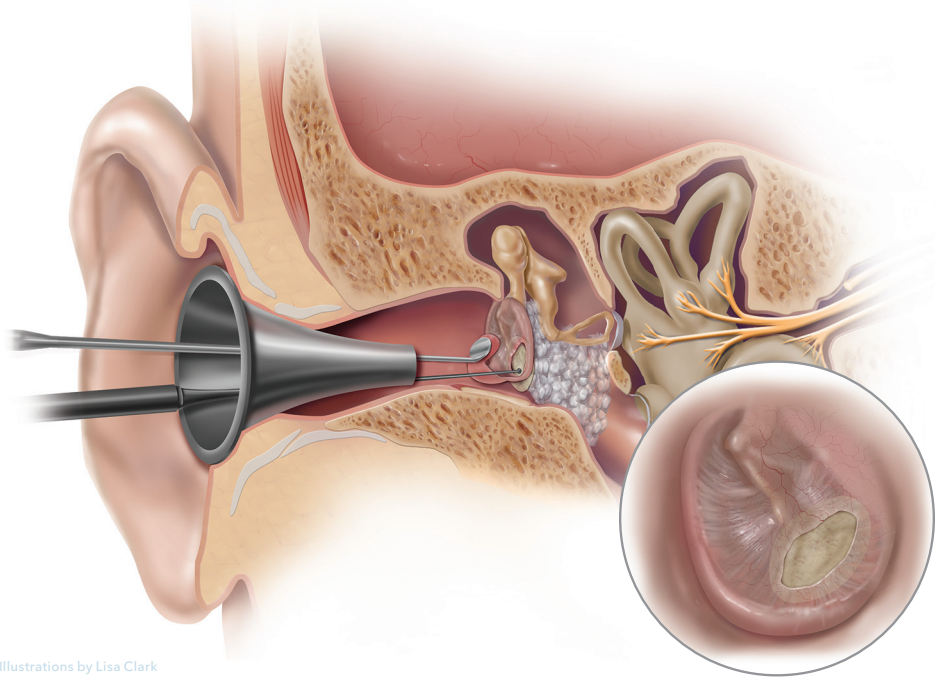
Harvest *results*, not patient tissue.[1]

Biodesign® Otologic Repair Graft

COOK® MEDICAL

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

The Biodesign Otologic Repair Graft enables a truly minimally invasive approach to ear surgery with no donor site required and thus, no additional scar for the patient.[2]

RELIABLE CLOSURE

The Biodesign Otologic Repair Graft completely remodels into natural host tissue, resulting in closure rates ranging from 83%–100% across published literature .[1–3]

EXCELLENT HANDLING

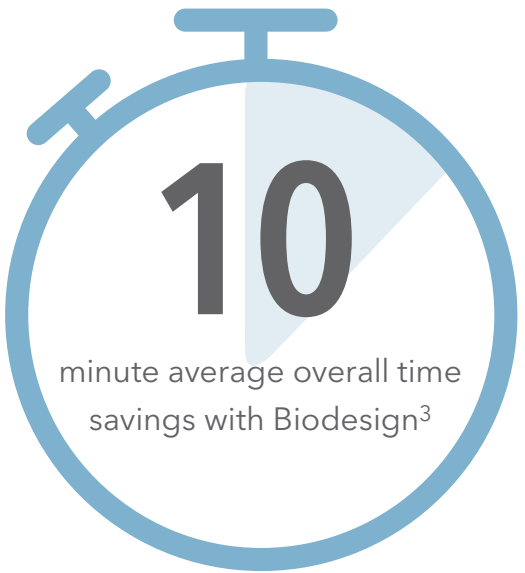
Biodesign material is easy to manipulate, allowing for improved surgical precision during graft placement.[2]

TIME SAVING

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

Time Saving

The Biodesign Otologic Repair Graft reduces the need to harvest patient tissue, resulting in an average of 10 minutes of time savings per procedure.[3]



Tips to help get the best possible results:

Graft may be cut to size when hydrated.

Underlay technique has been proven to be successful.[1]

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

Excellent Handling

Biodesign material is easy to manipulate, allowing for improved precision during graft placement.[4] The convenient sizing and packaging help simplify repairs. It comes with an optional hydration case, circular size options, and square sheet sizes that can be cut to a preferred size and shape.

Available product sizes

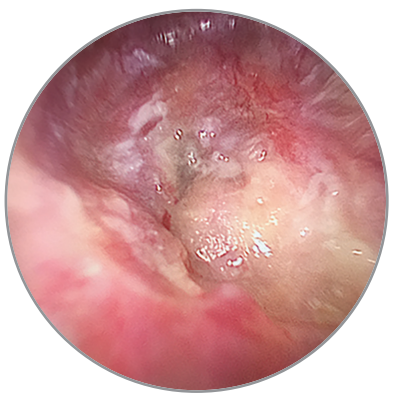
Shown at actual size.

Reliable Closure

The Biodesign Otologic Repair Graft offers a complete closure with neovascularization and avoids additional comorbidities and scarring associated with the harvest of patient tissue.[1]

Closure rates are comparable to temporalis fascia, ranging from **83%–100%** across published literature.[1-3]

Placement of a Biodesign graft



15 days post-op

40 days post-op

60 days post-op

Images of endoscopic tympanoplasty provided by Dott. Giuseppe Panetti, December 2014, Ascalesi Hospital-ASL Napoli.

References

1. D'Eredità R. Porcine small intestinal submucosa (SIS) myringoplasty in children: a randomized controlled study. *Int J Pediatr Otorhinolaryngol*. 2015;79(7):1085-1089.

2. James AL. Endoscope or microscope-guided pediatric tympanoplasty? Comparison of grafting technique and outcome. Laryngoscope. 2017;127(11):2659-2664.

3. De Zinis LO, Berlucchi M, Nassif N. Double-handed endoscopic myringoplasty with a holding system in children: preliminary observations. *Int J Pediatr Otorhinolaryngol*. 2017; 96:127-130.

4. Spiegel JH, Kessler JL. Tympanic membrane perforation repair with acellular porcine submucosa. *Otol Neurotol*. 2005;26(4):563-566.

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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