

BIODESIGN®

NIPPLE RECONSTRUCTION CYLINDER

FP0054-01D

COOK®

MEDICAL



Keep dry



Keep away from sunlight



MANUFACTURER

COOK BIOTECH
INCORPORATED
1425 Innovation Place
West Lafayette, IN 47906 U.S.A.
Phone: 812 339-2235
Toll Free: 800 457-4500
Toll Free Fax: (800) 554-8335

COOK (CANADA) INC.
111 Sandiford Drive
Stouffville, Ontario
L4A 7X5 CANADA
Phone: 905 640-7110
Toll Free: 800 668-0300



EC REPRESENTATIVE

COOK IRELAND
O'Halloran Road
National Technological Park
Limerick, IRELAND
Phone: +353 61 334440

WILLIAM A. COOK
AUSTRALIA PTY. LTD.
Brisbane Technology Park
12 Electronics Street
Eight Mile Plains
Brisbane, QLD 4113 Australia
Phone: +61 7 38 41 11 88

www.cookmedical.com
© COOK BIOTECH 2010

January 2010

BIODESIGN® NIPPLE RECONSTRUCTION CYLINDER

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 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.

PRECAUTIONS

- The cylinder is not for vascular use.
- **Do not resterilize.** Discard all open and unused portions.
- 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 cell in-growth and tissue remodeling.
- The 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 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 cylinder in patients who are pregnant, may become pregnant, or are breast feeding.

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 | • Discoloration |

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 should be stored in a clean, dry location at room temperature.

STERILIZATION

The cylinder has been sterilized with ethylene oxide.

USE OF ANTIMICROBIALS

Because the cylinder is at times used in surgical fields where sterility cannot be assured, the use of antimicrobials is common practice and may prevent infectious complications.¹ In these cases both antibiotic prophylaxis of the patient and antimicrobial soaking of the cylinder have been used. Typical flora can be expected to include a variety of aerobic and facultative anaerobic organisms, including, but not limited to, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, and *Escherichia coli*. Therefore the following points should be considered:

- Antimicrobials, if used topically or systemically, should provide coverage against a wide spectrum of aerobic and anaerobic organisms.²
- Antibacterial prophylaxis, if chosen, should be started prior to surgery and continued postoperatively.¹

The presence of certain antimicrobials may inhibit revascularization and/or infiltration of cells into the cylinder.^{3,5} For example, gentamicin is known to hinder neovascularization, epithelialization, and keratinocyte growth,⁴ while povidone iodine,⁶ bacitracin,^{3,6} polymyxin B,⁷ and vancomycin⁸ have all been reported to slow or inhibit wound healing. However, no studies have been conducted to evaluate the combination of antimicrobials with the cylinder.

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 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 cylinder size.
 - a. If a contralateral nipple is present, measure its diameter to determine the 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 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 cylinder from its pouch, and place it in the sterile field.
3. Using sterile forceps and gloved hands, aseptically remove the cylinder from the tray.
NOTE: Discard the cylinder if it falls out of the sterile field or its sterility is compromised.
4. Place the cylinder into a sterile dish in the sterile field.
5. Add rehydration fluid to the sterile dish or the cylinder's tray.
6. **IMPORTANT:** Allow the 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 cylinder during rehydration to avoid delamination.
7. Aseptically prepare the patient and surgical site.
8. Perform the surgical procedure using a standard nipple reconstruction flap technique, assuring that the cylinder has an adequate blood supply.
9. Aseptically transfer the cylinder to the surgical site.
10. **IMPORTANT:** Place the cylinder underneath the appropriate skin flap(s), maximizing contact with healthy, well-vascularized tissue to encourage cell in-growth and tissue remodeling.
11. Ensure fixation of the 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.
12. Complete the standard surgical procedure and close the incision sites.
13. Discard any unused portions according to institutional guidelines for medical waste.

POSTOPERATIVE CARE

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

REFERENCES

1. Mangram, A., et al, *Guideline for prevention of surgical site infection*, 1999. Centers for Disease Control and Prevention (CDC). 1999.
2. Aldridge, K.E., et al., *Multicenter survey of the changing in vitro antimicrobial susceptibilities of clinical isolates of Bacteroides fragilis group, Prevotella, Fusobacterium, Porphyromonas, and Peptostreptococcus species*. Antimicrob Agents Chemother, 2001. 45(4): p. 1238-43.
3. Petroustos, G., et al., *Antibiotics and corneal epithelial wound healing*. Arch Ophthalmol, 1983. 101(11): p. 1775-8.
4. Bang, K., et al., *Gentacoll hampers epithelialisation and neovascularisation in excisional wounds in hairless mice*. Scand J Plast Reconstr Surg Hand Surg, 1998. 32(2): p. 129-33.
5. Nelson, J.D., et al., *Corneal epithelial wound healing: a tissue culture assay on the effect of antibiotics*. Curr Eye Res, 1990. 9(3): p. 277-85.
6. Kjolseth, D., et al., *Comparison of the effects of commonly used wound agents on epithelialization and neovascularization*. J Am Coll Surg, 1994. 179(3): p. 305-12.
7. Nakamura, M., et al., *Effects of antimicrobials on corneal epithelial migration*. Curr Eye Res, 1993. 12(8): p. 733-40.
8. Petroustos, G., et al., *The effect of concentrated antibiotics on the rabbit's corneal epithelium*. Int Ophthalmol, 1984. 7(2): p. 65-9.