



# VENTRIO™ Hernia Patch

Self-Expanding Polypropylene and ePTFE Patch for Soft Tissue Reconstruction  
with *SORBAFLEX™ Memory Technology*

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## INSTRUCTIONS FOR USE

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Инструкции по применению



Single Use



Partially Absorbable

R<sub>x</sub> only

STERILE EO



Manufacturer:

**Davol Inc.**

Subsidiary of C. R. Bard, Inc.

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RH11 9BP



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**Clinical Information Line**

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**DAVOLD**

DAVOL INC.

PK3795555 111R



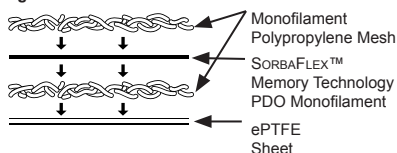
## VENTRIO™ Hernia Patch

Self-Expanding Polypropylene and ePTFE Patch for Soft Tissue Reconstruction  
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### DESCRIPTION

The VENTRIO™ Hernia Patch is a self-expanding, non-absorbable, sterile prosthesis, containing two primary layers of monofilament polypropylene mesh stitched with PTFE monofilament to an ePTFE sheet, forming a positioning pocket. The device contains SORBAFLEX™ Memory Technology, which provides memory and stability to the device, facilitating ease of initial insertion, proper placement, and fixation of the device. The SORBAFLEX™ Memory Technology is comprised of an extruded polydioxanone (PDO) monofilament. The extra large oval size patches contain two separate SORBAFLEX™ PDO monofilaments. The PDO monofilament is dyed violet by adding D & C Violet No.2. Polypropylene monofilaments are knitted into a mesh, which allows a prompt fibroblastic response through the interstices of the mesh. The ePTFE layer has a sub-micronal porosity, which minimizes tissue in-growth. The SORBAFLEX™ PDO monofilament fully degrades in vivo by means of hydrolysis. The PDO monofilament has been found to elicit an inflammatory response during absorption. Absorption is essentially complete in 6-8 months (see Figure 1).

Figure 1



### INDICATIONS

The VENTRIO™ Hernia Patch is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

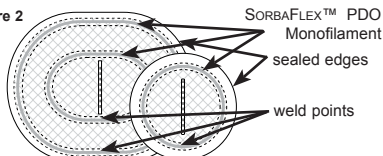
### CONTRAINDICATIONS

- Do not use the VENTRIO™ Hernia Patch in infants or children, whereby future growth will be compromised by use of such mesh material.
- Do not use the VENTRIO™ Hernia Patch for the reconstruction of cardiovascular defects.
- Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera.

### WARNINGS

- Do not cut or reshape the VENTRIO™ Hernia Patch, as this could affect its effectiveness. Care should be taken not to cut or nick the SORBAFLEX™ PDO monofilament. If the SORBAFLEX™ PDO monofilament is cut or damaged during insertion or fixation, additional complications may include bowel or skin perforation and infection.
- Follow proper folding techniques for all patches as described in these Instructions for Use as other folding techniques may break the SORBAFLEX™ PDO monofilament (see Figure 3).
- The device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.
- This device is for single use only. Do not resterilize or reuse any portion of the VENTRIO™ Hernia Patch.
- Ensure proper orientation; the solid white surface (ePTFE) must be oriented against the bowel or sensitive organs. Do not place the mesh surface against the bowel. There may be a possibility for adhesion formation when mesh is placed in direct contact with the bowel or viscera.
- Careful attention to the VENTRIO™ Hernia Patch handling, fixation, and suture technique is most important in the presence of known or suspected wound contamination or infection.
- 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.
- To prevent recurrences when repairing hernias, the prosthesis should be large enough to extend beyond the margins of the defect.
- To ensure a strong repair, the prosthesis should be secured through the polypropylene mesh structure. Suturing or tacking on sealed edge of mesh alone is not recommended.

Figure 2



10. The use of any permanent mesh or patch on a contaminated or infected wound could lead to fistula formation and/or extrusion of the prosthesis.

### PRECAUTIONS

- Please read all instructions prior to use.
- Only physicians qualified in the appropriate surgical techniques should use this prosthesis.
- Care should be taken not to cut or nick the SORBAFLEX™ PDO monofilament during fixation.
- Davol fixation devices and/or non-absorbable monofilament sutures are recommended to properly secure the prosthesis. If other fixation devices are used, they must be indicated for use in hernia repair. 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.

### ADVERSE REACTIONS

Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation, 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.

### INSTRUCTIONS FOR USE

#### Surface Orientation

It is extremely important that this product is oriented correctly to function as intended. The smooth, solid white (ePTFE) surface is designed with low porosity to minimize tissue attachment. Place this side of the prosthesis against those surfaces where minimal tissue attachment is desired, i.e., against bowel or other visceral structures. It is still recommended to pull down omentum wherever possible beneath the ePTFE side to further mitigate the risk of visceral adhesion. The porous mesh side offers the same tissue in-growth characteristics of polypropylene mesh alone. Therefore, this surface should face the surface where tissue in-growth is desired. The mesh surface should never be placed against the bowel or other visceral structures.

#### Patch Folding Technique

For open procedures, the smaller size patches (5.4" x 7.0" or smaller) should be rolled around the surgeon's fingers for insertion. All other patches should be rolled into thirds along the long axis and inserted into the intra-abdominal space as shown here. For laparoscopic procedures, all size patches should be rolled into thirds along the long axis, ePTFE side out, and inserted through a trocar site which is a minimum of 12mm (remove trocar, insert mesh, and reinsert trocar). Avoid folding or crimping the SORBAFLEX™ PDO monofilament directly on the weld points (see Figure 2 above), as this may cause the weld to break (see Figure 3).

Figure 3



#### Fixation

Davol fixation devices and/or non-absorbable monofilament sutures are recommended to properly secure the prosthesis. If other fixation devices are used, they must be indicated for use in hernia repair. 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.







#### Traceability

A traceability label which identifies the type, size and lot number of the prosthesis is enclosed in every package. This label should be affixed to the patient's permanent medical record to clearly identify the device which was implanted.

If you experience a product failure, please contact Davol Inc. at 1-800-556-6275 for instructions on returning the product.

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	ENGLISH	FRANÇAIS	DEUTSCH	ITALIANO	ESPAÑOL	NETHERLANDS	PORTUGUÊS
	Circle	Cercle	Kreis	Cerchio	Círculo	Cirkel	Círculo
	Oval	Ovale	Oval	Ovale	Óvalo	Ovaal	Oval
	Contents	Contenu	Inhalt	Contenuto	Contenido	Inhoud	Conteúdo
	Sterile unless package is damaged or open.	Sterile sauf si l'emballage a été ouvert ou endommagé.	Steril, solange die Verpackung ungeöffnet und unbeschädigt ist.	Sterile, se la confezione è intatta e non danneggiata.	Estéril, a menos que el envase esté abierto o dañado.	Steriel, tenzij de verpakking beschadigd of open is.	Estéril a menos que a embalagem esteja danificada ou aberta.
	Other Patents Pending	Autres brevets en instance	Weitere Patente ausstehend	Altri brevetti in corso di registrazione	Otras patentes pendientes	Andere octrooien aangevraagd	Outras patentes pendentes
	Partially Absorbable	Partiellement résorbable	Teilweise resorbierbar	Parzialmente assorbibile	Parcialmente reabsorbible	Gedeeltelijk resorbeerbaar	Parcialmente absorvível