

Open & Endoscopic Component Separation



Technique Guide

ALLOMAX™ Surgical Graft - Human Dermal Collagen

BAIRD

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This Technique Guide contains the opinions of
and personal surgical techniques practiced by
Dr. Scott Roth. He is a paid consultant to BARD.

The opinions and techniques presented herein are
for informational purposes only and the decision
of which technique to use in a particular surgical
application should be made by the surgeon based on
the individual facts and circumstances of the patient
and previous surgical experience.

OPEN AND ENDOSCOPIC COMPONENT SEPARATION

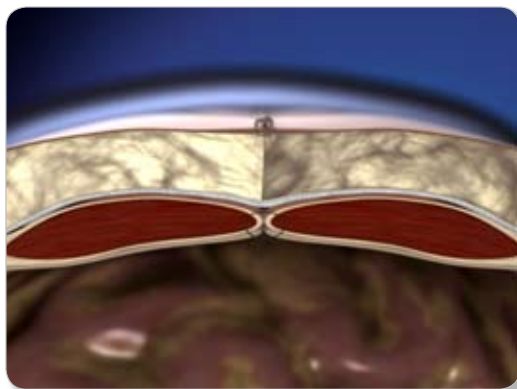
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OPEN COMPONENT SEPARATION

Basic Steps To Open CST

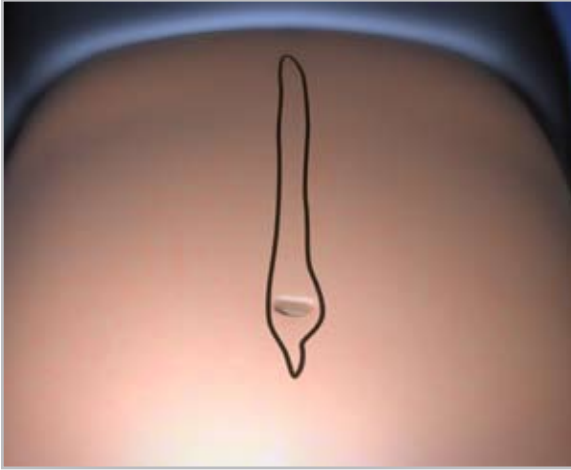


1. Enter the abdominal cavity and perform adhesiolysis.
2. Bilateral skin flaps raised.
3. Bilateral relaxing incisions made through external oblique 2-3 cm lateral to the linea semilunaris.
4. Midline closed.
5. ALLOMAX™ Surgical Graft is secured into place against the abdominal wall with sutures, followed by skin closure.

Patient Preparation

Place the patient in a supine position with both arms abducted and appropriate padding on all pressure points. Apply sequential pneumatic compression devices to the lower extremities to prevent deep venous thrombosis. Utilize preoperative heparin products as appropriate. Place a foley catheter for intra-operative monitoring of urine output. Nasogastric tubes are only utilized in the event of extensive adhesiolysis. Perform standard skin preparation which includes hair removal if necessary followed by a chlorhexidine skin preparation. Routine antibiotic prophylaxis is performed with either a first generation cephalosporin or equivalent in allergic patients.

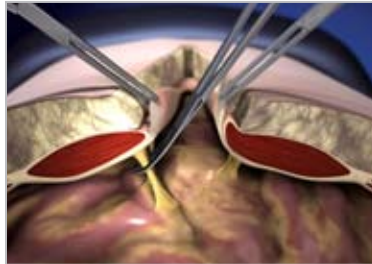
PATIENT PREPARATION



1A

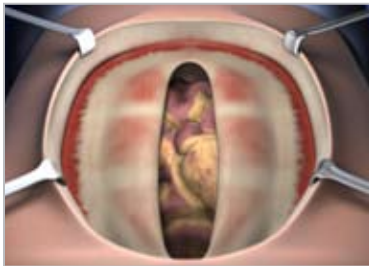
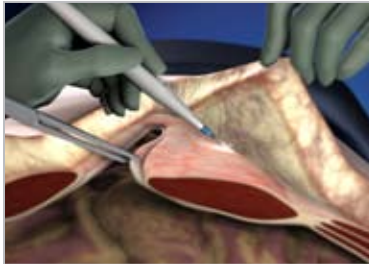
Entering the Abdominal Cavity and Adhesiolysis

- Use sharp dissection to enter the abdominal cavity.
- The incision is made adjacent to the prior surgical scar to allow for scar excision.



1B

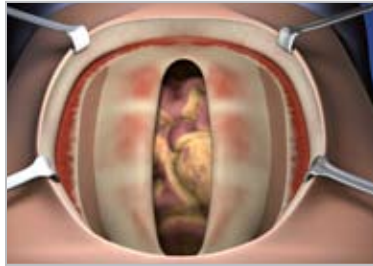
- Enter the abdominal cavity above or below the prior incision to gain access to the peritoneal cavity in an area free of adhesions.
- Open the remainder of the incision.
- Dissect bowel, omentum, and/or other adhered organs from the abdominal wall using direct visualization.
 - It is essential to free the entire anterior abdominal wall of all adhesions to allow for the greatest degree of advancement of the abdominal wall musculature.



2

Bilateral Skin Flaps Raised

- Release a flap consisting of skin and subcutaneous tissue from the underlying anterior rectus sheath using cautery.
 - Extend laterally beyond the linea semilunaris to the level of anterior axillary line.
 - Extend caudad to the inguinal ligaments and cephalad to a distance approximately 5 cm above the costal margins.
 - In most circumstances the releases are performed bilaterally.

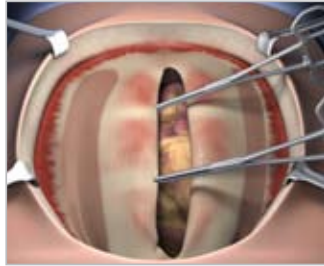
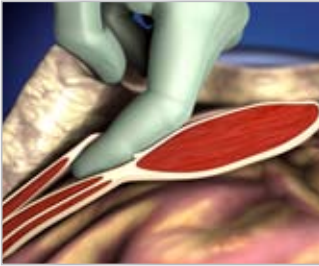


3A

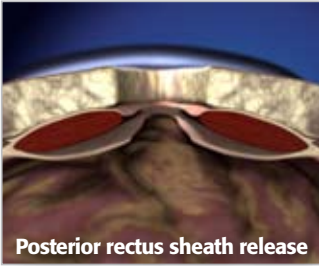
Create Relaxing Incisions

- Create a vertically oriented incision in the external oblique aponeurosis located 2-3 cm lateral to the linea semilunaris.
- The relaxing incision should extend from the inguinal ligament to at least the level of the costal margin.
- In the event of an epigastric defect, the incision should extend several centimeters above the costal margin.

Standard Release:



Additional Advancement Options:



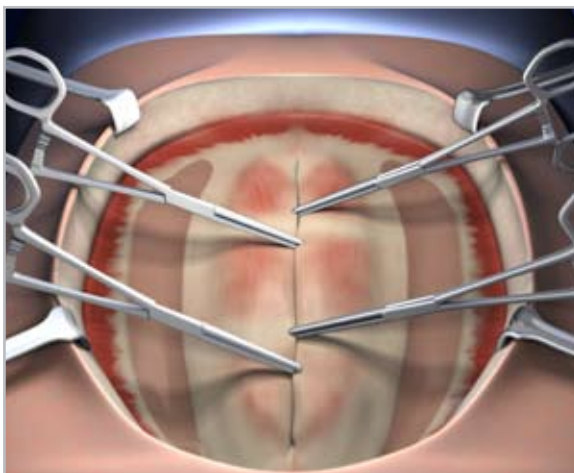
Posterior rectus sheath release



Extended release
above the costal margin

3B

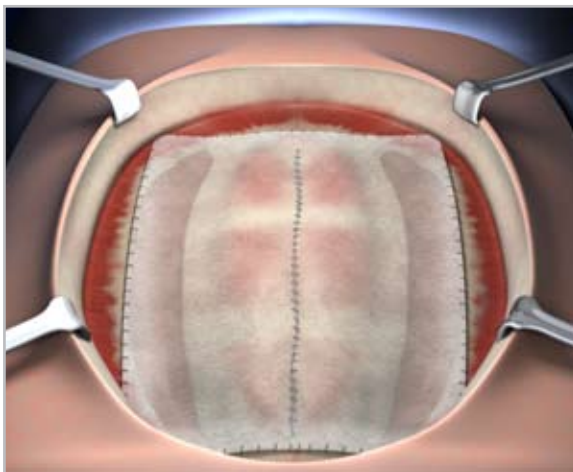
- After division of the external oblique, the plane between the external and internal oblique muscles is developed using blunt dissection and extending out to the anterior axillary line.
- Further advancement can be obtained by elevating the rectus from the posterior rectus sheath by incising the posterior rectus sheath 1-2 cm from the midline. The anterior rectus sheath should be left intact for suture placement.
- In most circumstances, the releases are performed bilaterally.



4

Midline Closure

- The hernia sac and attenuated fascia are debrided from the midline to ensure apposition of healthy well-vascularized tissue as the midline is closed.
- To assess the abdomen for closure, Kocher clamps are applied to the anterior rectus fascia on each side and brought to the midline.
- Monitor peak airway pressures during this maneuver.
- Absent a significant increase in peak airway pressures, plan to close the fascia primarily with interrupted sutures.



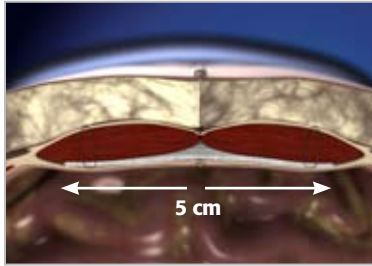
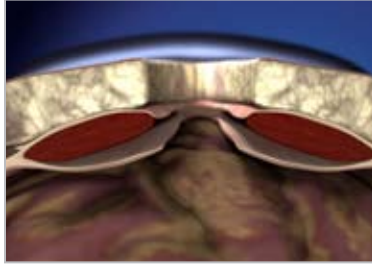
5A

Graft Placement

- Reinforce the hernia repair with an ALLOMAX™ Surgical Graft in an onlay or underlay position.
 - To address larger defects, multiple ALLOMAX™ Surgical Grafts may be sutured together with a running suture.
- Orient the ALLOMAX™ Surgical Graft in either a rectangular or diamond configuration to reinforce the entire abdominal wall and secure with a continuous suture.

For onlay mesh placement, suture the ALLOMAX™ Surgical Graft bilaterally to the released lateral edges of the external oblique and sew it to the anterior rectus sheath superiorly and inferiorly.

RETRO-MUSCULAR PLACEMENT

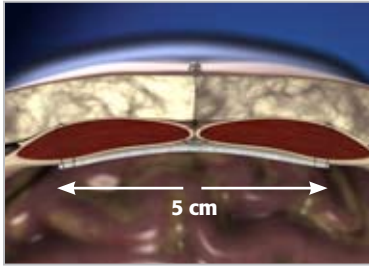
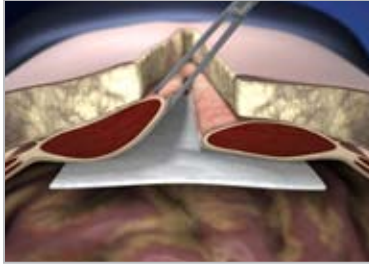


5A

Graft Placement continued

- For underlay mesh placement, place the ALLOMAX™ Surgical Graft either as an intraperitoneal graft or in the retro-rectus space.
 - If placed in the retro-rectus space, additional dissection is needed to create a pocket for the graft. Once the retro-rectus space has been developed, close the posterior rectus sheath with a running absorbable suture. This will create a space for the ALLOMAX™ Surgical Graft between the rectus muscle and the posterior rectus sheath.

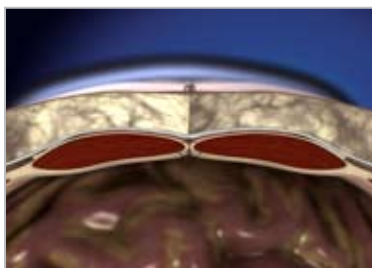
INTRAPERITONEAL PLACEMENT



5A

Graft Placement continued

- Reinforce the entire incision by overlapping the ALLOMAX™ Surgical Graft by approximately 5 cm.
- Suture the graft to the abdominal wall with a series of interrupted horizontal mattress sutures.
- Place the sutures laterally on the abdominal wall to allow for approximation of the midline fascia when the sutures are secured on each side.

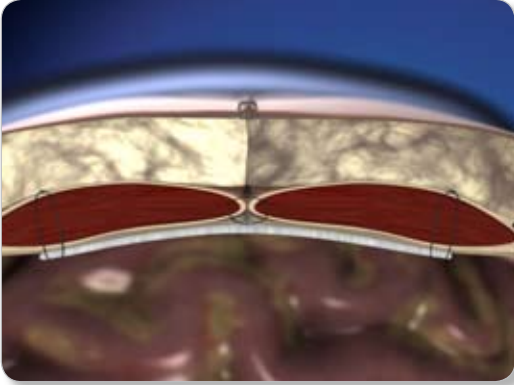


5B

- Irrigate the wound with sterile, normal saline.
- Place closed suction drains (Blake) beneath the flaps in the subcutaneous plane.
 - Maintain the drains until the output decreases to less than 30 milliliters per day for 2 consecutive days.
- Close the skin in a layered fashion due to the extensive undermining of skin.

Endoscopic Component Separation

Basic Steps To Endoscopic Component Separation

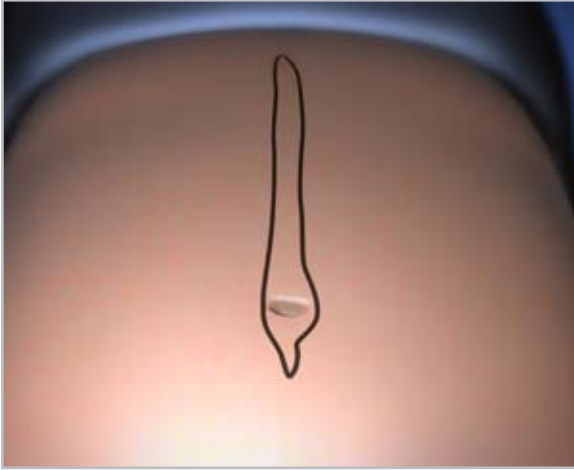


1. Enter the abdominal cavity and perform adhesiolysis.
2. Insert and expand balloon dissector between internal and external oblique.
3. Endoscopically divide the external oblique aponeurosis with cautery or ultrasonic dissection.
4. Assess the abdomen for closure.
5. Intraabdominal or preperitoneal mesh placement.
6. Midline closure.

Patient Preparation

Place the patient in a supine position with both arms abducted and appropriate padding on all pressure points. Apply sequential pneumatic compression devices to the lower extremities to prevent deep venous thrombosis. Utilize preoperative heparin products as appropriate. Place a foley catheter for intra-operative monitoring of urine output. Nasogastric tubes are only utilized in the event of extensive adhesiolysis. Perform standard skin preparation which includes hair removal if necessary followed by a chlorhexidine skin preparation. Routine antibiotic prophylaxis is performed with either a first generation cephalosporin or equivalent in allergic patients.

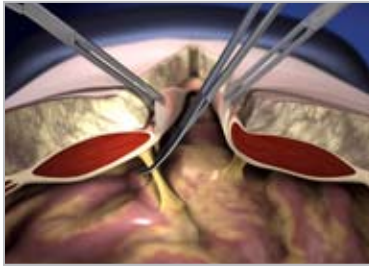
PATIENT PREPARATION



1A

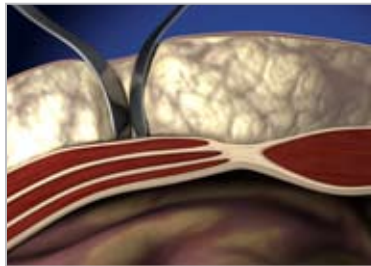
Entering the Abdominal Cavity and Adhesiolysis

- Use sharp dissection to enter the abdominal cavity.
- This incision is made adjacent to the prior scar to facilitate later scar excision.
- Advance the incision until the fascia or hernia sac is encountered.



1B

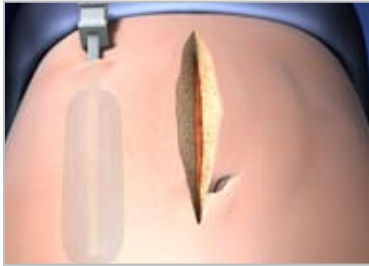
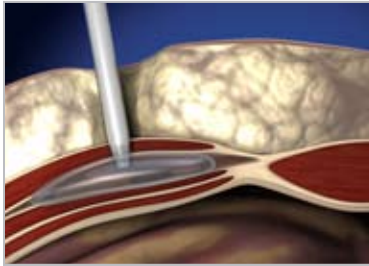
- Enter the abdominal cavity above or below the prior incision to gain access to the peritoneal cavity in an area free of adhesions.
- Open the remainder of the incision.
- Dissect bowel, omentum, and/or other adhered organs from the abdominal wall using direct visualization.
 - It is essential to free the entire anterior abdominal wall of all adhesions to allow for the greatest degree of advancement of the abdominal wall musculature.



2A

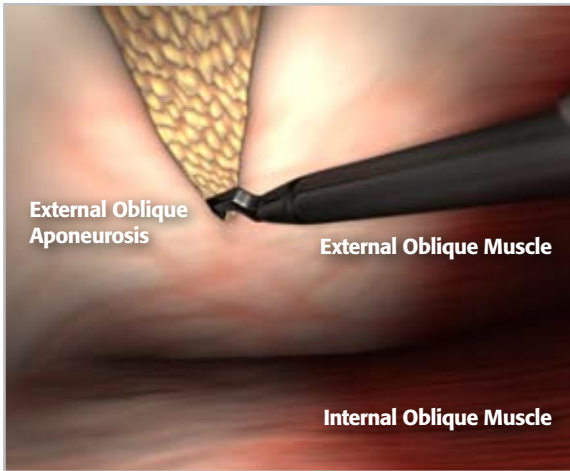
Insert and Expand Balloon Dissector

- Make a 2 cm incision directly over the costal margin at the level of the mid clavicular line.
 - This may occasionally need to be placed further lateral to ensure the incision is lateral to the linea semilunaris.
- Dissect down to the level of the external oblique muscle.
- Bluntly separate the external oblique muscular fibers with S-retractors. This allows for visualization of the underlying internal oblique aponeurosis below.



2B

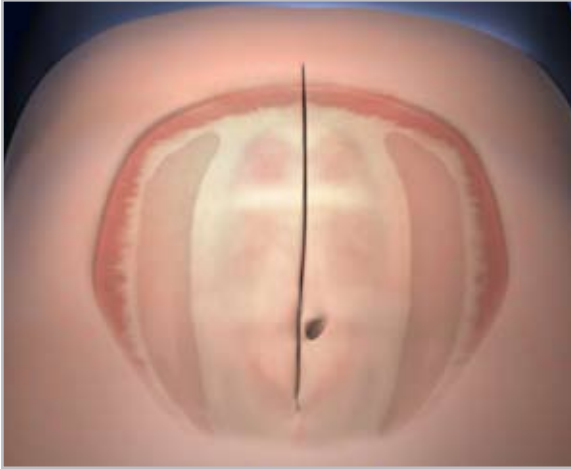
- Advance a balloon dissector between the internal and external oblique muscle down to the level of the inguinal ligament.
- Insufflate the balloon under endoscopic visualization.



3

Divide the External Oblique Aponeurosis

- Remove the dissecting balloon and replace with a balloon tip trocar.
 - Infuse carbon dioxide into the lateral abdominal cavity. Place a second 5 mm port into the lateral abdominal cavity to allow for dissection.
- Use cautery or alternatively ultrasonic dissection to divide the external oblique muscle from the costal margin down to the inguinal ligament.
 - Extending the dissection to the level of Scarpa's fascia results in even greater abdominal wall advancement.
 - This technique is generally performed bilaterally.

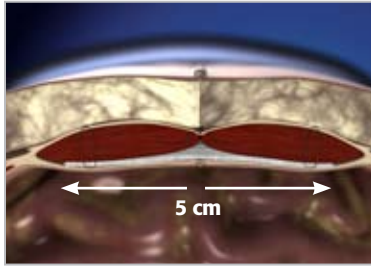
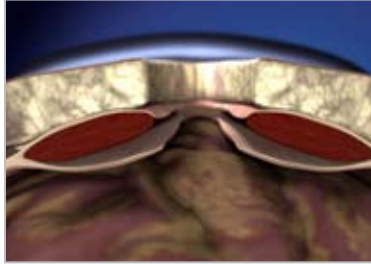


4

Assess the Abdomen for Closure

- The hernia sac and attenuated fascia are debrided from the midline to ensure apposition of healthy well-vascularized tissue as the midline is closed.
- To assess the abdomen for closure, Kocher clamps are applied to the anterior rectus fascia on each side and brought to the midline.
- Monitor peak airway pressures during this maneuver.
- Absent a significant increase in peak airway pressures, continue with graft placement and midline closure.

RETRO-MUSCULAR PLACEMENT

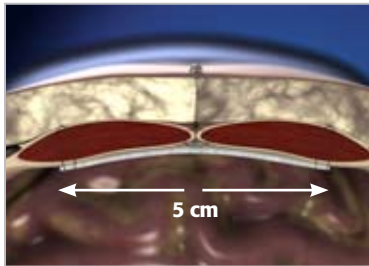
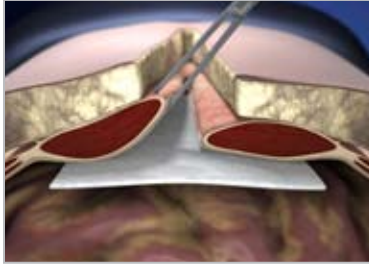


5A

Underlay Mesh Placement: Intraperitoneal or Retro-Muscular

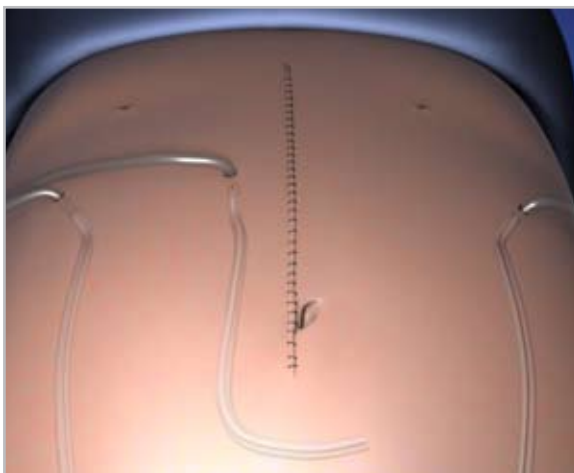
- Following bilateral release, place the ALLOMAX™ Surgical Graft either as an intraperitoneal graft or in the retro-rectus space.
 - If placed in the retro-rectus space, additional dissection is needed to create a pocket for the graft. Once the retro-rectus space has been developed, close the posterior rectus sheath with a running absorbable suture. This will create a space for the ALLOMAX™ Surgical Graft between the rectus muscle and the posterior rectus sheath.

INTRAPERITONEAL PLACEMENT



5B

- Reinforce the entire incision by overlapping the ALLOMAX™ Surgical Graft by approximately 5 cm.
- Suture the graft to the abdominal wall with a series of interrupted horizontal mattress sutures.
- Place the sutures laterally on the abdominal wall to allow for approximation of the midline fascia when the sutures are secured on each side.



6

Midline Closure

- Close the midline with a running fascial closure suture.
- Place a closed suction (Blake) drain into the midline wound and lateral abdominal cavities and close the skin in layers.
- Leave the drains in place until the drainage is minimal.

Uses:

ALLOMAX™ Surgical Graft is 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.

Collagenous connective tissue with three-dimensional intertwined fibers retains the multidirectional and mechanical properties of native collagen, while providing the basic formative structure to support replacement by new endogenous tissue.

Utilization/Implantation:

It is recommended that ALLOMAX™ Surgical Graft be rehydrated prior to use by soaking in sterile, endotoxin-free, room temperature 0.9% saline solution for up to 30 minutes, depending on the consistency desired, using aseptic/sterile technique, in order to improve suppleness and handling properties. If desired, a suitable antibiotic may be included in the soaking solution as a precaution against incidental infection.

Precautions:

1. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for implanting product as such conditions may compromise outcomes.
2. If the implanting physician 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.
3. Discard all grafts that have been damaged or contaminated.
4. Unused graft material may not be re-sterilized and should be properly discarded.
5. Single patient and single occasion use only (This product is NOT warranted for use on multiple patients or multiple surgeries).
6. Product remains sterile as long as the package is not opened and/or damaged.
7. The product must be used before the expiration date.
8. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the graft.
9. Appropriate placement and fixation are important factors of graft performance.

Adverse Effects:

As with all biological products, it is not possible to give an absolute guarantee of freedom of transmitting infectious diseases. Processing treatments shown to be capable of reducing the risk of any transmission as well as strict donor screening and laboratory testing are used to decrease the risk.

1. As with any surgical procedure, the possibility of infection exists.
2. Although the Tutoplast® process is designed to eliminate antigenic properties of the graft with no incidence of immunologic rejection, the possibility of such rejection is present in any allograft procedure.
3. Re-operation could be necessary to correct adverse effects.
4. Adverse reactions should be immediately reported to Davol Inc.

Storage:

This product should be stored in a clean, dry place at controlled room temperature of 1° to 37°C (33.8° to 98.6°F) and protected from direct sunlight.

ALLOMAX™ Surgical Graft

Catalog Number	Quantity	Shape	Size	
1180010	1/cs.	Rectangular	0.8" x 1.6" (2.0 cm x 4.0 cm)	<input type="checkbox"/>
1180020	1/cs.	Rectangular	2.0" x 3.1" (5.0 cm x 8.0 cm)	<input type="checkbox"/>
1180030	1/cs.	Rectangular	1.6" x 4.7" (4.0 cm x 12.0 cm)	<input type="checkbox"/>
1180040	1/cs.	Rectangular	2.0" x 3.9" (5.0 cm x 10.0 cm)	<input type="checkbox"/>
1180050	1/cs.	Rectangular	1.6" x 6.3" (4.0 cm x 16.0 cm)	<input type="checkbox"/>
1180060	1/cs.	Rectangular	2.8" x 3.9" (7.0 cm x 10.0 cm)	<input type="checkbox"/>
1180070	1/cs.	Square	3.9" x 3.9" (10.0 cm x 10.0 cm)	<input type="checkbox"/>
1180080	1/cs.	Rectangular	3.9" x 5.9" (10.0 cm x 15.0 cm)	<input type="checkbox"/>
1180090	1/cs.	Rectangular	5.1" x 5.9" (13.0 cm x 15.0 cm)	<input type="checkbox"/>
1180612	1/cs.	Rectangular	2.4" x 4.7" (6.0 cm x 12.0 cm)	<input type="checkbox"/>
1180616	1/cs.	Rectangular	2.4" x 6.3" (6.0 cm x 16.0 cm)	<input type="checkbox"/>
1180816	1/cs.	Rectangular	3.1" x 6.3" (8.0 cm x 16.0 cm)	<input type="checkbox"/>
1180420	1/cs.	Rectangular	1.6" x 7.9" (4.0 cm x 20.0 cm)	<input type="checkbox"/>
1180620	1/cs.	Rectangular	2.4" x 7.9" (6.0 cm x 20.0 cm)	<input type="checkbox"/>
1181220	1/cs.	Rectangular	4.7" x 7.9" (12.0 cm x 20.0 cm)	<input type="checkbox"/>
1181620	1/cs.	Rectangular	6.3" x 7.9" (16.0 cm x 20.0 cm)	<input type="checkbox"/>

ALLOMAX™ Surgical Graft 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.

(Reference sizes checked above)

Surgeon's Signature _____

Purchase Order Number _____

Catalog Number _____

Date _____ Quantity _____

Davol Inc. • Subsidiary of C. R. Bard, Inc. • 100 Crossings Boulevard
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Medical Services & Support 1.800.562.0027

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hazards, warnings and precautions.

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