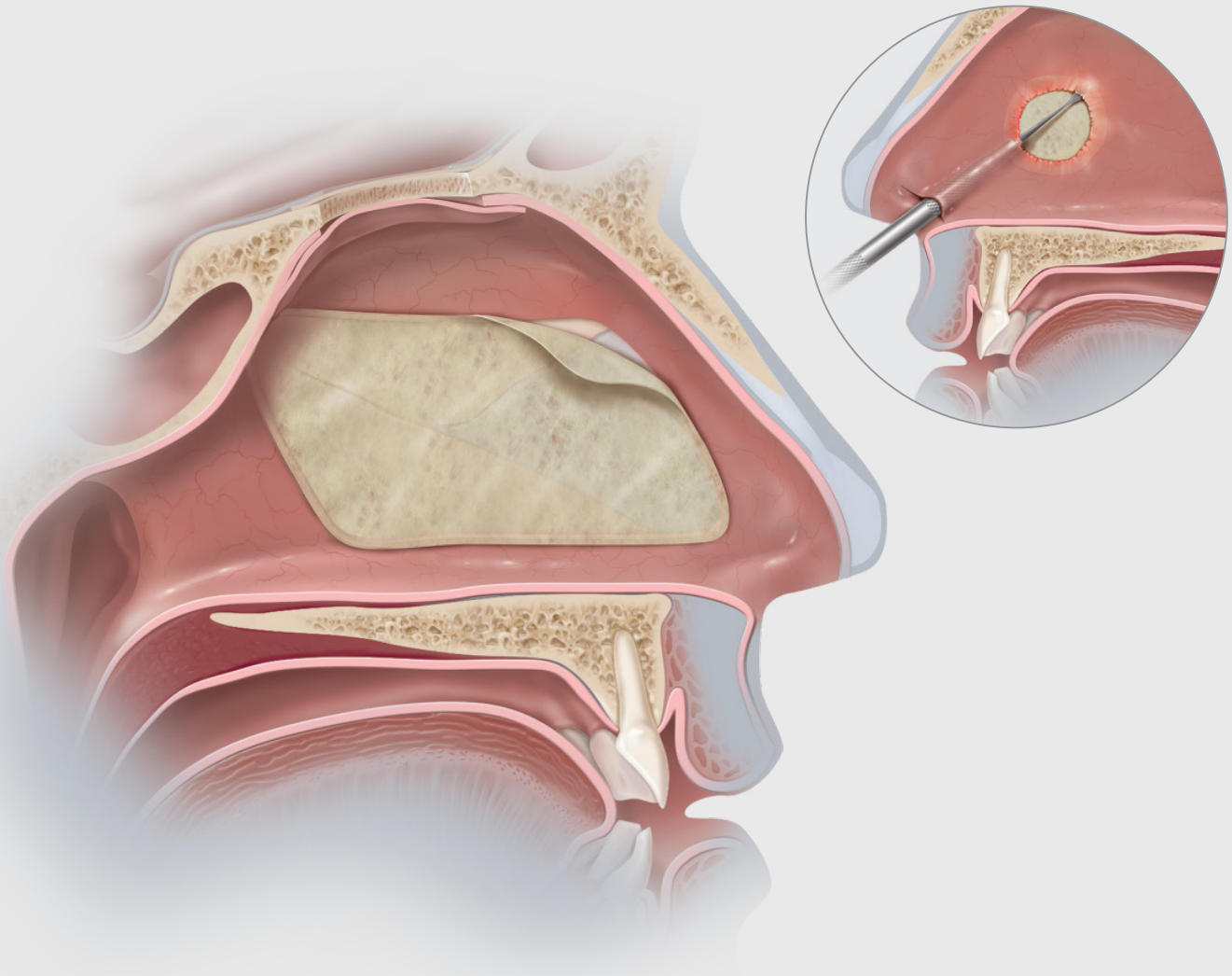
Restore patient tissue.[1]



Biodesign®
SINONASAL REPAIR GRAFT

Promotes remucosalization

Remucosalization at the nasal septum donor site significantly improved early and overall by 10.03% at 2 weeks and 8.13% across 12 weeks, respectively.[2]

Excellent handling

Biodesign material is easy to manipulate, allowing for improved surgical precision during graft placement.[3]

Multiple procedures

Published data supports applications for both nasoseptal perforation and donor site repair.[2, 3]

C2Dx®

Biodesign®
SINONASAL REPAIR GRAFT

Tips to help get the best possible results:

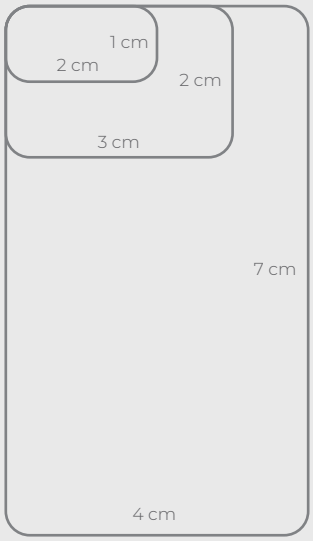
- Ensure adequate blood supply.
- Size the graft to allow for tissue overlap.
- Place the graft dry and then hydrate with sterile saline.

Order Number	Reference Part Number	Size cm	Nominal Thickness mm
Biodesign® Sinonasal Repair Graft			
G35947	ENT-TRG-1X2	1 x 2	.20
G35948	ENT-TRG-2X3	2 x 3	.20
G35949	ENT-TRG-4X7	4 x 7	.20
G35950	ENT-TRG-7X10	7 x 10	.20

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 10 cm.)



Biodesign® Sinonasal Repair Graft

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. 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.** SINONASAL REPAIR GRAFT This symbol means the following: Sinonasal Repair Graft. This product is intended for use by trained medical professionals.

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

PRECAUTIONS: 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 resterilize.** Discard all open and unused portions of the graft. • The graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken. • Discard graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date. • 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: The complications listed below are possible with the use of surgical graft materials in nasal/sinus surgery. If any of these conditions occur, the graft should be removed if possible. However, if graft removal is not possible due to graft incorporation, then appropriate care should be given to treat the complication. • Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation) • Allergic reaction • Bleeding • Excessive redness, pain, swelling, or blistering • Hematoma • Infection/Toxic Shock Syndrome • Nasal obstruction • Persistence of perforation or recurrence

See Instructions for Use for full product information.

AB_FP0089-01_REV3

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

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