Ventral hernia repair

The Biodesign Hernia Graft is used to reinforce soft tissue where weakness exists, including a hernia or body wall defect.

1. Hydrate the graft for no longer than one minute in room-temperature, sterile, lactated Ringer’s solution or sterile saline.

2. If you use an open procedure to place the graft, then preperitoneal, retrorectus, or intraperitoneal placement is recommended. For a laparoscopic procedure, intraperitoneal placement is recommended.

3. Trim the graft to fit the site, allowing overlap. Fundamental surgical principles suggest recurrence can be minimized if the mesh overlaps the surrounding tissue by 4-5 cm in all directions.¹ When 5 cm of overlap is not attainable, overlap as much tissue as possible.

4. Bridging the hernia with only the graft is not recommended. To attain primary closure of the defects, use relaxing incisions, perform component separation, or perform retrorectus placement. If bridging is unavoidable, follow the best practices described in the IFU.

5. Use permanent or long-term absorbable sutures and tacks. The horizontal mattress suture technique is recommended. Place sutures ≤ 3 cm apart and with a bite depth of 1 cm.

6. Place closed suction drains, and leave them in place for two to six weeks. Remove the drains when their output is < 20 mL per 24 hours for at least two consecutive days or until the drains are dry.

INTENDED USE

The Cook® Biodesign® Hernia Graft is intended for implantation to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect. The graft is supplied sterile and is intended for one-time use.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS: This graft is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

PRECAUTIONS: This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease. Do not resterilize. Discard all open and unused portions of the graft. The graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken. Discard graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date. Ensure that graft is rehydrated prior to cutting, suturing, stapling, tacking or loading of the graft laparoscopically. Ensure that all layers of the graft are secured when suturing, stapling, or tacking. Place graft in maximum possible contact with healthy, well-vascularized tissue to encourage cell ingrowth and tissue remodeling. Suturing, stapling, or tacking more than one graft together may decrease graft performance. No studies have been conducted to evaluate the reproductive impact of the clinical use of the graft. Extended rehydration or excessive handling could lead to partial delamination of superficial layers of the graft. Care should be taken to avoid damage to the graft when loading laparoscopically. It is recommended to load through a 10 mm or larger port. If wound is left open, keep graft moist to prevent dryness.

POTENTIAL COMPLICATIONS: Possible adverse reactions with the use of any prosthesis may include, but are not limited to: infection, inflammation, adhesion, fistula formation, seroma formation, hematoma, bowel erosion, recurrence of tissue defect, premature degradation. Complications, such as delayed wound infection, premature degradation, hernia recurrence, bowel erosion, and the need for re-operation, should be reasonably expected in patients who are critically ill or who have severely contaminated abdomens.

See package insert for full product information.

Cook Biotech Inc.
For U.S. distribution only

© 2020 Cook Biotech CBI-D57023-EN