.8" x 13.7" (27.4 cm x 34.9 cm)	
0010218	1/cs.	Extra Large Oval with ePTFE	7.7" x 9.7" (19.6 cm x 24.6 cm)	
0010219	1/cs.	Oval with ePTFE	6.1" x 10.1" (15.5 cm x 25.7 cm)	
I wou	e add these Id like to ha	marked products to my prove these marked products numbers checked) al these marked products.		
Purchase Orde	er Number		 Date	_

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Quantity