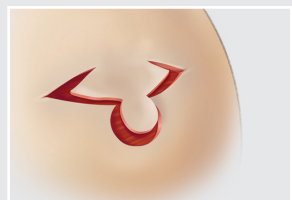


The techniques presented in this guide are recommendations that should help you achieve optimum results, but this guide is not meant to be a substitute for the IFU.

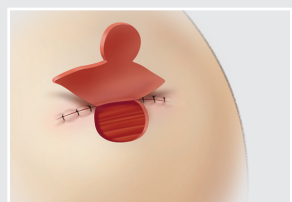
**Please note:** The Biodesign Nipple Reconstruction Cylinder can be used with a variety of nipple reconstruction techniques. All techniques must be modified to accommodate the additional volume of the cylinder. The selection of technique is based solely on physician discretion.



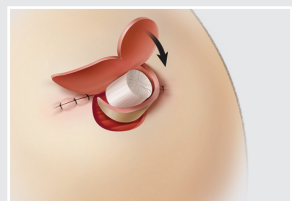
**1** Determine the position and the size of the new nipple. Using the flap template, draw the CV pattern on the breast where the nipple is to be reconstructed. Dissect the skin along the pattern. **Note:** Take care to ensure adequate blood supply to the skin flaps.



**2** Allow the skin flaps to relax.

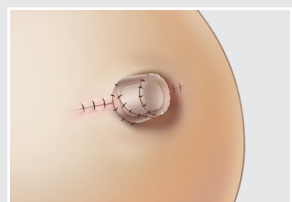


**3** Raise the skin flaps and close the donor area.



**4** Place the rehydrated Biodesign Nipple Reconstruction Cylinder in the desired location. Wrap the V-flaps around the cylinder and suture them into place.

Alternatively, suture the V-flaps together to create a “pillar” of tissue, then place the cylinder.



**5** With the V-flaps sutured into position and the cylinder in place, suture the C-flap closed to form a “cap” over the nipple. Use a horizontal suture through the base of the projection to prevent the nipple reconstruction cylinder from migrating (optional). The patient should wear a nipple protector, such as the HaloShield™ Nipple Protector, continuously for six weeks and during sleep for an additional three weeks.

Illustrations by Lisa Clark

## Biodesign® Nipple Reconstruction Cylinder

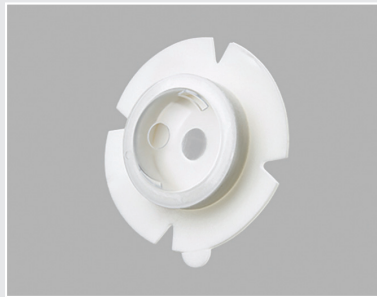
The Biodesign Nipple Reconstruction Cylinder (NRC) is a cylinder of extracellular matrix used for implantation to reinforce soft tissue, where weakness exists, in plastic and reconstructive surgery of the nipple. It is provided pre-shaped and ready to use. Each cylinder includes a 2.0 cm HaloShield™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

Order Number	Reference Part Number	Size (cm)
<b>Biodesign Nipple Reconstruction Cylinder</b>		
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
<b>HaloShield Nipple Protector</b>		Projection Clearance (cm)
G46289	C-SHIELD-1.0	1.0
G46290	C-SHIELD-2.0	2.0

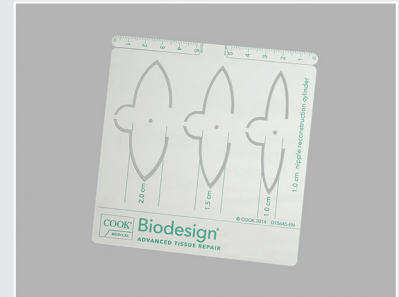
The Biodesign Nipple Reconstruction Cylinder includes:



**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](mailto:PlasticSurgery@CookBiotech.com) or visit [CookBiotech.com](http://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, resterilize, 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, resterilize 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.**

EPL\_FP0094-01D

**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



[cookbiotech.com](http://cookbiotech.com)