ALLODERM SELECT™
ALLODERM SELECT RESTORE™
ALLODERM SELECT DUO™
ALLODERM SELECT RESTORE DUO™

REGENERATIVE TISSUE MATRIX

Instructions for Use

Allergan Aesthetics
an AbbVie company

Processed from donated human tissue by:
LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876 USA
1-844-663-3742

DESCRIPTION

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

ALLODERM SELECT™ RTM is white to buff colored and uniform in appearance. The product is supplied as a ready to use tissue graft in various different sizes, shapes and thickness categories as specified on the labeling. Product configurations include perforated, non-perforated, meshed, non-meshed, and fenestrated. All labeled dimensions are at nominal values only.

The "ALLODERM SELECT™ RTM" product description above applies to the following proprietary name(s) and the instructions for use shall refer to the term "ALLODERM SELECT™ RTM" unless noted otherwise.

ALLODERM SELECT™ RTM

ALLODERM SELECT RESTORE™ RTM

ALLODERM SELECT DUO™ RTM

ALLODERM SELECT RESTORE DUO™ RTM

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.

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.

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

Polysorbate 20 is a component of the aqueous phosphate buffered preservation solution and therefore ALLODERM SELECT™ RTM should not be used in patients with a known sensitivity to this material.

Trace amounts of antibiotics may be present. ALLODERM SELECT™ RTM should not be used in patients with a known sensitivity to any of the antibiotics listed on the package labels.

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 any temperature monitoring device on the package 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**.) 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 AbbVie company at 1-844-663-3742.

STORAGE

- Store product at room temperature in its original packaging.
- Refer to the included temperature monitor(s) to ensure that product has been maintained within tolerance limits. Only use the product if the included temperature monitor(s) displays "OK" on the screen. **DO NOT** use if any 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 is processed and stored in a patented aqueous phosphate buffered preservation solution. The tissue graft undergoes a terminal sterilization process that includes electron beam irradiation to meet 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 product labeling.

ALLODERM SELECT™ RTM and ALLODERM SELECT RESTORE™ RTM contain 1 foil pouch, which is packaged in a carton (Contents: 1 tissue graft).

ALLODERM SELECT DUO™ RTM and ALLODERM SELECT RESTORE DUO™ RTM contain 2 foil pouches, which are packaged in a carton (Contents: 2 tissue grafts). The two tissue grafts are processed from the same donor and are matched with the same size and thickness.

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 graft. Always use sterile gloved hands or forceps when handling ALLODERM SELECT™ RTM.
4. Soak the tissue graft 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 graft.
5. Store the tissue graft in the room temperature sterile solution until ready for implantation. The tissue graft 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. The dermal side should be placed against the most vascular tissue.

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

Meshed ALLODERM SELECT™ tissue grafts contain a row of the letter “L” in the mesh pattern. When oriented correctly (basement membrane side up), the row of Ls should appear as it does in the diagram below. Alternatively, proper orientation may also be determined by the blood test described above.

IMPLANTATION INSTRUCTIONS

1. Prepare the surgical site using standard techniques.
2. ALLODERM SELECT™ RTM may be folded, trimmed or cut as required to fit the surgical site using aseptic technique, ensuring allowance for overlap.
3. Transfer ALLODERM SELECT™ RTM to the surgical site using sterile gloves or forceps.
4. Suture ALLODERM SELECT™ RTM into place.
5. Complete the standard surgical procedure.
6. Discard any unused portions of ALLODERM SELECT™ RTM as per institutional procedures.

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.
- 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.
- For abdominal wall repair applications, re-approximate rectus muscles back to the midline wherever possible. 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. Use of permanent sutures is recommended.
- 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 SKIN GRAFTING

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 grafting techniques before using ALLODERM SELECT™ RTM.

- After applying the ALLODERM SELECT™ RTM, dress it with multi-layered dressing to prevent surface desiccation, to prevent maceration, to provide protection from shearing forces, and to provide a suitable microbial barrier.

- Dressings should not be saturated, as this may cause maceration of the ALLODERM SELECT™ RTM, resulting in poor allograft engraftment.
- The ALLODERM SELECT™ RTM should remain undisturbed for a minimum of 7 days during the initial healing period to allow revascularization and reepithelialization.
- Outer layers of the dressing may require frequent changing during the first few days to prevent accumulation of fluid and bacteria. When changing, take extreme care not to disturb the graft.
- On or about Day 7, the inner layer may be removed. During this time period, some areas of the ALLODERM™ SELECT RTM may appear white/yellow or whiter than the surrounding epidermis, and may only weakly adhere. This is normal.
- Until the grafts are fully revascularized and reepithelialized, they should be re-dressed with a nonadherent dressing.
- As the epidermis establishes over the entire ALLODERM SELECT™ RTM surface and keratinocytes differentiate to form a cornified layer, protective dressings may be eliminated.

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 1-844-663-3742.

For clinical/medical questions, you may submit a medical information inquiry online at https://www.abbviemedinfo.com.

ALLODERM SELECT™ RTM is processed by LifeCell Corporation, an AbbVie company, One Millennium Way, Branchburg, NJ 08876 USA.

LifeCell Corporation holds Canadian CTO Registration No. 100128.

Patented in the US. Please see www.abbvie.com/patents. Additional patents may be pending or issued in the US and elsewhere.

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