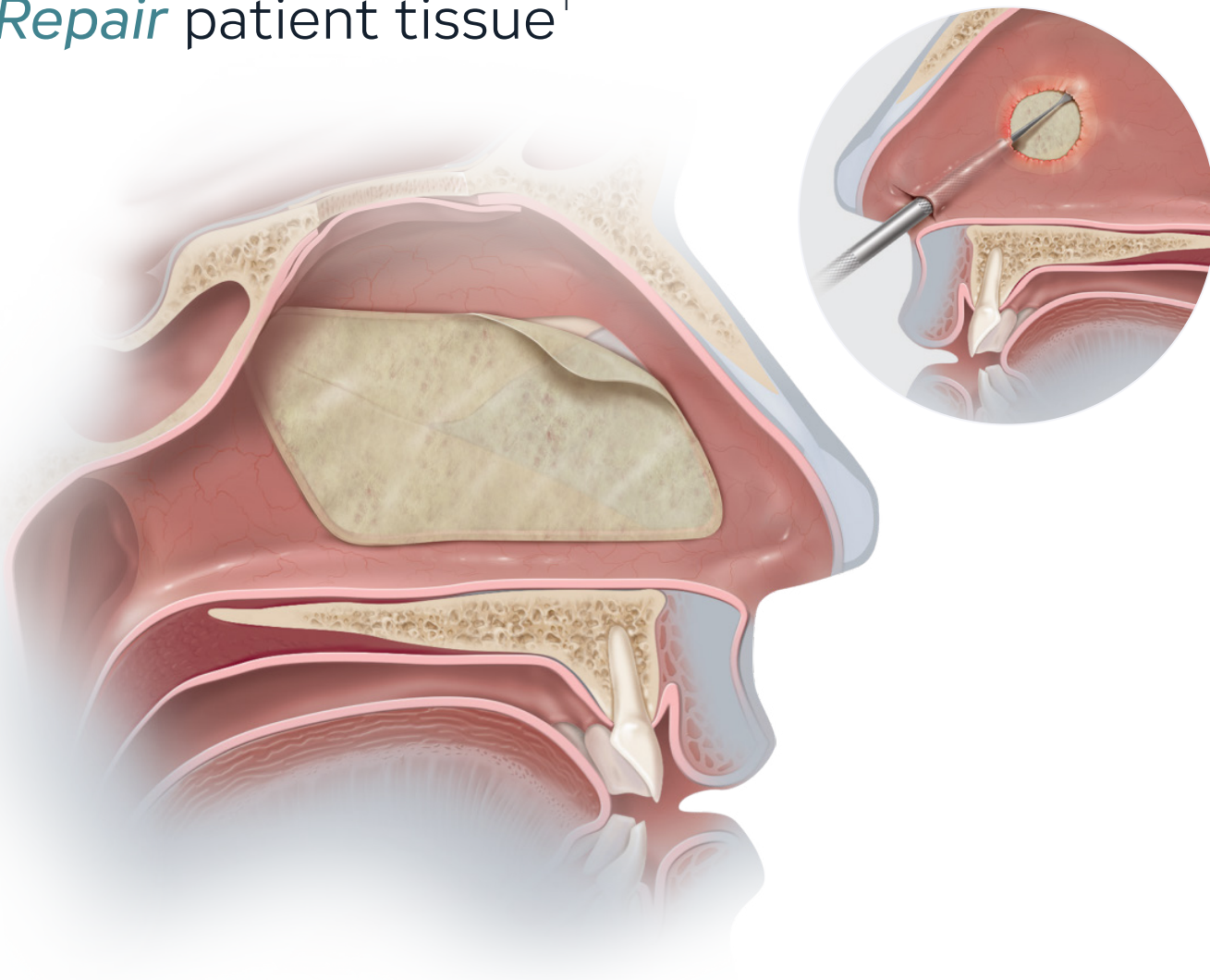


Biodesign[®]

SINONASAL REPAIR GRAFT

Repair patient tissue¹



Promotes Remucosalization

Remucosalization at the nasal septum donor site significantly improved early (2 weeks) and overall (2, 6, and 12 week follow-ups) by 10.03% and 8.13% respectively.²

Excellent Handling

Biodesign[®] material is easy to manipulate and modify.³

Multiple Procedures

Published data supports applications for both nasoseptal perforation and donor site repair.^{2,3}



Available product sizes

Shown at actual size.

(Also available in 7 x 10 cm)



Biodesign® Sinonasal Repair Graft

Order Number	Reference Part Number	Size cm	Nominal Thickness mm
G35947	ENT-TRG-1X2	1 x 2	0.20
G35948	ENT-TRG-2X3	2 x 3	0.20
G35949	ENT-TRG-4X7	4 x 7	0.20
G35950	ENT-TRG-7X10	7 x 10	0.20

Tips to help get the best possible results:

- Ensure adequate blood supply.
- Size the graft to allow for tissue overlap.
- Place the graft dry and then hydrate with sterile saline.

INTENDED USE:

The Biodesign Sinonasal Repair Graft is intended to separate tissue or structures compromised by surgical trauma and act as an adjunct to aid in the natural healing process. The device is indicated for use where an open wound dressing material is required in the nasal and/or sinus cavities following nasal and/or sinus surgery where separation of tissues or structures is desired during nasal septal perforation repair and donor site repair. The device is supplied sterile and is intended for one-time use.

CONTRAINDICATIONS:

This graft is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

PRECAUTIONS: The graft is designed for single use only. Do not reprocess, resterilize, and/or reuse • The graft should not be applied until excessive exudate, bleeding, acute swelling, and infection is controlled • Ensure that all layers of the graft are secured during fixation.

POTENTIAL COMPLICATIONS: Complications that can occur with the use of surgical graft materials in nasal/sinus surgery may include, but are not limited to: • allergic reaction • bleeding • blistering • excessive redness • hematoma • infection/toxic shock syndrome • inflammation • nasal obstruction • pain • persistence of perforation or recurrence

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. Ambro BT, Zimmerman J, Rosenthal M, Pribitkin EA, Nasal septal perforation repair with porcine small intestinal submucosa. *Arch Facial Plast Surg*. 2003;5(6):528-529.
2. Nayak JV, Rathor A, Grayson JW, et al. Porcine small intestine submucosal grafts improve remucosalization and progenitor cell recruitment to sites of upper airway tissue remodeling. *Int Forum Allergy Rhinol*. 2018;8(10):1162-1168.
3. Greywoode J, Hamilton J, Malhotra PS, et al. Repair of nasal septal perforation with porcine small intestinal submucosa xenograft. *J Otol Rhinol*. 2012;1(2).

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