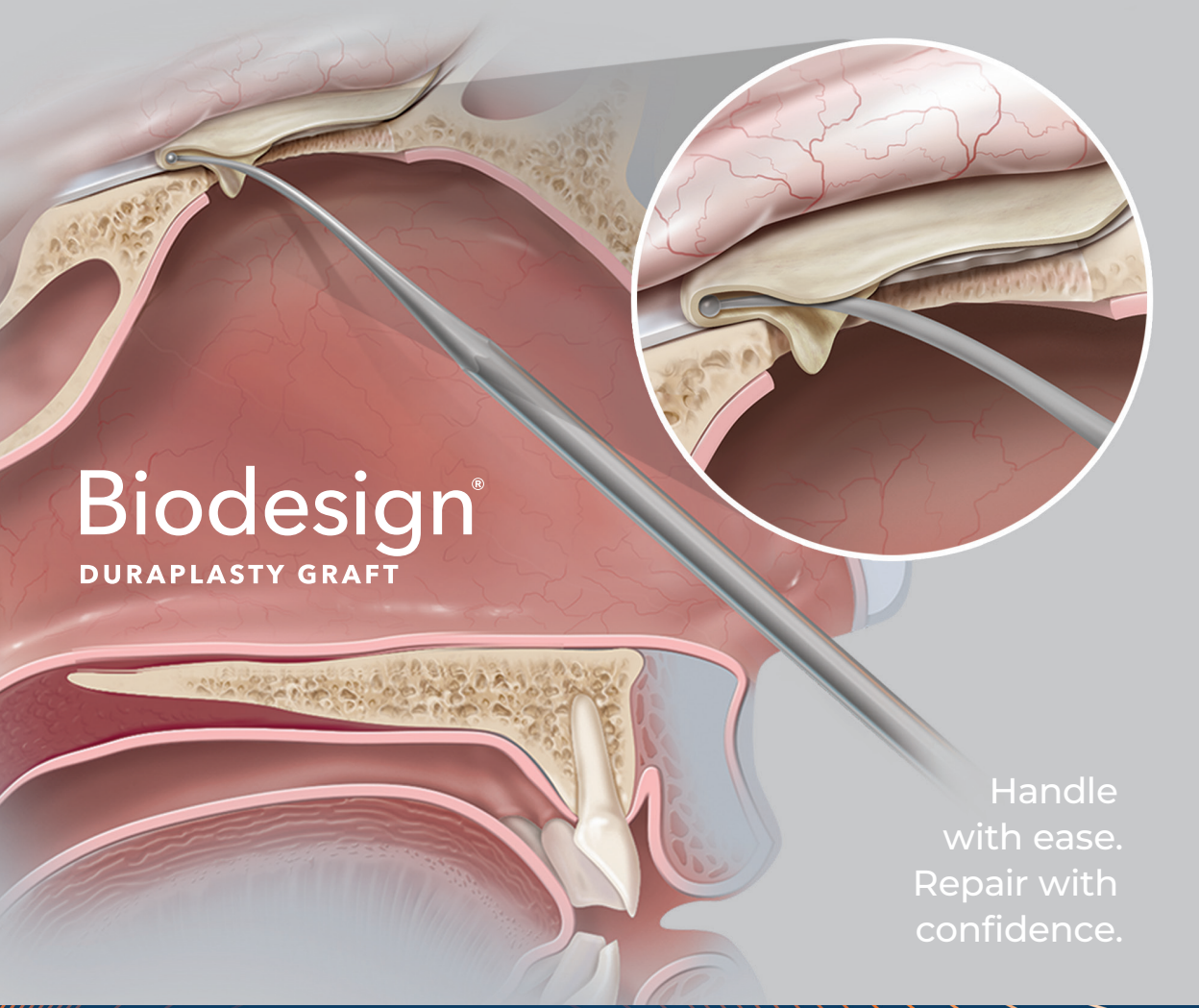

Biodesign®
DURAPLASTY GRAFT
Handle
with ease.
Repair with
confidence.

C2Dx®

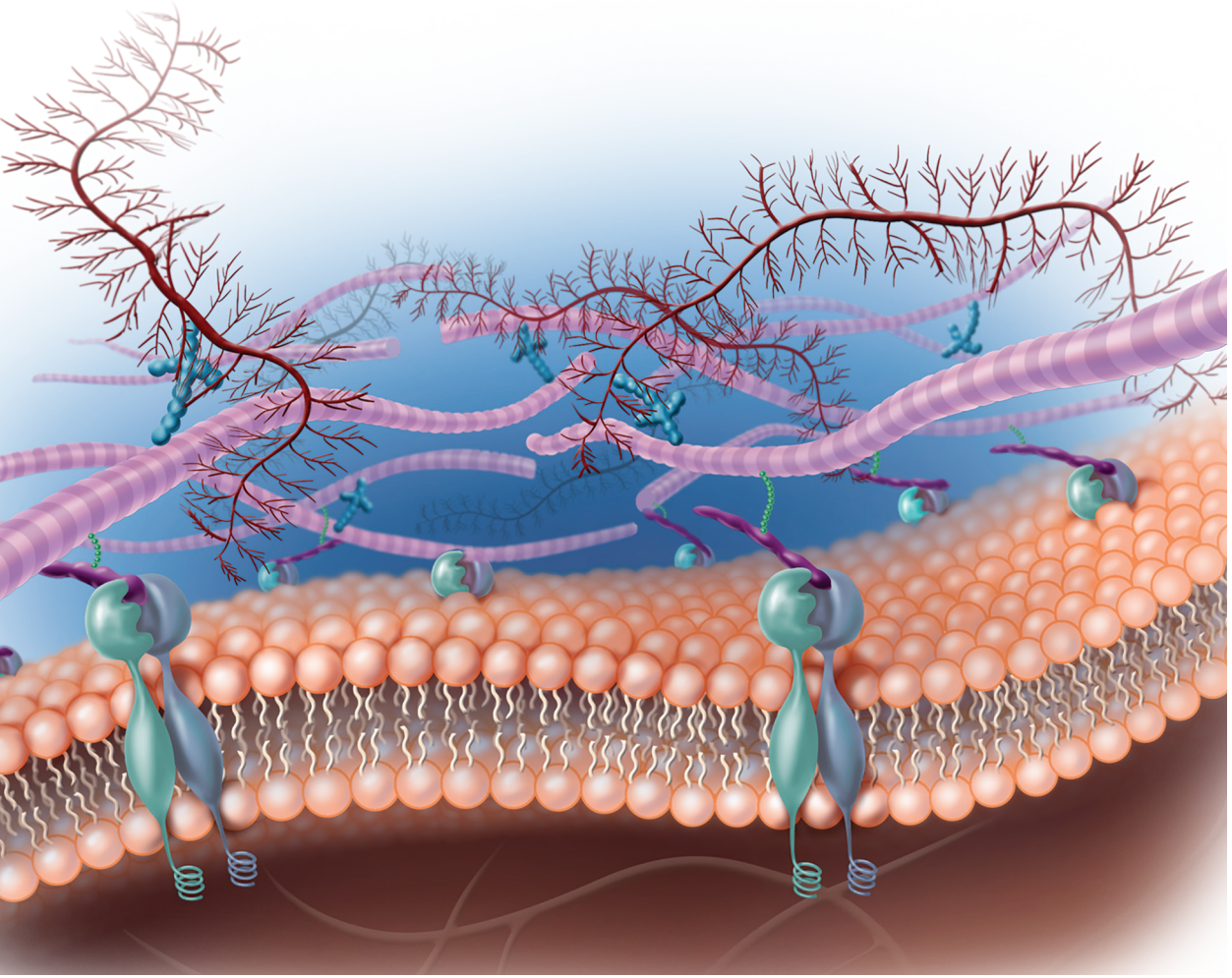


Illustration by Lisa Clark.

What is Biodesign?

Biodesign® is a platform technology behind numerous tissue repair products that span multiple medical specialties.

Biodesign is natural extracellular matrix (ECM) derived from porcine small intestinal submucosa (SIS).

The ECM is a complex latticework of proteins and signaling factors that helps guide the growth of cells.

The proprietary processing methodology decellularizes the SIS material while preserving natural matrix molecules such as collagen, proteoglycans, and glycosaminoglycans.[1]

The result is a scaffold that, when implanted, provides a location for host cells to infiltrate and remodel into well-vascularized tissue.

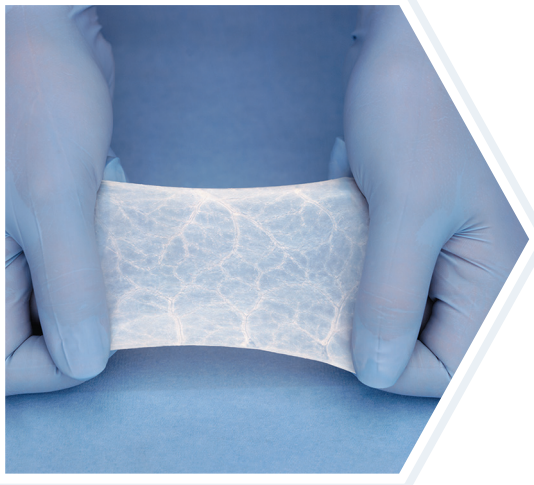
Why Porcine SIS?

Why pigs?

Pigs are a readily available source. This allows for tight control over the age, weight, and medical history of the source animal.

There is no documented TSE (transmissible spongiform encephalopathies) transmission between pigs and humans.

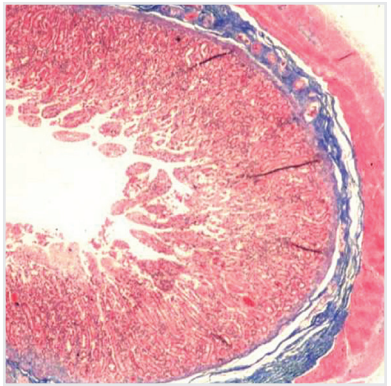
Biodesign is sourced from pigs, which eliminates potential for transmitting prion-based diseases. Biodesign is processed from animal tissue sourced in compliance with ISO 22442 standards.[3]



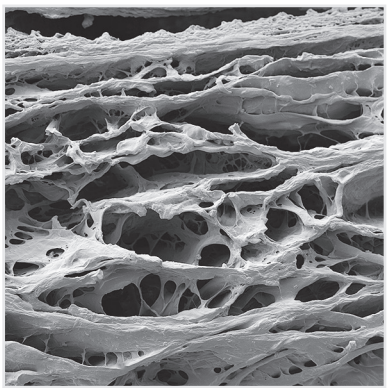
Why SIS?

The submucosa within the small intestine survives one of the harshest environments of the body and supports rapid cell turnover.

SIS's complex composition makes it an ideal candidate for soft tissue repair.



Porcine small intestine, submucosa in blue.



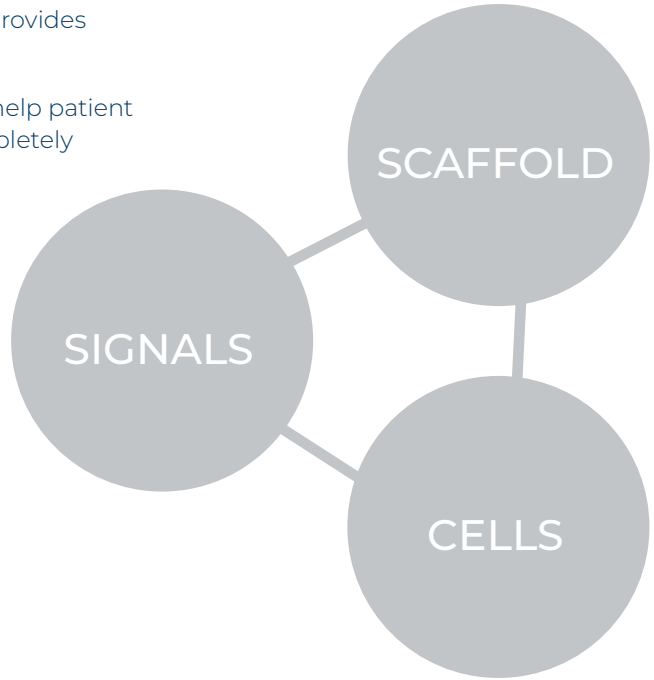
Extracellular matrix structure of lyophilized porcine small intestine submucosa

How does Biodesign work?

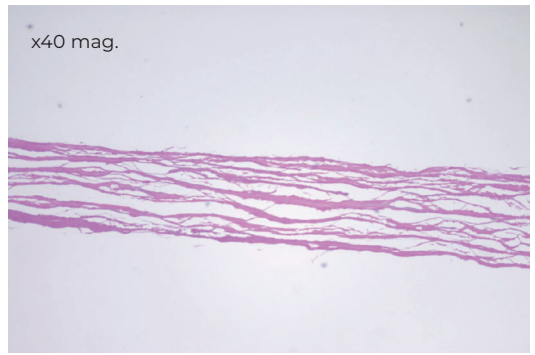
There are three essential components to healing: a scaffold, signals, and cells.

Biodesign's open lattice structure provides a scaffold for tissue ingrowth.

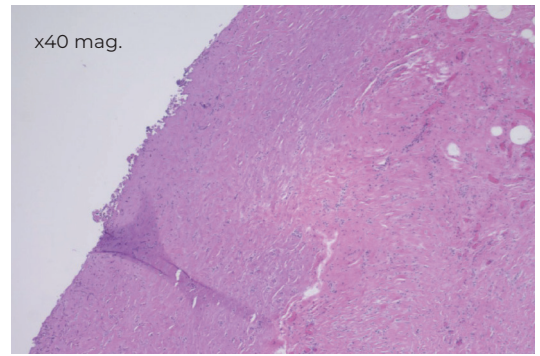
The body's signaling mechanisms help patient cells infiltrate the scaffold and completely remodel into natural host tissue.



Microscopic view of the remodeling process[2]

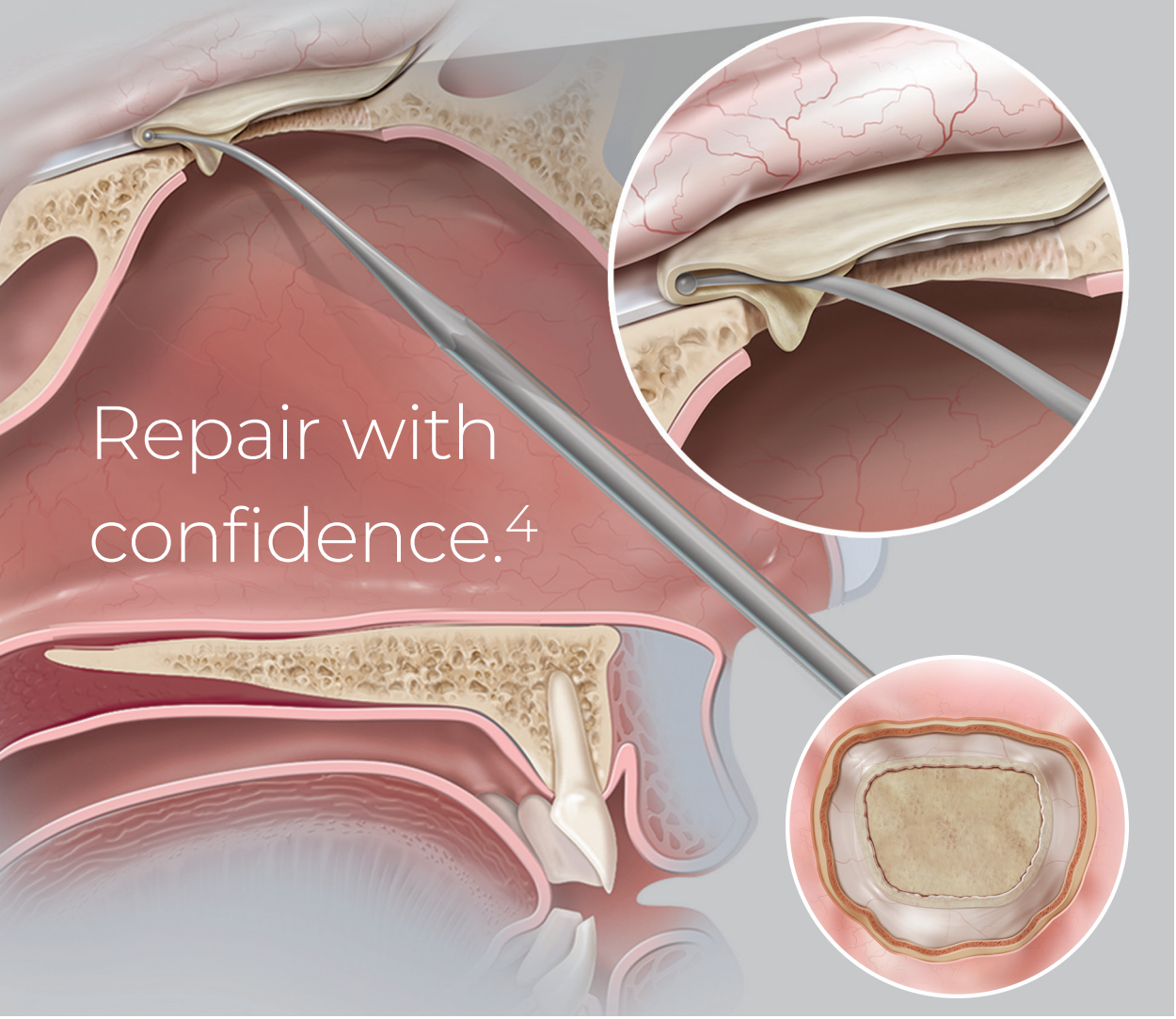


Biodesign graft prior to implantation



8 months after implantation

The Biodesign graft (left) allows for the substantial growth of organized tissue, as seen in this biopsy sample, taken eight months after implantation (right). The above images are of the Biodesign Plastic Surgery Matrix implanted in breast tissue.[3]



Illustrations by Lisa Clark.

Biodesign® Duraplasty Graft

STRONG SEAL

SUTURED/SUTURELESS FIXATION

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

EXCELLENT HANDLING

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. 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.** DURAPLASTY GRAFT 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

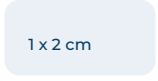
See instructions for use for full product information.

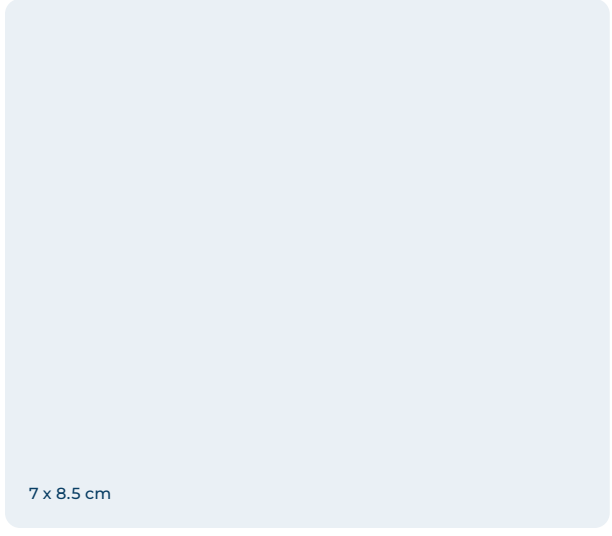
AB_FP0095-01_REV2

Biodesign® Duraplasty Graft

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.

Hydrate for at least two minutes before placement.

Product ordering information

Order Number	Reference Part Number	Size cm	Nominal Thickness mm
Biodesign Dural 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.

References

1. Hodde J, Janis A, Ernst D, Zopf D, Sherman D, Johnson C. Effects of sterilization on an extracellular matrix scaffold: Part I. Composition and matrix architecture. ***J Mater Sci Mater Med*** 2007;18:537-543.

2. Data on file.

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.

4. 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.

