Technique Guide
Nipple Reconstruction

Acellular Dermal Matrix Tissue for Nipple Reconstruction

Nipple Reconstruction Using
alloMAX™ Surgical Graft

A natural product for a natural repair.
This Technique Guide contains the opinions of, and personal surgical techniques practiced by, Dr. William L. Scarlett, DO, FACOS, FAACS. He is a paid consultant to Davol Inc., a subsidiary of C. R. BARD, Inc. The opinions expressed do not reflect those of C. R. BARD, Bucks County Aesthetic Center or the Philadelphia College of Osteopathic Medicine.

The technique presented herein is for informational purposes only. The decision of which techniques to use in a surgical application lies with the surgeon based on patient profile and previous surgical history.
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Introduction

Over the last several years, the number of women who have received post-mastectomy breast reconstruction has grown. Many of these reconstructions result in the removal of the nipple and areola. Patients who choose to have their nipple reconstructed may be candidates for the techniques outlined in this guide. These techniques in this guide have been tailored to optimize the use of the existing incisions previously used for the skin sparing mastectomy.
Patient Selection

The general principal of utilizing scars that are already present instead of skin grafting is preferable in order to reduce additional scaring and improve healing. As with any operative procedure, the surgeon must evaluate the patient’s overall health when discussing potential outcomes. Smoking status, diabetes, morbid obesity and previous radiation may be of concern when discussing nipple reconstruction. High risk patients such as these are more likely to have complications at the incision site. If the incision site breaks down or an infection occurs, this can lead to exposure and potential loss of an implant. In many cases, this can be managed post-operatively, but the risk is there and should be discussed with the patient.
Patient Education

Preoperatively, patients need to be informed about the following:

- Timing of suture removal
- Using a nipple shield for six weeks after surgery
- Concealing the shields with clothing/bras

Patients should be educated that immediately following surgery, the nipple will appear larger than it will appear when it is completely healed. Healing time is approximately six weeks.
*Determination of the skin flaps is done preoperatively with the patient in a sitting and/or standing position. The ideal position for the nipple is 19-21 cm from the mid-clavicular line and 9-11 cm from the mid-sternal line. When matching the native nipple, measure these two distances and mark according to those measurements. Most patients have a horizontal incision and the flaps are then based on the inferior or superior pedicle, depending on the position of the scar. (With a horizontal scar the flaps are rotated 90 degrees.) When performing bilateral nipple reconstruction; the base measurements may differ if the scars are not at the same level. This is done in order to create an even nipple position.

*Follow hospital protocol.*
Consider any previous biopsy sites or other scars that may be on the breast and may affect the blood supply to the pedicle.

The pendants are each 3 cm in length (6 cm total) and taper from a width of at least 1 cm. The base of the pedicle should also be at least 1 cm. When performing this technique on an individual who has had previous radiation, consider increasing the width of the pedicle. This may give the nipple a somewhat squared off appearance, but will provide a better blood supply to the flaps.
In the operating room, patients are placed in a supine position, with their hands out to their sides and the chest is prepped with chlorohexidine or Betadine®. Prep and drape the patient, have the staff perform a “time out” before beginning. Elevate the flaps full thickness down to either a thin layer of fat or the implant capsule. Do not thin the tips of the flaps because these are the furthest from the blood supply and may otherwise be at risk of necrosing.

Elevate the flaps to the pedicle using the scalpel or iris scissors. A #10 blade scalpel is recommended in these procedures. Apply electrocautery to achieve hemostasis of the donor site and then close in layered fashion with 3.0 Monocryl (Ethicon, Inc.) and 4.0 nylon.
In preparation for the next step, rehydrate a 2 cm x 4 cm piece of AlloMax™ Surgical Graft in accordance with the IFU. While the ADM is hydrating, rotate the two pendant flaps around each other. Try both positions because one always lies more naturally than the other. Suture the flaps to each other using 5.0 nylon.
Measure the depth and width of the nipple mound. Cut the rehydrated piece of AlloMax™ Surgical Graft and roll it into a cylinder with the deep dermal side out. The length and width of the AlloMax™ Surgical Graft is dependent on the flaps. Suture the AlloMax™ Surgical Graft to itself in two places with 3.0 Vicryl sutures in order to prevent the roll from telescoping.
After suturing the flaps and creating the cylinder, incise and deepithelialize a semicircle of skin in order to inset the rolled AlloMax™ Surgical Graft. Electrocautery is used to obtain hemostasis and the AlloMax™ Surgical Graft is then inset into the center of the newly formed nipple mound using 4.0 nylon suture.
Trim the height of the roll as needed to close the top of the nipple. Use 5.0 nylon suture to close the top. It is important not to round the top of the nipple by trimming the corners as doing so would most likely decrease the blood supply to the tips of the flaps. **DO NOT** include a piece of AlloMax™ Surgical Graft in the nipple closure. Doing so will increase the chance of incisional separation when the sutures are removed. Palpate the nipple after closing the top to make sure there is not too much tension on the flaps. When placing your finger on the nipple, it should easily compress. If you feel that the pressure created by the AlloMax™ Surgical Graft placement is too great, remove the AlloMax™ Surgical Graft and trim as needed.
Dressings

Dress the donor sites with benzoin and Steri strips (3M Healthcare) or follow hospital protocol. Place a sterile gauze dressing around the nipple (4 x 4 cm cut with a hole in the center), and apply antibiotic ointment to the projecting portion. Place a Tegaderm dressing (3M Healthcare) on top of the sterile gauze (again with a hole cut in the center). Use a plastic ocular shield (Aarron Medical) on top of the nipple, after creating multiple holes in the shield with an 18 gauge needle. Place another dressing on top of the shield if desired and then a sports bra, or leave the dressings alone after the nipple shield is in place. Care must be taken that the patient does not have any sensitivites or allergies to any of the materials used here.
Postoperative Care

Depending on the patient’s general health and depending on the postoperative course, it is recommended to examine the patient three to five days after surgery. Remove the dressings, but leave the sutures in place. Wash and replace the nipple shield after applying more antibiotic ointment to the suture line. Remove sutures 10 days later. Instruct the patient to wear the nipple shield for another four weeks whenever a bra is being worn. After the additional four weeks, remove the shield and schedule the patient for tattooing of the newly formed nipple.
Product Description:

AlloMax™ and AlloMax™ 1mm Surgical Grafts are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional (i.e., physician). This includes supplemental support and reinforcement of soft tissue in hernia repair, chest wall defect procedures and grafting for horizontal and vertical soft tissue augmentation of thickness and length such as post-mastectomy breast reconstruction. The implant is provided sterile and requires rehydration prior to use.

Storage & Shipping:

Storage Conditions
Store in a clean, dry environment at the temperature range specified on the product label. Keep away from sunlight.

Shipping Conditions
Implant is shipped at ambient temperature via expedited shipping methods.

Warnings:

The same potential medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, it is not possible to guarantee freedom from transmission of infectious agents or other adverse reactions such as hypersensitivity, allergic or immune response.
Precautions:

Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for procedures using this implant; as such conditions may compromise outcomes.

The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. If the surgeon determines that the clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken.

Appropriate placement and fixation of the implant are critical to success of the surgical procedure.

Instructions For Use:

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect the success of the surgical procedure.

General Instructions For Implant Handling:

- Use on a single occasion for a single patient only. Once the package is opened, the implant must be used for the current procedure or discarded.
- The box is non-sterile and is used to protect the implant during shipping and storage.
- Remove the double-barrier packaged product, the package insert, implant identification labels and Tissue Utilization Record from the box.
• Inspect the product, including all packaging and labeling materials carefully:
  – Do not use past expiration date specified on product label.
  – Do not use if the implant or packaging is damaged.
  – Do not use if there are discrepancies in label information.
• The implant’s sterile barrier is comprised of two sealed pouches. To prevent contamination of the implant, use sterile technique for preparation and implantation.
• Additional product should be available in case of unexpected need during the procedure.
• Do not re sterilize the implant.
• The implant and all packaging materials are latex-free.
• Use standard practices for handling and disposal of human tissue.
• Promptly report all product defects and patient adverse events to Davol Inc.

Directions For Implantation:
1. Open outer pouch and pass inner pouch to sterile field.
2. Open sterile inner pouch and remove implant.
3. Re-hydrate the implant prior to use by soaking in room temperature sterile saline for at least 5 minutes to improve suppleness and handling properties.
   Note: For bilateral breast reconstruction procedures, it is recommended to hydrate one implant at a time.
4. Pharmaceutical antibiotics or other antimicrobial agents prescribed by the surgeon as a precaution against incidental infection may be added to the soaking solution. The prescribing surgeon is responsible for selecting a suitable antibiotic or other antimicrobial agent at the appropriate concentration.

Please consult product labels and inserts for uses, hazards, warnings, precautions and instructions for use.

IFU Part # PK3795842 116R
Nipple Reconstruction using AlloMax™ Surgical Graft

The AlloMax™ Surgical Graft is processed by RTI Biologics.

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Please add the AlloMax™ Surgical Graft to my preference card.

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**AlloMax™ 1 mm Surgical Graft**

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Surgeon's Signature ____________________________________________

Purchase Order Number __________________________________________

Catalog Number _______________________________________________

Date __________________________ Quantity ________________________

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