TIME-TESTED TISSUE PROCESSING **FROM THE INDUSTRY LEADER**

Not actual patient or surgeon.

When you want to be sure your patients are getting a high-quality tissue matrix, choose the industry leader with a proven track record in acellular dermal matrices.[1]

LifeCell Corporation, an AbbVie company, is an AATB-accredited tissue bank that adheres to strict donor screening protocols. We consistently meet rigorous quality standards. However, producing high-quality tissue takes more than that. Meticulous processing and rigorous product-release testing are needed to achieve optimal results.

The LifeCell Corporation proprietary tissue processing and release testing fully meet standard requirements and the industry standards to produce a safe, intact acellular dermal matrix of high quality.

STRICT DONOR SCREENING → METICULOUS TISSUE PROCESSING → RIGOROUS PRODUCT RELEASE TESTING → AlloDerm™ RTM

Allergan Aesthetics™, an AbbVie company, is committed to providing surgeons and their patients with quality products

Be assured AlloDerm™ RTM is a high-quality product, as expected from the industry leader in acellular dermal matrices.[1]

Please see Important Safety Information on the back of this brochure.

REIMBURSEMENT HOTLINE SUPPORT

Contact Us:

Monday to Friday 8:30 AM - 6 PM ET (closed on major observed holidays)

AllerganPRM@thepinnaclehealthgroup.com | 1.888.543.3656 | 1.877.499.2986

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

The most commonly reported adverse events associated with the implant of a tissue graft include, but are not limited to the following: wound or systemic infection; seroma; 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 available at www.allergan.com/AlloDermIFU or call 1.800.678.1605.

To report an adverse reaction, please call Allergan at 1.800.433.8871.

References: 1. Data on file, Allergan, April 2020 Sales Tracker. **2.** AlloDerm SELECT™ Regenerative Tissue Matrix Instructions for Use, 2020. **3.** Harper JR, McQuillan DJ. Extracellular wound matrices: a novel regenerative tissue matrix (RTM) technology for connective tissue reconstruction. *Wounds*. 2007;19(6):163-168. **4.** Xu H, Wan H, Sandor M, et al. Host response to human acellular matrix transplantation in a primate model of abdominal wall repair. *Tissue Eng* Part A. 2008;14(12):2009-2019. **5.** Data on file, Allergan. 2018. Sales Data. **6.** Wainwright DJ. Use of an acellular allograft dermal matrix (AlloDerm) in the management of full-thickness burns. *Burns*. 1995;21(4):243-248. **7.** Data on file, Allergan. PubMed search performed in June 2020.

For more information about AlloDerm™ RTM, call Customer Service at **1.800.367.5737** or visit **WWW.ALLODERM.COM/HCP**.

Allergan Aesthetics
an AbbVie company

AlloDerm SELECT™
Regenerative Tissue Matrix

Not actual surgeons.

SAFETY AND QUALITY YOU EXPECT FROM THE INDUSTRY LEADER[1]

ALLODERM SELECT™ Regenerative Tissue Matrix
INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

ALLODERM SELECT™ Regenerative Tissue Matrix (ALLODERM SELECT™ RTM refers to both ALLODERM SELECT™ RTM and ALLODERM SELECT RESTORE™ 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. This product is intended for single patient one-time use only. ALLODERM SELECT™ RTM is not indicated for use as a dural substitute or intended for use in veterinary applications.

Please see Important Safety Information on the back of this brochure.

DEDICATED TO RIGOROUS QUALITY AND SAFETY MEASURES

Our process meets the highest industry standard

Thorough and strict screening process

Careful screening of donors leads to high-quality tissue. Our process eliminates any donors that don't meet our strict criteria.

Our team of medical directors thoroughly reviews all donor records and does not accept those showing evidence of anything that may affect the quality and safety of the dermis.

Fully meets AATB and FDA requirements

AlloDerm™ Regenerative Tissue Matrix (RTM) is processed in accordance with the requirements of the American Association of Tissue Banks (AATB), Food & Drug Administration (FDA), and other regulatory bodies concerning banked human tissue.[2]

- Comprehensive medical and social history screening meets all AATB and FDA requirements
- All of our Tissue Recovery Partners are compliant with all AATB and FDA requirements

Donor exclusion criteria:

- No donors with infectious diseases, including HIV and hepatitis B and C
- No donors with communicable diseases such as rashes, oral thrush, or jaundice
- No donors with high-risk behaviors such as intravenous drug abuse, genital lesions, and condylomas

US-based donors only

LifeCell accepts only donors from the United States.

Experts in tissue matrices

While other companies might concentrate on bone and different types of tissue, for decades LifeCell has expertise focused solely on dermal tissue.

THE LIFECELL 3-PHASE **PROCESSING APPROACH**

PHASE 1
Donor Screening and Testing

- All tests required by FDA regulations and AATB standards[2]
- Final transfer vetted by 3-tiered review system consisting of specialists, nurses, and physicians

PHASE 2
Tissue Processing

- Skin recovery and temperature verification performed
- Cells removed while preserving the integrity of the tissue matrix[2]
- Rigorous controls and thorough documentation[2]
- Terminally sterilized without damaging the tissue matrix
- Final quality control inspection

PHASE 3
Product-release Testing

LifeCell Corporation tests tissues from every donor prior to release to ensure that it is an intact, acellular dermal matrix (ADM) designed to regenerate and strengthen weak tissues

H&E testing
- Successful removal of epidermis
- Intact papillary to reticular transition
- Intact collagen structure

Immunohistochemistry staining
- Intact basement membrane
- Successful removal of cells and cellular membrane
- Preserved structural integrity

THE END RESULT: AlloDerm™ RTM, the undamaged, intact acellular dermal matrix that is the most widely used ADM for dermal tissue reinforcement[1-3]

THE FINAL PRODUCT—ALLODERM™ RTM

In the end, product performance matters, and the facts speak for themselves

Final tissue characteristics:

- Critical biochemical components are preserved while maintaining an intact tissue matrix
- Decellularized dermal matrix
- Supports a positive immunologic response[4,*]

Proven performance:

- 25 years of processing and more than 2.5 million implants[5,6]
- No documented cases of disease transmission
- The most published ADM, with hundreds of scientific and clinical articles[7]

Results lead to assurance that your patients are receiving a safe, high-quality tissue from the proven industry leader.[1] Surgeons have valued these results for the last 25 years.[6]

Please see Important Safety Information on the back of this brochure.

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