

Biodesign® Nipple Reconstruction Cylinder Pre-shaped

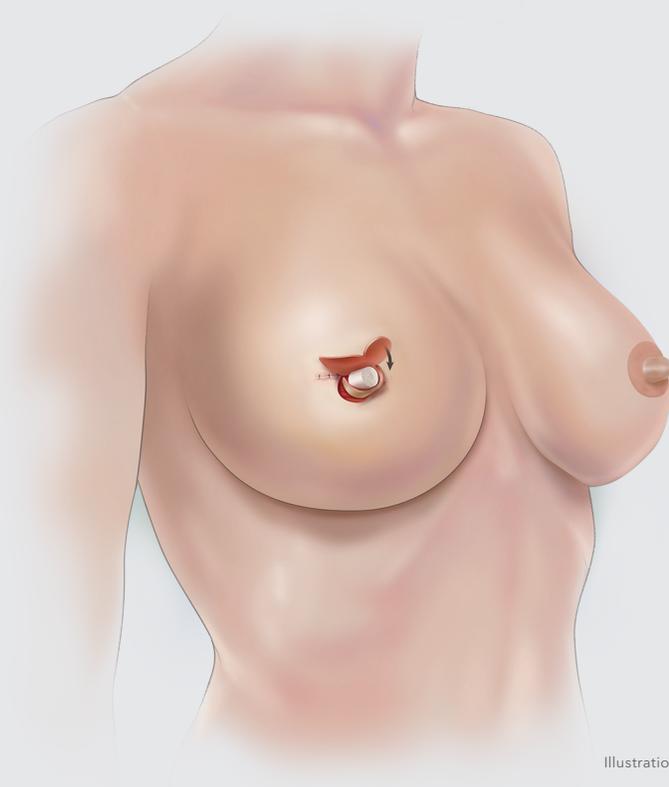


Illustration by Lisa Clark



Biodesign®
ADVANCED TISSUE REPAIR

Safety and efficacy

Biodesign is one of the most **well studied** biologic tissue-repair technologies available. Once implanted, Biodesign allows for angiogenesis and cell migration, leaving behind only naturally reinforced patient tissue.²⁻⁴ More than 4,600 Biodesign Nipple Reconstruction Cylinders have been distributed.⁵

1450

Published articles

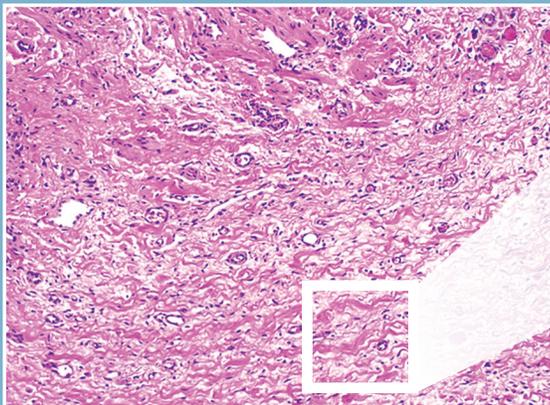
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Level 1 Clinical Trials

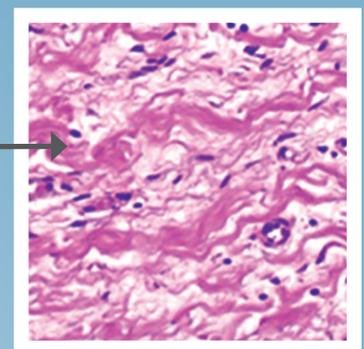
The Biodesign Nipple Reconstruction Cylinder completely remodels into organized natural tissue.⁶ It provides an extracellular matrix (ECM) scaffold to re-establish a natural nipple with strong, vascularized tissue, providing long-term volume and projection.¹

Biodesign Advanced Tissue Repair

The body completely remodels Biodesign material into patient tissue that has an organized deposition of collagen.⁶



Organized collagen



Satisfaction

A multi-center study found that re-creation of the nipple following mastectomy and breast reconstruction has a high correlation with overall patient satisfaction and acceptance of body image. The study followed 82 nipple reconstructions in 50 patients. **Ninety-eight percent of patients recommended nipple reconstruction surgery following mastectomy.**¹

Patient Satisfaction at 12 months¹

Nipple Characteristic	% of nipples rated "pleased" or "very pleased"
Size	89
Position	96
Color	90
Softness	93
Symmetry	90
Sensation	30
Appearance	86
Clothed appearance	92
Nude appearance	84
Overall outcome	93

Post-operative adverse events: cylinder extrusion - 3.7%, ischemia/necrosis - 2.4%, wound dehiscence - 2.4%, cylinder exposure - 1.2%, excessive bleeding - 1.2%, wound drainage - 1.2%.¹

1. Collins B, Williams JZ, Karu H, Hodde JP, Martin VA, Gurtner GC. Nipple reconstruction with the Biodesign nipple reconstruction cylinder: A prospective clinical study. *Plast Reconstr Surg Global Open*. 2016;4:e832.
2. Centeno RF. Surgisis acellular collagen matrix in aesthetic and reconstructive plastic surgery soft tissue applications. *Clin Plast Surg*. 2009;36:229-240.
3. Wiedemann A, Otto M. Small intestinal submucosa for pubourethral sling suspension for the treatment of stress incontinence: first histopathological results in humans. *J Urol*. 2004;172:215-218.
4. Badylak SF, Park K, Peppas N, McCabe G, Yoder M. Marrow-derived cells populate scaffolds composed of xenogeneic extracellular matrix. *Exp Hematol*. 2001. 29:1310-1318.
5. Internal Cook Biotech document: D00205869.
6. Franklin ME Jr, Treviño JM, Portillo G, et al. The use of porcine small intestinal submucosa as a prosthetic material for laparoscopic hernia repair in infected and potentially contaminated fields: long-term follow-up. *Surg Endosc*. 2008;22(9):1941-1946.

Biodesign® Nipple Reconstruction Cylinder

The Biodesign Nipple Reconstruction Cylinder (NRC) is a cylinder of extracellular matrix used for implantation to reinforce soft tissue, where weakness exists, in plastic and reconstructive surgery of the nipple. It is provided pre-shaped and ready to use. Each cylinder includes a 2.0 cm HaloShield™ Nipple Protector and a flap template with sizing options for achieving the desired aesthetic.

Order Number	Reference Part Number	Size (cm)
Biodesign Nipple Reconstruction Cylinder		
G49127	C-NRC-0.7X1.0	0.7 x 1.0
G49126	C-NRC-1.0X1.0	1.0 x 1.0
G52549	C-NRC-1.0X1.5	1.0 x 1.5
HaloShield Nipple Protector		Projection Clearance (cm)
G46289	C-SHIELD-1.0	1.0
G46290	C-SHIELD-2.0	2.0

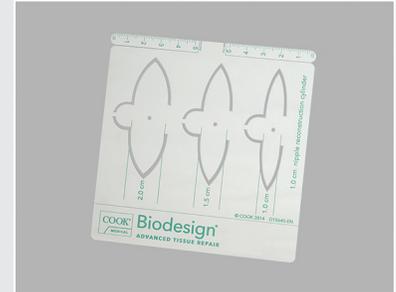
The Biodesign Nipple Reconstruction Cylinder includes:



Biodesign Nipple Reconstruction Cylinder (pre-shaped)



2.0 cm HaloShield Nipple Protector



Nipple Reconstruction Flap Template

For product details, contact Cook Biotech at PlasticSurgery@CookBiotech.com or visit CookBiotech.com. Some products or part numbers may not be available in all markets.

BIODESIGN® NIPPLE RECONSTRUCTION CYLINDER

INTENDED USE: The Biodesign® Nipple Reconstruction Cylinder is intended for implantation to reinforce soft tissue, where weakness exists, in plastic and reconstructive surgery of the nipple. The cylinder 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. [NIPPLE RECONSTRUCTION CYLINDER]** This symbol means the following: Nipple Reconstruction Cylinder. This product is intended for use by trained medical professionals.

CONTRAINDICATIONS: • The cylinder is derived from a porcine source and should not be used in patients with known sensitivity to porcine material. • The cylinder should not be used in patients with thin or irradiated skin who do not have pectoralis fascia.

PRECAUTIONS: • This device is designed for single use only. Attempts to reprocess, sterilize, and/or reuse may lead to device failure and/or transmission of disease. • The cylinder is not for vascular use. • **Do not resterilize.** Discard all open and unused portions of the cylinder. • The cylinder is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken. • Discard the cylinder if mishandling has caused possible damage or contamination, or if the cylinder is past its expiration date. • Users should be familiar with the surgical technique for nipple reconstruction. • Ensure that the cylinder is rehydrated prior to implanting. • The cylinder should be placed in maximum possible contact with healthy, well-vascularized tissue to encourage cellular in-growth and tissue remodeling. • The cylinder should not be implanted in infected or potentially infected tissue beds, or over open cavities, because infection, migration, or extrusion may result. • Compromised patients (such as those with autoimmune disease, diabetes, or undergoing chemotherapy or radiation therapy) may not experience normal wound healing. • Extended rehydration or excessive handling could lead to partial delamination of the cylinder. • Excessive internal pressure within the reconstructed nipple may increase the risk of extrusion, ischemia, or

HALOSHIELD™ NIPPLE PROTECTOR

INTENDED USE: The HaloShield™ Nipple Protector is intended to be used as a wound cover protector for the areola and nipple in breast reconstruction or surgery. **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. [NIPPLE PROTECTOR]** This symbol means the following: Nipple Protector.

PRECAUTIONS: This device is designed for single use only. Attempts to reprocess, sterilize and/or reuse may lead to device failure and/or transmission of disease. • Do not resterilize. • The protector is sterile if the packaging is dry, unopened and undamaged. Do not use if the package seal is broken. • Discard the protector if mishandling has caused possible damage, contamination, or if the protector is past its expiration date. • The protector should not be placed in direct contact with breached or compromised tissue.

premature flattening. • Trimming the cylinder to a length less than 1.0 cm may reduce long-term projection. • No studies have been conducted to evaluate the performance of the cylinder in patients who are pregnant, may become pregnant, or are breast feeding. • For irradiated patients, consider waiting to implant the cylinder for at least 6 months following their final treatment. • Smokers should abstain from smoking for at least 6 weeks prior to cylinder implantation and should remain smoke free for 6 to 8 weeks after implantation. • Tissue at the implant site should demonstrate an ability to elastically recoil before implanting the cylinder. Ensure preoperatively that the patient has adequate skin elasticity by performing a pinch test and watching for elastic recoil. • Timing of tattoo placement, quality of tattooing instruments, and tattooing technique can affect nipple projection. • Failure to wear the nipple protector according to post-op care guidelines may increase the risk of projection loss. • Selecting an improper flap size can compromise long-term nipple reconstruction success. The product kit contains a flap template with sizing options that can be consulted as a general guideline for use with different sized cylinders.

POTENTIAL COMPLICATIONS: Complications that can occur during nipple reconstruction include, but are not limited to: • Inflammation • Migration • Extrusion • Seroma formation • Hematoma • Numbness • Paresthesia • Infection • Tissue Ischemia • Localized necrosis • Epidermolysis • Discoloration • Induration • Implant Exposure • Wound dehiscence • Excessive bleeding • Insufficient or excessive augmentation. If any of the following conditions occur and cannot be resolved, cylinder removal should be considered: • Infection • Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation) • Allergic reaction

See package insert for full product information.

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POTENTIAL COMPLICATIONS: Complications that can occur with use of the protector include, but are not limited to: • Inflammation • Abrasion • Skin Irritation • Pain • Infection • Tissue Necrosis • Wound Dehiscence • Allergic Reaction • Nipple Compression

If infection, acute or chronic inflammation, or allergic reaction occur and cannot be resolved, protector removal and discontinuation should be considered.

See package insert for full product information.

EPL_FP0112-01B



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