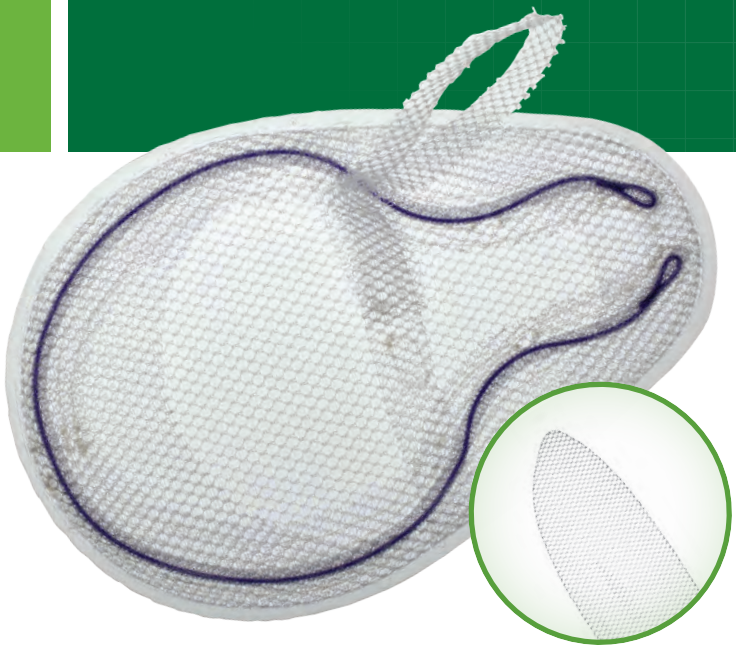
BARD® MK™ Hernia Repair

Featuring Modified ONFLEX™ Mesh



Technique Guide

Anterior Approach to a Preperitoneal
Inguinal 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.

Bard® MK™ Hernia Repair Featuring Modified Onflex™ Mesh

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Benefits of the BARD® Modified ONFLEX™ Mesh with SORBAFLEX™ Memory Technology

Total Confidence

- The SORBAFLEX™ Memory Technology helps to avoid buckling and folding of the mesh, which helps the mesh lay flat and conform to the anatomy in the preperitoneal space
- Mesh covers the entire groin region, including the direct, indirect and femoral spaces, and is designed to help minimize the risk of recurrence or missed hernias
- Biomechanics of intraabdominal pressure help secure the mesh in place[1]

Patient Comfort

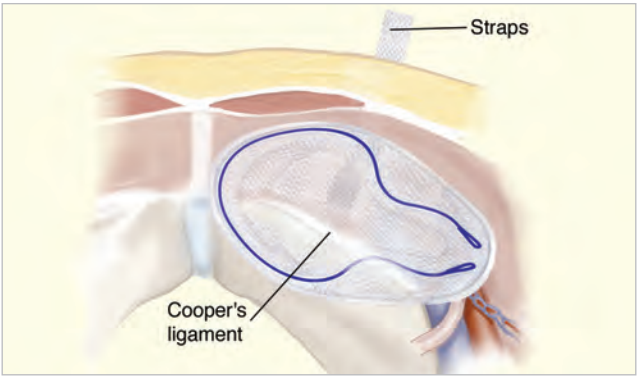
- Technique can be performed through one small 4-6 cm incision
- Minimal fixation requirement may help reduce postoperative pain and the risk of neuralgia[2]
- A tension-free repair technique helps to minimize patient discomfort and provides the potential for rapid return to normal activity[3]
- Can be performed using local or regional anesthesia
- The SORBAFLEX™ PDO monofilament absorbs via hydrolysis in 6-8 months*

1 Kugel, R., Minimally Invasive Repair of Groin and Ventral Hernias Using a Self-Expanding Mesh Patch. *Surgical Technology International* X, 2002, pp. 81-87.

2 Millikan, KW et al, A Prospective Study of the Mesh-Plug Hernioplasty. *The American Surgeon*, March 2001, pp. 285-289.

3 Robbins, AW, Rutkow, IM, Open Mesh Plug Hernioplasty: The Less Invasive Procedure. *Surgical Technology International* V, Universal Medical Press, Inc., 1996, pp. 87-91.

* Preclinical data on file at C. R. Bard, Inc. Results may not correlate to performance in humans.

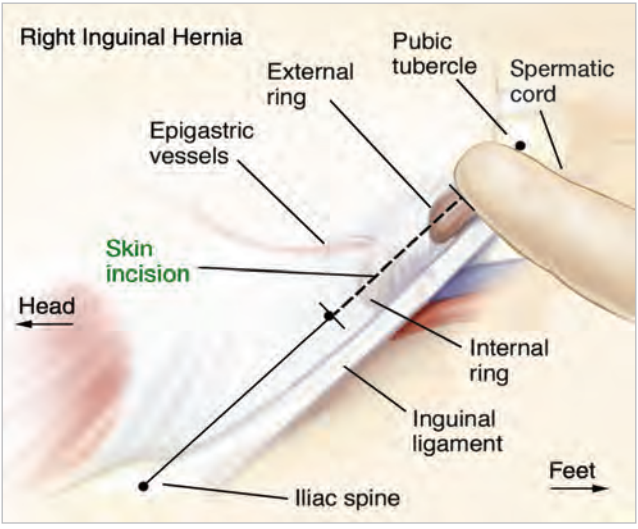


The Bard® MK™ hernia repair technique is a minimally invasive, tension-free technique that can be completed through a small 4-6 cm incision and minimal requirement of fixation. It is a preperitoneal repair performed through an open, anterior approach that can be completed using local or regional anesthesia.

The Modified Onflex™ Mesh with SorbaFlex™ Memory Technology is a self-expanding polypropylene mesh that allows for sufficient overlap of the hernia defect. Tissue ingrowth into the polypropylene mesh and deep placement of the mesh allow for a strong repair. Once the mesh is placed, the SorbaFlex™ Memory Technology helps to avoid buckling and folding – which helps the mesh lay flat in the preperitoneal space.

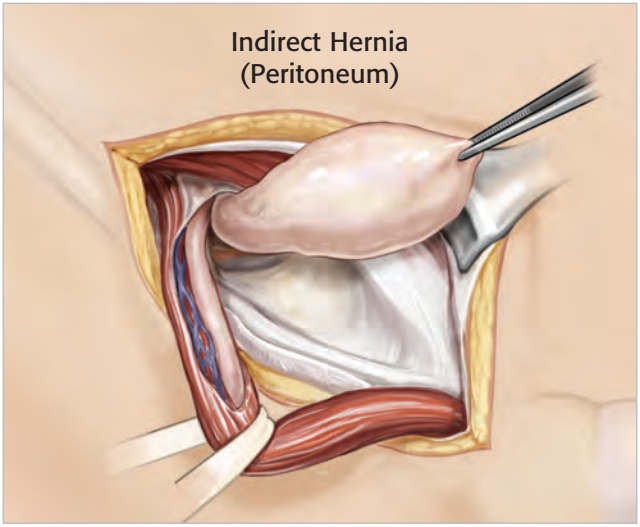
The entire groin region, including the direct, indirect and femoral spaces, is typically protected, therefore, the optional onlay mesh packaged with each Modified Onflex™ Mesh is not necessarily required. A positioning strap and pockets are designed to facilitate placement, positioning and fixation of the device.

Technical Steps to the Procedure



1 Entry into the Inguinal Canal

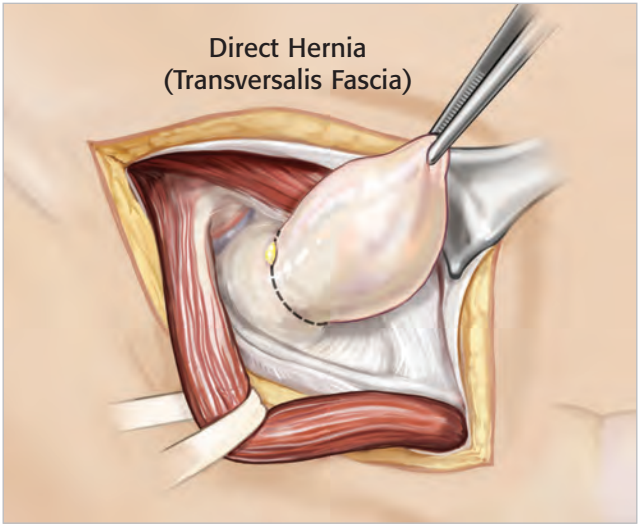
- Mark the anterior superior iliac spine and the pubic tubercle.
- Make a 4-6 cm oblique incision one finger width up from the pubic tubercle extending towards the anterior superior iliac spine.
- Enter the inguinal canal through the external oblique.



2 Dissect and Reduce the Hernia Sac

Indirect Inguinal Hernia Repair

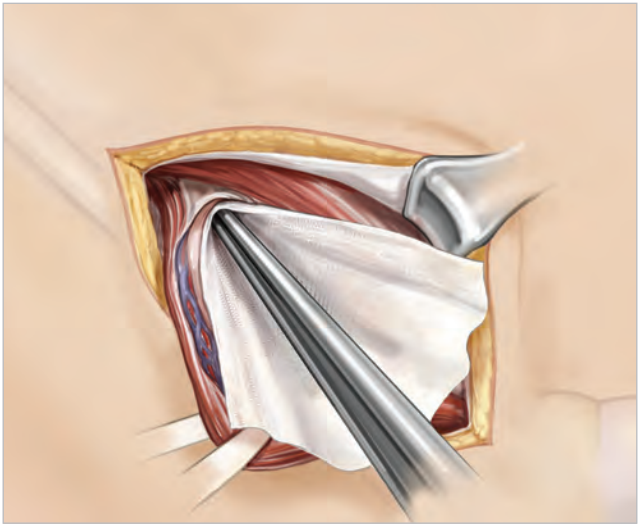
- Mobilize the spermatic cord and separate the cremasteric fibers.
- Using a high dissection, free the hernia sac from the cord structures. Complete the dissection below the point where the vas deferens and testicular vessels diverge to help reduce the risk of the sac slipping under the mesh, creating a potential recurrence.
- Reduce the hernia sac through the internal ring.



3 Dissect and Reduce the Hernia Sac

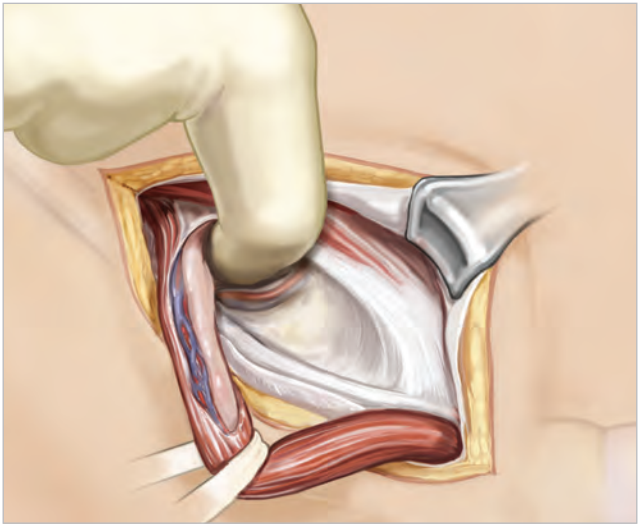
Direct Inguinal Hernia Repair

- Mobilize the spermatic cord and dissect the hernia sac to the base of Hesselbach's triangle.
- Circumscribe the transversalis fascia at the base of the hernia and reduce the hernia sac into the preperitoneal space.



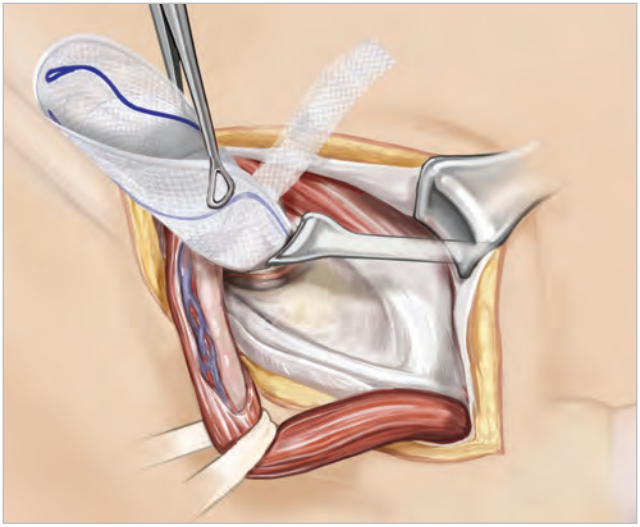
3A Initiate the Preperitoneal Pocket

- Insert one or more 4" x 4" gauze sponge(s) to actualize the preperitoneal space. Remove sponges prior to placing the mesh.



3B Complete the Preperitoneal Pocket

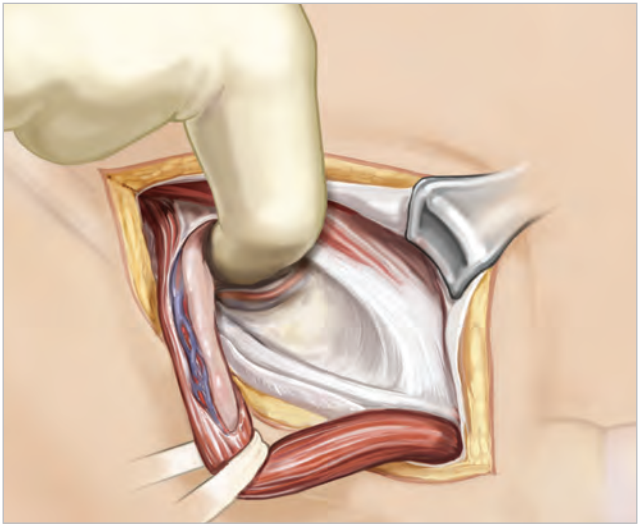
- Locate and retract the inferior epigastric vessels (medial to the internal ring and lateral to the direct space).
- Using blunt dissection, extend the pocket by separating the preperitoneal fat from the posterior transversalis fascia, staying inferior to the epigastric vessels and the spermatic cord.
- Sweep medially and then laterally to create a pocket just large enough to accommodate the mesh.



4A Insert the Modified ONFLEX™ Mesh

- Roll the mesh up in a "taco-like" fashion and grasp the medial edge with sponge forceps, keeping the positioning strap outside the body.
- Continue to retract and elevate the epigastric vessels while placing the mesh.
- Insert the mesh into the preperitoneal space medially toward the pubic tubercle and then laterally toward the anterior superior iliac spine. Make sure that the mesh will go beyond the pubic tubercle approximately by 1-2 cm.
- The mesh should lie between the cord and the peritoneum and deep to the epigastric vessels.
- The SORBAFLEX™ Memory Technology will help the mesh to spring open.

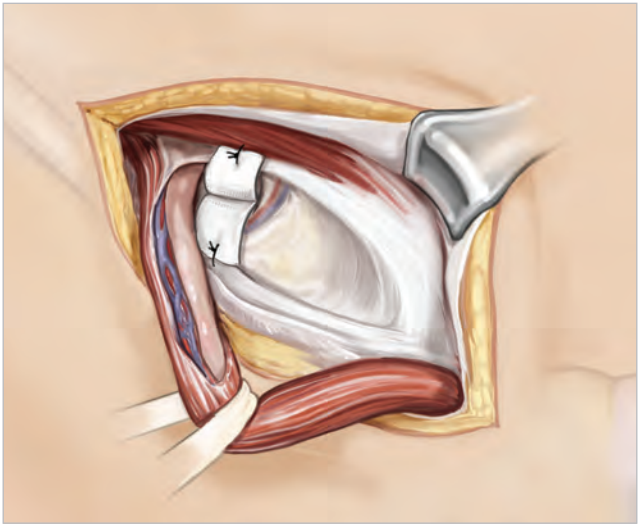
NOTE: A malleable retractor used like a "shoe horn" can facilitate insertion of the mesh.



4B Complete Insertion of the Mesh

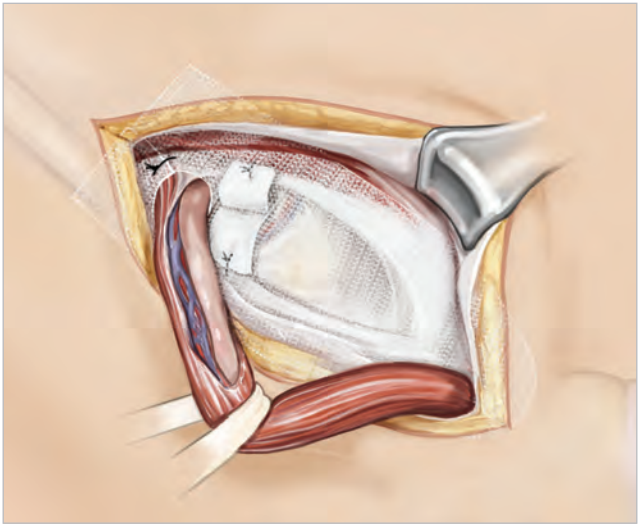
- Pull up on the positioning strap to position and hoist the mesh up against the abdominal wall posteriorly.
- While pulling up on the positioning strap, slide a forefinger into the positioning pocket and sweep circumferentially to ensure the mesh is lying flush against the posterior inguinal wall.

NOTE: If the mesh does not open completely, the dissection is probably incomplete. Running a finger along the periphery of the mesh to perform additional dissection will typically correct this situation. Otherwise, remove the mesh and extend the dissection.



5 Fixate the Straps

- Pull the straps apart and suture one strap to the conjoined tendon and the second strap to the shelving edge of the inguinal ligament.
- Avoid suturing the straps in the area of the epigastric vessels and surrounding nerves.
- Cut off excess strap material and discard.



6 Place the Optional Onlay Mesh*

- Bluntly dissect a pocket under the external oblique to make room for the optional onlay mesh.
- Create a keyhole in the mesh to accommodate the spermatic cord.
- Secure the tails of the mesh loosely around the spermatic cord with 1 or 2 tacking sutures.
- Lay the mesh on the inguinal floor so it extends approximately 2 cm beyond the pubic tubercle and 2 cm lateral to the internal ring.
- Fixation of the onlay mesh is left to the discretion of the surgeon.

*** NOTE:** The onlay mesh is not required.

Modified Onflex™ Mesh

INDICATIONS:

The Modified Onflex™ Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, such as in the repair of inguinal hernias.

CONTRAINDICATIONS:

1. Use of this device is contraindicated for infants, children, or pregnant women, whereby future growth will be compromised by use of such mesh material.
2. Literature reports that there is a possibility for adhesion formation when polypropylene is placed in direct contact with the bowel or viscera.

WARNINGS:

1. The use of any synthetic mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh and is not recommended.
2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. Unresolved infection may require removal of the mesh.
3. Do not cut or reshape the Modified Onflex™ Mesh, except for the positioning strap, as this could affect its effectiveness. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament.
4. Excess positioning strap material above the fixation point must be cut off at the level of the fascia and discarded to eliminate excess material from remaining in the body.

PRECAUTIONS:

Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament.

ADVERSE REACTIONS:

Possible complications may include, but are not limited to, seroma, adhesion, hematoma, pain, infection, inflammation, extrusion, erosion, migration, fistula formation and recurrence of the hernia or soft tissue defect. If the SorbaFlex™ PDO monofilament is cut or damaged, additional complications may include, but are not limited to, bowel or skin perforation and infection.

Modified ONFLEX™ Mesh

Catalog Number	Qty	Description	
0115610	1/case	Anatomical, 3.4" x 5.6" (8.6 cm x 14.2 cm)	☐
0115611	1/case	Anatomical, 4" x 6.2" (10.2 cm x 15.7 cm)	☐

Each Modified ONFLEX™ Mesh with SORBAFLEX™ Memory Technology comes with an optional pre-shaped onlay patch measuring 2.4" x 5.4" (6 cm x 13.7 cm).

Order Form

☐ Please add Modified ONFLEX™ Mesh to my preference card.

☐ I would like to have Modified ONFLEX™ Mesh in stock.

☐ I would like to trial Modified ONFLEX™ Mesh.

Purchase Order Number _____ Date _____

Catalog Number(s) _____ Quantity _____

Surgeon's Signature _____

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