ONSTEP Technique

Technical Aspects of the ONSTEP Inguinal Hernia Repair Technique
Using the PolySoft™ Hernia Patch with Interrupted “Memory Recoil Ring”

Technique Guide*
Anterior Approach to a Part Preperitoneal, Part Intramuscular Inguinal Hernia Repair

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*PolySoft™ Hernia Patch is not approved for sale in the United States
The technique presented herein is for informational purposes only and describes the ONSTEP technique as performed by the inventing surgeons, Dr. A. Lourenço and Dr. R. Soares da Costa. The decision of which technique to use in a surgical application depends on the surgeon and on the patient profile and previous surgical experience. Exceptions to and variations of the step-by-step approach may vary, depending on the patient’s anatomy and needs or on physician preference. Please consult product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.
ONSTEP Inguinal Hernia Repair

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Elements of the ONSTEP Technique for inguinal hernia repair

1. The ONSTEP Inguinal Hernia Repair technique offers the advantages of an anterior approach:
   - The anterior anatomy is familiar to many surgeons and therefore assists in a shorter learning curve.
   - The technique allows for good visualisation of the inguinal canal and preperitoneal space.
   - Locoregional anesthesia is possible.

2. The ONSTEP Inguinal Hernia Repair technique may offer advantages over other open anterior approaches, by providing:
   - A simple and concise 12 step technique.
   - An incision located in an area that avoids major nerve structures to minimize risk of chronic pain.
   - A technique designed to have a short operating time (17 +/- 6 mins)\(^1\).

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• The ONSTEP Inguinal Hernia Repair Technique is a minimally invasive, tension-free repair that can be completed through a small 3–4 cm incision, and requires no fixation due to type and extent of dissection in combination with the implant. It is a part preperitoneal, part intramuscular repair performed through an open, anterior approach that can be completed using regional anesthesia.

• The PolySoft™ Hernia Patch has an oval anatomical shape that fits with the anatomical structures. The size of the implant must be selected to allow for sufficient overlap of the hernia defect.

• Tissue ingrowth into the polypropylene mesh and preperitoneal placement of the patch allows for a strong repair. Once the patch is placed, the interrupted “memory recoil ring” helps ensure the patch will spring open and maintain its shape.

• The PolySoft™ Hernia Patch is made of soft polypropylene mesh, surrounded by an interrupted non-absorbable memory ring made of a PET polymer, designed for tailoring the implant to the patients anatomical needs.
### Summary of 12 Key Steps

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ONSTEP Technique

1 Select the Incision Site

- Draw two straight lines, superior and lateral from the midpoint of pubic symphysis.
- Place the index and middle fingers against each line.
- Mark an incision line from the intersection point of the index fingers, resulting in a 4 cm horizontal and lateral line.

Note: The location of the incision line can also be identified by measuring 4 cm cranially and then 4 cm laterally from the midpoint of the pubic symphysis.
• Incise the marked skin down to the level of the subcutaneous tissue.

• Identify and cauterise the superficial epigastric vein.

Note: The superficial epigastric vein, if present, should be in the medial portion of the 3–4 cm incision line. A deviation from this point suggests the incision line may be too medial.

The superficial epigastric vein is present in the majority of patients, but may be absent in around 18% of patients.
ONSTEP Technique

Dissection to the Level of the Internal Oblique Aponeurosis

- Continue sharp dissection of Scarpa’s fascia and subcutaneous fat, to reach the external oblique aponeurosis.

- Carefully begin dissection of the external oblique aponeurosis with diathermy, exposing the underlying internal oblique aponeurosis. Take care not to dissect the anterior surface of the internal oblique aponeurosis.

- Complete dissection of the external oblique aponeurosis with diathermy.

Note: It is important to confirm that the correct tissue plane is properly identified which is evidenced by the visualisation of the avascular and white fibrous anterior surface of the internal oblique aponeurosis.
• Digitally dissect the space between the external and internal oblique aponeurosis, sweeping laterally and cranially up the superior iliac spine, to create a dissected tissue plane that will subsequently accommodate the placement of the lateral tails of the PolySoft™ Hernia Patch.

• Continue the sweeping motion medially down the inguinal ligament to the pubic bone, to complete this dissection, and gain access to the posterior wall of the inguinal canal.
Identification and Isolation of the Spermatic Cord

- Identify and mobilise the spermatic cord structures by sweeping medial to lateral with an upward facing probing finger.

- Once the cord has been mobilised from the posterior wall of the external oblique aponeurosis, elevate the cord up and out of the incision site and isolate with a surgical loop.
ONSTEP TECHNIQUE

Entry to Space of Retzius

- Digitally explore the transversalis fascia down to the pubic bone and obliquely enter the space of Retzius, through spreading the fibers of the transversalis fascia.

Note: This can be done by either digitally dissecting through the fascia, or with the use of an appropriate surgical instrument to gently spread the fibers before digitally penetrating through the transversalis fascia.
Using blunt forceps, guide a large (20 x 20 cm) moist sterile gauze, down the index finger, into the retropubic space (space of Retzius), maintaining the position of the index finger behind the pubic bone.

The index finger will act as support for the posterior wall of the inguinal canal, preventing the transversalis fascia from entering the space of Retzius, when the gauze is pushed into this space.

Note: No digital dissection of the preperitoneal space or the space of Retzius is performed during the ONSTEP technique. All blunt dissection is completed by the gauze, when placed into the Space of Retzius.
ONSTEP TECHNIQUE

8  Reduction of Hernia Sac

• If an indirect hernia is identified, reduce the sac and contents and ligate / remove the excess sac as appropriate, according to general surgical practice.

• If a direct hernia is identified, it will be repaired with the placement of the PolySoft™ Hernia Patch. In the case of a direct hernia, always ensure there is no indirect hernia present.

Note: Hernia sacs should always be well dissected, to ensure they can be properly reduced, prior to the placement of the PolySoft™ Hernia Patch.
ONSTEP Technique

Preparation of the POLYSOFT™ Hernia Patch

• Cut an axial slit in the prosthetic patch between the interrupted ends of the memory recoil ring, down to the apex of the curved notch of the patch. **Do not cut the recoil ring.**

• Place the inferior tail of the POLYSOFT™ Hernia Patch under the spermatic cord, so that the tails are pointing lateral.

Note: The curved notch of the POLYSOFT™ Hernia Patch is always placed under the spermatic cord.

Do not place the POLYSOFT™ Hernia Patch directly on the skin at any time during the procedure.
ONSTEP TECHNIQUE

Preparation of the POLYSOF™ Hernia Patch

- Place three non-absorbable interrupted sutures into the POLYSOF™ Hernia Patch to join the prosthetic tails together.
  - The first suture is placed to close the outer margin of the POLYSOF™ Hernia Patch.
  - The second suture is placed in the midpoint of the slit made in the POLYSOF™ Hernia Patch.
  - The third suture is placed adjacent to the spermatic cord. Appropriate space must be left to ensure good perforation of the cord.

Note: Take care that the three sutures are placed, to ensure the opening around the spermatic cord is not too tight or too wide.
Removal of Gauze

- Remove the sterile gauze from the operative site and return to the scrub nurse.
ONSTEP Technique

11a Placement of the POLYSOFT™ Hernia Patch

- Grasp the medial apex of the POLYSOFT™ Hernia Patch with 2 index fingers (one finger on top of the patch and one placed underneath the patch). Insert into the incision and push the mesh down into the space of Retzius under the pubic bone, leaving the tails of the patch outside the incision.

- Digitally explore the POLYSOFT™ Hernia Patch ensuring that it is fully deployed under the pubic bone, in the space of Retzius.

Note: If the POLYSOFT™ Hernia Patch does not fully deploy within the Space of Retzius, further blunt dissection may be required. Remove the POLYSOFT™ Hernia Patch from this space and perform additional blunt dissection.
ONSTEP TECHNIQUE

Mesh Placement

11b

- Insert the lateral tails of the PolySoft™ Hernia Patch into the previously dissected space between the external and internal oblique aponeurosis, and digitally explore and smoothen the PolySoft™ Hernia Patch to ensure proper placement.
Closure of Incision Site

- Close the external oblique aponeurosis with a suture type and technique of choice. There is no need to close Scarpa’s fascia.
- Inject local anaesthetic of choice as appropriate.
- Close the skin with suture or clips of your choice as appropriate.
Indications:

The Bard® PolySoft™ Hernia Patch is intended for use in hernia repair requiring reinforcement with a non-absorbable support material.

Contraindications:

1. Do not use the Bard® PolySoft™ Hernia Patch for applications in infants or children, whereby future growth will be compromised by use of such mesh material.

2. Literature reports that there is a possibility for adhesion formation when the Bard® PolySoft™ Hernia Patch is placed in direct contact with the bowel or viscera.

Warnings:

1. Do not cut or reshape the Bard® PolySoft™ Hernia Patch, (except at the opening in the interrupted recoil “ring”) as this could affect its effectiveness. Care should be taken not to cut or nick the PET recoil ring. If the recoil ring is cut or damaged during insertion or fixation, additional complications may include bowel or skin perforation and infection. The patch must be replaced immediately if the ring or the ring pouch have been compromised during the implant procedure.

2. The device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.

3. 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.

4. This device is for single use only. Do not resterilize or reuse any portion of the Bard® PolySoft™ Hernia Patch. 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.

5. Careful attention to the **BARD® Polysoft™** Hernia Patch handling, fixation and suture technique is most important in the presence of known, or suspected, wound contamination or infection.

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

7. Where previous surgery has been performed in that region of the preperitoneal space (e.g., radical prostatectomy, previous preperitoneal herniorrhaphy), repair of the hernia may be more difficult.

8. 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. To ensure a strong repair, the prosthesis should be secured using sutures. Do not staple or tack the prosthesis in place.

3. Care should be taken to ensure that the patch is adequately fixated to the abdominal wall. If necessary, additional sutures should be used.

4. Only physicians qualified in the appropriate surgical techniques should use this prosthesis.

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

*Polysoft™* Hernia Patch is not approved for sale in the United States
Notes:
# PolySoft™ Hernia Patch

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
<th>Size</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>0130030</td>
<td>Medium Oval</td>
<td>14 cm x 7.5 cm</td>
<td>2/cs</td>
</tr>
<tr>
<td>0130040</td>
<td>Large Oval</td>
<td>16 cm x 9.5 cm</td>
<td>2/cs</td>
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For details about BARD® PolySoft™ Hernia Patch or any other of the many BARD® hernia repair products, please contact:

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**References:**


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