AlloDerm SELECT™
Regenerative Tissue Matrix

Not actual surgeons.

Converting From Freeze-Dried To Ready-To-Use AlloDerm SELECT™ RTM

AlloDerm SELECT™ Regenerative Tissue Matrix (RTM) is ready-to-use and designed to have similar clinical and intraoperative performance to AlloDerm™ RTM

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.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information throughout this brochure.

BIOHORIZONS®

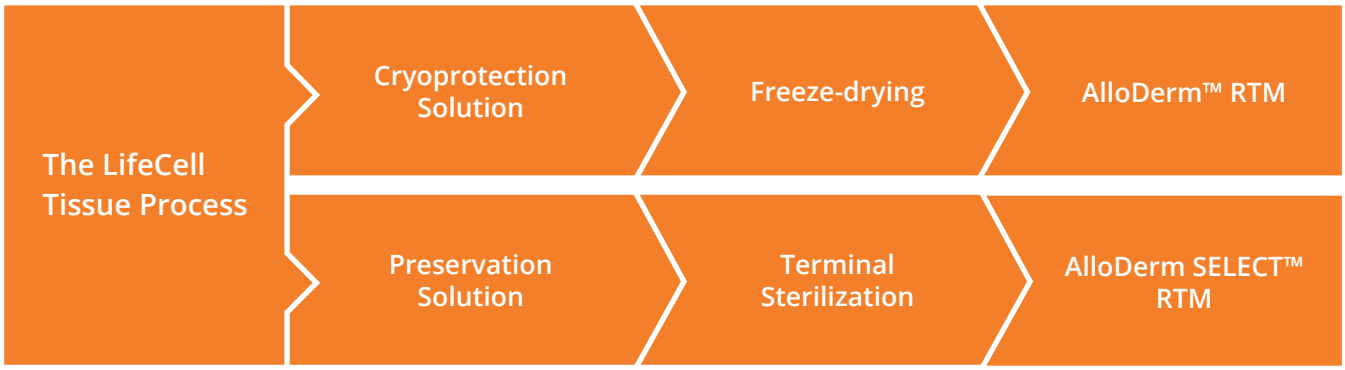
The Trusted Performance of AlloDerm™ RTM With Additional Proven Benefits

AlloDerm™ RTM was originally launched in 1994 as a freeze-dried acellular dermal matrix (ADM). In 2011, a ready-to-use version, AlloDerm SELECT™ RTM was developed and has since become the preferred version.[1] AlloDerm SELECT™ RTM is the optimal choice for ADM support because it features:

- The same gentle processing technique as AlloDerm™ RTM
- Sterility without compromise to matrix integrity
- The convenience of being ready-to-use[2]

The Same Core Processing as AlloDerm™ RTM

Both products are processed with the same trusted and proven technique. However, AlloDerm™ RTM is aseptic and comes in freeze-dried form, while AlloDerm SELECT™ RTM is sterile and ready-to-use.



The Same Handling and Pliability as AlloDerm™ RTM, and So Much More

Sterile[2]
with a Sterility Assurance Level (SAL) of 10^{-3}

Ready-to-use[2]
with minimum 2-minute soak

Purposeful inner packaging
for a smoother, straighter product out of package, which may be placed directly into the sterile field

IMPORTANT SAFETY INFORMATION (continued)

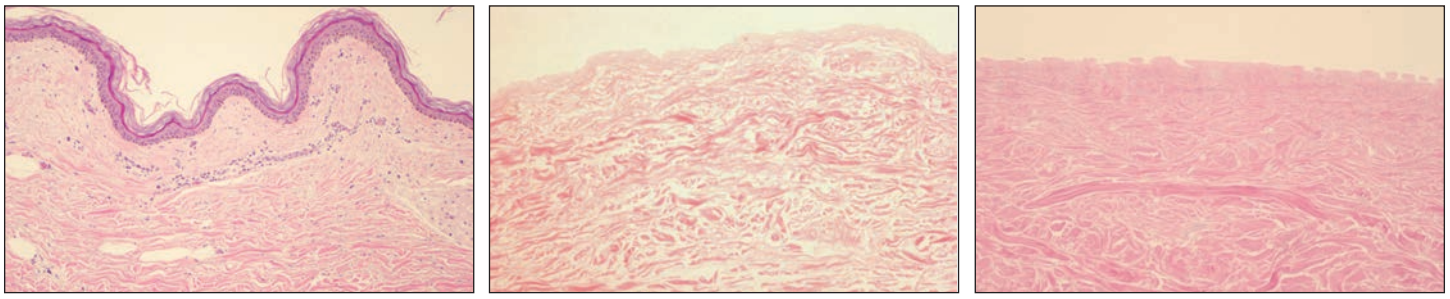
WARNINGS

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.

Preserves Tissue Structure and Integrity

The native collagen architecture, including basement membrane structure, is maintained through gentle processing in both AlloDerm SELECT™ RTM and AlloDerm™ RTM.[3]

Native Dermis | AlloDerm™ RTM | AlloDerm SELECT™ RTM

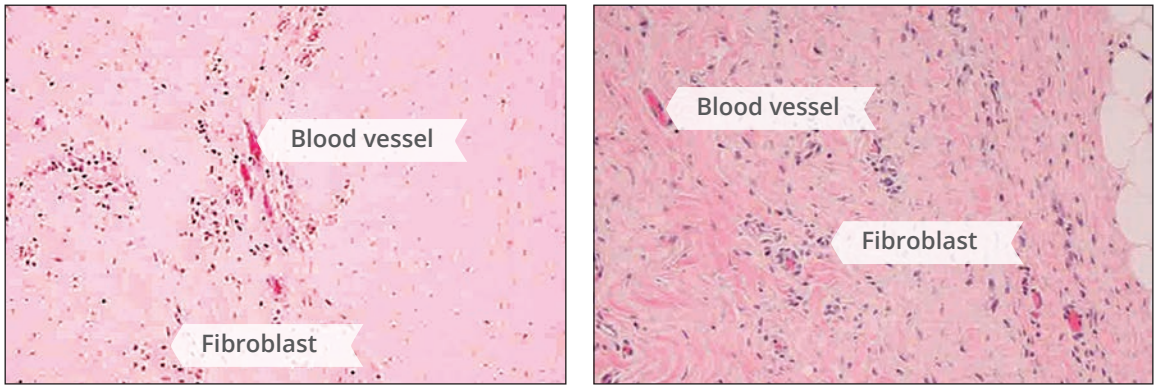


H&E stain. Histology comparisons of human dermis to AlloDerm™ RTM and AlloDerm SELECT™ RTM.

Strikes a Balance Between Sterility and Regeneration

AlloDerm SELECT™ RTM is sterile with a SAL of 10^{-3}, which has been shown through benchtop testing to allow for the preservation of the matrix properties that support regeneration.[1] Primate studies have shown that AlloDerm SELECT™ RTM supports rapid revascularization, cell repopulation, and white cell migration in a manner similar to AlloDerm™ RTM.[4-6]*

AlloDerm™ RTM | AlloDerm SELECT™ RTM



H&E stain. Histology of abdominal wall explants at 3 months in primate model.

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

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS (continued)

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.

Please see additional Important Safety Information throughout this brochure.

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IMPORTANT SAFETY INFORMATION (continued)

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.

REFERENCES

1. Data on file, Allergan. LRD-2017-01-010. 2. AlloDerm Select and AlloDerm Select Restore Regenerative Tissue Matrix Instructions for Use, 2017. 3. Data on file, Allergan. LRD-2016-08-014. 4. Data on file, Allergan. LRD-2005-08-003. 5. Data on file, Allergan. LRD-2010-04-005. 6. Xu H, Wan H, Sandor M, et al. Host response to human acellular dermal matrix transplantation in a primate model abdominal wall repair. *Tissue Eng Part A.* 2008;14(2):2009-2019.

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