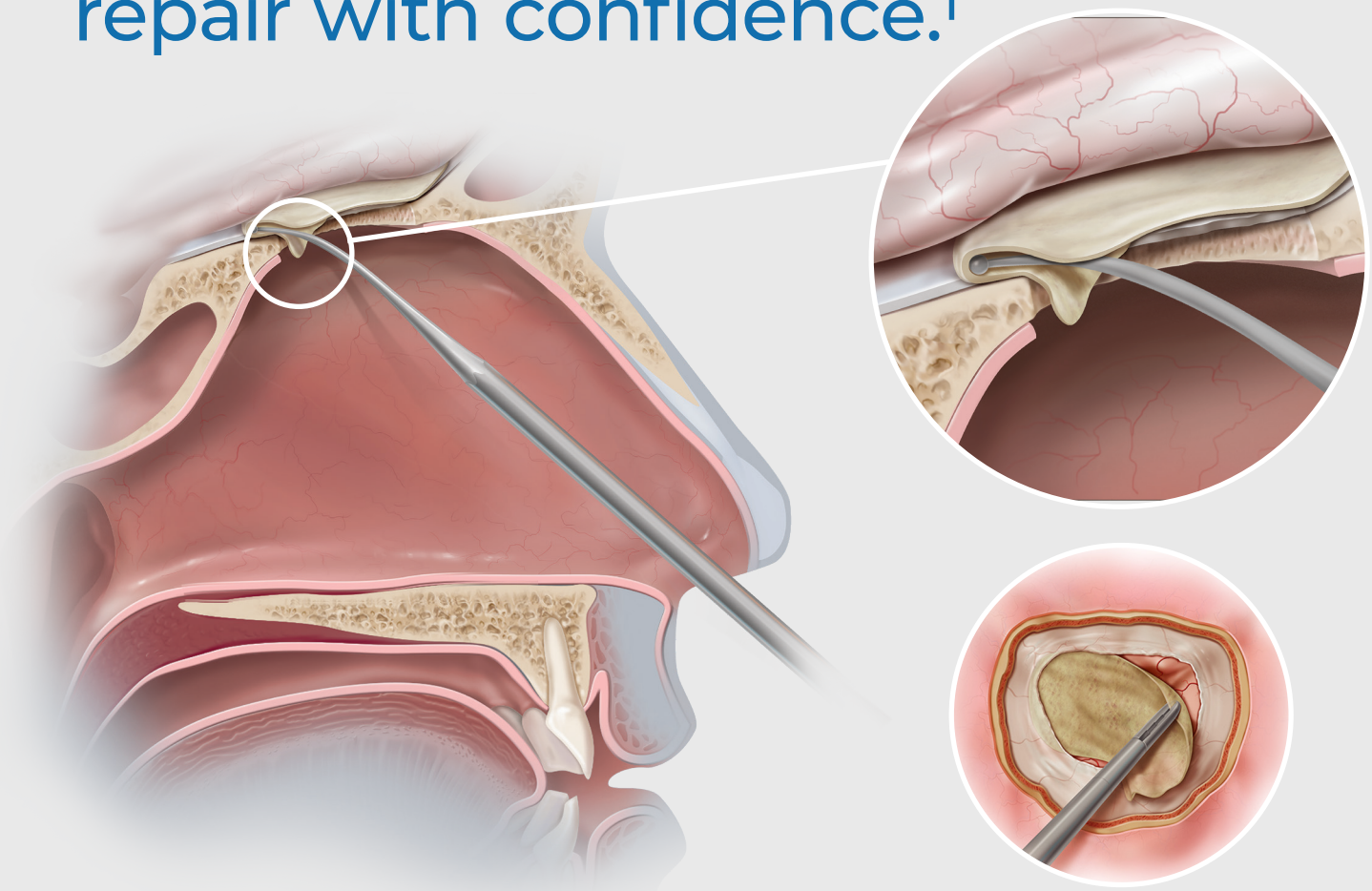
Handle with ease, repair with confidence.[1]



Biodesign®
DURAPLASTY GRAFT

Strong seal

The Biodesign Duraplasty Graft is completely remodeled into natural host tissue, resulting in a post-op leak rate as low as 1.7%.[1]

Excellent handling

Biodesign material is easy to manipulate, doesn't swell with hydration, and doesn't fold onto itself.[2]

Sutured/Sutureless fixation

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

C2Dx®

Biodesign®

DURAPLASTY GRAFT

Tips to help get the best possible results:

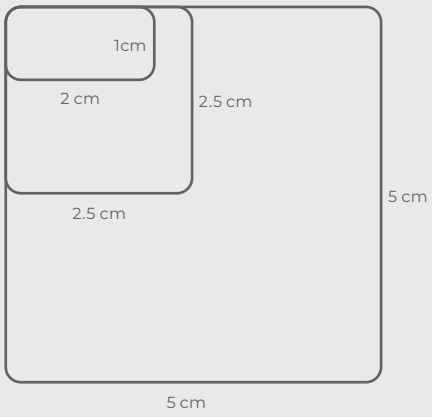
- Ensure adequate blood supply.
- Size the graft to allow some tissue overlap.
- Hydrate the graft for at least two minutes before placement.

Order Number	Reference Part Number	Size cm	Nominal Thickness mm
Biodesign Duraplasty Graft			
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

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

Available product sizes

Shown at actual size.
(Also available in 7 x 8.5 cm.)



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. 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.

Biodesign® Duraplasty Graft

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 is intended for one-time use. 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 symbol means the following: Duraplasty Graft. This product is intended for use by trained medical professionals.

CONTRAINDICATIONS: The Biodesign Duraplasty Graft is not designed, sold or intended for use except as described in the indications for use and is contraindicated: • For use in patients with a known history of hypersensitivity to porcine derived materials; • For repair of spinal neural tube defects; and • For anterior spinal surgery with dural resection (e.g. transoral surgery). Additionally: • Use with caution in infected regions. • It is not recommended to cover defects involving mastoid cells. • It is not recommended for large defects at the skull base following surgery; however the Biodesign Duraplasty Graft may be used to augment other forms of specific repair (e.g. pedicled flaps or vascularized pedicled flaps).

PRECAUTIONS: The Biodesign Duraplasty Graft is designed to augment skull base repair where layering techniques such as bony buttressing, pedicled flaps or vascularized pedicled flaps and packing are currently used. The graft should not replace standard layering techniques or be implanted as a stand-alone repair. • Peer reviewed literature has reported the use of this material as a dural substitute at the skull base in defects up to 4.5 cm^2. • 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 use if the product package is damaged or opened. • Discard graft if damage or contamination is observed, or if the graft is past its expiration date. • Prior to touching the graft, wash surgical gloves thoroughly to remove the glove powder. • Ensure that graft sterility is maintained during preparation and implantation at repair site. • Suturing is not required but if the graft is to be sutured, tensionless suturing technique must be used. • Discard all open and unused portions of the graft sheets. • The graft should be cut to size ensuring an overlap to cover the existing dura. • Ensure that graft is rehydrated and all layers of the graft are secured if fixation with suture is employed.

POTENTIAL COMPLICATIONS: The following complications are possible with the use of surgical graft materials in neurosurgical procedures. • Infection, adhesion, CSF leak, delayed hemorrhage and calcification • Acute or chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation.) • Allergic reaction

See instructions for use for full product information.

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