Biodesign®

OTOLOGIC BUTTERFLY GRAFT

FP0172-01B

COOK® MEDICAL

LOT Batch code	MR Magnetic resonance safe
REF Catalogue number	Manufacturer
Consult instructions for use	MD Medical device
BIO Contains biological material of animal origin	Single sterile barrier with protective packaging inside
US Country of manufacture	STERILE EO Sterilized using ethylene oxide
Do not resterilize	UDI Unique device identifier
Do not re-use	Use-by date
Do not use if package is damaged and consult instructions for use	
Keep dry	

Manufacturer
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BIODESIGN® OTOLOGIC BUTTERFLY GRAFT

PRODUCT DESCRIPTION

The Biodesign® Otologic Butterfly Graft is a porous biomaterial composed of laminated extracellular collagen matrix derived from porcine small intestinal submucosa (SIS). SIS is obtained from the intestine using a process that retains the natural composition of matrix molecules such as collagen (types I, III, IV, VI), glycosaminoglycans (hyaluronic acid, chondroitin sulfate A and B, heparin, and heparin sulfate), proteoglycans, and fibronectin.[1,2,3]

INTENDED USE

The Biodesign Otologic Butterfly Graft is intended for use as an implant material to aid in the natural healing process in myringoplasty and tympanoplasty procedures.

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.

This product is intended for use by medical professionals trained in otologic procedures.

CONTRAINDICATIONS

The otologic butterfly graft is derived from a porcine source and should not be used in patients with known sensitivity to porcine materials.

GENERAL

Users should be familiar with the surgical technique for myringoplasty and tympanoplasty. The application section in this IFU provides a description of the implantation technique used in pre-clinical studies using animal and benchtop models following a trans-canal approach.

PRECAUTIONS

- Do not implant the device in the presence of an active infection.
- This device **has not been evaluated for use in pediatric populations.**
- The device **has not been studied in patients who have cholesteatoma or ossicular chain abnormalities.**
- This device **has not been studied in marginal perforations, perforations abutting the malleolus, or with defects that involve more than 50% of the tympanic membrane.**
- This device **has not been studied in** myringoplasty and tympanoplasty **procedures involving a canalectomy or lifting of the tympanomeatal flap.**
- This device **has only been studied in** myringoplasty and tympanoplasty **procedures using a trans-canal approach.**
- This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse the device may lead to device failure and/or transmission of disease.
- **Do not resterilize.** Discard all open and unused portions of the device.
- The device is sterile if the package is dry, unopened, and undamaged. Do not use if the package seal is broken.
- Discard the device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Open the tray packaging carefully to ensure that the device remains seated in the tray.
- **Discard the device if it has been removed from the tympanic membrane perforation. Removal may cause the overlay (cross) and underlay (circle) to separate.**
- After placement of the device, pack the ear canal with non-adherent dressings while avoiding excessive pressure.

POTENTIAL COMPLICATIONS

The following complications are possible with the use of surgical device materials in otologic procedures:

- Abscess formation
- Allergic reaction
- Calcification
- Cholesteatoma
- Discharge
- Excessive redness, pain, swelling, or blistering
- Fever
- Infection
- Inflammation
- Mastoiditis
- Migration
- Persistence of perforation
- Recurrence
- Reduced Hearing
- Retraction pockets
- Seroma
- Squamous cysts
- Thickening of the tympanic membrane

STORAGE

Store the device in a clean, dry location at room temperature.

STERILIZATION

This device has been sterilized with ethylene oxide.

INSTRUCTIONS FOR USE

Required Materials

- Sterile basin
- Sterile alligator forceps
- Sterile House-Rosen needle, probe, or other appropriate instrument
- Hydration fluid: sterile room-temperature saline solution or sterile lactated Ringer's solution

NOTE: Handle the device using aseptic technique, minimizing contact with latex gloves.

The following implantation technique was used in pre-clinical studies in animal and benchtop models using a trans-canal approach.

PREPARATION

1. Prepare the tympanic membrane repair site using standard surgical techniques. Ensure that the area is free of exudate and devitalized tissue. Initial site excision or debridement may be necessary to ensure the defect edges contain viable tissue.
2. Control bleeding prior to implanting the device.

SELECTION

3. Choose the device size based on the size of the defect, ensuring the underlay (circle) portion of the device covers the entire defect area and extends slightly beyond the defect margins. Pre-clinical testing in animal models used a total overlap of 1mm of viable tissue (4mm device for a 3mm defect, etc.)
4. Aseptically remove the device from the packaging.

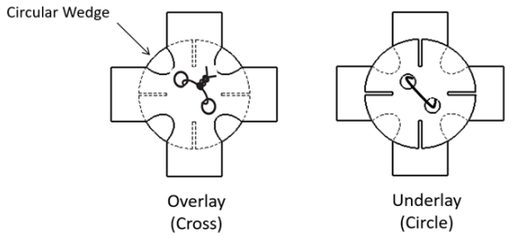

Figure 1. Device diagram

APPLICATION

5. Hydrate the device in hydration fluid for no longer than 1 minute.
6. Using alligator forceps, deliver the device to the defect location with the underlay (round) component facing the lateral TM surface. The procedure should not be performed starting with the overlay (cross) facing the lateral TM surface.
7. Place the device centrally over the defect and verify that the underlay (circle) side extends beyond the defect margins by at least ½ mm. Reposition the device as necessary.

NOTE: Centering the overlay (cross) over the perforation may ease implantation.

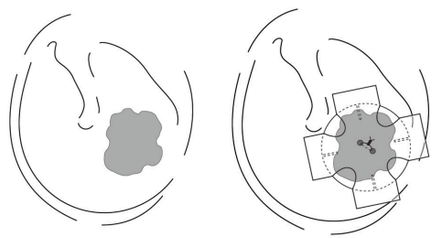

Figure 2: Perforated tympanic membrane (left). Device placed with the underlay (circle) fully covering defect (right)

8. Using a House-Rosen needle, probe, or other appropriate instrument, push the underlay (circle) down through the defect using gentle pressure through each of the four circular wedge gaps in the overlay (cross). Tuck each quadrant of the underlay (circle) through the defect to the medial side of the tympanic membrane.

NOTE: Rotating the overlay (cross) may increase the contact of the underlay (circle) with the medial tympanic membrane surface.

NOTE: If the device has been removed from perforation during or after this step, discard and get a new device.

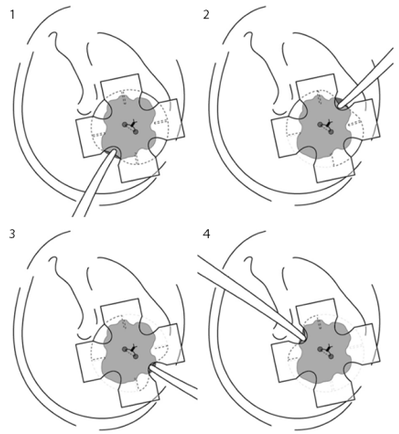

Figure 3. Using House-Rosen needle to tuck underlay quadrants through the tympanic membrane defect

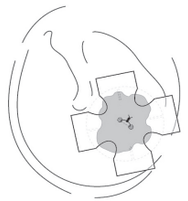

Figure 4. Fully implanted device with all four wedges underlay quadrants contacting the medial tympanic membrane surface

9. Complete the surgical procedure.
10. Pack the ear canal with non-adherent antibiotic-soaked gel sponge dressings while avoiding excessive pressure.
11. Discard any unused portions of the device according to institutional guidelines for medical waste.

POSTOPERATIVE CARE

To provide the best environment for tissue integration, provide the patient with a list of standard post-procedure recommendations. The following should be considered:

- Continued daily use of antibiotic drops for up to two weeks following the procedure.
- Avoid submerging the surgical site in water for 3 weeks.
- Avoid exposing the surgical site to rapid changes in pressure for 4 to 6 weeks (e.g., loud music, diving, or flying).

REASSESSMENT

NOTE: Successful integration of the otologic butterfly graft may result in the formation of a caramel-colored or off-white gel. DO NOT REMOVE THIS GEL BY DEBRIDEMENT. This gel/slough is part of the wound healing process and will eventually resolve without intervention.

1. As healing occurs, the overlay (cross) of the device should naturally detach from the lateral tympanic membrane surface into the external auditory canal. Do not manipulate or forcibly remove any portion of the overlay (cross) until it has completely detached from the lateral surface of the tympanic membrane. Do not disturb the underlay (circle) at any point during the healing process.
2. Gently cleanse the defect site with sterile saline; leave the ECM gel intact.
3. Carefully reassess the defect and record healing progression and other relevant information.

REFERENCES

1. Hodde J, Janis A, Ernst D, Zopf D, Sherman D, Johnson C. Effects of sterilization on an extracellular matrix scaffold: Part I. Composition and matrix architecture. *J Mater Sci Mater Med.* 2007;18(4):537-543.
2. Hodde JP, Badylak SF, Brightman AO, Voytik-Harbin SL. Glycosaminoglycan content of small intestinal submucosa: A bioscaffold for tissue replacement. *Tissue Eng.* 1996;2(3):209-217.
3. Data on file, Cook Biotech Incorporated.