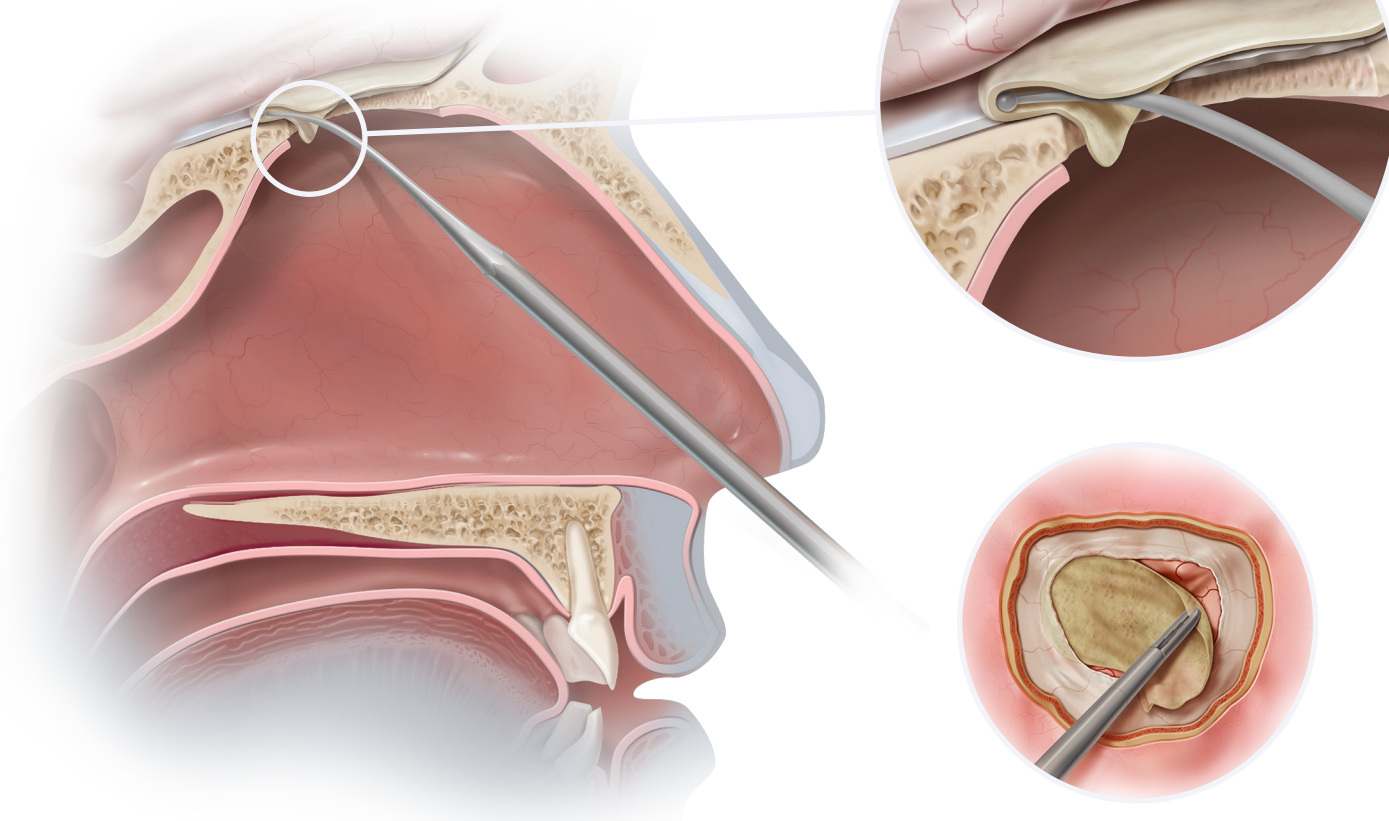


Biodesign[®]

DURAPLASTY GRAFT

Handle with ease,
repair with *confidence*¹



Strong Seal

The Biodesign[®] Duraplasty Graft is remodeled into natural host tissue, resulting in a post-op leak rate as low as 1.7% and has been demonstrated in animals to be non-discernible by day 28.^{1,2}

Excellent Handling

Biodesign[®] material is easy to manipulate, doesn't swell with hydration, and doesn't adhere to itself when folded.³

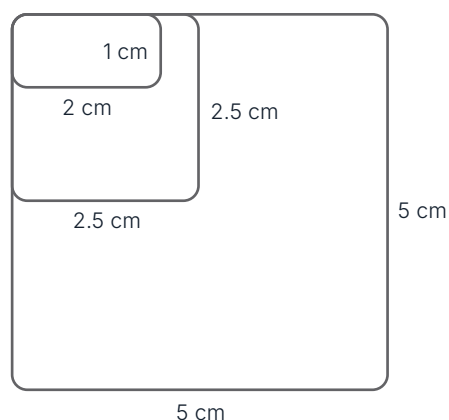
Sutured/Sutureless Fixation

The Biodesign[®] Duraplasty Graft can be secured in place with or without sutures, depending on clinician preference.

Available product sizes

Shown at actual size.

(Also available in 7 x 8.5 cm)



Biodesign® Duraplasty Graft

Order Number	Reference Part Number	Size cm	Nominal Thickness mm
G34977	ENT-CBD-1X2	1 x 2	0.25
G34978	ENT-CBD-2.5X2.5	2.5 x 2.5	0.25
G34979	ENT-CBD-5X5	5 x 5	0.25
G34980	ENT-CBD-7X8.5	7 x 8.5	0.25

Tips to help get the best possible results:

- Ensure adequate blood supply.
- Size the graft to allow some tissue overlap.
- Hydrate the graft for at least two minutes before placement.

INTENDED USE:

The Biodesign Duraplasty Graft is intended for use as a dura substitute for the repair of dura mater. This graft is supplied sterile in peel-open packages and intended for one-time use.

CONTRAINDICATIONS:

- Do not use in patients with a known sensitivity to porcine materials.
- Not for repair of spinal neural tube defects.
- Not for anterior spinal surgery with dural resection.
- Use with caution in infected regions.
- Covering defects involving mastoid cells is not recommended
- Not recommended for repair of large defects at the skull base following surgery; however, the graft may be used to augment other forms of specific repair.

PRECAUTIONS: In skull base repair procedures, the graft should not replace standard layering techniques or be implanted as a stand-alone repair • The graft is for single use only. Do not reprocess, resterilize, and/or reuse • If the graft is to be sutured, tensionless suturing technique is recommended • The trimmed graft should ensure an overlap to cover the existing dura • Ensure that all layers of the graft are secured if suturing the graft into place.

POTENTIAL COMPLICATIONS: Complications that can occur with the use of surgical graft materials in neurosurgical procedures may include, but are not limited to: • adhesion • allergic reaction • calcification • CSF leak • delayed hemorrhage • infection • inflammation

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. Bejjani GK, Zabramski J; Durasis Study Group. Safety and efficacy of the porcine small intestinal submucosa dural substitute: results of a prospective multicenter study and literature review. *J Neurosurg.* 2007;106(6):1028-1033.
2. Cobb MA, Badyalak SF, Janas W, Boop FA. Histology after dural grafting with small intestinal submucosa. *Surg Neurol* 1996;46:389-394
3. Illing E, Chaaban MR, Riley KO, Woodworth BA. Porcine small intestine submucosal graft for endoscopic skull base reconstruction. *Int Forum Allergy Rhinol.* 2013;3(11):928-932.

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