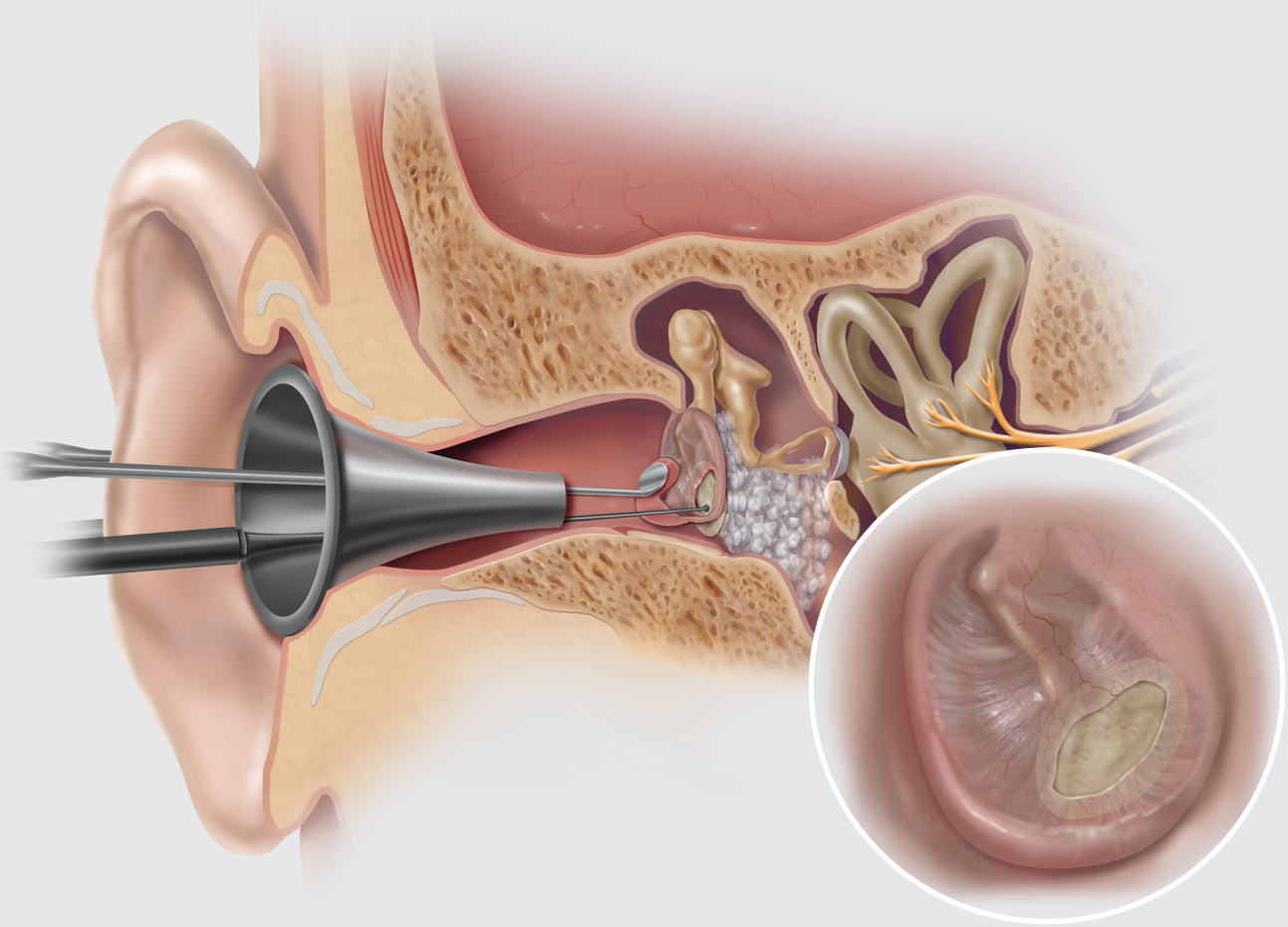
Harvest *results*, not patient tissue.[1]



Biodesign®
OTOLOGIC REPAIR GRAFT

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]

C2Dx®

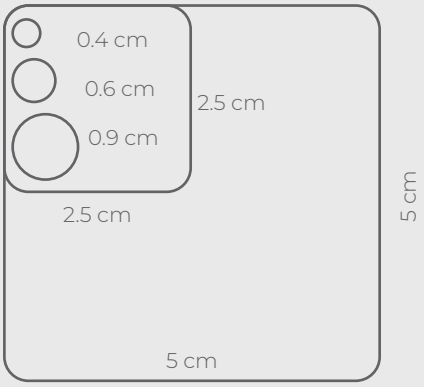
Biodesign®
OTOLOGIC REPAIR GRAFT

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.

Available product sizes

Shown at actual size.



Order Number	Reference Part Number	Size cm	Nominal Thickness mm
Biodesign Otologic Repair Graft			
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

Some products or part numbers may not be available in all markets. Contact your local C2Dx representative or Customer Support for details.

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.

AB_FP0108-01_REV3

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