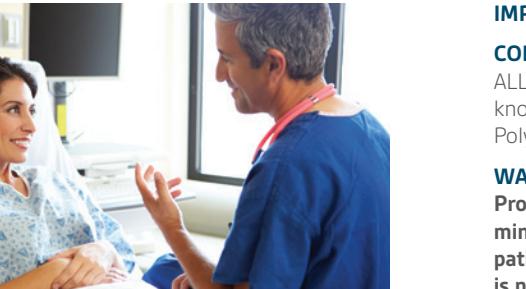


## TIME-TESTED TISSUE PROCESSING FROM THE INDUSTRY LEADER



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.<sup>1</sup>**

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.



**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.<sup>1</sup>

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

### 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.

References: 1. Data on file, Allergan Aesthetics; December 2023. Plastic Surgery Aesthetic Monthly 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 Aesthetics; AlloDerm Global Product Sales 2023. 6. LifeCell Corporation reports second quarter results. News release. LifeCell Corporation; August 3, 1994. 7. Data on file, Allergan Aesthetics; LIS Publication search performed March 2024.

### 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

For more information about AlloDerm™ RTM,  
call Customer Service at **1.800.367.5737** or  
visit our online resources.



AlloDerm™ HCP website  
[www.AlloDerm.com](http://www.AlloDerm.com)



AlloDerm™ Instagram  
[@AlloDermHCP](https://www.instagram.com/AlloDermHCP)

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ALS128445-v4 04/24



**SAFETY AND QUALITY YOU EXPECT  
FROM THE INDUSTRY LEADER<sup>1</sup>**

### 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. ALLODERM SELECT™ RTM is intended for use in post-mastectomy breast reconstruction surgical procedures where the use of the acellular dermal matrix (ADM) is considered homologous, such as managing a potential skin defect created from harvesting tissue for use in autologous tissue reconstruction. Examples of uses in post-mastectomy breast reconstruction not considered homologous include use of an ADM to form an extension of the submuscular pocket for placement of a breast implant or tissue expander, and use to prevent expander or implant extrusion, or to constrain the expander or implant in the correct position. This product is intended for use in 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.

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

## DEDICATED TO RIGOROUS QUALITY AND SAFETY MEASURES

## THE LIFECELL 3-PHASE PROCESSING APPROACH

## THE FINAL PRODUCT—ALLODERM™ RTM

### 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.

#### 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



#### 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.<sup>2</sup>

- 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



#### 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.

### PHASE 1 Donor Screening and Testing

- All tests required by FDA regulations and AATB standards<sup>2</sup>
- 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<sup>2</sup>
- Rigorous controls and thorough documentation<sup>2</sup>
- 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<sup>1-3</sup>

### 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<sup>4,\*</sup>

#### Proven performance:

- 30 years of processing and more than 4 million implants<sup>5,6</sup>
- No documented cases of disease transmission
- The most published ADM, with over a thousand of scientific and clinical articles<sup>7,\*</sup>

Results lead to assurance that your patients are receiving a safe, high-quality tissue from the proven industry leader.<sup>1,\*</sup> Surgeons have valued these results for 30 years.<sup>6</sup>