AlloDerm SELECT™ RTM history and processing

Advancing surgery and improving patients' lives

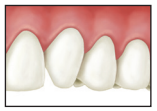
For over two decades, LifeCell™, an AbbVie affiliate, has launched innovative products which have been used in a wide range of applications. Our success could not have been possible without the insight and guidance of healthcare professionals.

1986 — LifeCell Corporation formed

1994 — AlloDerm™ RTM

1998 — Burn treatment; Head and neck reconstruction

2000 — Dental



2004 — Challenging hernia repair

2008 — STRATTICE™ Reconstructive Tissue Matrix (RTM)

2009 — STRATTICE™ RTM EU

2011 — AlloDerm SELECT™ RTM **Ready to use**

2017 — ARTIA™ Reconstructive Tissue Matrix

More than 3 million grafts to date[1]

Quality and processing

Tissue recovery

- Comprehensive medical and social history screening meets Food and Drug Administration (FDA) and American Association of Tissue Banks (AATB) requirements
- Independent 3rd Party Tissue Recovery Partners (TRP) obtain consent for procurement of the tissue
- All TRPs are compliant with all AATB and FDA requirements
- No donors with infectious diseases including HIV and Hepatitis B & C are accepted
- AbbVie's screening process does not accept tissue that shows evidence of anything that may affect the quality and safety of the dermis
- Final donor screening and testing is vetted by a 3-tiered review system consisting of specialists, nurses, and physicians

Final AlloDerm™ RTM product

- Successful removal of cells and cellular membrane
- No evidence of microbial pathogens detected
- Critical biochemical components are preserved while maintaining an intact tissue matrix
- More than 25 years of processing with no documented cases of disease transmission[5,6]

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.[2,3,4,†]

LifeCell processing method

Undamaged Tissue Matrix → **POSITIVE Recognition[2,3]** (body recognizes as self) → • Revascularization • Fibroblast repopulation • Reduced inflammatory response → **REGENERATION**

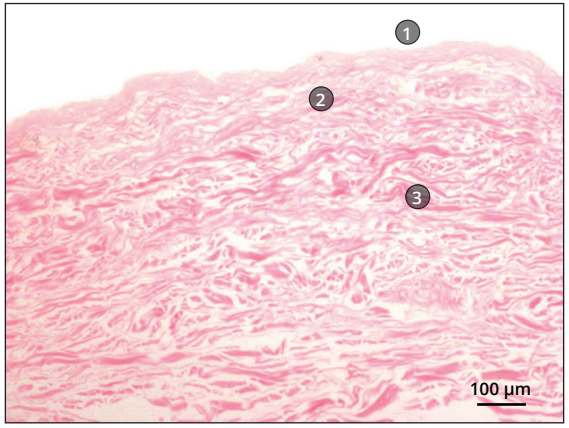
Alternative

Damaged Tissue Matrix → **NEGATIVE Recognition[2,4]** (body recognizes as foreign) → • Increased inflammatory response • Tissue is degraded or walled off • Scar tissue formation → **DEGRADATION ENCAPSULATION**

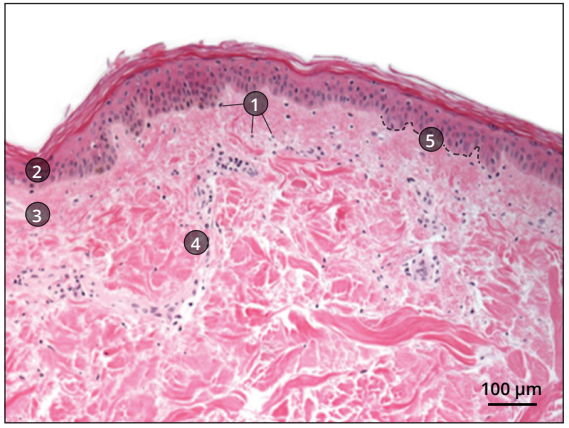
† Correlation of these results, based on animal studies, to results in humans has not been established.

REFERENCES: 1) Data on file, Allergan Aesthetics, 2022; Number of AlloDerm™ RTM Units Sold 2) Extracellular wound matrices: a novel regenerative tissue matrix (RTM) technology for connective tissue reconstruction. *Wounds*. Harper JR, McQuillan DJ. 2007;19(6):163-168. 3) 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. 4) 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. 5) Use of an acellular allograft dermal matrix (AlloDerm) in the management of full-thickness burns. *Burns*. Wainwright DJ. 1995;21(4):243-248. 6) Data on file, Allergan Aesthetics, October 2022. 7) Out of Package Histologic Comparison of Dental Matrices, Sandor, M 2021.

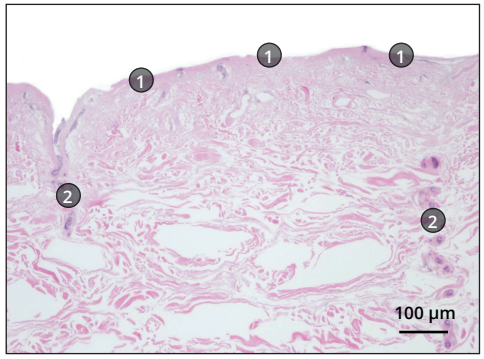
AlloDerm SELECT™ RTM
out-of-package histology[7]



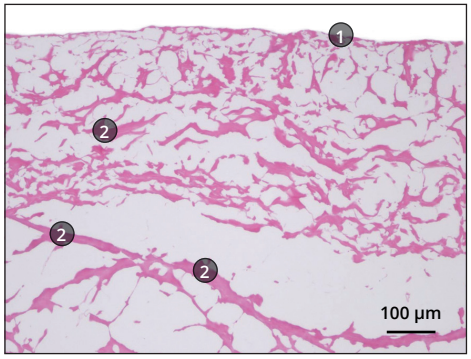
AlloDerm SELECT™ RTM
1) Intact basement membrane
2) Papillary dermis
3) Reticular dermis



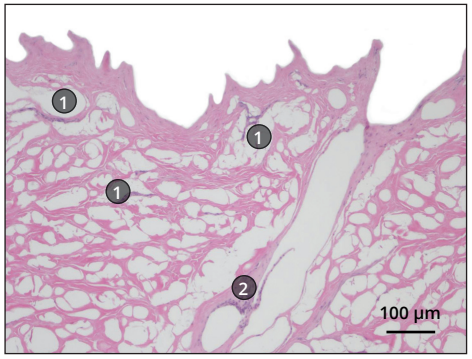
Human Dermis
1) Cells
2) Epidermis
3) Papillary dermis
4) Reticular dermis
5) Basement membrane



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

Out-of-package samples were stained with Hematoxylin & Eosin (H&E). Images shown at 100x magnification. Data on file, AbbVie 2012, 2021. Clinical significance has not been established.

AlloDerm SELECT™ RTM
other information

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.

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.

 SPMP12289 REV C NOV 2022 ALB159811 11/22