# OPTIFIX™ OPEN

## Absorbable Fixation System


# Technique Guide

Open Ventral Hernia Repair

BARD
DAVOL INC.

SOFT TISSUE REPAIR

Right Procedure. Right Product. Right Outcome.

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.

# Introduction

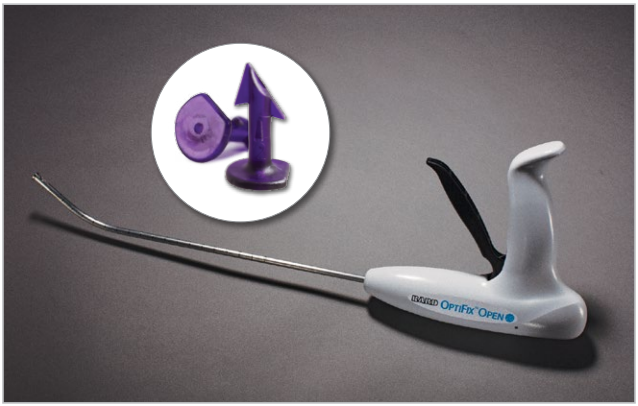
The OptiFix™ Open Absorbable Fixation System was designed for improved ease of use when fixating surgical meshes to the abdominal wall in open ventral hernia procedures by reducing limitations that exist with current laparoscopic straight devices.

The device is indicated for the fixation of surgical mesh to tissues during open surgical procedures, such as hernia repair.

The OptiFix™ Open Absorbable Fixation System comes preloaded with 20 fasteners that are deployed via a 27 cm, curved cannula delivery system.

# OPTIFIX™ OPEN

## Absorbable Fixation System

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# Benefits of the OPTIFIX™ OPEN Absorbable Fixation System

## Ergonomically Designed Handle

- Designed for surgeon comfort across a wide range of hand sizes[1]
- Inverted trigger placement designed to improve hand placement in open ventral hernia repairs[2]

## 27 cm, Curved Cannula

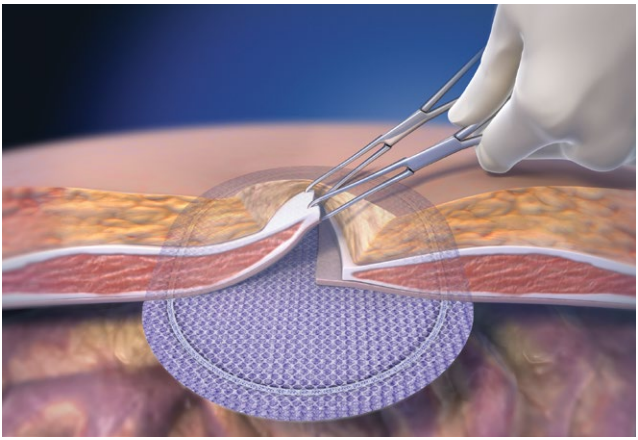
- Designed to:
  - Consistently deliver fasteners perpendicular to mesh and tissue[3]
  - Improve insertion, handling, ergonomics, and access in open ventral hernia procedures.
- Shortens the distance between the surgeon and mesh in open ventral hernia repair procedures.

## Fully Absorbable PDLLA Fastener

- Provides strength during the early healing phase, slowly resorbs over time, leaving less foreign material in the body[4]
- Broader fastener surface area coverage results in more secure mesh fixation[3]

1 Survey of surgeons attending preclinical lab. Results may not correlate to clinical outcomes. Data on file.
2 Survey of surgeons attending market research initiative. Results may not correlate to clinical outcomes. Data on file.
3 C. R. Bard Inc., bench data on file. Results may not correlate to clinical outcomes.
4 Preclinical data on file. Results may not correlate to clinical outcomes.

# Open Ventral Hernia Repair Using OptiFix™ Open Absorbable Fixation System and the Ventrio™ ST Hernia Patch

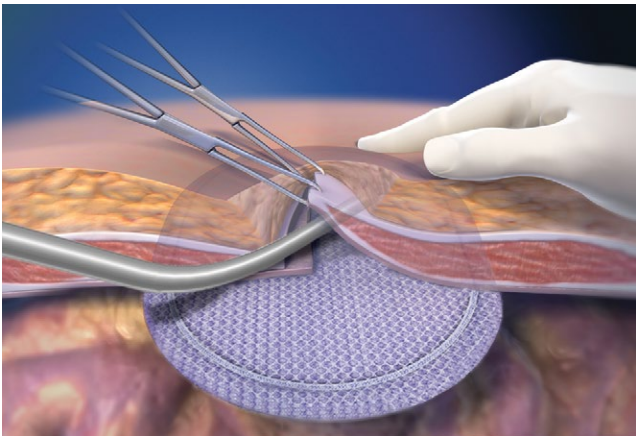


## 1 Pretensioning

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.

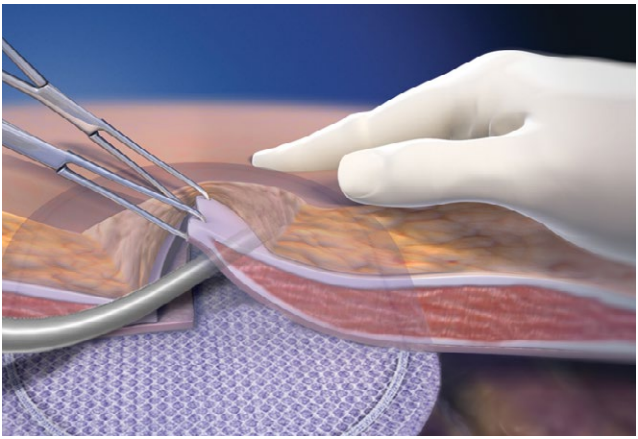
If the margins of the defect are to be reapproximated, it is important to ensure that the patch lies completely flat in the intraabdominal space. To accomplish this, the healthy tissue around the defect should be appropriately pretensioned prior to fixation. Pretensioning can be accomplished by grasping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



## 2 Fixation Device Positioning

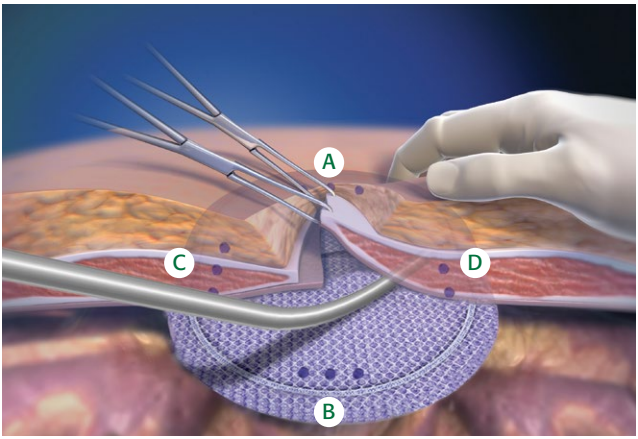
To fixate:

- Place the fixation device through the incision and into the outer positioning pocket (in between the two layers of the patch).
- Make sure 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 to achieve a 90˚ position for optimal fastener deployment.



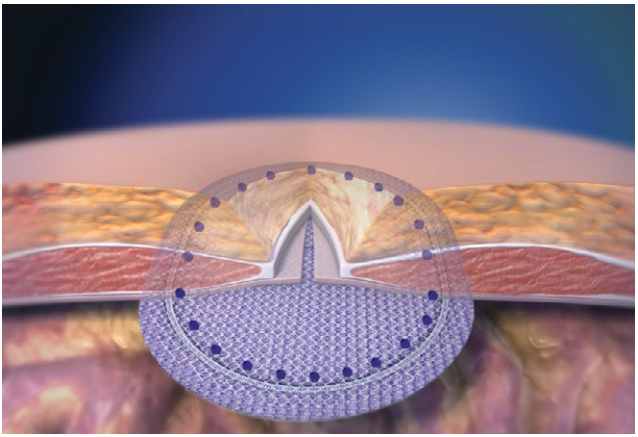
## 3 Fixation Technique

- 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 no bowel, omentum or other abdominal content has slipped between the abdominal wall and the patch.
- Using a low opposition force, actuate the fixation device and deploy a fastener.




## 4 Fastener Positioning

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.



## 5 Final Fixation

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

### Verify Fastener Placement

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.

# OptiFix™ Open Absorbable Fixation System

## INDICATIONS

The OptiFix™ Open Absorbable Fixation System is indicated for the fixation of surgical mesh to tissues during open surgical procedures, such as hernia repair.

## CONTRAINDICATIONS

1. This device is not intended for use except as indicated.
2. Do not use this device where hemostasis cannot be verified visually after application.
3. Contraindications associated with open surgical procedures relative to mesh fixation apply, including but not limited to:
   - Fixation of vascular or neural structures
   - Fixation of bone and cartilage or
   - Situations with insufficient ingrowth of tissue into the mesh over time, which could result in inadequate fixation once the fastener is absorbed.
4. Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as nerves, vessels, viscera or bone. Use of the OptiFix™ Open Absorbable Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener below the fastener head is 6.1 mm, the fastener head is another 0.6 mm (total 6.7 mm).
5. This device should not be used in tissues that have a direct anatomic relationship to major vascular structures. This would include the deployment of fasteners in the diaphragm in the vicinity of the pericardium, aorta, or inferior vena cava during diaphragmatic hernia repair.

## WARNINGS

1. The OptiFix™ Open Absorbable Fixation System is intended for Single Use Only – DO NOT RESTERILIZE. 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.
2. Do not use beyond the expiration date on the package.
3. Prior to use, carefully examine package and product to verify neither is damaged and that all seals are intact. Do not use if the foil pouch or package is damaged or open, or if the center of the temperature indicator on the foil pouch is black.
4. As with any implant material the presence of bacterial contamination may enhance bacterial infectivity. Accepted surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

5. Users should be familiar with surgical procedures and techniques involving synthetic absorbable materials before employing OptiFix™ Open Absorbable Fixation System fasteners for wound closure, as the risk of wound dehiscence may vary with the site of application and the material used.
6. The device may not fixate through prosthetics derived from biologic material such as xenografts and allografts. Prosthetic should be evaluated for compatibility prior to use.

## PRECAUTIONS

1. Please read all instructions before using the OptiFix™ Open Absorbable Fixation System.
2. Only persons having adequate medical training and familiarity with surgical techniques should perform surgical procedures. Consult the medical literature relative to technique, complications and hazards prior to any surgical procedure.
3. Counterpressure should be applied on the target area. Avoid placing hand/finger directly over the area where fastener is being deployed to prevent injury.
4. Use caution when applying the OptiFix™ Open 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 OptiFix™ Open fastener.
5. Insertion of fasteners is possible into some collagenous structures such as ligaments and tendons, but is NOT possible directly into bone or cartilage. This may damage the device and result in compromised fixation strength.
6. Care should be taken not to use excessive counterpressure as this may damage the distal tip of the device as well as the mesh and/or tissue.
7. If the device locks and cannot be separated from a fastener that has been deployed into mesh and/or tissue, place a grasper adjacent to the deployed fastener and pull to free the device. If needed, you may use laparoscopic scissors to cut below the fastener head. The remaining portion of the fastener stem left in the mesh can be removed with graspers. The device should then be discarded and a new device should be used.
8. If the fastener does not deploy properly, remove the device from the patient and test the device in gauze to ensure proper fastener deployment. Once proper fastener deployment is confirmed, the device may be reinserted into the patient.

## ADVERSE REACTIONS

Adverse reactions and potential complications associated with fixation devices such as the OptiFix™ Open Absorbable Fixation System may include, but are not limited to the following: hemorrhage, pain, edema and erythema at wound site, allergic reaction to Poly(D, L)-lactide, infection/septicemia, hernia recurrence/wound dehiscence.

# 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

1. Do not use the VENTRIO™ ST Hernia Patch in infants or children, whereby future growth will be compromised by use of such mesh material.
2. 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.
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 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 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.

## OptiFix™ Open Absorbable Fixation System

| Catalog Number | Configuration | Qty |
|---|---|---|
| 0113320 | 20 Absorbable Fasteners | 5/case |

## Order Form

☐ Please add the OptiFix™ Open Absorbable Fixation System to my preference card.

☐ I would like to have the OptiFix™ Open Absorbable Fixation System in stock.

☐ I would like to trial the OptiFix™ Open Absorbable Fixation System.

Purchase Order Number _____ Date _____

Catalog Number(s) _____ Quantity _____

Surgeon's Signature _____

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



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