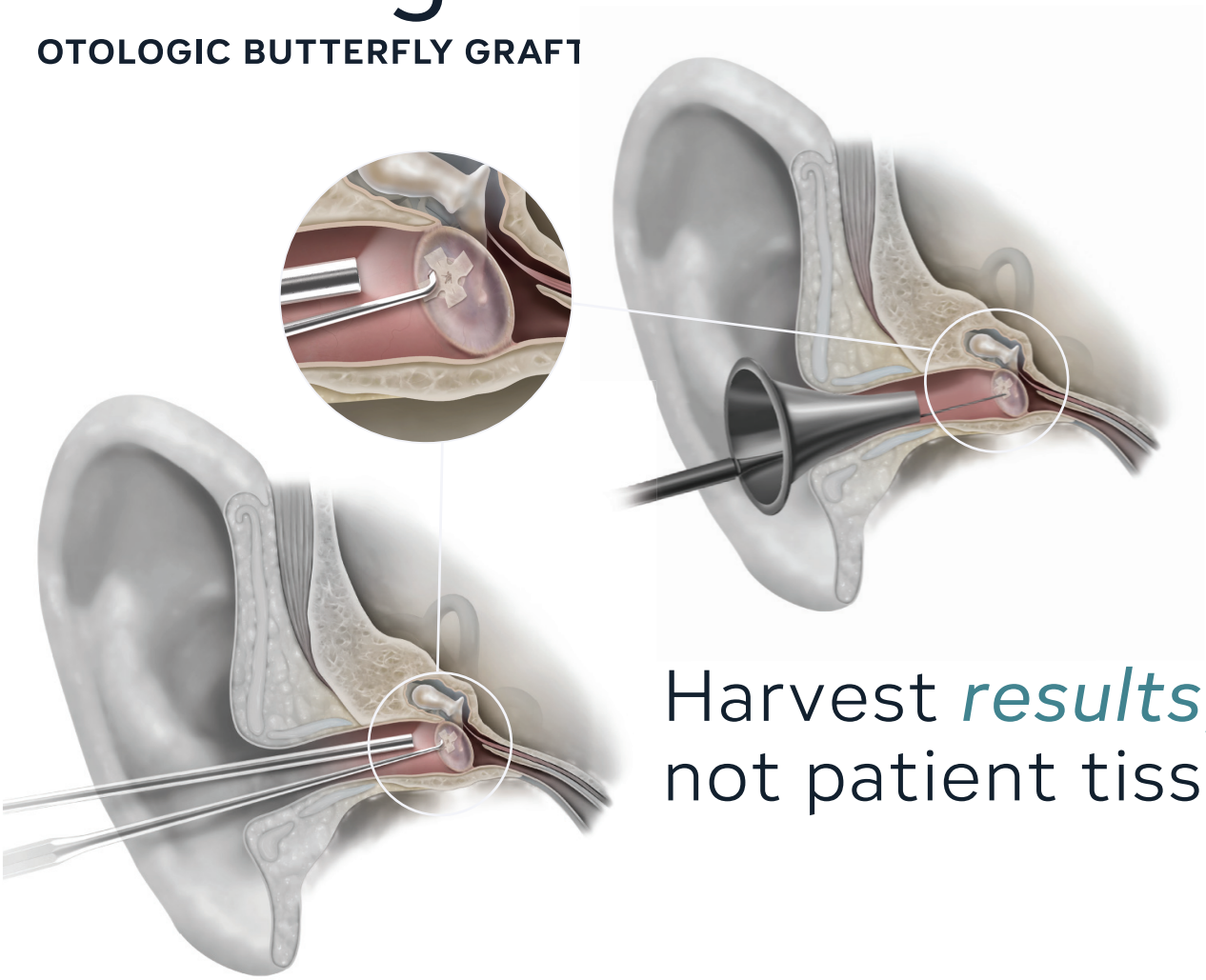
Biodesign®

OTOLOGIC BUTTERFLY GRAFT



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

A transformative approach to traditional butterfly graft tympanic membrane repair[1,2]

Reliable Closure

Biodesign® material remodels into natural host tissue with an overall success rate of 91% across published literature[3-11] with no statistically significant difference in audiometric results when compared to temporalis fascia.[3, 12]

Excellent Handling

Biodesign® material is easy to manipulate, allowing for improved surgical precision during graft placement.[3]

Time Saving

The Biodesign® material reduces the need to harvest autologous tissue, significantly decreasing intraoperative time.[3]

PROCEDURE VIDEO

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Biodesign® Otologic Butterfly Graft

Order Number	Reference Part Number	Size cm	Nominal Thickness mm
G60285	ENT-OTO-BFLY-0.4-0.6	0.4, 0.6	0.25

Available product sizes

Shown at actual size.

Tips to help get the best possible results:

- Ensure adequate blood supply.
- Size the graft to allow some tissue overlap.
- Place the graft dry or hydrate it for less than one minute before placement.

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.

CONTRAINDICATIONS:
The device is derived from a porcine source and should not be used for patients with known sensitivity to porcine materials.

PRECAUTIONS: This device has only been studied in the indicated procedures using a trans canal approach in defects in the center of the tympanic membrane with no anatomical complications • Do not implant the device in the presence of an active infection • This device is designed for single use. Do not reprocess, resterilize, and/or reuse the device • Open the tray packaging carefully to ensure that the device remains seated in the tray • Discard the device if it has been implanted and removed. • After placement, pack ear canal with non-adherent dressings avoiding excessive pressure.

POTENTIAL COMPLICATIONS: Complications that can occur with the use of surgical device materials in otologic procedures may include, but are not limited to: • 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

VULNERABLE POPULATIONS: Safety data for this device has been collected in otherwise healthy populations. While no specific risks have been identified in vulnerable groups (e.g., patients with complex comorbidities or pregnancy), data in these populations is limited. Use in such cases should be guided by clinical judgment, including consultation with relevant specialists when appropriate.

References

1. Internal white paper; "Evaluation of industry opinion on endoscopic transcanal TM repair as a conservative and minimally invasive procedure". Available on request.
2. https://www.accessdata.fda.gov/cdrh_docs/pdf23/K232646.pdf; Published K232646 510k summary describing device usability testing data in benchtop and animal models following an endoscopic transcanal approach.
3. D'Eredità R. Porcine small intestinal submucosa (SIS) myringoplasty in children: a randomized controlled study. *Int J Pediatr Otorhinolaryngol*. 2015;79(7):1085-1089.
4. 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.
5. Chen CK, Hsieh LC. Clinical outcome of exclusive endoscopic tympanoplasty with porcine small intestine submucosa in 72 patients. *Clin Otolaryngol*. 2020;45(6):938-943.
6. Barron C, Lukens J, Niermeyer W, et al. Investigation of novel grafts in use for pediatric tympanoplasty. *Ann Otol Rhinol Laryngol*. 2019;128(12):1111–1115.
7. Redaelli 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.
8. James AL. Endoscope or microscope-guided pediatric tympanoplasty? Comparison of grafting technique and outcome. *Laryngoscope*. 2017;127(11):2659-2664.
9. Ranguis SC, Leonard CG, James AL. Prospective comparison of pediatric endoscopic lateral graft and interlay tympanoplasty. *Otol Neurotol*. 2021;42(6):867-875.
10. Wang N, Isaacson G. Collagen matrix as a replacement for Gelfilm for post-tympanostomy tube myringoplasty. *Int J Pediatr Otorhinolaryngol*. 2020;135:110136.
11. 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.
12. Dontu P, Shaigany K, Eisenman DJ. Anatomic and audiometric outcomes of porcine intestinal submucosa for tympanic membrane repair. Laryngoscope Investig Otolaryngol 2022;7:2069-2075.

Manufactured by Cook Biotech Incorporated.

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Printed in U.S.A.
DOC-6851 Rev 2

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