Onflex™ Mesh

For Open Preperitoneal Inguinal Hernia Repair

BD

Same proven technique – new and improved mesh

Anatomical coverage for a proven technique

Specifically designed to fit the inguinal anatomy during preperitoneal placement

Expanded medial and inferior coverage for direct and femoral spaces

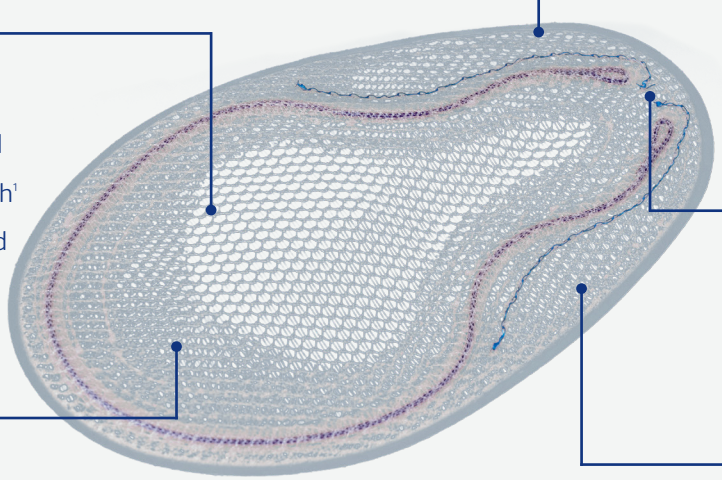
Improved mesh design

Light weight, large pore mesh

- Reduces the amount of foreign material implanted
- Allows good tissue ingrowth[1]
- Results in more flexible and compliant scar formation[1]

Positioning pocket

- Medial pocket to aid in proper placement



Absorbable SorbaFlex™ Memory Technology

- Allows the patch to open and conform to the anatomy
- Aids proper positioning of the device

Interrupted PDO monofilament

- Enables easy mesh insertion into preperitoneal space

Inguinal notch

- Designed to conform to iliac vessels

1 Brown C, Finch J. Which mesh for hernia repair? Annals of The Royal College of Surgeons of England 2010;92(4):272-278.

Easy

- Inguinal hernia repair in 4 key steps
- An efficient reproducible procedure.[2]

Efficient

- Can be performed in less than 20 minutes[3]
- Shorter procedure time allows for more inguinal procedures potentially decreasing the waiting list
- Potentially less patient anesthesia time required

Reduced pain

- The fixation-free technique eliminates the risk of patient pain due to fixation
- Incision site helps to avoid nerves

SorbaFlex™ Technology absorption profile*

Polydioxanone (PDO) mono-filament is commonly used in surgical products (e.g. sutures).

Absorption via hydrolysis is essentially complete in 24–32 weeks.*

These images are from a porcine study using the Ventrio™ Hernia Patch which contains the same SorbaFlex™ Memory Technology.

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

Ordering information

Product code	Qty.	Description	Dimensions	
115410	1/cs.	Onflex™ Mesh, Medium	8.6 x 14.2 cm	☐
115411	1/cs.	Onflex™ Mesh, Large	10.2 x 15.7 cm	☐

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. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard mesh with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be large enough to provide sufficient overlap beyond the margins of the defect. If fixation is used, careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels, or spermatic cord structures. 6. The mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 7. This device is for single use only. Do not resterilize or reuse any portion of the Onflex™ Mesh. 8. Do not cut or reshape the Onflex™ Mesh, except at the opening in the interrupted SorbaFlex™ PDO monofilament, to accommodate the spermatic cord and outside the blue limit line in the lateral portion of the mesh, as this could affect its effectiveness. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament.

Precautions. 1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this prothesis. 3. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament. 4. If fixation is used, care should be taken to ensure that the mesh is adequately fixated. If necessary, additional fasteners and/or sutures should be used. **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.

Please note, not all products, services or features of products and services may be available in your local area. Please check with your local BD representative.

2 Andresen K, Burcharth J, Rosenberg J. The learning curve of ONSTEP among experienced general surgeons. Poster presented at the 35th Congress of the European Hernia Society, Gdansk, Poland. 2013 May.
3 Lourenço A, Costa R. The ONSTEP inguinal hernia repair technique: Initial clinical experience of 693 patients, in two institutions. Hernia. 2013 Jun;17(3):357-364.

CE
2797

BD Switzerland Sarl, Terre Bonne Park – A4, Route De Crassier, 17, 1262 Eysins, Vaud. Switzerland.
T: + 41 21 556 3000

bd.com