Biodesign®

DURAPLASTY GRAFT

FP0095-01A

COOK® MEDICAL

Manufacturer

Attention, see instructions for use

Temperature limit

Keep dry

Use-by date

STERILE EO **Sterilized using ethylene oxide**

Do not re-use

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BIODESIGN® DURAPLASTY GRAFT

DESCRIPTION

Cook® Biodesign Duraplasty Graft is a nonporous, absorbable multi-layer sheet of extracellular collagen matrix derived from porcine small intestinal submucosa. The graft is non-pyrogenic and has sufficiently low endotoxin levels to make it suitable for applications where it will contact cerebrospinal fluid during repair of dura mater.

INDICATIONS FOR USE

The Biodesign Duraplasty Graft is indicated for use as a dura substitute for the repair of dura mater. This graft is supplied sterile in peel-open packages and is intended for one-time use.

Rx ONLY This symbol means the following:

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

DURAPLASTY GRAFT This symbol means the following: Duraplasty Graft

This product is intended for use by trained medical professionals.

CONTRAINDICATIONS

The Biodesign Duraplasty Graft is not designed, sold or intended for use except as described in the indications for use and is contraindicated:

- For use in patients with a known history of hypersensitivity to porcine derived materials;
- For repair of spinal neural tube defects; and
- For anterior spinal surgery with dural resection (e.g. transoral surgery)

Additionally:

- Use with caution in infected regions.
- It is not recommended to cover defects involving mastoid cells.
- It is not recommended for large defects at the skull base following surgery; however the Biodesign Duraplasty Graft may be used to augment other forms of specific repair (e.g. pedicled flaps or vascularized pedicled flaps).

PRECAUTIONS

- The Biodesign Duraplasty Graft is designed to augment skull base repair where layering techniques such as bony buttressing, pedicled flaps or vascularized pedicled flaps and packing are currently used. The graft should not replace standard layering techniques or be implanted as a stand-alone repair.
- Peer reviewed literature[9] has reported the use of this material as a dural substitute at the skull base in defects up to 4.5 cm^2.
- 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 use if the product package is damaged or opened.
- Discard graft if damage or contamination is observed, or if the graft is past its expiration date.
- Prior to touching the graft, wash surgical gloves thoroughly to remove the glove powder.
- Ensure that graft sterility is maintained during preparation and implantation at repair site.
- Suturing is not required but if the graft is to be sutured, tensionless suturing technique must be used.
- Discard all open and unused portions of the graft sheets.
- The graft should be cut to size ensuring an overlap to cover the existing dura.
- Ensure that graft is rehydrated and all layers of the graft are secured if fixation with suture is employed.

POTENTIAL COMPLICATIONS

The following complications are possible with the use of surgical graft materials in neurosurgical procedures.

- Infection, adhesion, CSF leak, delayed hemorrhage and calcification
- Acute or chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation.)
- Allergic reaction

STORAGE

This graft should be stored in a clean, dry location at controlled room temperature. Do not freeze this graft.

STERILIZATION

This graft has been sterilized with ethylene oxide.

USE OF ANTIMICROBIALS

Because the graft is at times used in surgical fields where sterility cannot be assured, the use of antimicrobials is common practice and may prevent infectious complications.[1] In these cases both antibiotic prophylaxis of the patient and antimicrobial soaking of the graft have been used. Typical flora can be expected to include a variety of aerobic and facultative anaerobic organisms, including, but not limited to, *Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa, and Escherichia coli*. Therefore the following points should be considered:

- Antimicrobials, if used topically or systemically, should provide coverage against a wide spectrum of aerobic and anaerobic organisms.
- Antibacterial prophylaxis, if chosen, should be started prior to surgery and continued post-operatively.[1]

The presence of certain antimicrobials may inhibit revascularization and/ or infiltration of cells into the graft. For example, gentamicin is known to hinder neovascularization, epithelialization, and keratinocyte growth,[2-4] while povidone iodine,[5] bacitracin,[3,5] polymyxin B,[6] and vancomycin[7] have all been reported to slow or inhibit wound healing. However, no studies have been conducted to evaluate the combination of antimicrobials with the graft with respect to graft placement.

INSTRUCTIONS FOR USE

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

- Biodesign Duraplasty Graft is an onlay graft and does not require sutures.

NOTE: Always handle the graft using aseptic technique, minimizing contact with latex gloves.

REQUIRED MATERIALS

- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Rehydration fluid: at least 100 mL of sterile, room temperature, saline or sterile, room temperature lactated Ringer's solution for each graft sheet

1. Using aseptic technique, remove the graft inner pouch from its outer pouch, and place the inner pouch in the sterile field.
2. Open the inner pouch carefully, and aseptically remove the graft sheet with the sterile forceps.
3. Place the graft sheet into the sterile dish in the sterile field. (Multiple graft sheets may be rehydrated simultaneously in the same dish.)
4. Add to the dish at least 100 mL of the rehydration fluid for each graft sheet.
5. Allow graft sheets to rehydrate for at least two minutes.
6. Using aseptic technique, trim the graft sheet to fit the site, providing a small allowance for overlap.
   NOTE: An alternative method is to cut the graft sheet to size prior to rehydration. If this method is selected, be sure to rehydrate the graft sheet prior to fixing it into place. See step 5.
7. Using aseptic technique, transfer the graft sheet to the graft site and fix into place. Suturing is not required, but tensionless, atraumatic stay sutures may be used if desired.
   NOTE: Surgical experience indicates that fixing graft sheets with close tissue approximation produces better outcomes.
8. Complete the surgical procedure.
9. Closed suction wound drainage is recommended for 1-3 days postoperatively.
10. Discard any unused portions according to institutional guidelines for medical waste.

REFERENCES

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