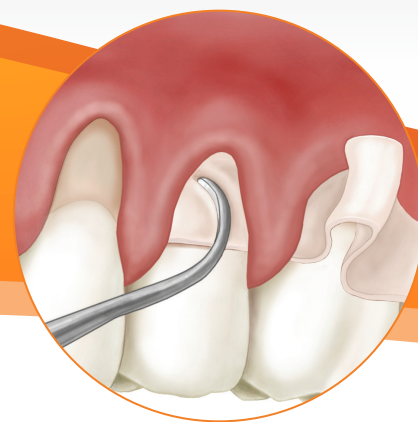


AlloDerm SELECT™ RTM

Surgical Technique Guide



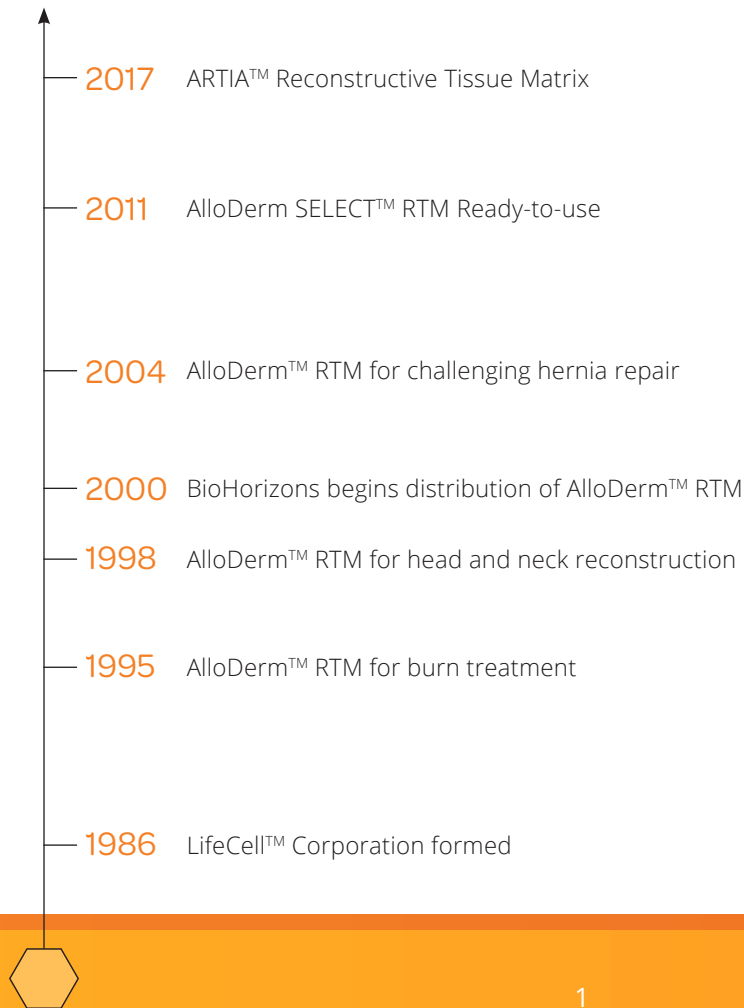
INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS: ALLODERM SELECT™ Regenerative Tissue Matrix (ALLODERM SELECT™ RTM refers to both ALLODERM SELECT™ RTM and ALLODERM SELECT GBR™ RTM products) is intended to be used for repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument including gingival. This product is intended for one patient on a single occasion. ALLODERM SELECT™ RTM is not indicated for use as a dural substitute or intended for use in veterinary applications.

BIOHORIZONS®

About LifeCell™ Corporation, an AbbVie Company

For over two decades, LifeCell™ has developed innovative products for use in a wide range of applications.



AlloDerm SELECT™ Regenerative Tissue Matrix (RTM)

Since its introduction to dentistry in 1999, AlloDerm SELECT™ Regenerative Tissue Matrix (RTM) has been a widely accepted acellular dermal matrix (ADM) for soft tissue applications. As demonstrated in preclinical studies, AlloDerm SELECT™ supports tissue regeneration by allowing rapid revascularization and cell repopulation*^{1,2}—ultimately transitioning into host tissue for a strong repair. (Thickness range of 1.6mm ± 0.4mm.)



- Use of AlloDerm SELECT™ RTM results in reduced postoperative bleeding and swelling as reported in a case series^{3,†}
- No recognizable difference between AlloDerm SELECT™ RTM and connective tissue in terms of recession reduction, clinical attachment gain, and reduction in probing depth at six months^{4,‡}
- Most published ADM in implant dentistry⁵
- Sterile and ready to use

applications include⁶

- root coverage
- gingival augmentation
- soft tissue ridge augmentation
- soft tissue augmentation around implants

ordering information

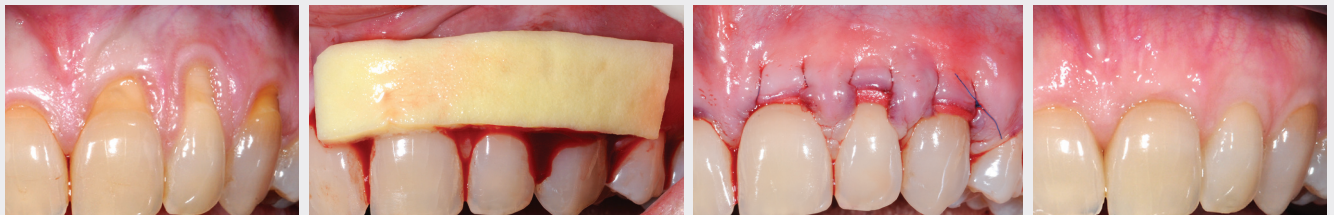
RTU-0101	AlloDerm SELECT™ 1cm x 1cm
RTU-0102	AlloDerm SELECT™ 1cm x 2cm
RTU-0104	AlloDerm SELECT™ 1cm x 4cm
RTU-0204	AlloDerm SELECT™ 2cm x 4cm

* Correlation of these results, based on animal studies, to results in humans has not been established



"Compared to palatal CTG, AlloDerm SELECT™ RTM provides good esthetics and a more pleasant experience for the patient, especially when treating multiple teeth. The palate is no longer a factor in patient acceptance or the number of teeth that can be treated in a single appointment."

Edward P. Allen, DDS, PhD

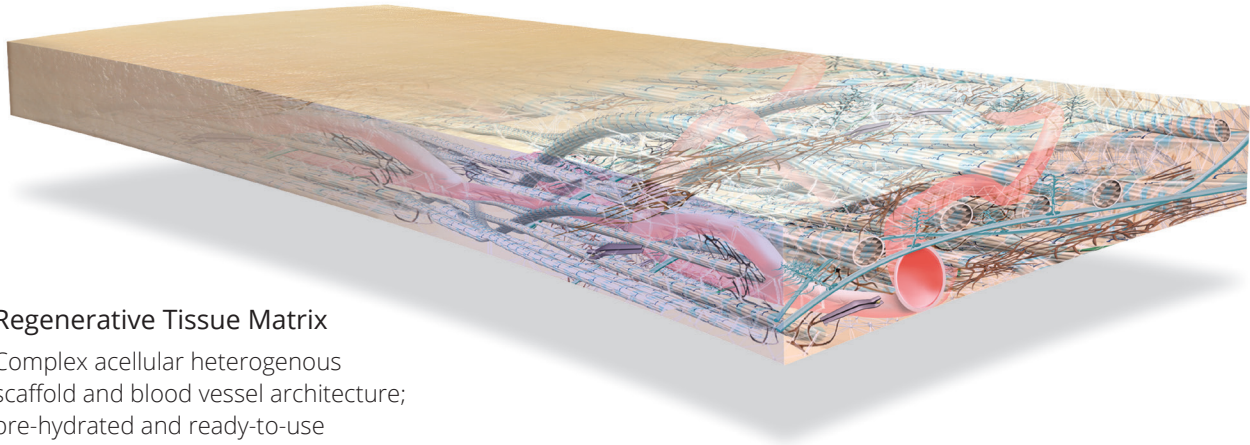


AlloDerm SELECT™ RTM case images courtesy of Dr. Edward P. Allen, Dallas, Texas

Before use, physicians should review all risk information, which can be found in the AlloDerm SELECT™ RTM Instructions for Use. † Based on questionnaire given to 228 patients at 1 week post-treatment covering 331 procedures who received an AlloDerm SELECT™ RTM (n=89 procedures) or autogenous soft tissue (n=242 procedures) graft for gingival augmentation. ‡ Results obtained from 30 gingival recessions in 9 patients treated with AlloDerm SELECT™ RTM (15 recessions) or autogenous soft tissue (15 recessions).

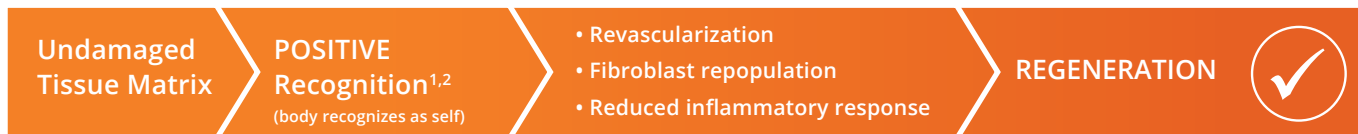
Mechanism of Action

The processing of a biological material ultimately impacts the clinical outcome.

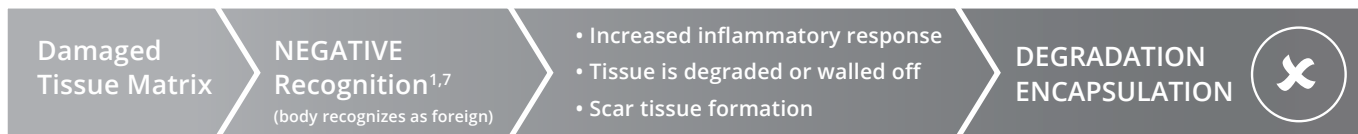


The undamaged, intact dermal matrix that enables positive recognition and supports regeneration as demonstrated in preclinical models.^{1,2,7,†}

LifeCell processing method



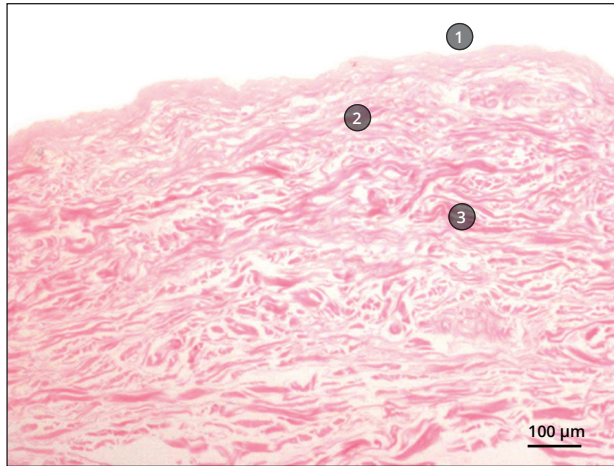
Alternative



† Correlation of these results, based on animal studies, to results in humans has not been established.

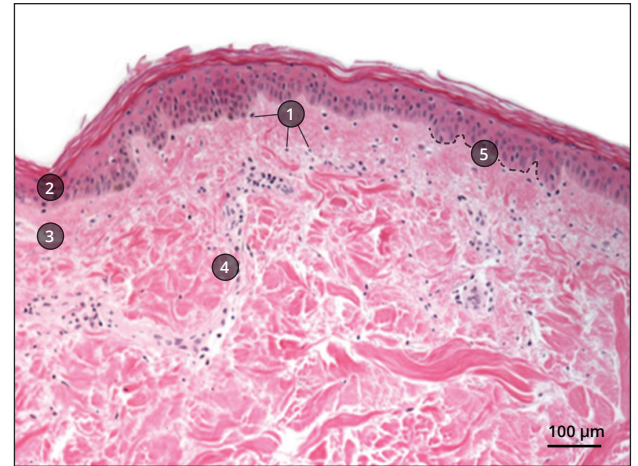
Out-of-Package Histology⁸

All images 100x, H&E stained



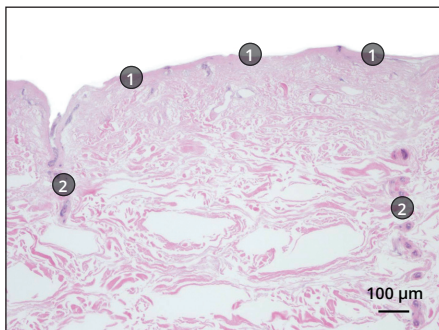
AlloDerm SELECT™ RTM

- 1) Intact basement membrane
- 2) Papillary dermis
- 3) Reticular dermis



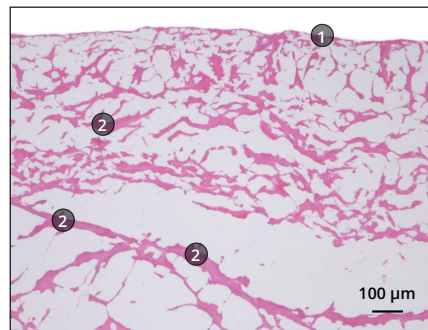
Human Dermis

- 1) Cells
- 2) Epidermis
- 3) Papillary dermis
- 4) Reticular dermis
- 5) Basement membrane



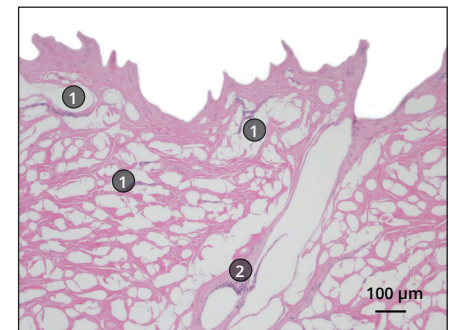
Puros® Dermis

- 1) Modified basement membrane, no undulation
- 2) Cellular remnants



Mucograft®

- 1) No basement membrane
- 2) Modified collagen bundles



PerioDerm®

- 1) Separation between collagen bundles
- 2) Cellular remnants

Surgical Tunnel Technique

As described by Edward P. Allen, DDS, PhD

Dr. Allen is a consultant to BioHorizons and AbbVie

Treating multiple tooth recession defects traditionally requires a significant palatal tissue harvest to adequately supply enough donor material to successfully treat the defect. This often can lead to undesired surgical and post-surgical sequelae for both the surgeon and the patient. AlloDerm SELECT™ RTM can be used as an alternative to palatal tissue in tooth recession and gingival applications.² The following is a surgical technique for treating recession defects around teeth first described by Dr. Edward P. Allen in 2010. The technique has been adapted for use based on his clinical experience and can be modified to be applicable to similar clinical presentations.

This content is only intended as a reference. Proper surgical procedures and techniques are the sole responsibility of the dental professional. Each surgeon must evaluate the appropriateness of the techniques based on his or her own dental training and expertise.

For more details about this technique, please refer to:

Subpapillary continuous sling suturing method for soft tissue grafting with the tunneling technique.

Allen EP. *Int J Periodontics Restorative Dent.* 2010 Oct;30(5):479-85.

1) Pre-op

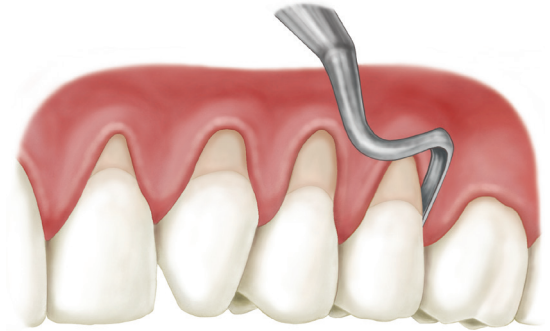
This technique will demonstrate the Tunnel Technique for root coverage grafting with AlloDerm SELECT™ RTM. Prepare the AlloDerm SELECT™ RTM according to the Instructions for Use (IFU) provided with the product.

Gingival recession involving 4 maxillary teeth, the left lateral incisor through the left second premolar. There is no loss of interdental bone or soft tissue fill. Typical Miller Class I or II recession defects are noted.



2) Intrasulcular incisions

Using an End-Cutting Intrasulcular Knife or similar microsurgical instrument, make intrasulcular incisions facially and proximally around each tooth with recession defects, as well as one additional tooth anterior and posterior to the teeth with recession.



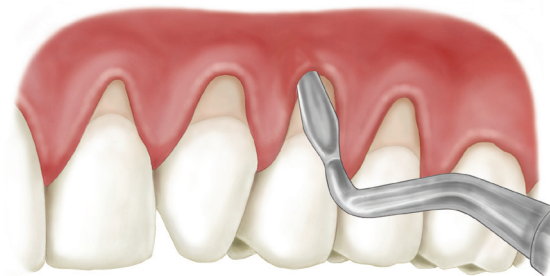
3) Blunt dissection

A microsurgical elevator is used to elevate a mucoperiosteal pouch 4-5mm apical to the mucogingival junction at each tooth with recession, as well as an additional tooth mesially and distally to facilitate tissue mobilization. Extend the blunt dissection under the papillae facially.



4) Sharp dissection

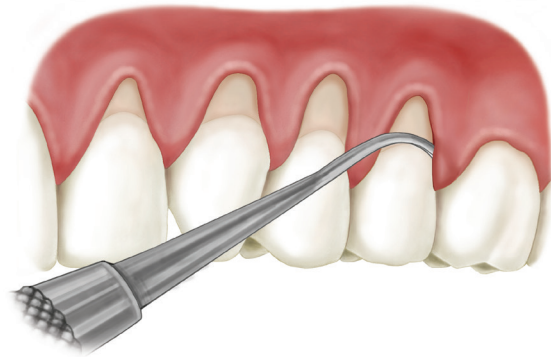
Using a Modified Orban Knife, sharp dissect immediately supraperiosteally to mobilize and extend the tunnel 12-15mm apical to the gingival margin at each tooth with recession, as well as an additional tooth mesially and distally. **Stay in contact with bone to ensure a patent tunnel.**



Surgical Tunnel Technique

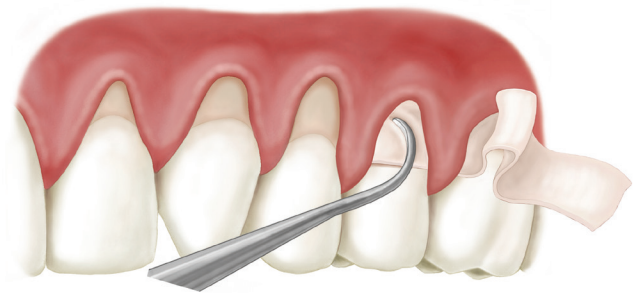
5) Elevate papillae interdentally

Detach the papillae from the interdental bone crest using a Younger-Good curette or similar instrument. Extend this blunt (subperiosteal) elevation to the palatal line angles.



6) AlloDerm SELECT™ RTM insertion

Trim the graft to extend from the distal of the central incisor to the mesial of the molar, with a vertical dimension of 8mm. The graft is inserted into the sulcus of a terminal tooth with recession and passed through the tunnel using a Younger-Good curette or similar instrument. Orient the graft with the reticular (connective tissue) side facing bone.



7) AlloDerm SELECT™ RTM alignment

The graft should be positioned to extend from the distal of the central incisor to the mesial of the molar so that it lies completely under the papillae mesial and distal to the teeth with recession.



8) Preparation for suturing

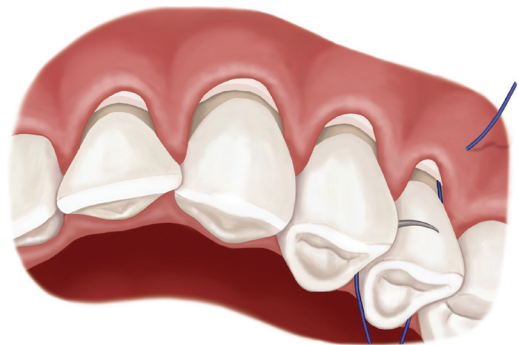
Displace the graft within the tunnel so that the coronal border of the graft is level with the tissue margin in preparation for simultaneous coronal advancement of the graft with the overlying tissue. The recommended suture is a 6-0 monofilament polypropylene.

NOTE: A continuous sling suture or interrupted sling sutures may be used.



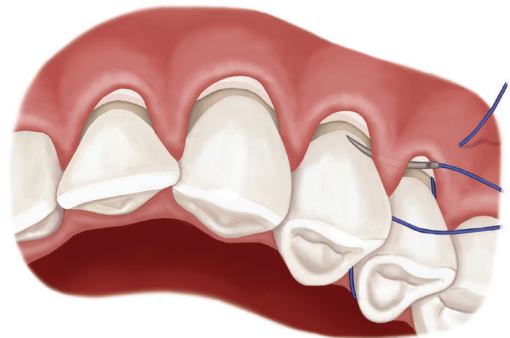
9a) Continuous sling suture

Penetrate the overlying tissue and graft at the distal root line angle of the second premolar, 4mm apical to the tissue margin. Exit through the sulcus and pass the needle through the distal embrasure, around the palatal aspect and back to the facial through the mesial embrasure.



9b) Continuous sling suture

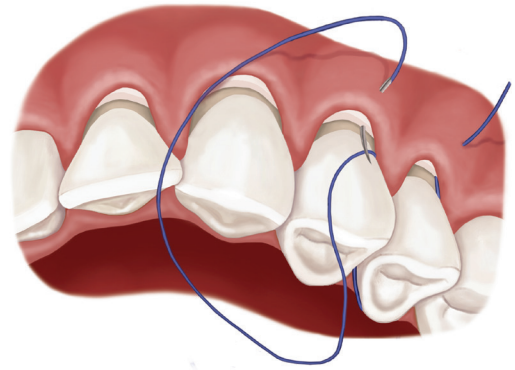
Pass under the papilla from the second premolar toward the first premolar.



Surgical Tunnel Technique

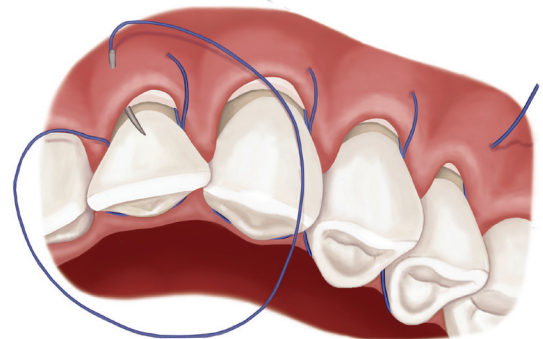
9c) Continuous sling suture

Penetrate the overlying tissue and graft at the distal root line angle of the first premolar and repeat the previous steps until reaching the lateral incisor.



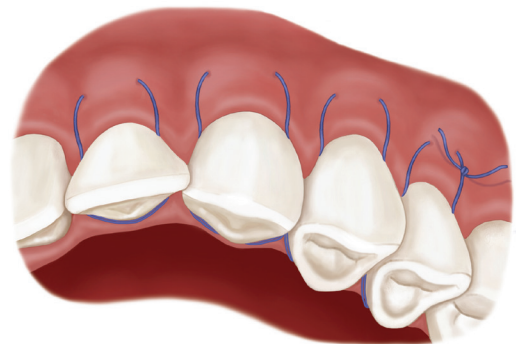
9d) Continuous sling suture

After passing around the palatal of the lateral incisor and returning to the facial through the mesial embrasure, penetrate the overlying tissue and graft at the mesial root line angle.



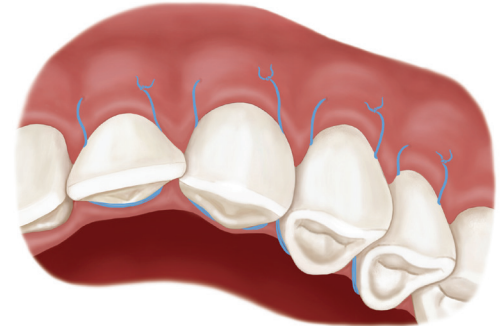
9e) Continuous sling suture

Work back to the starting point, always passing under the papillae. The suture will be tied only at the distal of the second premolar.



10) Interrupted sling sutures

Penetrate the overlying tissue and graft at the distal root line angle of the second premolar, 4mm apical to the tissue margin. Exit through the sulcus and pass the needle through the distal embrasure, around the palatal aspect and back to the facial through the mesial embrasure. Penetrate the overlying tissue and graft at the mesial root line angle of the second premolar 4mm apical to the tissue margin, pass through the mesial embrasure around the palatal aspect of the second premolar and return to the facial through the distal embrasure. Tie the suture and repeat the process for each tooth. Ideally, the graft should be completely covered. Exposure of 1mm or less should not impact the outcome.



11) Post-op: suture removal

Sutures are removed at 2 months. Sutures may be removed earlier in some cases although it is more comfortable for the patient to wait until the swelling has completely subsided before suture removal. Complete root coverage in Miller Class I and II recession with an increase in marginal tissue thickness and stability should be achieved.



Hu-Friedy® Sutures

- 300 Series Stainless Steel, a highly suitable alloy for dental suture needles, ensures a strong sharp needle pass after pass
- Manufactured from an alloy composition, increasing ductile strength. If the needle does bend, it is less likely to break when reshaping.
- Laser-drilled needles for reduced tissue disruption

Dr. Edward P. Allen's Recommended Suture For use in oral plastic surgery procedures



HF-PSN8384P

Perma Sharp® Suture
6-0 Polypropylene 18", C-17.
Finer point geometry for smoother penetration.

Allen Oral Plastic Surgery Kit



HF-ALLENKIT

Allen Oral Plastic Surgery Kit

Developed by Dr. Edward P. Allen, this comprehensive kit provides precision microsurgical instruments specifically designed for invasive soft tissue grafting procedures.



HF-SYRCW

Cook-Waite Anesthetic Aspirating Syringe, 1.8ml



HF-NHM-5026R

Micro Castroviejo, Straight, Diamond Dusted



HF-PCP116

Color-Coded Probe 3-6-8-11



HF-10-130-05

#5 Scalpel Handle, Round, Straight



HF-SYG7/89E2

Younger-Good 7/8 EverEdge® (2 per kit)



HF-PPAELPX

Allen Periosteal Elevator, Posterior, Black Line



HF-SP20

Corn Suture Pliers



HF-PPAELAX

Allen Periosteal Elevator, Anterior, Black Line



HF-PPAELX

Allen Periosteal Elevator, Black Line



HF-S5080

Goldman-Fox Perma Sharp®
Scissors, Straight



HF-KPAX

Allen End-Cutting Intrасulcular Knife,
Black Line



HF-KO12KPO3R9

Allen Modified Orban Knife 1/2,
Round, EverEdge®



HF-8-905DD

Precision Dressing Forceps,
Diamond Dusted



HF-ALLENCARD

Allen Membrane Measurement Card



HF-KO12KP3R49

Allen Arrowhead Knife



HF-MIR5/3

#5 Front Surface Mouth Mirror, 3 pack



HF-MH6

#6 Satin Steel® Mirror Handle (2 per kit)

HF-MCUPE

Immunity Steel Cup, Modified

additional items available individually

HF-KO12KPO3AR

Allen Modified Orban Knife 1/2, Round, #6 Satin Steel® Handle



HF-KO12KPO3A6

Allen Modified Orban Knife 1/2, #6 Satin Steel® Handle



HF-KO12KPO3A9

Allen Modified Orban Knife 1/2, EverEdge®



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1. Extracellular wound matrices: a novel regenerative tissue matrix (RTM) technology for connective tissue reconstruction. *Wounds*. Harper JR, McQuillan DJ. 2007;19(6):163-168.
2. Host response to human acellular dermal matrix transplantation in a primate model abdominal wall repair. *Tissue Eng Part A*. Xu H, Wan H, Sandor M, et al. 2008;14(2):2009-2019.
3. Postoperative complications following gingival augmentation procedures. Griffin T, Cheung W, Zavaras A, Damoulis P. *Journal of Periodontology*. December 2006.
4. Comparative 6-Month Clinical Study of a Subepithelial Connective Tissue Graft and Acellular Dermal Matrix Graft for the Treatment of Gingival Recession*. Arthur B. Novaes Jr., Daniela C. Grisi, Gustavo O. Molina, Sérgio L.S. Souza, Mario Taba Jr., and Márcio F.M. Grisi. *J Periodontol*. 2001; 72(11): 1477-1484.
5. Pub Med search AlloDerm, Sept 2021
6. Reference manufacturer's Instructions for Use (IFU) package insert.
7. Host response to implanted porcine-derived biologic materials in a primate model of abdominal wall repair. *Tissue Eng Part A*. Sandor M, Xu H, Connor J, et al. 2008;14(12):2021-2031.
8. Out of Package Histologic Comparison of Dental Matrices. Sandor, M. 2012.

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Indications and Important Safety Information

INDICATIONS

ALLODERM SELECT™ Regenerative Tissue Matrix (ALLODERM SELECT™ RTM refers to both ALLODERM SELECT™ RTM and ALLODERM SELECT GBR™ RTM products) is intended to be used for repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument including gingival. This product is intended for one patient on a single occasion. ALLODERM SELECT™ RTM is not indicated for use as a dural substitute or intended for use in veterinary applications.

CONTRAINDICATIONS

ALLODERM SELECT™ RTM should not be used in patients with a known sensitivity to any of the antibiotics listed on the package and/or Polysorbate 20.

WARNINGS

Processing of the tissue, laboratory testing, and careful donor screening minimize the risk of the donor tissue transmitting disease to the recipient patient. As with any processed donor tissue, ALLODERM SELECT™ RTM is not guaranteed to be free of all pathogens. No long-term studies have been conducted to evaluate the carcinogenic or mutagenic potential or reproductive impact of the clinical application of ALLODERM SELECT™ RTM.

DO NOT re-sterilize ALLODERM SELECT™ RTM. **DO NOT** reuse once the tissue graft has been removed from the packaging and/or is in contact with a patient. Discard all open and unused portions of the product in accordance with standard medical practice and institutional protocols for disposal of human tissue. Once a package or container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded. **DO NOT** use if the foil pouch is opened or damaged. **DO NOT** use if the seal is broken or compromised. **DO NOT** use if the temperature monitoring device does not display "OK". **DO NOT** use after the expiration date noted on the label. Transfer ALLODERM SELECT™ RTM from the foil pouch aseptically. **DO NOT** place the foil pouch in the sterile field.

PRECAUTIONS

Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for implanting ALLODERM SELECT™ RTM as such conditions may compromise successful clinical outcome. Whenever clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken.

ALLODERM SELECT™ RTM has a distinct basement membrane (upper) and dermal surface (lower). When applied as an implant, it is recommended that the dermal side be placed against the most vascular tissue. Soak the tissue for a minimum of 2 minutes using a sterile basin and room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the tissue. If any hair is visible, remove using aseptic technique before implantation.

ALLODERM SELECT™ RTM should be hydrated and moist when the package is opened. **DO NOT** use if this product is dry. Use of this product is limited to specific health professionals (e.g., physicians, dentists, and/or podiatrists). Certain considerations should be made to reduce the risk of adverse events when performing surgical procedures using a tissue graft. Please see the Instructions for Use (IFU) for more information on patient/product selection and surgical procedures involving tissue implantation before using ALLODERM SELECT™ RTM.

ADVERSE EVENTS

Potential adverse events which may result from surgical procedures associated with the implant of a tissue graft include, but are not limited to the following: wound or systemic infection; dehiscence; hypersensitive, allergic or other immune response; and sloughing or failure of the graft.

ALLODERM SELECT™ RTM is available by prescription only.

For more information, please see the Instructions for Use (IFU) for ALLODERM SELECT™ RTM and ALLODERM SELECT GBR™ RTM or call 1.800.678.1605 for a copy of the IFU.

To report an adverse reaction, please call BioHorizons Customer Care at 1.888.246.8338.

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