

BIODESIGN®

NIPPLE RECONSTRUCTION CYLINDER

FP0094-01D



MANUFACTURER

TEMPERATURE LIMIT

USE-BY-DATE

DO NOT REUSE



ATTENTION, SEE INSTRUCTIONS FOR USE



KEEP DRY



STERILIZED USING ETHYLENE OXIDE



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BIODESIGN® NIPPLE RECONSTRUCTION CYLINDER

PRODUCT DESCRIPTION

The Biodesign® Nipple Reconstruction Cylinder is a rolled cylinder of extracellular collagen matrix derived from porcine small intestinal submucosa. The Biodesign® Nipple Reconstruction Cylinder is implanted by a trained physician to support weakened soft tissue during surgery of the nipple. The template provides the physician with suggested surgical flap designs to correspond with each cylinder size. The nipple protector provides the patient with post-operative protection of the reconstructed nipple.

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 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

STORAGE

The cylinder, nipple protector, and flap template should be stored in a clean, dry location at room temperature.

STERILIZATION

The cylinder, nipple protector, and flap template have been sterilized with ethylene oxide.

INSTRUCTIONS FOR USE

Required Materials

- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Rehydration fluid: room temperature sterile saline or sterile lactated Ringer's solution
- Surgical marker or pen (3mm tip or smaller)

NOTE: Always handle the device using aseptic technique. Minimize contact with latex gloves.

PROCEDURE

- Determine the proper cylinder diameter (A):
 - If a contralateral nipple is present, measure its diameter to determine the cylinder size that most closely matches, taking into account post-operative contraction and tissue thickness.
 - If a contralateral nipple is not present, the following factors should be considered when determining the proper cylinder diameter: overall size of the reconstructed breast, presence or absence of a well-vascularized skin flap, thickness of skin flap(s), and/or the patient's desired final appearance.
- Aseptically prepare the patient and surgical site.
- Aseptically remove all components from their pouches and place them in the sterile field. Avoid dumping any component out of its pouch as it may bounce out of the sterile field. Discard any component that falls out of the sterile field.
- Obtain the flap template and place it on the breast mound at the site of the intended reconstruction.
- Choose a flap stencil that corresponds to the desired level of projection and does not exceed the length of the cylinder provided in the kit. Position the flap stencil at the desired location while looking through the template as it rests on the breast mound.
- Position the flap to optimize the blood supply. For best outcomes, orient the pedicle (blood supply) of the flap away from the mastectomy scar line. If possible, position the flap to avoid intersecting the scar line.
- Using a fine-tipped surgical marker and the selected stencil, trace the edge of the flap pattern from the stencil onto the patient's breast mound to guide the creation of the skin flap.

NOTE: If the surgeon's preference is to use a flap not included on the template, ensure:

 - The flap is drawn large enough to create a silo for the selected cylinder without having to stretch the flap.
 - The flap is drawn to avoid additional trimming of the flap.
 - The flap is drawn to maintain a good blood supply. If possible, orient the pedicle (blood supply) of the flap away from the mastectomy scar line.
- Dissect along the nipple flap pattern to create a free-moving skin flap. Ensure that bleeding is observed from the flap. In patients with insufficient subcutaneous tissue (<5mm), pectoralis muscle fascia can be mobilized if there is adequate underlying muscle to provide blood supply and support.
- Grasp the nipple flap by the flap cover and raise the entire flap until it is completely free of the donor site except at the pedicle (blood supply), as shown in Figure 1A.
- Keep the flap in the raised position and, using the ruler on the template, measure the length from the base of the flap to the base of the C-cap on the flap as shown in Figure 1B.

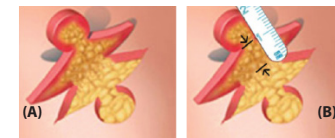


Figure 1

- Close the donor site using non-resorbing or slow resorbing suture, as shown in Figures 2A and 2B.



Figure 2

12. Two methods can be used to prepare the nipple flap and place the cylinder. One method is to suture the flap to create a silo, followed by placement of the prepared cylinder within the silo. The other method is to first prepare the cylinder and then to wrap the flap around the cylinder and suture it in place.

Method 1: Silo Prepared Prior to Cylinder Placement (Steps 13-15)

13. Suture the flap into an appropriately sized silo using non-resorbing or slow resorbing suture, as shown in Figure 3. Avoid stretching the skin flap or placing tension on the skin flap while suturing.



Figure 3

14. Prepare the cylinder for placement.

NOTE: The cylinder provided can be trimmed to length for the desired final appearance. It is not recommended to trim the device less than 1.0 cm due to risk of projection loss after post-operative contraction.

- Using sterile forceps and gloved hands, aseptically remove the cylinder from the tray. Discard the cylinder if it falls out of the sterile field or its sterility is compromised.
 - Trim the cylinder length with a fresh sterile scalpel or sterile scissors to desired height. Use the measurement taken in Step 10 to determine the necessary cylinder length. Repeat sizing with ruler if needed.
 - Place the cylinder into a sterile dish in the sterile field.
 - Add sterile saline or sterile lactated Ringer's solution to the sterile dish.
 - Allow the cylinder to rehydrate, fully submerged, for less than or equal to 10 seconds.
IMPORTANT: Cylinder rigidity is lost as the rehydration time is increased. Minimize manipulation of the cylinder during rehydration to avoid delamination.
15. Place the cylinder into the prepared skin flap silo, maximizing contact with well-vascularized tissue. Avoid applying excessive pressure during implantation.

Method 2: Wrap the Flaps Around the Prepared Cylinder (Steps 16-17)

16. Prepare the cylinder for placement.

NOTE: The cylinder provided can be trimmed to length for the desired final appearance. It is not recommended to trim the device less than 1.0 cm due to risk of projection loss after post-operative contraction.

- Using sterile forceps and gloved hands, aseptically remove the cylinder from the tray. Discard the cylinder if it falls out of the sterile field or its sterility is compromised.
 - Trim the cylinder length with a fresh sterile scalpel or sterile scissors to desired height. Use the measurement taken in Step 10 to determine the necessary cylinder length.
 - Place the cylinder into a sterile dish in the sterile field.
 - Add sterile saline or sterile lactated Ringer's solution to the sterile dish.
 - Allow the cylinder to rehydrate, fully submerged, for less than or equal to 10 seconds.
IMPORTANT: Cylinder rigidity is lost as the rehydration time is increased. Minimize manipulation of the cylinder during rehydration to avoid delamination.
17. Place the cylinder so that it contacts the base of the donor site and has good contact with the pedicle (blood supply). Wrap the flap around the cylinder to provide complete contact between the cylinder and vascularized tissue flap, leaving no gap between them. Suture the flap into place using non-resorbing or slow resorbing suture, as shown in Figure 4.



Figure 4

18. Fix the cylinder firmly to the skin flap using a slow resorbing suture.

- To help maintain projection, place a suture through the top of the cylinder and secure firmly to the flap cover to suspend the cylinder in the silo, as shown in Figure 5.
- Additionally, a horizontal suture can be placed in an "X" pattern through the base of the cylinder and secured to the base of the silo.



Figure 5

19. Complete the surgical procedure by closing all incision sites with a non-resorbing or slow resorbing leak tight suture line, as shown in Figure 6.



Figure 6

20. Discard any unused portions of the cylinder according to institutional guidelines for medical waste.
21. Please refer to HaloShield™ Nipple Protector Instructions for Use, also included in this kit, for recommendations on the use of nipple protection.

POSTOPERATIVE CARE

- The nipple protector should be worn continuously for 6 weeks following cylinder implantation, and then for an additional 3 weeks during periods of sleep.
NOTE: Additional HaloShield™ Nipple Protectors can be purchased separately in quantities of five per box. Please contact your local Cook Representative for more information.
 - HaloShield™ Nipple Protector (G46289) has a maximum clearance of 10 mm.
 - HaloShield™ Nipple Protector Extended (G46290) has a maximum clearance of 20 mm.
- Basic local wound care should be applied to the surgical site in the immediate post-operative period.
- The patient should immediately report purulent drainage from the incision line or exposure of the device.
- The patient should not trim or pull on scabs, exposed material, or exposed strands of cylinder material.
- Nipple sutures should remain in place for at least 6 weeks. Donor site sutures may be removed at approximately 10 days based upon visualized tissue healing.
- Moisture should be avoided around the site for at least 7 days.
- The patient should wear loose or other non-compressive clothing for at least 8 weeks following nipple reconstruction.
NOTE: If the surgeon's preference is to create or use his or her own protector, ensure that the protector:
 - Provides a firm but flexible area of protection around the reconstructed nipple and is capable of keeping compressive loads away from the nipple area.
 - Does not compress peripheral blood supply.
 - Does not contact the suture lines around the reconstructed nipple.
 - Is breathable and vented.
 - Provides a soft, comfortable skin-contacting layer.

REFERENCES

- Illustrations provided by Dr. Heather Karu, Sanford Health, Sioux Falls, SD.