BARD™ COMPOSIX™ E/X Mesh

Polypropylene and ePTFE Prosthesis Designed for Ventral Hernia Repair

Instructions for Use

Mode d'emploi • Gebrauchsanweisung
Istruzioni per l'uso • Instrucciones de uso
Gebruiksaanwijzing • Instruções de utilização
Οδηγίες χρήσης • Brugervejledning
Bruksanvisning • Käyttöohjeet
Bruksanvisning • Instrukcja użycia
Használati útmutató • Návod k použití
Kullanım Talimatları • 使用説明
사용 설명서 • Инструкции по применению

℞ Only | STERILE EO | Nonabsorbable | Single Use

BARD

DAVOL INC.

en

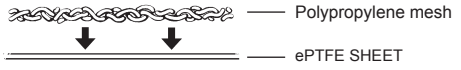
BARD™ COMPOSIX™ E/X Mesh

Polypropylene and ePTFE Prosthesis Designed for Ventral Hernia Repair

PRODUCT DESCRIPTION

BARD™ COMPOSIX™ E/X Mesh is a nonabsorbable, sterile prosthesis designed for the reconstruction of soft tissue deficiencies. It is presized and shaped to offer maximum ready-to-use benefits. Its lower profile makes it easier to deploy laparoscopically.

BARD™ COMPOSIX™ E/X Mesh is constructed of one layer of polypropylene mesh and one layer of expanded polytetrafluoroethylene (ePTFE). The layers are stitched together with PTFE monofilament.



For maximum performance, the edge of the polypropylene mesh layer is heat sealed to the ePTFE layer. As additional tailoring or customizing of the prosthesis may sometimes be necessary, the mesh and ePTFE layers are stitched together to permit maximum attachment while handling.

The ePTFE sheet is extruded and expanded to impart a low porosity. The mesh surface encourages tissue ingrowth while the ePTFE minimizes tissue ingrowth.

The layered prosthesis exhibits high burst strength and tensile strength.

INDICATIONS

BARD™ COMPOSIX™ E/X Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects.

CONTRAINDICATIONS

1. Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.
2. Do not use the BARD™ COMPOSIX™ E/X Mesh in infants or children whereby future growth will be compromised by use of such material.
3. Do not use BARD™ COMPOSIX™ E/X Mesh for the reconstruction of cardiovascular defects.

WARNINGS

1. **This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.**
2. **This device is for single use only. Do not resterilize. After opening, discard unused portions of the prosthesis.**
3. **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.**
4. **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.**
5. **If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the prosthesis. An unresolved infection may require removal of the prosthesis.**
6. **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. Only physicians qualified in the appropriate surgical techniques should use this prosthesis.
3. DAVOL™ fixation devices or nonabsorbable 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.

INSTRUCTIONS FOR USE

Surface Orientation

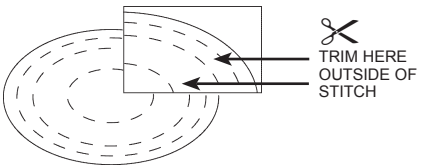
It is extremely important that this product is oriented correctly to function as intended. The solid white (ePTFE) surface is designed with low porosity to minimize tissue attachment. Place this side of the prosthesis against those surfaces where minimal tissue attachment is desired, i.e., against bowel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

Laparoscopic Use

The larger sizes of BARD™ COMPOSIX™ E/X Mesh may inhibit deployment through small trocars. Use appropriate size trocar to allow mesh to slide down the trocar with minimal force. It is recommended that the polypropylene side of the prosthesis be rolled to the outside to protect the ePTFE as it is deployed. If mesh will not easily deploy down the trocar, remove trocar and insert mesh through incision. Reinsert trocar.

SIZING

The prosthesis can be tailored to offer bi-directional elasticity to adapt to various stresses encountered in the body. Use sharp surgical instruments to trim the prosthesis. The stitch pattern of the BARD™ COMPOSIX™ E/X Mesh allows the prosthesis to be trimmed without separation of the two layers. Trim the mesh just outside the stitching (see diagram). If an overlap is desired, trim further out from stitching (approximately 1 cm) then fold back the edge of the ePTFE layer and perform a second trim of just the polypropylene mesh. To minimize chance of recurrence, trim the prosthesis such that it extends beyond the margins of the defect. If the material is cut too small, tension may be placed on the fixation line, which may result in a recurrence of the original defect.



FIXATION

DAVOL™ fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the prosthesis. If other fixation devices are used, they must be indicated for use in hernia repair. **To ensure a strong repair, sutures or tacks should be placed at least 0.5 cm inside the outermost row of stitching. Suturing or tacking on sealed edge of mesh alone is not recommended.** 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. Tacker choice, size and spacing should be determined by surgeon preference.

ADVERSE REACTIONS

Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

TRACEABILITY

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

Manufacturer:
Davol Inc.
Subsidiary of C. R. Bard, Inc.
100 Crossings Boulevard
Warwick, RI 02886 USA
1-401-825-8300 • 1-800-556-6275

EC REP
Bard Limited
Crawley, UK
RH11 9BP

CE
0086

Medical Services & Support
Clinical Information Line
1-800-562-0027

PK3795800
117R