Biodesign®

ENT REPAIR GRAFT

FP0089-01C

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

Manufacturer

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BIODESIGN® ENT REPAIR GRAFT

INTENDED USE

The Biodesign® ENT Repair Graft is intended to separate tissue or structures compromised by surgical trauma, help control minimal bleeding, and act as an adjunct to aid in the natural healing process. The device is indicated for use where an open wound dressing material is required in the nasal and/or sinus cavities following nasal and/or sinus surgery where separation of tissues or structures is desired.

The device is supplied sterile 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.

ENT REPAIR GRAFT This symbol means the following: ENT Repair Graft

This product is intended for use by trained medical professionals.

CONTRAINDICATIONS

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

COMPOSITION

Biodesign is an extracellular membrane derived from the Small Intestinal Submucosa (SIS) of pigs from qualified animal production facilities. SIS is obtained from the intestine using a process that retains the natural composition of matrix molecules such as collagen (Types I, III, VI), glycosaminoglycans (hyaluronic acid, chondroitin sulfate A and B, heparin, and heparan sulfate), proteoglycans, growth factors (FGF-2, TGF-β), and fibronectin.[1,2,3]

PROPERTIES

Biodesign adapts to the dimensions of the surgical site once hydrated. After hydration in the site, the material remains in place and is not disrupted by the closure of the surgical site. If desired, Biodesign can be fixated with a suture.

SAFETY

A viral inactivation study using the Biodesign ENT Repair Graft material demonstrated at least a 6.1-log reduction of the PrV virus, a 5.5-log reduction in Reo-3, 4.3-log reduction in A-MuLV and 3.6 log in PPV. This represented a reduction in viral burden to the level of detection in the test. Data were published in the peer reviewed article cited in the references.[4]

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.
- The graft should not be applied until excessive exudate, bleeding, acute swelling, and infection is controlled.
- Ensure that all layers of the graft are secured during fixation.

POTENTIAL COMPLICATIONS

The complications listed below are possible with the use of surgical graft materials in nasal/sinus surgery. If any of these conditions occur, the graft should be removed if possible. However, if graft removal is not possible due to graft incorporation, then appropriate care should be given to treat the complication.

- Infection/Toxic Shock Syndrome
- Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation)
- Allergic reaction
- Excessive redness, pain, swelling, or blistering

STORAGE

This graft should be stored in a clean, dry location at room temperature.

STERILIZATION

This graft has been sterilized with ethylene oxide.

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.

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

PREPARATION

1. Prepare the wound bed using standard methods to ensure it is free of exudate and devitalized tissue. An initial excision or debridement of the wound may be necessary to ensure the wound edges contain viable tissue.
2. Wait for any bleeding to be controlled before applying Biodesign.
3. Cleanse the wound thoroughly with sterile saline.

SELECTION

1. Cut the graft to a size and shape that will cover the entire wound surface and will extend slightly beyond the wound margins.

APPLICATION

1. For ease of handling, apply the graft by placing it in a dry state over the wound.
2. Position the dry graft to completely contact the entire surface of the wound bed and extend slightly beyond all wound margins. If multiple grafts are necessary to cover the wound, slightly overlap the edges of the grafts.
3. Thoroughly hydrate the graft by applying sterile saline.
4. As required, securely anchor the graft with physician's preferred fixation method (e.g., sutures, nasal packing, splinting or other appropriate method) based on the type of wound, location of wound, patient's mobility, and patient compliance.

ASSESSMENT

NOTE: If a gel forms on the wound surface, do not attempt to forcibly remove it. Successful absorption of Biodesign may form a caramel-colored or off-white gel. Do not remove this gel by debridement. This caramelization contains extracellular matrix (ECM), which continues to replace deficient and missing ECM in the wound.

1. As healing occurs, sections of Biodesign may gradually peel. Carefully remove any remaining loose product around the edge as needed.
2. Gently cleanse the wound surface with sterile saline; leave the ECM gel intact.
3. Carefully reassess the wound and record healing progression such as wound dimensions, wound depth, wound type, and other relevant information.

   NOTE: During follow-up screening or imaging, previously deployed Biodesign ENT Repair Graft should be considered in the differential diagnosis of clinical findings present in recurrent, new or persistent pathology. The literature has shown that the graft will be remodeled into patient tissue approximately 13 weeks after application.[5]

REFERENCES

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2. Hodde JP, Badylak SF, Brightman AO, et al. "Glycosaminoglycan Content of Small Intestinal Submucosa: A Bioscaffold for Tissue Replacement." Tissue Engineering, 1996; 2: 209-217.
3. Data on File, Cook Biotech, Inc.
4. Hodde J, Hiles M. Virus safety of a porcine-derived medical device: evaluation of a viral inactivation method. Biotechnol Bioeng. 2002; 79: 211-216.
5. Nevins M, Nevins M, Camelo J, Camelo M, Schupbach P, Kim D. The clinical efficacy of DynaMatrix extracellular membrane in augmenting Keratinized Tissue. International Journal of Periodontics & Restorative Dentistry. 2010; 30: 151-161.