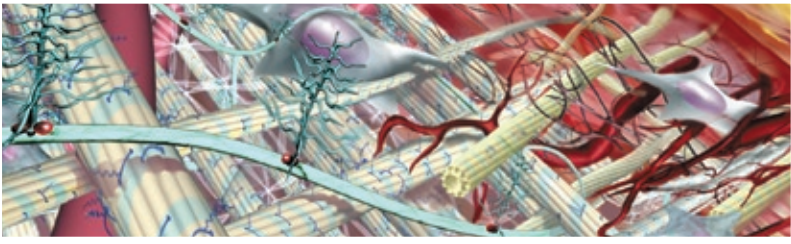


AlloDerm[®]

Regenerative Tissue Matrix



Soft tissue replacement
without a palatal harvest

Science

Simplicity

Value

BIOHORIZONS[®]

AlloDerm®

Regenerative Tissue Matrix



What is AlloDerm Regenerative Tissue Matrix?

AlloDerm is donated human soft tissue that is processed to remove dermal cells, leaving behind a regenerative collagen matrix. It provides the components needed to allow the body to restore health to missing tissue, with fast healing and excellent cosmetic results. The intact, acellular matrix is recognized as normal tissue by the host body, thus reducing the likelihood of specific immunological and nonspecific inflammatory reactions.

AlloDerm allows clinicians to perform soft tissue regeneration procedures without the discomfort and second-site morbidity often associated with palatal tissue harvesting. Because it is available in unlimited quantities, treatment of all necessary areas can be accomplished with fewer procedures than would be possible with palatal harvesting. AlloDerm is ideal for patients who either lack adequate harvestable tissue, or prefer not to undergo a palatal harvest.

Widely used in root coverage procedures, AlloDerm has demonstrated clinical and esthetic results equivalent to those with palatal tissue.¹⁻⁴ It may also be used for free gingival grafting, soft tissue ridge augmentation and a cell-occlusive barrier for bone grafting. It is available in two thickness ranges: 0.9 - 1.6mm (AlloDerm) and 0.5 - 0.9mm (AlloDerm GBR) to suit the various indications.

Procurement and Safety

The donor tissue undergoes the same stringent screening criteria for presence of diseases including HIV and hepatitis as any other implantable tissue or organ (heart, lungs & kidneys, etc.). The processor, LifeCell Corporation, only accepts tissue from organizations that meet the standards of the American Association of Tissue Banks (AATB), and the tissue must also pass rigid guidelines set by the U.S. Food & Drug Administration. LifeCell's proprietary tissue processing adds substantially to the safety profile of the product including substantially reducing the potential for viral contamination.

AlloDerm is widely used in both medicine and dentistry for reconstructive surgery. Originally developed to treat burn patients, it is now used in general, orthopedic and urogenital surgery in addition to its applications in dental surgical procedures. Since its introduction in 1994, there have been more than 800,000 AlloDerm grafts placed with no confirmed incidence of disease transmission.⁵

The processing procedure has been demonstrated to reduce HIV and Hepatitis C surrogate virus to non-detectable levels. Additional testing for presence of pathogens is performed prior to and following processing to ensure that AlloDerm is disease-free before release for patient care.

Processing of AlloDerm

During the proprietary processing a buffered salt solution gently separates the epidermis from the basement membrane. Multiple cell types within the dermis are then solubilized and washed away using a patented series of non-denaturing detergent washes.

The tissue matrix is then preserved using a patented freeze-drying process, which prevents damaging crystal formations; thereby retaining the critical biochemical and structural components needed to maintain the tissue's natural regenerative properties. The graft is then ready for rehydration and implantation to help the patient's body begin its tissue regeneration process.

How does AlloDerm work?



Processing - Removal of epidermal layer and cellular components.



Implantation - Critical components intact at implantation.



Revascularization - Rapid revascularization brings host stem cells into graft.



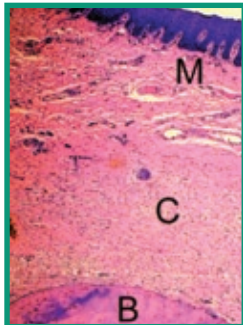
Transition - Complete architectural transition to host tissue.

AlloDerm provides a matrix consisting of collagens, elastin, blood vessel channels, and proteins that support revascularization, cell repopulation and tissue remodeling. When the graft is left exposed, as in guided bone regeneration or a free gingival graft, the AlloDerm matrix will support epithelial migration through creeping substitution across the basement membrane.

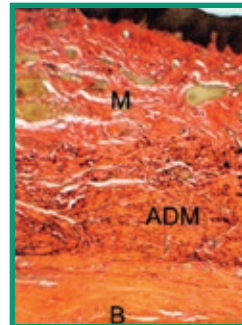
After placement, the patient's blood infiltrates the AlloDerm graft through retained vascular channels, bringing host stem cells that bind themselves to proteins in the matrix. Significant revascularization can begin as early as one week after implantation. The host cells respond to the local environment and the matrix is remodeled into the patient's own tissue, in a fashion similar to the body's natural cell attrition and replacement process.

Histological evidence of remodeling

A human histologic evaluation of AlloDerm and connective tissue (CT) documented that both formed a band of dense collagenous tissue when placed beneath a coronally advanced flap. Gingival attachment, a combination of long junctional epithelium and connective tissue adhesion, was comparable for both groups. At six months postoperatively, the overall histologic outcomes were similar for both CT and AlloDerm grafts. ⁶



Connective tissue specimen demonstrating mucosal tissue (M) overlying dense grafted connective tissue (C) and osseous crest (B). Original magnification 40X; hematoxylin and eosin (H&E) staining.



Acellular dermal matrix specimen demonstrating mucosal tissue (M) overlying the area of graft placement (ADM) and osseous crest (B). Original magnification 40X. Verhoff solution stained elastin fibers help differentiate graft area from host tissue.

Cummings et al. Histologic Evaluation of Autogenous Connective Tissue and Acellular Dermal Matrix Grafts in Humans. *J Periodontol* 2005;76:178-186.

Ease of use



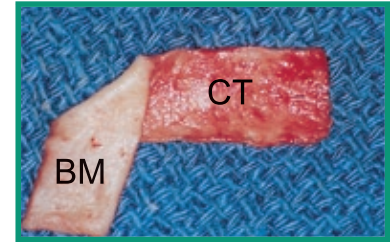
Remove from pouch

- AlloDerm has a 2-year shelf-life when stored between 1°-10°C (34°-50°F).
- Open outer foil pack. Drop graft into saline bath directly from inner pouch.



Rehydrate

- Rehydrate in two consecutive 10-20 minute sterile saline baths.
- Remove paper backing from AlloDerm between first and second baths.



Two distinct surfaces

- Basement membrane side (BM) is smooth and does not absorb blood.
- Connective tissue side (CT) is rougher and will absorb blood.

Important: Before use, clinicians should review all risk information, which can be found on the packaging and in the "Information for Use" attached to the packaging of each AlloDerm graft.

Documented equivalence to autogenous connective tissue

Multiple, randomized clinical trials (RCT) have shown root coverage results with AlloDerm to be equivalent to autogenous connective tissue, and concluded that the procedure was predictable and practical. A meta-analysis of eight RCT showed no statistically significant differences between groups for measured outcomes: recession coverage, keratinized tissue formation, probing depth and clinical attachment levels.⁷

Keys for successful root coverage include:

- Flap or Pouch design that minimizes loss of vascularity
- Tension-free coronal repositioning of flap or pouch to cover AlloDerm
- Thorough root conditioning and/or restoration removal

ROOT COVERAGE

AlloDerm is ideal for treating multiple defects in a single procedure. Available sizes include: 1cm x 1cm, 1cm x 2cm, 1cm x 4cm and 2cm x 4cm. After hydration it may be trimmed to the desired size with a scalpel or sharp scissors.

PRE-OP



Gingival recession with root surface restorations.

PREPARATION



Removal of root surface restorations and recipient site preparation.

GRAFT PLACED



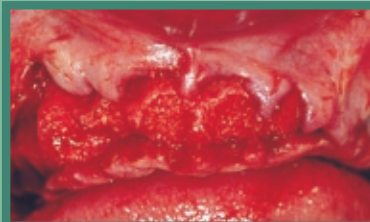
AlloDerm graft placed in pouch and sutured.

A Biological Barrier for Better Hard and Soft Tissue Response

GUIDED BONE REGENERATION

AlloDerm GBR is produced by exactly the same process as regular AlloDerm, but it is thinner (0.5 to 0.9mm) for easier handling. It readily adapts to graft sites and can be secured with either sutures or tacks.

GRAFTED SITES



Extraction sites grafted with GRAFTON® DBM.

LEFT EXPOSED



AlloDerm GBR covering the ridge beneath the flap to obtain tension-free closure.

HEALTHY TISSUE



Post-operative result shows excellent soft tissue coverage.

References

Mean Defect Coverage with AlloDerm

Michael J. Mehlbauer and Henry Greenwell. Complete Root Coverage at Multiple Sites Using an Acellular Dermal Matrix Allograft. <i>Compendium 2005;21:727-733.</i>	96%
Hirsch et al. A 2-Year Follow-Up of Root Coverage Using Subpedicle Acellular Dermal Matrix Allografts and Subepithelial Connective Tissue Autografts. <i>J Periodontol 2005;76:1323-1328.</i>	95.9%
Woodyard et al. The Clinical Effect of Acellular Dermal Matrix on Gingival Thickness and Root Coverage Compared to Coronally Positioned Flap Alone. <i>J Periodontol 2004; 75:44-56.</i>	99%
Henderson R et al. Predictable Multiple Site Root Coverage Using an Acellular Dermal Matrix Allograft. <i>J. Periodontol, 72:571-582, 2001.</i>	95%

The abstracts of cited articles and additional AlloDerm references can be viewed at www.biohorizons.com/alloderm.htm

Photos courtesy of Dr. Edward P. Allen, Dallas, Texas

POUCH SUTURED



Pouch coronally positioned and sutured.

2 WEEKS



Complete root coverage at two weeks postoperatively.

1 YEAR



Complete root coverage at one year postoperatively.

Photos courtesy of Dr. Craig Misch, Sarasota, Florida



Unlike other periodontal membranes that either resorb too quickly or do not resorb at all, AlloDerm GBR actually allows the body to remodel it into the patient's own tissue. This results in improved bone regeneration while benefiting soft tissue quality and esthetics.⁸⁻⁹

AlloDerm GBR, unlike conventional barrier membranes, may be left exposed with a significantly reduced chance of infection and loss of graft volume. A recent study demonstrated that sites covered with AlloDerm generated 16% more vital bone in extraction sockets than did sites covered with an ePTFE membrane.¹⁰

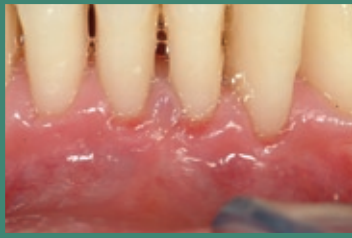
A separate study concluded that AlloDerm, used as a barrier over resorbable hydroxyapatite in extraction sites, was able to preserve ridge dimensions and significantly increase the width of keratinized tissue.¹¹

Additional Indications for AlloDerm

FREE GINGIVAL GRAFT

AlloDerm is useful in areas of insufficient attached tissue and to increase the depth of the vestibule.

PRE-OP



Preoperative presentation of thin, mobile tissue.

PLACEMENT



The AlloDerm is oriented with the connective tissue surface against the periosteum and sutured with chromic gut.

1 WEEK



Due to lack of initial pigmentation the graft appears white, except where revascularization has begun.

SOFT TISSUE RIDGE AUGMENTATION

AlloDerm can be used effectively for soft tissue ridge augmentation. A tunnel or pouch may be created beneath the defect into which the AlloDerm can be inserted.

PRE-OP



Alveolar ridge deficiency at site of missing maxillary left lateral incisor and canine, and anterior gingival asymmetry.

PREPARATION



Semi-lunar crestral incisions are made at site of missing teeth for pouch preparation.

GRAFT FOLDED



The AlloDerm graft is folded and sutured prior to placement in pouch.

SOFT TISSUE AUGMENTATION AROUND DENTAL IMPLANTS

AlloDerm is effective in augmenting thin tissue around dental implants to create more attached tissue.

PRE-OP



Treatment plan for revision of a failing 2-implant overdenture to a 5-unit cemented bar overdenture.

REVISION



Three additional implants are placed. Patient presents a peri-implant bony defect.

GRAFT PREP



A tissue punch is used to prepare the AlloDerm graft to saddle the ridge over the implants.

Photos courtesy of Dr. Michael Imberman, Tarzana, California

Keys to success with this procedure include scoring the periosteum to promote revascularization of the graft, treatment planning to account for approximately 40% shrinkage, and secure suturing of the graft to the periosteum.

2 WEEKS



Revascularization continues, and the patient's cells begin remodeling the graft.

3 WEEKS



Graft is well incorporated and color and contour are returning to normal.

10 MONTHS



10 months postoperatively there is restoration of thick, attached tissue.

Photos courtesy of Dr. Edward P. Allen, Dallas, Texas

If multiple layers of AlloDerm are used for increased thickness, it is recommended that it be layered, rather than rolled. In this indication, orient the connective tissue surfaces on the outside of the graft.

SUTURING



AlloDerm graft is sutured within pouch.

POST-OP



Provisional FPD with reshaped ovate pontics cemented and pouch sutured. Esthetic crown lengthening was performed on the right side.

3 MONTHS



3 months postoperatively there is restoration of normal alveolar ridge contour and establishment of gingival symmetry.

Photos courtesy of Dr. Carl E. Misch, Beverly Hills, Michigan

DEFECT FILLED



The bony defect is grafted using autologous bone from osteotomies. The AlloDerm is oriented with basement membrane up.

GRAFT TACKED



The graft is tacked into place using the AutoTac[®] Titanium Tack system. The flap is then re-approximated in a tension-free manner.

3 MONTHS



Postoperative results show thick, immobile tissue.

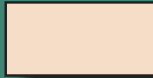
AlloDerm®

Regenerative Tissue Matrix

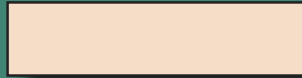
Soft tissue replacement without palatal autograft harvesting



1cm x 1cm



1cm x 2cm



1cm x 4cm



2cm x 2cm
(GBR only)



2cm x 4cm

www.biohorizons.com

BioHorizons USA

One Perimeter Park South
Birmingham, Alabama 35243
866-872-9785
205-967-7880

BioHorizons Canada

21 Amber Street, Unit # 7
Markham, Ontario L3R 4Z3
866-468-8338
905-944-1894

BioHorizons Ibérica

Bocángel, 38 - 1a Pl.
28028 Madrid, Spain
34 91 713 10 84
34 91 355 83 75

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