

BARD® KUGEL™ Hernia Repair

Featuring ONFLEX™ Mesh and
SORBAFLEX™ Memory Technology



Technique Guide

Posterior 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® KUGEL™ Hernia Repair Featuring ONFLEX™ Mesh



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Benefits of the BARD® KUGEL™ Hernia Technique Using 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 to stay open and conform to the anatomy in the preperitoneal space
- Mesh is designed to cover the direct, indirect and femoral space, and to help minimize the risk of recurrent or missed hernias
- Same mesh placement as in laparoscopic TEP repair
- Biomechanics of intraabdominal pressure help secure the mesh in place¹

Patient Comfort

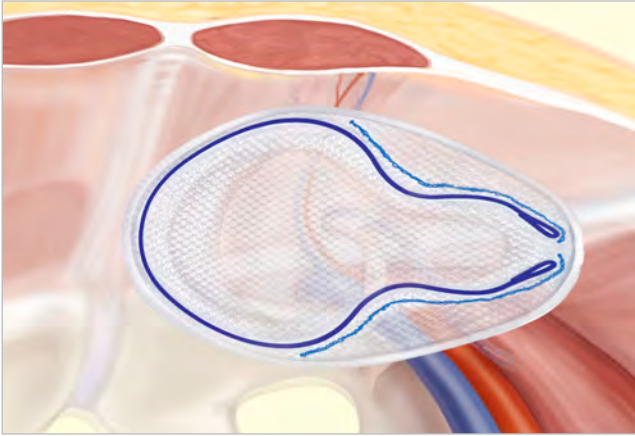
- Technique can be performed through one small 3-4 cm incision
- Minimal fixation requirement may reduce postoperative pain and the risk of neuralgia²
- The SORBAFLEX™ PDO monofilament absorbs via hydrolysis in 6-8 months*
- A tension-free repair technique minimizes patient discomfort and provides the potential for rapid return to normal activity³
- Can be performed using local or regional anesthesia

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.

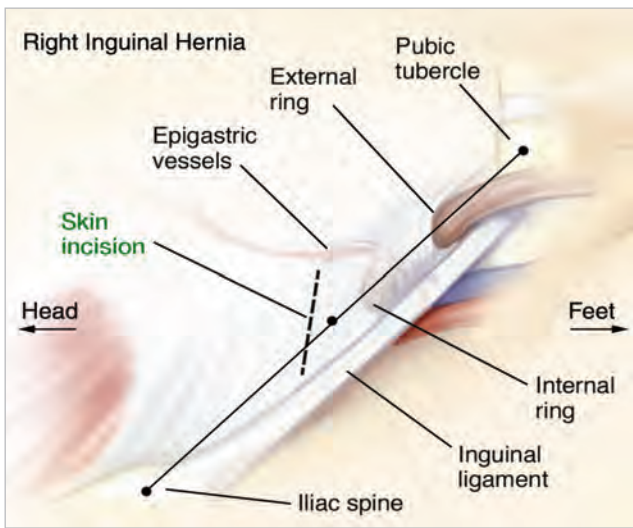
* Preclinical data on file at C. R. Bard, Inc. Results may not correlate to performance in humans.



The BARD® KUGEL™ repair technique is very similar to a laparoscopic repair in that the entire groin region is potentially protected against further herniation. As in a laparoscopic TEP repair, the preperitoneal space is accessed using digital dissection instead of a balloon dissection. The procedure is typically performed through a small 3-4 cm incision made directly above the spermatic cord in the preperitoneal plane. Clear visualization of the operative site must be maintained throughout the procedure with proper dissection and retraction. The use of a headlamp is highly recommended.

The 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.

Operative Technique



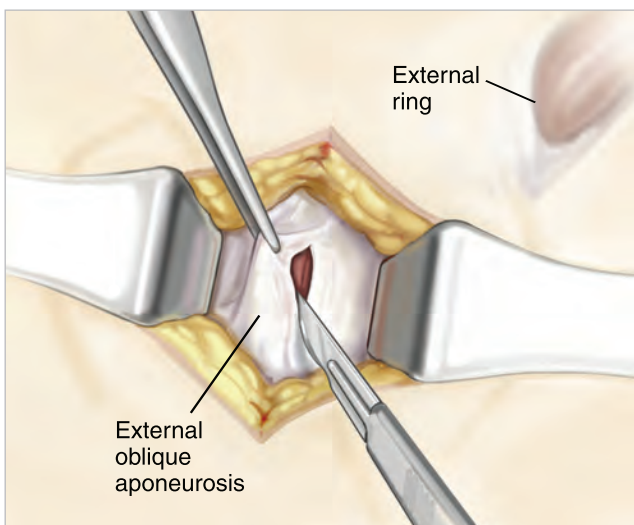
1

Identify Key Landmarks

The following process for locating the proper incision site is recommended for all repairs. The objective is to enter the preperitoneal space approximately 2-3 cm superior to the internal ring.

- Mark the pubic tubercle and the anterior superior iliac spine.
- Draw a line connecting the pubic tubercle and the anterior superior iliac spine, mark the midpoint.
- Approximately 1 cm above the midpoint, draw a 3-4 cm transverse line that is 1/3 lateral and 2/3 medial. This is the incision site.

NOTE: It may be necessary to make a larger incision in overweight patients.

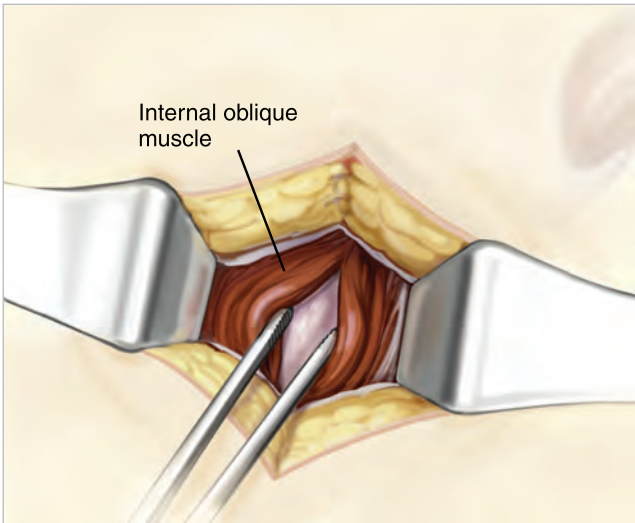


2

Entry into the Preperitoneal Space

Success with the BARD® KUGEL™ repair is dependent on entering into the correct anatomical plane.

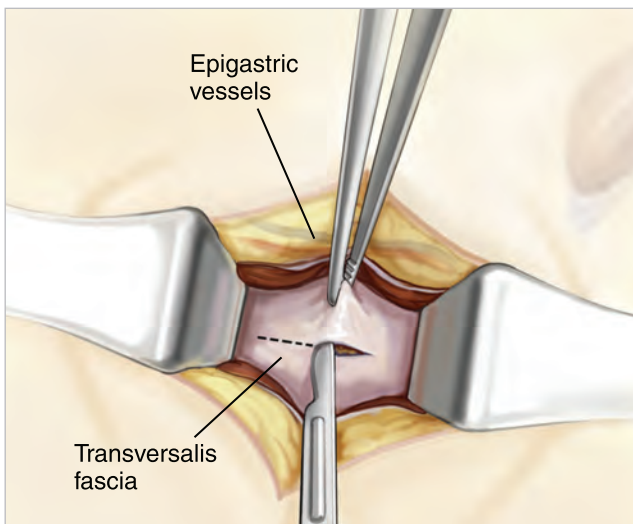
- Incise Scarpa's fascia and dissect the subcutaneous fat down to the level of the external oblique aponeurosis.
- Incise the external oblique aponeurosis parallel with its fibers, but avoid cutting through the external ring.



3

Dissect Through the Internal Oblique Muscle

Use a muscle-splitting incision, similar to that used for appendectomies, to dissect through the internal oblique muscle, exposing the transversalis fascia.



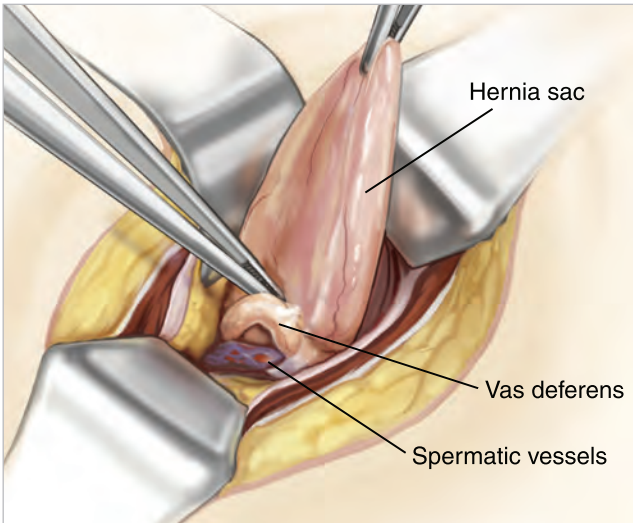
4

Open the Transversalis Fascia

Open the transversalis fascia vertically and parallel to the inferior epigastric vessels, but not through the internal ring. The vertical incision helps to reduce the risk of damage to the epigastric vessels.

NOTE: Entry into the proper plane can be confirmed by feeling the pulsation of the iliac vessels and/or the banding of the epigastric vessels. Throughout the procedure, the epigastric vessels should be elevated to assist with visualization and to avoid slipping into the wrong space.

The Proper Dissection



5

Dissect and Reduce the Hernia Sac

Placing the patient in a Trendelenburg position and rotating the patient slightly away from the hernia can help with the dissection, particularly in obese patients.

5A

Indirect Hernia

- Reduce the hernia sac.
- Keep traction on the peritoneum and separate the cord structures from the hernia sac as it is pulled out of the inguinal canal.
- Complete the dissection below the point where the vas deferens and testicular vessels diverge to reduce the risk of the sac slipping under the mesh, creating a potential recurrence.
- To test the dissection, gently tug on the testicle. If peritoneum advances, further dissection is required..

5B

Direct Hernia

A direct defect is medial to the epigastric vessels. Frequently a "pseudo-sac" is formed from the attenuated transversalis fascia.

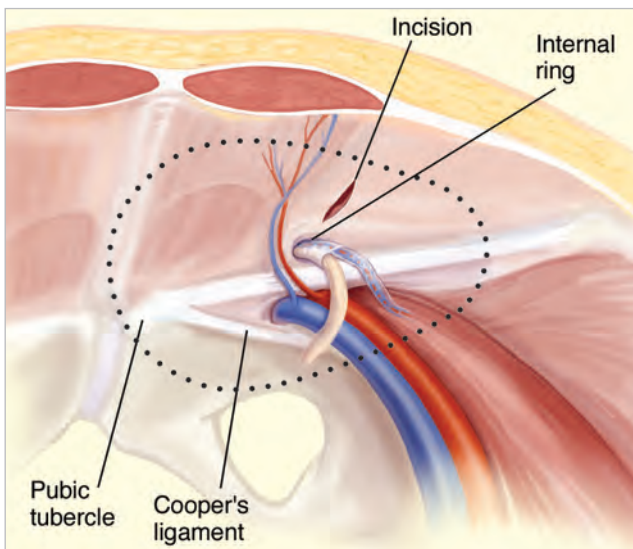
- Using blunt dissection, separate all preperitoneal fat and peritoneum from this pseudo-sac.
- Cooper's ligament must be visible to ensure dissection is complete.

5C

Femoral Hernia

The mesh will not lie flat unless the femoral space is cleared of any herniated material.

- Reduce the hernia sac using careful finger dissection.



6

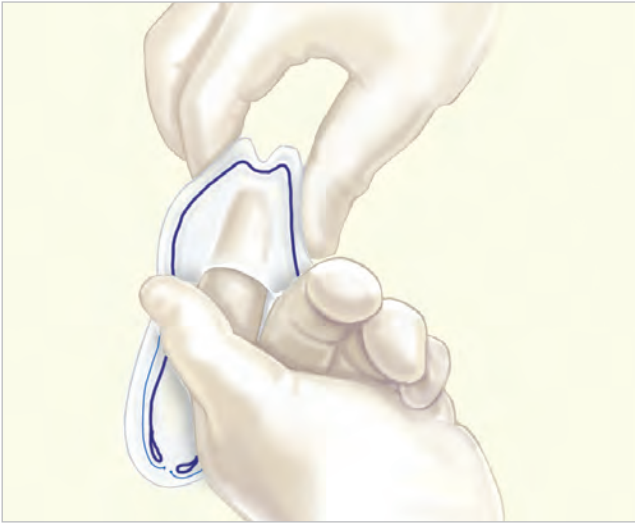
Dissect the Preperitoneal Space

Dissect a preperitoneal pocket just large enough to accommodate the ONFLEX™ mesh.

Key landmarks are:

- Medial to the pubic symphysis
- 3 cm below Cooper's ligament
- 2-3 cm lateral to the internal ring
- 2-3 cm beyond the transversalis incision

NOTE: Loose connective tissue attached to the posterior edge of Cooper's ligament may require sharp dissection, carefully avoiding damage to aberrant obturator vessels.

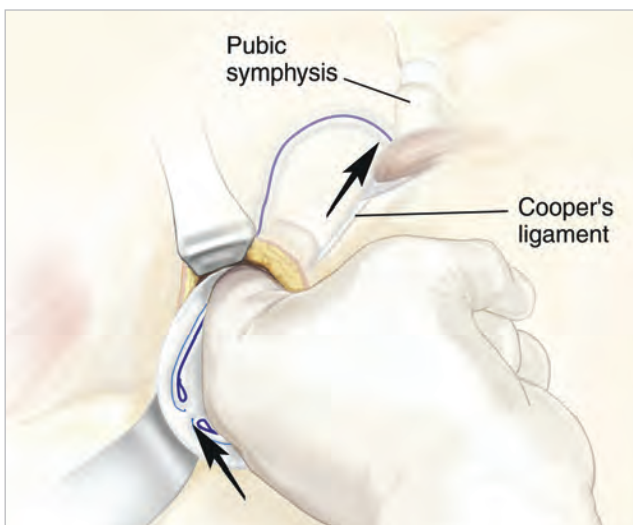


7A

Insert the ONFLEX™ Mesh

Medium (8.6 x 14.2 cm) and Large (10.2 x 15.7 cm) anatomical ONFLEX™ Meshes are designed to cover the entire groin region. Size selection is typically based on the size of the defect, the level of dissection performed, or the size of the patient, while some surgeons believe broader coverage reduces the risk of recurrence.

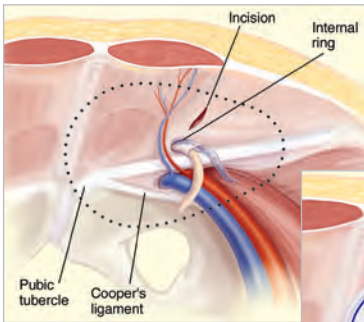
- Place a gauze sponge over the peritoneum and hold back the gauze and preperitoneal contents using a malleable retractor.
- Place index finger of contralateral hand into the anterior medial pocket of the mesh and roll the mesh up in a “taco-like” fashion.



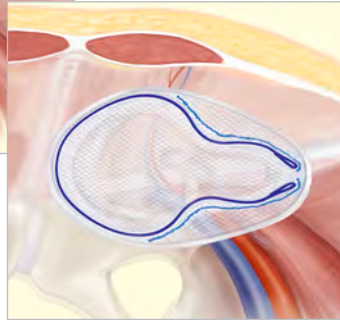
7B

- Insert the mesh from lateral to medial into the preperitoneal pocket, over a malleable retractor used like a “shoe horn.”
- Slide the mesh along Cooper’s ligament medially to the pubic symphysis.
- If necessary, remove finger and insert the malleable retractor into the mesh pocket to finish inserting the mesh.

The ONFLEX™ Mesh lies parallel with the inguinal ligament and is placed between the cord structures and the peritoneum. Controlled dissection and the intraabdominal pressure help secure the mesh in position.



Anterior View



Posterior View

7C

Mesh Placement

- Sweep the upper edge of the mesh under the transversalis fascia so the SORBAFLEX™ memory PDO monofilament is approximately 2-3 cm superior and lateral to the incision.
- Place the inferior edge of the mesh over the iliac vessels so it extends below Cooper's ligament.
- The medial edge of the mesh lies under the pubic bone, up against Cooper's ligament.
- The SORBAFLEX™ memory PDO monofilament should not be visible.

NOTE: If the mesh does not open completely, the dissection is probably insufficient. 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.

8

Closure

- Close the transversalis fascia with interrupted stitches using an absorbable suture.
- Spray a long-acting local anesthetic into the preperitoneal space.
- Close the external oblique with a simple running stitch, and reapproximate Scarpa's fascia and the skin layers in the usual fashion.

ONFLEX™ Mesh

INDICATIONS:

The 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 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

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.

NOTES

ONFLEX™ Mesh

Catalog Number	Size	Qty	Description	
0115410	Medium	1/case	3.4" x 5.6" (8.6 cm x 14.2 cm)	<input type="checkbox"/>
0115411	Large	1/case	4" x 6.2" (10.2 cm x 15.7 cm)	<input type="checkbox"/>

Order Form

- Please add ONFLEX™ Mesh to my preference card.
- I would like to have ONFLEX™ Mesh in stock.
- I would like to trial ONFLEX™ Mesh.

Purchase Order Number

Date

Catalog Number(s)

Quantity

Surgeon's Signature

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