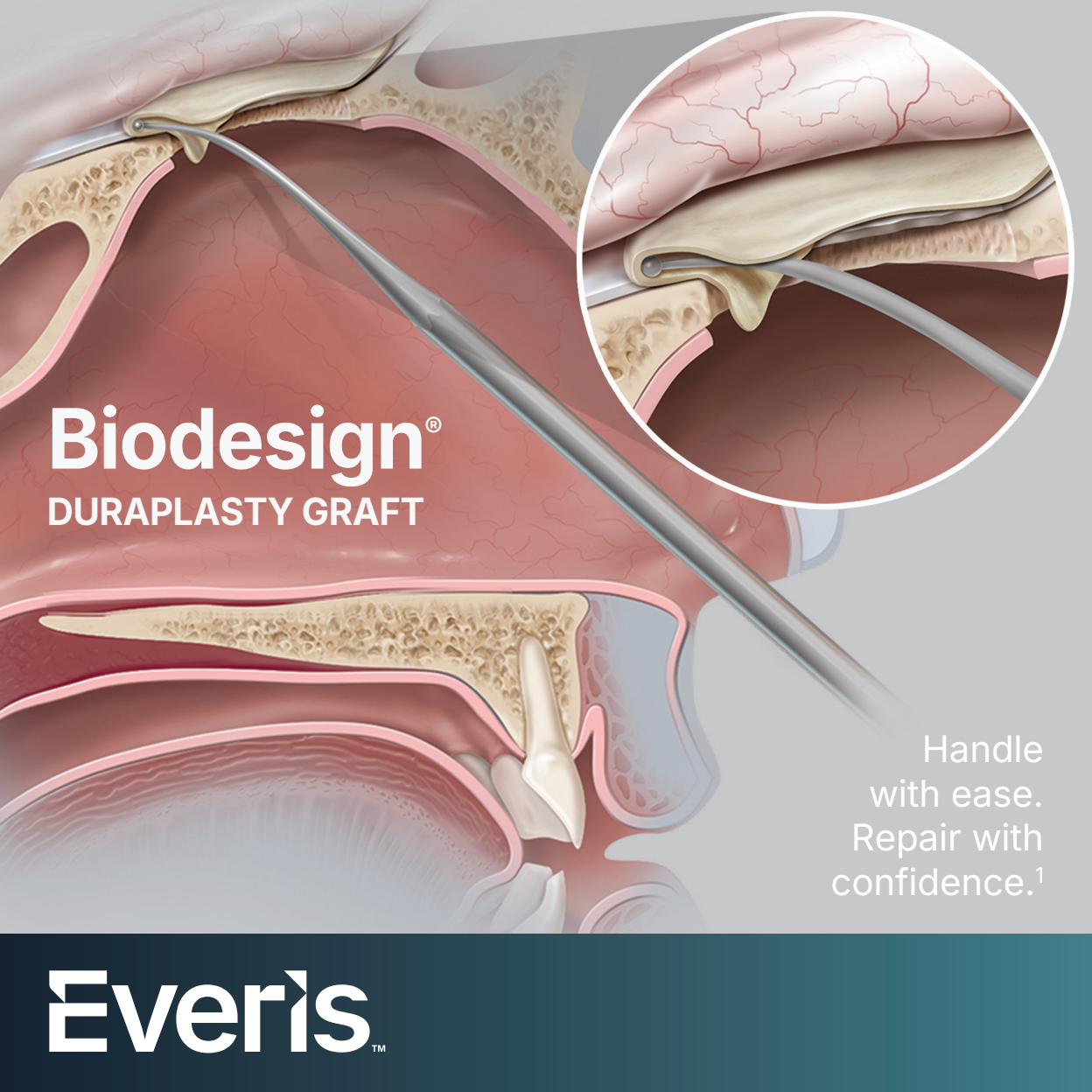
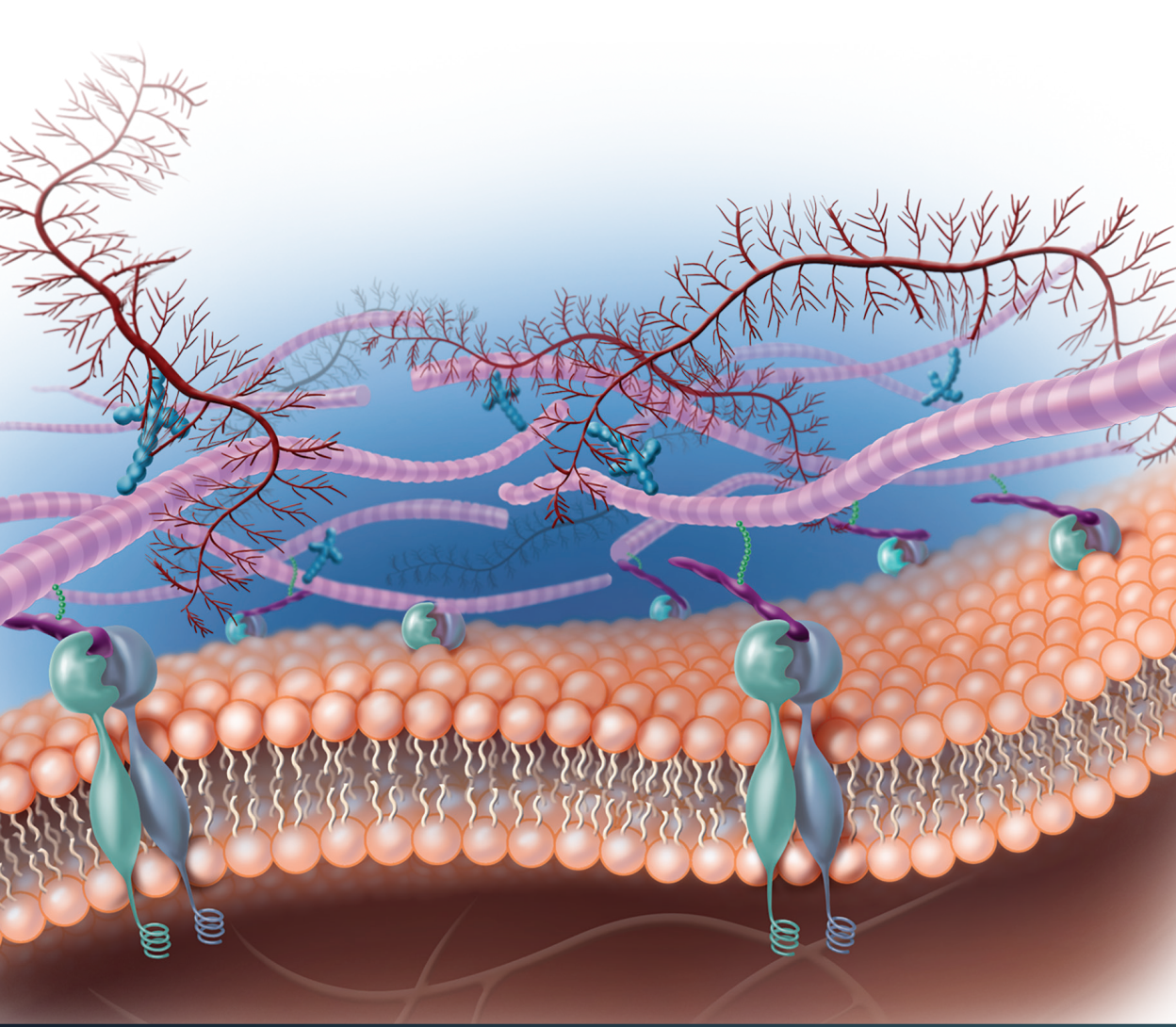

Biodesign®
DURAPLASTY GRAFT
Handle with ease. Repair with confidence.[1]
Evertis™



What is Biodesign® material?

Biodesign grafts are composed of natural extracellular matrix (ECM) derived from porcine small intestinal submucosa (SIS).

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

The ECM is a complex latticework that helps guide the growth of cells.[2]

The proprietary processing methodology decellularizes the SIS material while preserving natural matrix molecules such as collagen, proteoglycans, and glycosaminoglycans.[3]

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

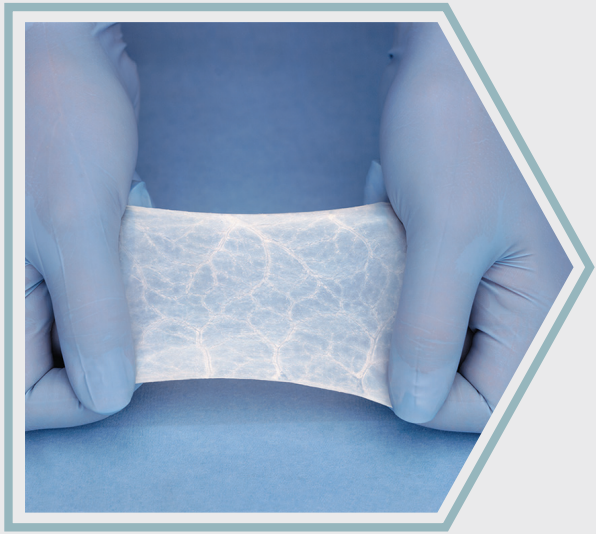
Why Porcine SIS?

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.[4]

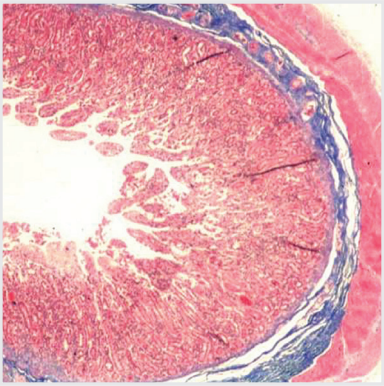
Biodesign material is sourced from pigs, which eliminates potential for transmitting prion-based diseases. Biodesign material is processed from animal tissue sourced in compliance with ISO 22442 standards.



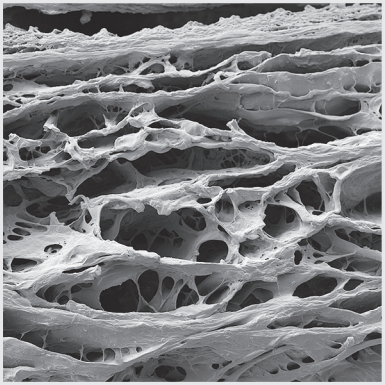
Why SIS?

The submucosa is derived from the small intestine, which is one of the harshest environments of the body, and supports cell ingrowth.

SIS's complex composition makes it an ideal candidate for soft tissue repair.[4]



Porcine small intestine, submucosa in blue.



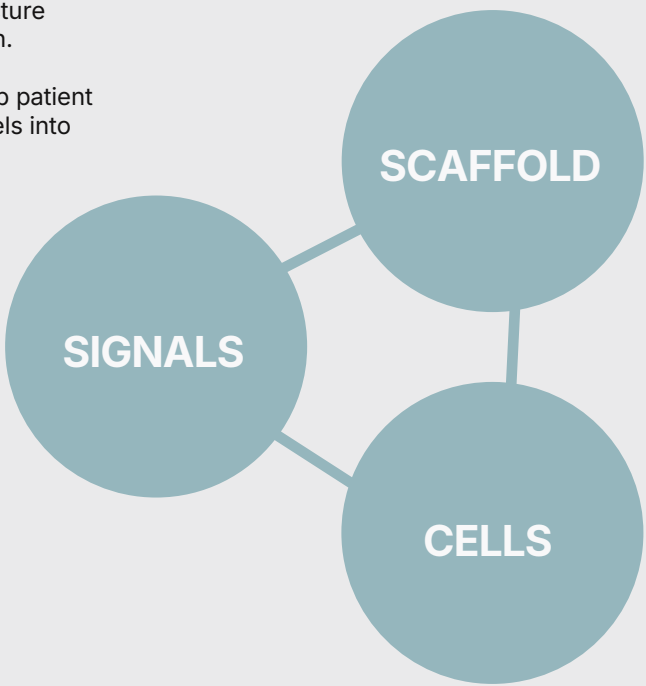
Extracellular matrix structure of lyophilized porcine small intestine submucosa

How does Biodesign material work?

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

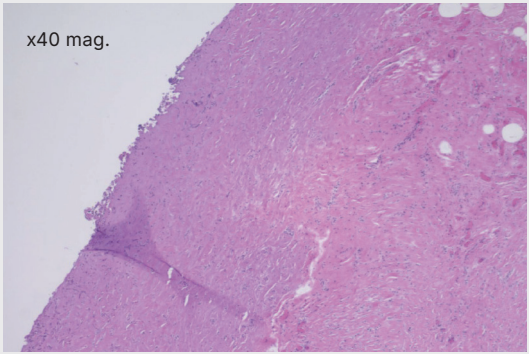
Biodesign material's open lattice structure provides a scaffold for tissue ingrowth.

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



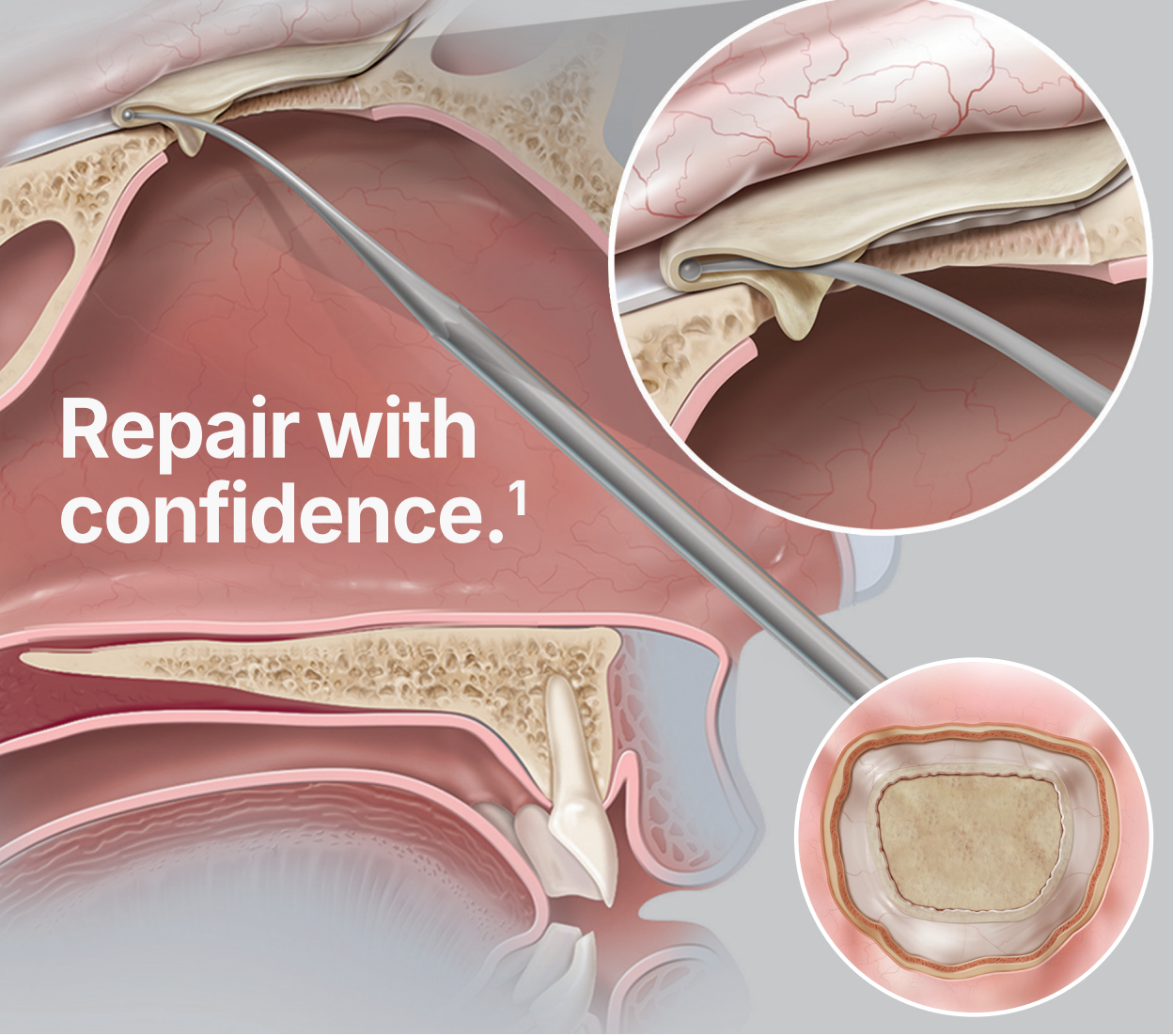
Microscopic view of the remodeling process

Biodesign graft prior to implantation



8 months after implantation

The Biodesign graft (left) allows for the 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.[5]


Repair with confidence.[1]

Biodesign® Duraplasty Graft

WATERTIGHT SEAL[1]

SUTURED/SUTURELESS FIXATION

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

EXCELLENT HANDLING[1]

Risk Information:

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 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 • alergic reaction • calcification • CSF leak • delayed hemorrhage • infection • inflammation

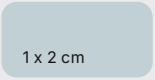
VULNERABLE POPULATIONS: Safety data for this device has been collected in otherwise healthy populations. While no specific risks have been identified in vulnerable groups (e.g., patients with complex comorbidities or pregnancy), data in these populations is limited. Use in such cases should be guided by clinical judgment, including consultation with relevant specialists when appropriate.

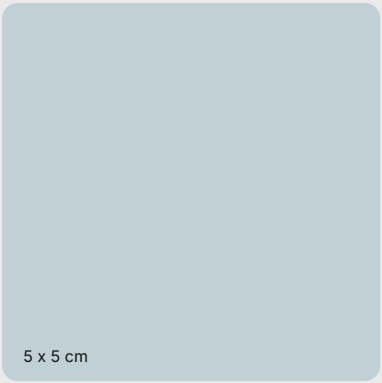
See Instructions for Use for full product information at everismedical.com

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 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 Everis representative or Customer Service for details.

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. Hubbell JA. Materials as morphogenetic guides in tissue engineering. Curr Opin Biotechnol. 2003;14:551-558.
3. 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 Meda*** 2007;18:537-543.
4. Illing E, Chaaban MR, Riley KO, Woodworth BA. Porcine small intestine submucosal graft for endoscopic skull base reconstruction. a ***Int Forum Allergy Rhinol.*** 2013;3(11):928-932.
5. Data on File with Evergen.