

Harvest **results**,
not patient tissue.¹

Biodesign[®]
OTOLOGIC REPAIR GRAFT



COOK[®]
MEDICAL

The Biodesign Otologic Repair Graft enables a truly minimally invasive approach to ear surgery with no donor site required and, therefore, no additional scar for the patient.⁶

RELIABLE CLOSURE



Biodesign material remodels into natural host tissue with an overall success rate of 91% across published literature¹⁻⁹ and no statistically significant difference in audiometric results when compared to temporalis fascia.^{1, 10}

EXCELLENT HANDLING



Biodesign material is easy to manipulate, allowing for improved surgical precision during graft placement.¹

TIME SAVING

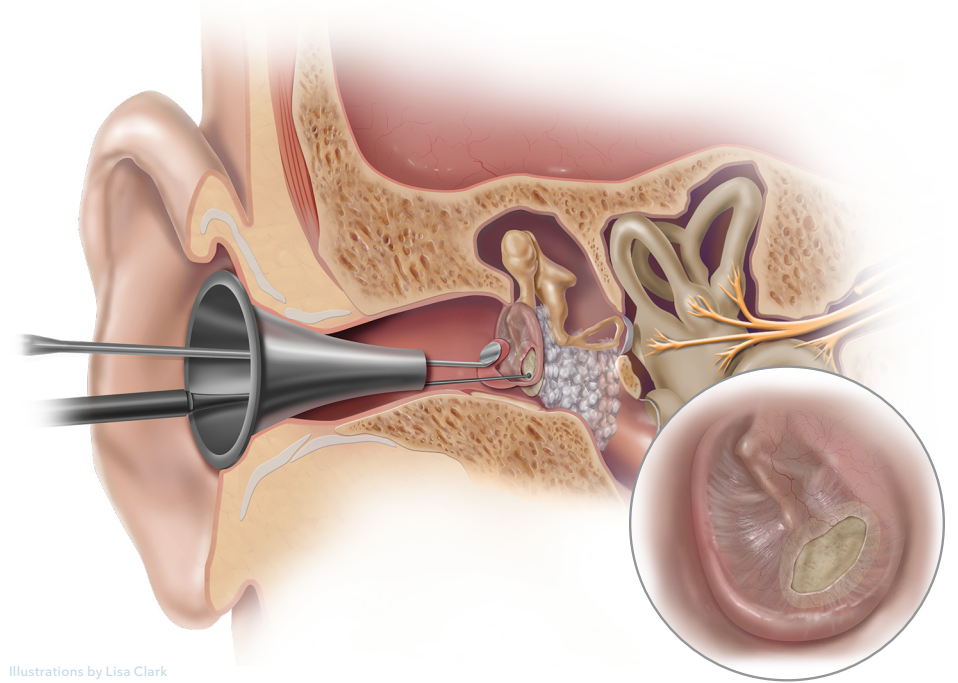


The Biodesign Otologic Repair Graft reduces the need to harvest autologous tissue, significantly decreasing intraoperative time.¹

Biodesign®

OTOLOGIC REPAIR GRAFT

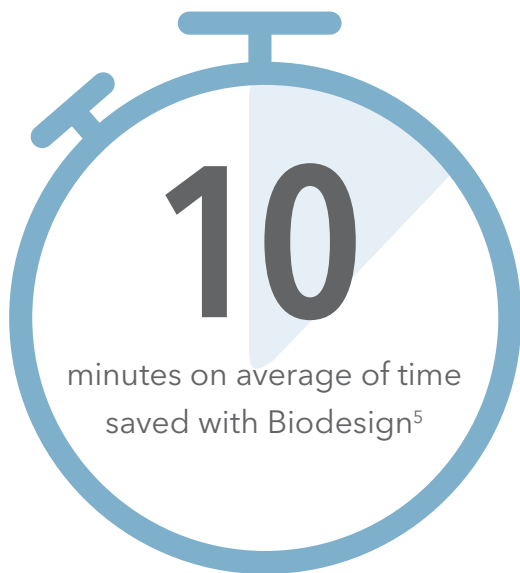
The Biodesign Otologic Repair Graft is an implantable biomaterial that aids in the natural healing process in various otologic procedures including, but not limited to, myringoplasty and tympanoplasty.



Illustrations by Lisa Clark

Time savings

The Biodesign Otologic Repair Graft reduces the need to harvest patient tissue, resulting in an average of 10 minutes of time saved per procedure.⁵



Tips to help get the best possible results:



The graft may be cut to size when it is hydrated.



The underlay technique has been proven to be successful.¹



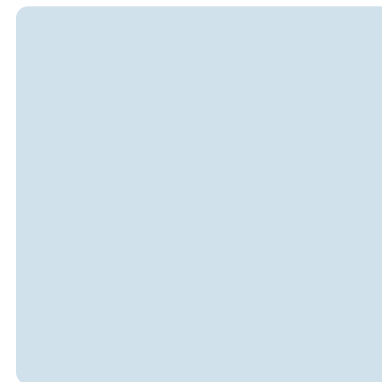
Place the graft dry or hydrate it no longer than one minute prior to placement.

Excellent handling

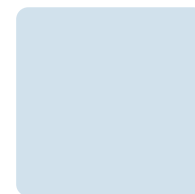
Biodesign material is easy to manipulate, allowing for improved precision during graft placement.¹ The convenient sizing and packaging help simplify repairs. It comes with a case and circular size options, or square sheet sizes that can be cut to a preferred size and shape.

Available product sizes

Shown at actual size.



50 x 50 mm



25 x 25 mm



9 mm



6 mm



4 mm

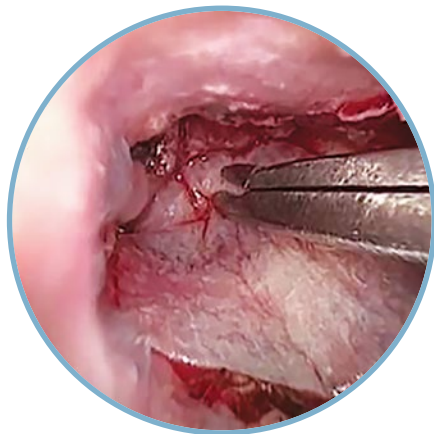


RELIABLE CLOSURE

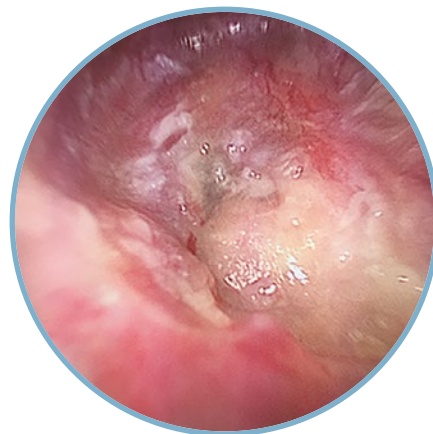
THE BIODESIGN OTOLOGIC REPAIR GRAFT CLOSES THE PERFORATION

with neovascularization and avoids additional comorbidities and scarring associated with the harvest of patient tissue.¹

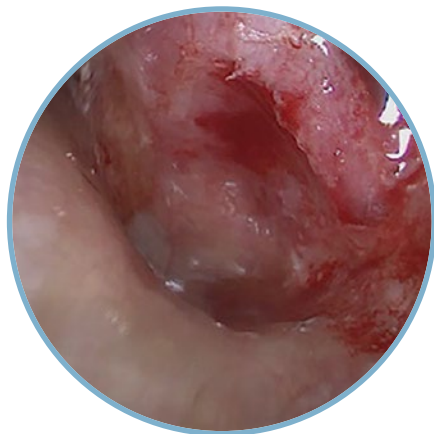
91%
success rate
across published
literature.¹⁻⁹



Placement of a Biodesign graft



15 days post-op



40 days post-op

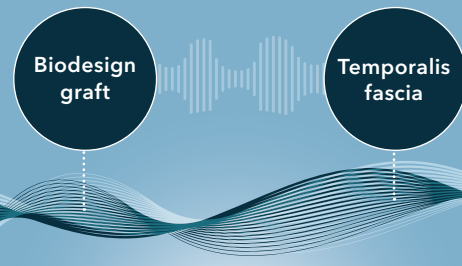


60 days post-op

Images courtesy of Dr. Giuseppe Panetti,
Ascalesi Hospital-ASL, Napoli, Italy.

AUDIOMETRIC RESULTS

ABG, PTA, air-to-air*



NO STATISTICALLY
SIGNIFICANT
DIFFERENCE

($p=0.7$) WHEN **COMPARED TO**

TEMPORALIS FASCIA¹

*Audiometric tests include air-bone gap (ABG), pure tone averages (PTA), and air-to-air thresholds.

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2. Cass ND, Hebbe AL, Meier MR. et al. Pediatric primary tympanoplasty outcomes with autologous and non-autologous grafts. *Otol Neurotol.* 2022;43(1):94-100.
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8. Wang N, Isaacson G. Collagen matrix as a replacement for Gelfilm for post-tympanostomy tube myringoplasty. *Int J Pediatr Otorhinolaryngol.* 2020;135:110136.
9. Yawn RJ, Dedmon MM, O'Connel BP, et al. Tympanic membrane perforation repair using porcine small intestinal submucosal grafting. *Otol Neurotol.* 2018;39(5):e332-e335.
10. Dontu P, Shaigany K, Eisenman DJ. Anatomic and audiometric outcomes of porcine intestinal submucosa for tympanic membrane repair. *Laryngoscope Investig Otolaryngol.* 2022;7(6):2069-2075.

Biodesign® Otologic Repair Graft

INTENDED USE: The Cook® Biodesign® Otologic Repair Graft is intended for use as an implant material to aid in surgical repairs and as an adjunct to aid in the natural healing process in various otologic procedures, including but not limited to myringoplasty and tympanoplasty. 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 trained medical professionals.** **OTOLOGIC REPAIR GRAFT** This symbol means the following: Otologic Repair Graft

CONTRAINDICATIONS: This device is derived from a porcine source and should not be used for 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 device. • The device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken. • Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date. • Avoid packing external canal with adherent dressings or applying excessive pressure in the ear canal. • Please take care when opening tray packaging to ensure that device remains seated in the tray.

POTENTIAL COMPLICATIONS: The following complications are possible with the use of surgical device materials in otologic procedures: • Abscess formation • Allergic reaction • Calcification • Cholesteatoma • Excessive redness, pain, swelling, or blistering • Fever • Infection • Inflammation (initial application of surgical device materials may be associated with transient, mild, localized inflammation) • Mastoiditis • Migration • Persistence of perforation • Recurrence • Retraction pockets • Seroma • Squamous cysts • Thickening of the tympanic membrane

See instructions for use for full product information.

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