

ALLODERM SELECT™
ALLODERM SELECT RESTORE™
REGENERATIVE TISSUE MATRIX

Instructions for Use



Processed from donated human tissue by:

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DESCRIPTION

ALLODERM SELECT™ Regenerative Tissue Matrix (“ALLODERM SELECT™ RTM”) and ALLODERM SELECT RESTORE™ Regenerative Tissue Matrix (“ALLODERM SELECT RESTORE™ RTM”) are donated allograft human dermis, processed to remove cells while preserving biologic components and structure of the dermal matrix.

ALLODERM SELECT™ RTM and ALLODERM SELECT RESTORE™ RTM are white to buff colored and uniform in appearance. The products are supplied as a ready to use tissue graft in various different size configurations and thicknesses as specified on the label. All labeled dimensions are at nominal values only.

Note: The term “ALLODERM SELECT™ RTM” in the following instructions for use shall refer to both ALLODERM SELECT™ RTM and ALLODERM SELECT RESTORE™ RTM products.

REGULATORY CLASSIFICATION

ALLODERM SELECT™ RTM is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation. ALLODERM SELECT™ RTM is processed and provided in accordance with the FDA’s requirements for banked human tissue (21 CFR, Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products) and Standards for Tissue Banking of the American Association of Tissue Banks (AATB). LifeCell is compliant with the AATB Standards for Tissue Banking and various states as applicable.

DONOR SCREENING AND TESTING

LifeCell has determined the donor of this tissue graft to be an eligible donor based on the results of donor screening and testing records and thereby declare the tissue to be safe for transplantation.

Donor screening includes, but may not be limited to, review of relevant medical records including a current donor risk assessment interview, a physical examination of the donor, laboratory test results, existing coroner and autopsy results, and other information pertaining to risk factors for relevant communicable diseases.

Comprehensive donor screening and testing is performed on all tissue donors in accordance with FDA regulations, AATB standards and applicable state requirements. Refer to the Summary of Records label provided with each graft for details of the testing.

Due to limitations in testing technology, testing and donor screening cannot totally eliminate the risk that human source material will transmit disease.

INDICATIONS FOR USE

ALLODERM SELECT™ RTM is intended to be used for repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument.

Each package of ALLODERM SELECT™ RTM is intended for use in one patient, on a single occasion.

ALLODERM SELECT™ RTM is not indicated for use as a dural substitute.

ALLODERM SELECT™ RTM is not intended for use in veterinary applications.

CONTRAINDICATIONS

ALLODERM SELECT™ RTM is contraindicated for use in any patient who is sensitive to any of the antibiotics listed on the package 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 product after 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). (See **ORIENTATION**.) 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 ALLODERM SELECT™ RTM is dry.
- ALLODERM SELECT™ RTM is limited to use by specific health professionals (e.g., physicians, dentists, and/or podiatrists).
- Certain considerations should be made in order to reduce the risk of adverse events when performing surgical procedures using a tissue graft. Please see the following sections 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; seroma; dehiscence; hypersensitive, allergic or other immune response; and sloughing or failure of the graft.

Adverse outcomes potentially attributed to ALLODERM SELECT™ RTM must be reported promptly to your local sales representative or call LifeCell Corporation, an Allergan affiliate at 1.800.433.8871.

STORAGE

- Store product at room temperature in its original packaging.
- Refer to the included temperature monitor to ensure that product has been stored within tolerance limits. Only use the product if the included temperature monitor displays "OK" on the screen. **DO NOT** use if the screen displays anything other than "OK".
- It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

- The expiration date for the product is recorded on the product labeling as 4 digit year and 2 digit month (YYYY-MM) or 4 digit year, 2 digit month, and 2 digit day (YYYY-MM-DD). The product expires on the last day of the month indicated.
- **DO NOT** use product after the expiration date. Expiration date printed on the labeling is valid as long as product is stored at room temperature and in an unopened foil pouch. If the product is past its expiration date, discard in accordance with standard medical practice and institutional protocols for disposal of human tissue.

HOW SUPPLIED

ALLODERM SELECT™ RTM undergoes a terminal sterilization process that includes electron beam irradiation, is sterile to a Sterility Assurance Level (SAL) of 10^{-3} , and is supplied in a plastic holder, which is enclosed within a foil pouch. Product thickness category and size are clearly marked on the label located on the foil pouch.

IMPORTANT: It is the responsibility of the healthcare practitioner to maintain recipient records for the purpose of tracing tissue post-implantation. Patient tracking labels are provided for convenience.

INSTRUCTIONS FOR PREPARING ALLODERM SELECT™ RTM FOR SURGICAL USE

These instructions are designed to serve as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. Users should be familiar with surgical procedures and techniques involving tissue implantation before using ALLODERM SELECT™ RTM.

REQUIRED MATERIALS

- Sterile forceps
- Soaking fluid: room temperature sterile saline or room temperature sterile lactated Ringer's solution
- One sterile basin per piece of ALLODERM SELECT™ RTM

PREPARATION INSTRUCTIONS

1. Open the carton and remove the foil pouch.
2. Peel open the foil pouch and remove the plastic holder using aseptic technique. The plastic holder is sterile and may be placed directly into the sterile field.
3. Open the plastic holder carefully and aseptically remove the tissue. Always use sterile gloved hands or forceps when handling ALLODERM SELECT™ RTM.
4. 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.

5. Store the tissue in the room temperature sterile solution until ready for implantation. The tissue can be stored in sterile solution for a maximum of 4 hours.

Orientation

ALLODERM SELECT™ RTM has two distinct sides, the “dermal” side and the “basement membrane” side. The dermal side absorbs blood. The basement membrane side repels blood. When applied as an implant, the dermal side should be placed against the most vascular tissue.

Procedure for determining orientation

To determine proper orientation, add a drop of blood to both sides of the tissue and rinse with sterile solution. The dermal side will have a bloody appearance, whereas the basement membrane side will appear pink.

CONSIDERATIONS FOR PATIENT/PRODUCT SELECTION

The following considerations are intended to serve only as general guidelines. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. Users should be familiar with surgical procedures and techniques involving tissue implantation before using ALLODERM SELECT™ RTM.

- Carefully consider the risk/benefit balance of using a tissue graft in patients with significant co-morbidities, including but not limited to: obesity, active tobacco use, diabetes, immunosuppression, malnourishment, poor tissue oxygenation or perfusion, and pre- or post-operative radiation.
- Carefully consider patient factors (e.g., skin flap size and tissue viability) and product sizing when selecting a tissue graft, such as ALLODERM SELECT™ RTM.

TECHNIQUE CONSIDERATIONS

The following considerations are intended to serve only as general guidelines. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. Users should be familiar with surgical procedures and techniques involving tissue implantation before using ALLODERM SELECT™ RTM.

- As with any tissue graft, careful aseptic technique should be practiced and contact of the graft with the patient’s skin should be minimized.
- As a standard practice, utilize bioburden-reducing techniques in significantly contaminated or infected cases to minimize contamination levels at the surgical site, including but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior to implantation of the tissue graft.

- The surrounding tissue should be carefully assessed for quality and adequate thickness. Ensure that the patient's tissue is well-perfused prior to implanting a tissue graft, such as ALLODERM SELECT™ RTM.
- ALLODERM SELECT™ RTM should be covered with healthy, viable tissue; portions of the tissue that appear ischemic or necrotic should be addressed using professional clinical judgment prior to implantation.
- Surgeons should prepare surgical site and complete surgical procedure following current standard-of-care guidelines and institutional protocols. Surgeons should use professional clinical judgment when addressing patient care.
- Carefully consider appropriate placement and fixation of the tissue graft. The tissue graft should be sized and sutured in place under appropriate physiological tension and potential dead space should be minimized to reduce the risk of fluid accumulation. Care should be taken to avoid excessive tension on the overlying skin at the time of closure.
- Surgeons should follow current standard-of-care guidelines and institutional protocols for type, placement, and dwell time of active closed-suction surgical drains to minimize the risk of fluid accumulation.

CONSIDERATIONS FOR HERNIA REPAIR

The following considerations are intended to serve only as general guidelines. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. Users should be familiar with surgical procedures and techniques involving tissue implantation before using ALLODERM SELECT™ RTM.

Minimize bioburden

- Prior to ALLODERM SELECT™ RTM implantation, it is recommended that bioburden-reducing techniques be used to minimize contamination levels at the surgical site, including pulse lavage and surgical debridement of contaminated soft tissue.

Technique

- Re-approximate rectus muscles back to midline whenever possible and use ALLODERM SELECT™ RTM as an underlay, and/or onlay to relieve tension and reinforce primary fascial closure. If primary closure is not achievable, reduce the size of the defect as much as possible, and underlay ALLODERM SELECT™ RTM at least 3–5 cm or as far in as required to reach healthy tissue.

Establishing appropriate tension

- Suture ALLODERM SELECT™ RTM under significant tension to ensure the laxity is removed as much as possible.

- Removing the laxity will increase the surface area of each graft by 30–50%. For example, a 16x20 cm graft will expand up to 19x25 cm when sutured under significant tension.

Suture

- Permanent suture (e.g., polypropylene) is recommended.

Drains

- Liberal use of fluted drains is recommended. Leave drains in until output is 30 ml or less per drain, per 24-hour period, for three consecutive days. This often takes about 3 weeks after surgery.

TISSUE TRANSPLANT RETURN RECORD

The Tissue Transplant Return Record (TTRR): follow the directions provided on the form for completion and return to LifeCell Corporation.

INQUIRIES

For product complaints and potential adverse events, please contact your local Sales Representative, or 1.800.433.8871.

For clinical/medical questions, please contact Medical Information at IR-Medcom@allergan.com or call 1-800-678-1605, Option 2.

ALLODERM SELECT™ RTM and ALLODERM SELECT RESTORE™ RTM are processed by LifeCell Corporation, One Millennium Way, Branchburg, NJ 08876 USA.

LifeCell Corporation holds Canadian CTO Registration No. 100128.

Patented in the US. See www.allergan.com/patents. Additional patents may be pending or issued in the US and elsewhere.

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