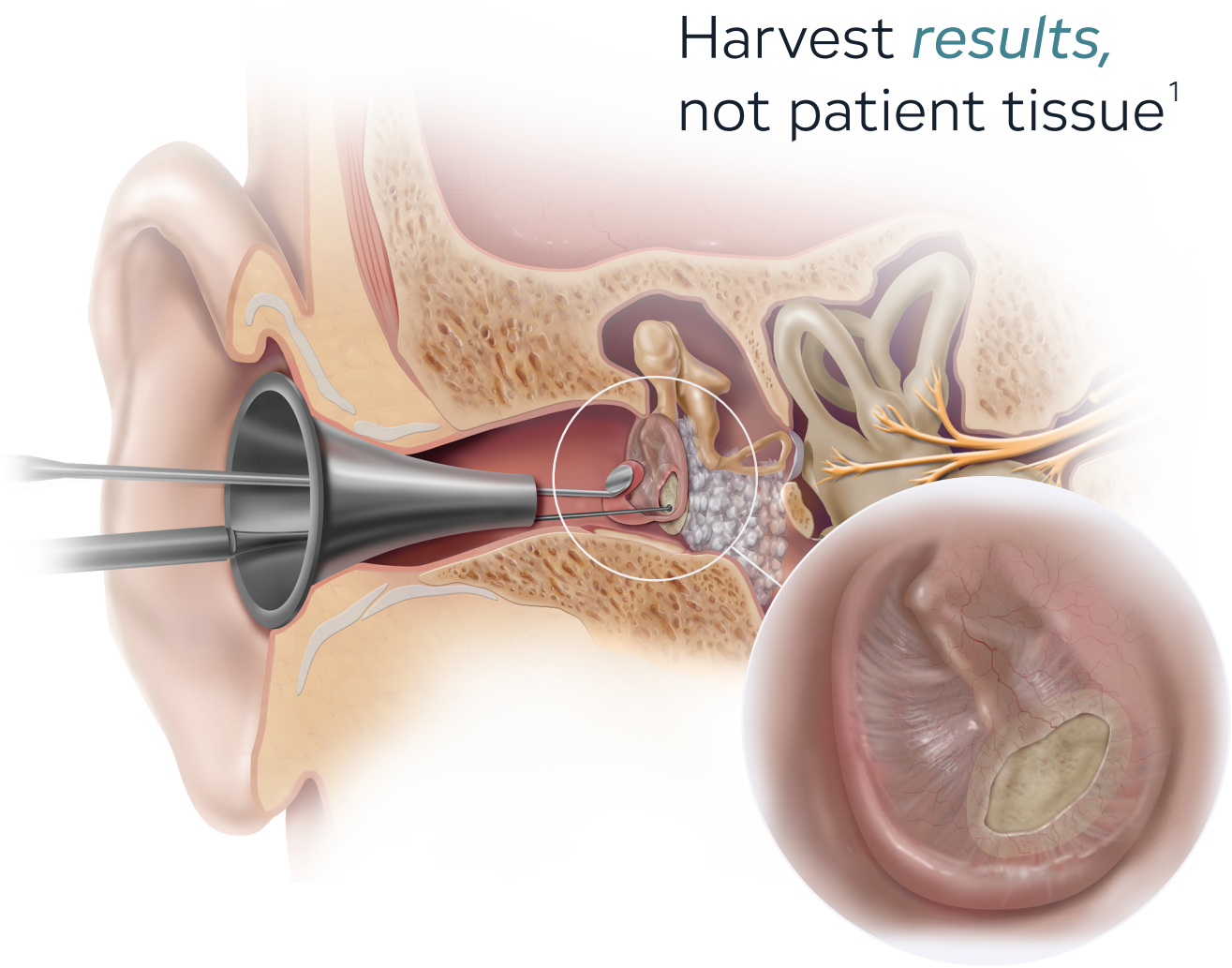
Biodesign®

OTOLOGIC REPAIR GRAFT

Harvest *results,*
not patient tissue[1]



Reliable Closure

Biodesign® material remodels into natural host tissue with an overall success rate of 91% across published literature[1-9] with 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]

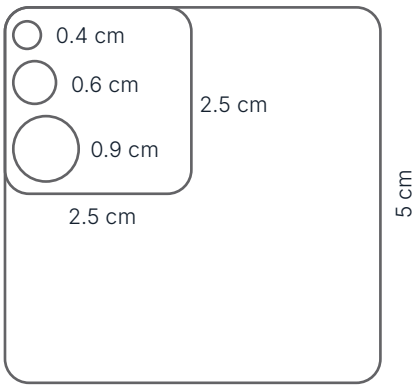
Time Saving

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

Everis™

Available product sizes

Shown at actual size.



Biodesign® Otologic Repair Graft

Order Number	Reference Part Number	Size cm	Nominal Thickness mm
G44840	ENT-OTO-0.4-0.6	0.4, 0.6	0.25
G44839	ENT-OTO-0.6-0.9	0.6, 0.9	0.25
G44451	ENT-OTO-2.5X2.5	2.5 x 2.5	0.25
G44452	ENT-OTO-5X5	5.0 x 5.0	0.25

INTENDED USE:
The 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.

CONTRAINDICATIONS:
The device should not be used for patients with known sensitivity to porcine material.

PRECAUTIONS: This device is designed for single use only, do not reprocess, resterilize, and/or reuse • 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: 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 • excessive redness, pain, swelling, or blistering • fever • infection • inflammation (initial application of 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

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

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Manufactured by Cook Biotech Incorporated.

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