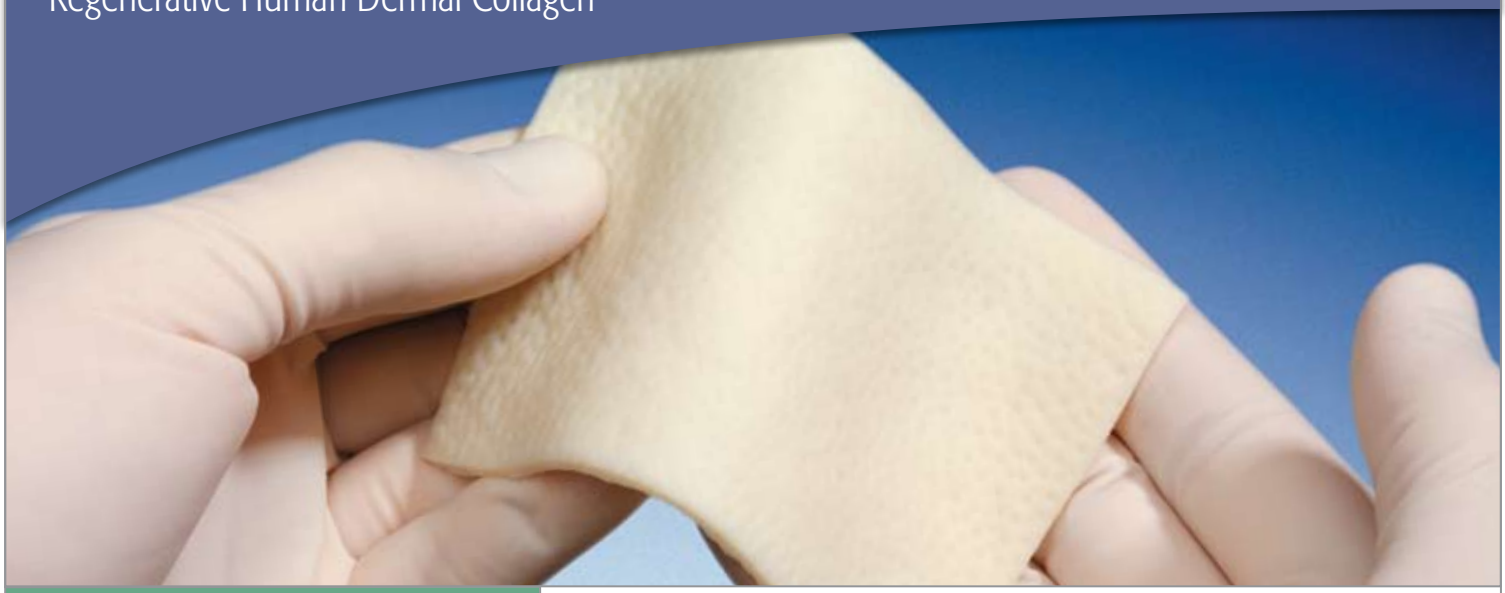
AlloMax™ Surgical Graft

Regenerative Human Dermal Collagen



Safety:

- Terminally sterilized
- Virally inactivated
- 1.5 million implants
- No documented cases of donor-to-recipient disease transmission

Handling:

- Supple material conforms easily to the body
- Limited stretch
- Hydrates rapidly

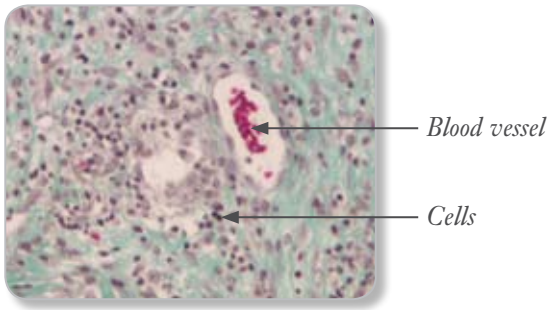
Performance:

- Over 450 publications on various Tutoplast® Processed procedures
- Early cell ingrowth and revascularization, allowing the body to remodel the graft*

AlloMax™ Surgical Graft is a natural option for soft tissue repair of hernia and abdominal wall defects.

AlloMax™ Surgical Graft is a sterile sheet of acellular human dermal collagen that retains its constituent elastin fibers.

- It is prepared using the proven Tutoplast® process (with over 30 years of experience) to remove non-collagenous cellular components.
- With a wide range of sizes up to 16 x 20 cm, the optimal size grafts are available for a variety of procedures.
- Pre-clinical studies demonstrate neovascularization as early as 7 days post implant.[1]



AlloMax™ After 7 Days.[1]
Masson's Trichrome stain 100x.

BARD DAVOL INC.

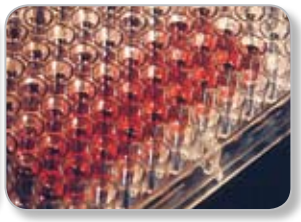
TECHNOLOGY
TECHNIQUE
TRAINING
TRUST

AlloMax™ Surgical Graft

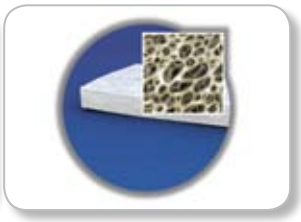
Regenerative Human Dermal Collagen

PROVEN PROCESS

Donor Screening



Blood Testing



Tutoplast Tissue Process

Proprietary Tutoplast® Tissue Process

Developed more than 30 years ago to sterilize and preserve tissue for implantation. The process includes validated procedures for:

- Decellularization
- Viral inactivation
- Low dose sterilization of SAL 10^{-6}

SAFETY AND STERILITY

- The only terminally sterilized human dermal graft for hernia repair with over 30 years of processing experience.
- Over 1.5 million implants have been processed without a documented case of donor to recipient disease transmission.

Why is sterilization important?

Because of window periods, false negative serological test results have been documented[2,3,4,5] by tissue processors, which may risk transmission of disease to patients if the tissue has not been sterilized through a validated sterilization process.

What should you ask before using tissue?

- Has the tissue been sterilized?
- Is the sterilization process validated to completely penetrate the tissue matrix, inactivate or remove blood, lipids, bacteria, bacterial spores, fungi, yeasts and viruses (enveloped and nonenveloped)?
- Does the sterilization process meet these requirements while maintaining the biomechanical integrity and biocompatibility of the tissue?

"Aseptic processing does not eradicate contamination with organisms, and antibiotic/antifungal solutions will not eliminate spores of organisms such as Clostridium spp."

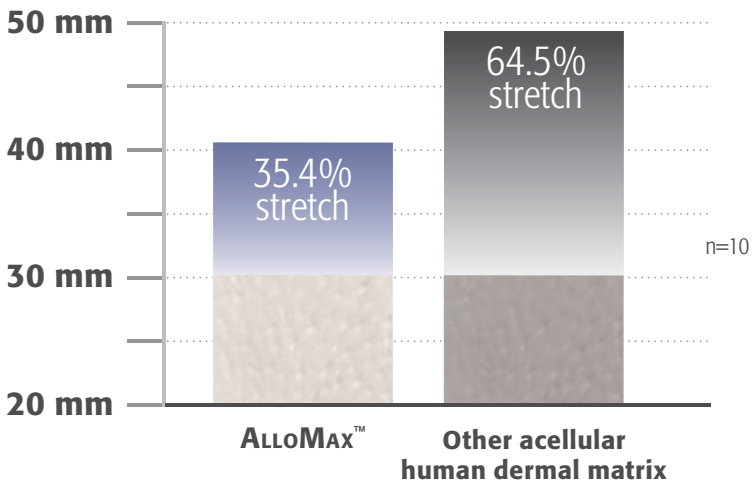
— Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, March 15, 2002

References:

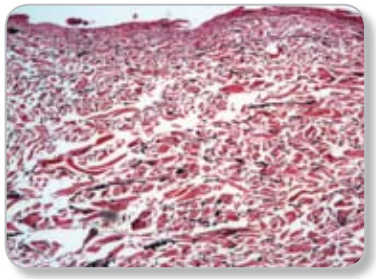
1. Greenspan, David C., Phd et al Histology of Surgically Implanted AlloMax™ Surgical Graft.
2. Prevalence Rates of HIV, HBV and HCV Among Musculoskeletal Tissue Donors. Jeffrey Wang, MD, Los Angeles, CA; Robert Kennedy, MD, Arlington, TX; C. Randal Mills, PhD, and Michael R. Roberts, MA; Gainesville, FL. Presented at North American Spine Society (November 2001) and Congress of Neurosurgeons (October 2001) annual meetings.
3. Trends in Recalls of Musculoskeletal Tissue Allografts: Analysis of FDA Recall Data. Jeffrey Wang MD, Randal Mills PhD, Michael Roberts, MA, Dayna Buskirk, DC. Presented at North American Spine Society annual meeting (November 2001).
4. Musculoskeletal Allograft Contamination and Recipient Exposure to Pathogens. Robert Kennedy, MD, PhD, Jeffrey Want, MD, C. Randal Mills, PhD, Michael R. Roberts, MA. Presented at North American Spine Society annual meeting (November 2001.)
5. MMWR (2002): Update: Allograft-Associated Bacterial Infections – United States, 2002. MMWR Morb Mortal Wkly Rep 51 (10), 207-210.

HANDLING

- Easy to suture and trim to fit the anatomy.
- 54% less stretch than other human dermal matrix under load.*



- Hydrates rapidly, no refrigeration necessary, 5 year shelf life.
- Retains its constituent elastin fibers responsible for the recoil of stretched skin.[6]



■ *Elastin*
■ *Collagen*

PERFORMANCE

- Tissue processed using the Tutoplast® process has been described in over 450 publications.
- Pre-clinical studies demonstrate early cellular infiltration and neovascularization as early as 7 days post implant.[1]
- Clinical studies have demonstrated adequate incorporation and evidence of vascular integration three months after insertion.[7]

* Data generated from bench and/or animal study. Data on file. Results may not correlate to performance in humans.

[6] Connective Tissue & Its Heritable Disorders. Ch 2 Part 1 K.A. Holbrook, C.J. Smith, pgs 51-71 1993 Kiley-Liss Inc.

[7] Losken, Albert, MD. Early Results Using Sterilized Acellular Human Dermis (Neoform) in Post-Mastectomy Tissue Expander Breast Reconstruction. Surg Endosc DOI 10.1097/PRS.0b013e31819c4337.

CASE REPORT†:

Keith R Bucklen, MD, FACS
Carolinas Medical Center
Lincolnton, N.C.

Demonstrating the use of the AlloMax™ Surgical Graft along with component separation technique to repair a complex abdominal wall hernia.**

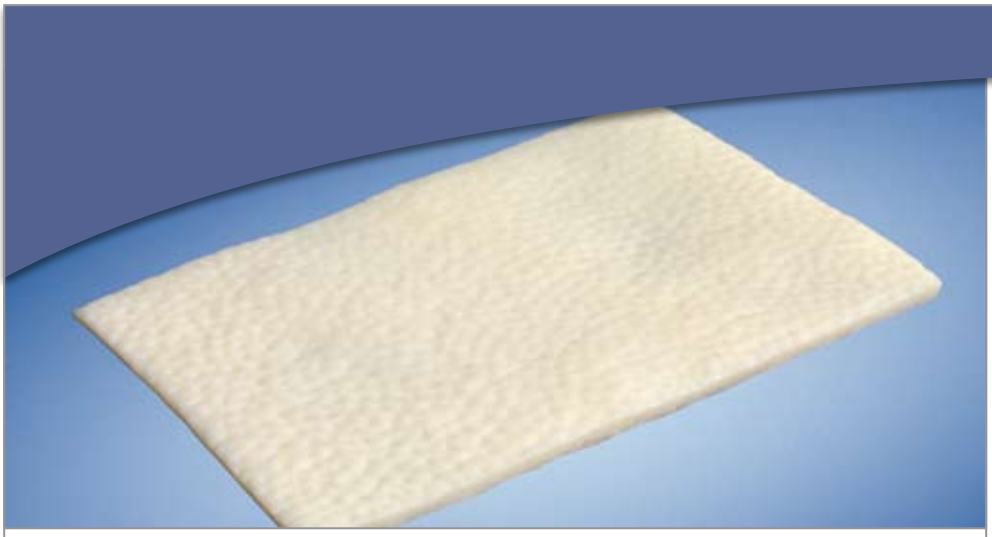
Pre-op

Post-op component separation with AlloMax™ Surgical Graft.

Front view

Lateral

*** Individual results may vary based on individual patient characteristics.*



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

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.

Surgeon's Signature _____

Purchase Order Number _____

Catalog Number _____

Date _____ Quantity _____

Please consult product labels and inserts for uses, hazards, warnings and precautions. Not intended for purely aesthetic purposes.

References:

† The opinions and clinical experiences presented herein are for informational purposes only. The results from the case study may not be predictive for all patients. The physician has been compensated by Davol Inc. for the time and effort in preparing the clinical case study for Davol's further use and distribution.

The AlloMax surgical graft is processed by RTI Biologics.

MMAMSS4

AlloMax™ Surgical Graft

is just one in a complete family of hernia repair products:

Tissue Regeneration Products

CollaMend™ FM Implant
XenMatrix™ Regenerative Collagen Matrix

Ventral Hernia Repair Products

Ventralex™ Hernia Patch
Ventrio™ Hernia Patch
Sepramesh™ IP Composite
Composix™ L/P Mesh
Dulex™ Mesh

Inguinal Hernia Repair Products

PerFix™ Plug
PerFix™ Light Plug
3DMax™ Mesh
3DMax™ Light Mesh
MK™† Patch
Kugel™ Patch
Bard® Soft Mesh
Visilex™ Mesh
Bard® Mesh Flats and Pre-Shapes

Specialty Products

CK™ Parastomal Hernia Patch
CruraSoft™ Patch

Fixation Products

SorbaFix™ Absorbable Fixation System
PermaFix™ Permanent Fixation System
PermaSorb™ Disposable Fixation Device

Bard® Surgical Education

Clinical Education Program

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Speaker Program

Educational presentations are given at Grand Rounds, Society Meetings and other venues.

Procedure Introduction Kits

Video programs that describe specific hernia repair techniques and their benefits to you, your patients and your surgical practice.

These services are available for many of the Bard® hernia repair products. Please ask your representative, or visit **www.davol.com**.

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