

# BIODESIGN™

## NIPPLE RECONSTRUCTION CYLINDER

FP0054-01C



### Manufacturer:

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### INTENDED USE

The BIODESIGN™ Nipple Reconstruction Cylinder is intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The Nipple Reconstruction 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.**

**This product is intended for use by trained medical professionals.**

### CONTRAINDICATIONS

- The Nipple Reconstruction Cylinder is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

### PRECAUTIONS

- The Nipple Reconstruction Cylinder is not for vascular use.
- Do not re-sterilize. Discard all open and unused portions.
- The Nipple Reconstruction Cylinder is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard the Nipple Reconstruction Cylinder if mishandling has caused possible damage or contamination, or if the Nipple Reconstruction Cylinder is past its expiration date.
- Users should be familiar with the surgical technique for nipple reconstruction.
- Ensure that the Nipple Reconstruction Cylinder is re-hydrated prior to implanting.
- The Nipple Reconstruction Cylinder should be placed in maximum possible contact with healthy, well-vascularized tissue to encourage cell in-growth and tissue remodeling.
- The Nipple Reconstruction Cylinder should not be implanted in infected or potentially infected tissue beds or over open cavities, because infection or extrusion may result.
- Compromised patients (such as those with autoimmune disease, diabetes, or undergoing radiation therapy) may not experience normal wound healing.
- Extended rehydration or excessive handling could lead to partial delamination of the Nipple Reconstruction Cylinder.
- Excessive internal pressure, which can be caused by implants, may increase the risk of extrusion or premature flattening.
- No studies have been conducted to evaluate the performance of the Nipple Reconstruction Cylinder in patients who are pregnant, may become pregnant, or are breast feeding.
- The Nipple Reconstruction Cylinder is not for vascular use.

### POTENTIAL COMPLICATIONS

Complications that can occur during nipple reconstruction include, but are not limited to: inflammation, migration, extrusion, seroma formation, hematoma, numbness, paresthesia, infection, ischemia, localized necrosis, epidermolysis, and discoloration. If any of the following conditions occur and cannot be resolved, Nipple Reconstruction 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 Nipple Reconstruction Cylinder should be stored in a clean, dry location at room temperature.

### STERILIZATION

The Nipple Reconstruction Cylinder has been sterilized with ethylene oxide.

### SUGGESTED INSTRUCTIONS FOR USE

These recommendations are designed to serve only as a general guideline. They are not intended to supersede the institutional protocols or professional clinical judgment concerning patient care.

**NOTE: Always handle the Nipple Reconstruction Cylinder using aseptic technique, minimizing contact with latex gloves.**

### Required Materials

- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Rehydration fluid: room temperature sterile saline or sterile lactated Ringer's solution

1. **IMPORTANT:** Select the proper Nipple Reconstruction Cylinder size.
  - a. If a contralateral nipple is present, measure its diameter to determine the Nipple Reconstruction Cylinder that most closely matches in size.
  - b. If a contralateral nipple is not present, the following factors should be considered when determining the proper Nipple Reconstruction Cylinder size: overall size of the reconstructed breast, presence or absence of a well-vascularized skin flap, size of skin flap(s), and/or the patient's desired final appearance.
2. Aseptically remove the tray containing the Nipple Reconstruction Cylinder from its pouch, and place it in the sterile field.
3. Using sterile forceps and gloved hands, aseptically remove the Nipple Reconstruction Cylinder from the tray.
4. **NOTE: Discard the Nipple Reconstruction Cylinder if it falls out of the sterile field or its sterility is compromised.**
5. Place the Nipple Reconstruction Cylinder into a sterile dish in the sterile field.
6. Add rehydration fluid to the sterile dish or the Nipple Reconstruction Cylinder's tray.
7. **IMPORTANT:** Allow the Nipple Reconstruction Cylinder to rehydrate, fully submerged, for less than or equal to 10 seconds. Rigidity is lost as the rehydration time is increased. Minimize manipulation of the Nipple Reconstruction Cylinder during rehydration to avoid delamination.
8. Aseptically prepare the patient and surgical site.
9. Perform the surgical procedure using a standard nipple reconstruction flap technique, assuring that the Nipple Reconstruction Cylinder has an adequate blood supply.
10. Aseptically transfer the Nipple Reconstruction Cylinder to the surgical site.
11. **IMPORTANT:** Place the Nipple Reconstruction Cylinder underneath the appropriate skin flap(s), maximizing contact with healthy, well-vascularized tissue to encourage cell in-growth and tissue remodeling.
12. Ensure fixation of the Nipple Reconstruction Cylinder using the appropriate skin flap(s). Depending on technique, an anchoring suture may be needed if patient's dermis is loosely connected to the underlying tissue.
13. Complete the standard surgical procedure and close the incision sites.
14. Discard any unused portions according to institutional guidelines for medical waste.

### POSTOPERATIVE CARE

1. Basic local wound care should be applied to the surgical site immediately post-operation.
2. **IMPORTANT:** The reconstructed nipple should be supported and protected by using a nipple shield or equivalent.
3. **IMPORTANT:** The patient should wear an appropriately-fitting, non-compressing bra following the operation to prevent premature Nipple Reconstruction Cylinder flattening, migration, or extrusion.