Immediate Post-Mastectomy Breast Reconstruction Using

**ALLOMAX™ Surgical Graft**

*A natural product for a natural repair.*

Acellular Dermal Matrix Tissue In Conjunction With Soft Tissue Repair

**Technique Guide**

Post-Mastectomy Breast Reconstruction

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This Technique Guide contains the opinions of, and personal surgical techniques practiced by Dr. Adam J. Vernadakis. 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, Lahey Clinic or Tufts University School of Medicine.

The technique presented herein is for informational purposes only. The decision of which techniques to use in a particular surgical application lies with the surgeon based on patient profile, particular circumstances surrounding the defect and previous surgical experience.
AlloMax™ Surgical Graft Technique Guide

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Introduction

There is growing acceptance of the use of human acellular dermal matrix grafts in the treatment of post-mastectomy defects since the initial description in 2005. The procedure allows for muscle elevation to be limited to the pectoralis major muscle alone, the ability to balance the filling of the submuscular and subcutaneous pockets in the skin-sparing mastectomy and for precise control of the location and shape of the inframammary fold. The AlloMax™ Surgical Graft has clinical properties which offer distinct benefits.

Prior to the acceptance and usage of acellular dermal matrix implants, the prosthetic-based reconstructions utilizing total submuscular coverage often presented with constricted or malpositioned inframammary folds and high-riding implants. Release of the costal margin of the pectoralis major without total submuscular coverage caused the muscle to ‘window shade’ superiorly. Often this produced visible rippling in the lower pole of the reconstructed breast, which had skin-only coverage. The technique presented in this guide has been modified from previous techniques to create an aesthetic and natural appearance to the reconstructed breast. The contralateral breast can be modified subsequently to create a more symmetric result.
Benefits of using the AlloMax™ Acellular Dermal Matrix Graft

• All natural human collagen provides support for incorporation into and remodeling by native tissues.

• Supple material with excellent handling characteristics.

• Hydrates rapidly, 5 year shelf life, no refrigeration necessary.

• 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. (Please refer to the instructions for use.)

• 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.
Patient Selection

The timing of the reconstruction and the choice of technique used for post-mastectomy reconstruction is an individual decision made between the patient and the surgical oncological team involved in her care. The choice is based on multiple factors including patient preference, medical comorbidities, tumor characteristics, size of the breast, choice of unilateral versus bilateral procedures and the need for adjuvant therapy. When tissue expander-based reconstruction is the procedure of choice, a detailed discussion is held regarding the use, characteristics, safety and efficacy of the AlloMax™ Surgical Graft. Most patients who are able to undergo a mastectomy will be candidates for this procedure if the above factors are considered.
Preoperative Preparation

The patient is typically photographed bilaterally prior to surgery in the AP, lateral and oblique views, regardless of whether the reconstruction is to be unilateral or bilateral. Measurement of the width of the chest wall is made during the preoperative consultation to assist with implant selection and facilitate preoperative planning. Preoperatively, the mastectomy incision(s) and inframammary folds are marked externally in the unsupported, vertically upright position, using a permanent marker. Marking the mastectomy incision allows for greater control of the mastectomy flaps and the subsequent reconstruction. These markings may then be transferred internally using small volumes of methylene blue on a 25 gauge needle to facilitate intraoperative definition of the inframammary fold by the surgeon. For bilateral procedures, the lateral borders of the sternum may be similarly defined to prevent the incidental creation of symmastia.
Patient Positioning and Preparation

The patients are placed in the supine position with the arms placed symmetrically on well padded arm boards abducted to approximately sixty degrees. Care is taken to protect the brachial plexus from traction and the ulnar and median nerves from pressure. The chest wall is prepped widely to include the breasts bilaterally and the lateral chest wall to the mid-axillary line. The plastic surgeon is preferably present to assist with the surgical preparation, including draping during the initial stage of the operation. Mastectomy is then completed by the breast surgeon. If a bilateral mastectomy is planned, it is recommended to have both mastectomies completed prior to the initiation of the reconstruction to prevent crowding at the surgical field and to allow for symmetric restoration of both breasts and inframammary folds.
The sternal origin and costal margin of the pectoralis major muscle is inspected following the mastectomy. There is a large degree of variation in the size and thickness of the pectoralis major, and this difference can often be marked between the sides on a bilateral mastectomy. The costal margin often exhibits tremendous variability in the bilateral procedure.
The inframammary fold is transposed internally and marked using a surgical marker (or methylene blue in a syringe) to facilitate placement of the AlloMax™ Surgical Graft dermal implant. The pectoralis major muscle is elevated from a lateral to medial direction, leaving the pectoralis minor muscle in its anatomic position on the chest wall. Note the superior retraction or ‘window shading’ of the pectoralis major once released from the costal margin.

The IMF boundaries are marked accordingly. The muscle naturally contracts or “window shades” cephalad when released.
The submuscular plane is developed using electrocautery, dividing the submuscular costal attachments. The inferior costal margin is released to the 4 or 5 o’clock position on the right and to the 7 or 8 o’clock position on the left. Care must be taken medially to identify the medial perforators when in the submuscular plane. The more inferior perforators often require division to allow for medial placement of the implant. The submuscular pocket is developed sufficiently to allow placement of a tissue expander.

Note the medial attachment of the pectoralis muscle. It is crucial to leave this attachment in order to avoid medial expansion of the pocket, which often leads to symmastia.

These general reference points are applicable in most patients. The most important aspect of this stage of the operation is not to oversize the breast pocket.
The graft must be hydrated for at least 5 minutes in accordance with the instructions for use. It is important to hydrate the graft in room temperature sterile saline and not in hot or cold saline. Following hydration, the inferior lateral corner of the AlloMax™ Surgical Graft is resected in a curvilinear pattern which allows the implant to contour along the lateral chest wall.

Make sure the AlloMax™ Surgical Graft is completely submerged in saline during hydration (see IFU for details).

This illustration shows graft is cut curving to the patient’s right side, to be used on the right breast.
Proper placement of the graft in relation to the IMF is crucial to providing the patient with the desired breast height and ptosis. The graft should be placed so that the caudal perimeter of the graft is taut, but not tight, and ripples are minimized.

The inferior medial corner of the implant is anchored to the medial most portion of the divided pectoralis major muscle using a 3-0 PDS suture in a horizontal mattress fashion. The suture is tied on the AlloMax™ Surgical Graft which serves as a pledget. The implant is then inset medially in a gentle curve to allow for a rounded medial aspect of the reconstructed breast without constriction.
Sutures are passed through the sling shaped AlloMax™ Surgical Graft, into the fascia and then through the graft so that all knots are secured on the surgical graft. The sling is then anchored at the most inferior portion of the inframammary fold and superolaterally at the junction of the serratus anterior and the lateral border of the pectoralis major. Interrupted sutures are placed in this order to allow for smooth draping of the dermal matrix. Once the matrix is positioned appropriately, additional anchoring sutures are placed in close approximation medially for stability and further laterally to allow for drainage of the submuscular space. For this patient, a 6 x 20 cm piece of the acellular dermal matrix was selected. The 20 cm length allows complete lateral coverage of the implant, preventing lateral migration, while the 6 cm width prevents undue traction on a potentially attenuated pectoralis major muscle.

The added length of the graft is used to assure complete pocket closure lateral and superolateral. This ensures that the expander will not migrate laterally toward the underarm area.
The sutures are placed external to the submuscular pocket, which allows the AlloMax™ Surgical Graft to fold gently over the reconstructed inframammary fold and prevents the suture from contacting the implanted tissue expander.
The appropriate expander is selected and placed. In this example, a textured 650 cc Mentor® implant was utilized.

The appropriate tissue expander should be chosen based on the individual patient’s needs. In this example, a tall height expander will most closely approximate the dimensions of the round implant which will be placed subsequently. Medium height expanders closely approximate the dimensions of anatomic implants and low height implants allow for differential lower pole expansion. This differential lower pole expansion often is not needed as the lower pole is defined by the tissue graft, allowing ptosis of the reconstructed breast. Initially all residual air is aspirated and 50-100 cc of injectable saline is instilled. The partially filled expander is then placed, positioning the base medially along the sternal border and inferiorly along the newly created inframammary fold. It is often easier to achieve optimal inferior and medial positioning with a minimally filled expander.
The superomedial corner of the AlloMax™ Surgical Graft is then removed, tailoring it so it is flush with the inferior border of the pectoralis major muscle. The superior border of the matrix is then secured to the inferior border of the pectoralis major muscle using 5 to 6 interrupted absorbable monofilament horizontal mattress sutures. Full thickness bites of muscle are taken and the knots are tied on the graft to prevent tearing. The tissue expander is protected from puncture using a small malleable retractor. A running 3-0 absorbable monofilament suture is used to fully approximate the edges of the matrix to the muscle. Pleats in the matrix are smoothed out as much as possible by differential travel on the running absorbable monofilament suture.

It is important to make sure there is minimal rippling of the graft once it is secured. This will ensure maximum contact between the graft and the skin flap, helping to minimize the likelihood of seroma.
Additional saline may be added at any stage following expander placement. The final fill volume creates a balance between the submuscular and subcutaneous pockets and may range from 100 cc to 400 cc or more.
Drains are then placed along the inframammary fold and beneath the superior mastectomy flap. The wider spacing of the lateral anchoring sutures allows for drainage of the submuscular space. Round channel drains are recommended for their resistance to clot and reduce discomfort on removal.

Drains are left in place until they drain less than 30 cc per day for two consecutive days. It is recommended to remove one drain first and the other 1-2 days later to ensure that drainage levels remain acceptable.
The skin is then closed using monofilament dermal and subcuticular sutures. Additional skin may be resected to achieve the appropriate balance between the submuscular pocket and the mastectomy flaps in the large or pendulous breast. (Care must be taken not to over inflate the expander as pressure on the mastectomy flaps may lead to an increased incidence of flap necrosis.) Expansion is then initiated at 2-3 weeks and then proceeds every 1-2 weeks until the final fill volume is reached.
Implant Exchange

The final volume of the expander is determined by the collaborative efforts of the patient and the surgeon. Once this has been achieved, it is preferable to wait 6 months post expansion before exchanging the expander for a final implant. This period allows for adjustments of the volume to achieve maximum patient satisfaction, ensures the incorporation of the AlloMax™ Surgical Graft acellular dermal matrix and allows for maturation of the implant capsule. During implant exchange, it is preferable to enter the lateral portion of the incision and divide the incorporated dermal graft. The AlloMax™ Surgical Graft acellular dermal matrix should be revascularized at this stage, and bleeding may be noted from the divided dermal graft.

Ideally, implant exchange will take place 6 months after the initial procedure. Here you can see a well incorporated graft with healthy vascularization.
Conclusion:

The technique described is a modification of pre-existing techniques. The use of acellular dermal matrices as a graft has improved the aesthetic outcomes by defining the inframammary fold and allowing a greater degree of ptosis and a more natural breast appearance. AlloMax™ Surgical Graft acellular dermal matrix offers many advantages in breast reconstruction including sterility, 5 year shelf life and intraoperative ease of handling.

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 resterilize 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 Bard 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. Rehydrate the implant prior to use by soaking in sterile, endotoxin-free, room temperature, 0.9% physiological saline solution 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.

5. Abdominal Wall Repair
   Note: The surgeon should close or minimize the midline prior to implantation.
   a. Size the implant according to the tissue defect. The edges should extend a minimum of 3-5 cm beyond the perimeter of the defect on all sides. If necessary, multiple pieces of implant may be sutured together to cover a larger defect.
b. Place the implant securely to prevent displacement and to aid incorporation. Either absorbable or non-absorbable suture material may be used, with a round atraumatic needle. Select the appropriate suture size for the surgical procedure. If absorbable sutures are used, it is recommended to select the longest lasting materials available. Place the stitches at least 4-5 mm from the edge of the implant. Use the implant where it is under minor to moderate tension.

6. Breast Reconstruction
   a. Size the implant according to the tissue defect and trim so that free edges of the implant do not protrude.

   b. Place the implant securely to prevent displacement and to aid incorporation. Either absorbable or non-absorbable suture material may be used, with a round trauma needle. Select the appropriate suture size for the surgical procedure. Place the stitches 2-3 mm from the edge of the implant where possible. Use the implant where it is under minor to moderate tension.

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

The AlloMax™ Surgical Graft is processed by RTI Biologics.
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Tutoplast is a registered trademark of RTI Biologics, Inc. All other trademarks are the property of their respective owners.

Part # PK3795357 109R
## AlloMax™ Surgical Graft

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**AlloMax™ thickness is 0.8 mm—1.8 mm**

- Please add the AlloMax™ Surgical Graft to my preference card.
- I would like to have the AlloMax™ Surgical Graft in stock.
- I would like to trial the AlloMax™ Surgical Graft.

## AlloMax™ 1 MM Surgical Graft

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Surgeon’s Signature _____________________________________________

Purchase Order Number _________________________________________

Catalog Number _______________________________________________

Date ___________________________ Quantity _________________________

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