



Instructions for Use



Processed from Donated Human Tissue by:
LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876 USA
1.800.433.8871

DESCRIPTION

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

ALLODERM™ RTM is white to buff colored and is uniform in appearance.

REGULATORY CLASSIFICATION

ALLODERM™ RTM is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation. ALLODERM™ 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 applicable state requirements.

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; as well as 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.

Samples of the donor skin are tested for and shown to be free of bacterial and fungal pathogens; non-pathogenic skin bacteria may be present.

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™ RTM is 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™ RTM is intended for use in one patient, on a single occasion only.

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

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

CONTRAINDICATIONS

ALLODERM™ 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 risks of the donor tissue transmitting disease to the recipient patient. As with any processed donor tissue, ALLODERM™ RTM cannot be 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™ RTM.

DO NOT STERILIZE ALLODERM™ RTM.

DO NOT USE ALLODERM™ RTM if either the outer foil bag or the inner (Tyvek®) pouch is perforated or torn. A damaged foil bag or inner (Tyvek) pouch may result in degradation or contamination of the product.

The inner (Tyvek) pouch that contains the ALLODERM™ RTM is NOT STERILE; **DO NOT PLACE** THE INNER (Tyvek) POUCH IN THE STERILE FIELD.

DO NOT USE product after expiration date noted on the label.

Transfer ALLODERM™ RTM from packaging aseptically. **DO NOT PLACE** either the foil bag or the inner (Tyvek) pouch in the sterile field. (See *INSTRUCTIONS FOR REHYDRATION*.)

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™ 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™ 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.
- When applied to the wound bed in a grafting procedure, it is recommended that the dermal side be placed against the wound bed with the basement membrane side facing up.

Success in grafting applications is enhanced by proper dressing of the graft. (See *SUGGESTED DRESSING INSTRUCTIONS FOR GRAFTING*.)

Prior to rehydration, **DO NOT BEND** because this may cause the ALLODERM™ RTM to fracture. **DO NOT USE** the ALLODERM™ RTM if it is bent, broken or cracked.

DO NOT USE the ALLODERM™ RTM if prior to rehydration it is not uniformly white to buff in coloration.

Normal rehydration of ALLODERM™ RTM is usually accomplished in 10-40 minutes, depending on thickness.

If any hair is visible, remove before implantation.

Use of ALLODERM™ RTM is limited to specific health professionals (e.g., physicians, dentists, and/or podiatrists).

Once a package or container has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.

Discard all open and unused portions of the product or expired product according to local institutional requirements.

ADVERSE REACTIONS

Potential adverse reactions 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™ RTM must be reported promptly to your local sales representative or call LifeCell Corporation, an Allergan affiliate at 1.800.433.8871.

STORAGE

Store at room temperature in its original packaging. Do not store the product outside of the tolerance limits of 1-28°C. 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 container labeling as year (4 digits) and month (2 digits) and 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 bag.

HOW SUPPLIED

ALLODERM™ RTM is supplied on a printed paper backing and is sealed in an inner (Tyvek) pouch, which is enclosed within an outer foil bag. Product thickness range and size are clearly marked on the label located on the outer 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 REHYDRATION

When preparing to use ALLODERM™ RTM in the operating room (OR), the following rehydration procedure should begin early enough to allow for adequate rehydration prior to intended implantation.

For best results when rehydrating ALLODERM™ RTM, use liberal amounts of warmed saline solution in a two-step bath with light agitation.

Normal rehydration of ALLODERM™ RTM is usually accomplished in 10-40 minutes, depending on thickness.

Equipment required

- 2 sterile dishes large enough to accommodate the ALLODERM™ RTM without bending
- Sterile saline or sterile lactated Ringer's solution that is sufficient to completely submerge the graft
- Sterile atraumatic forceps

Rehydration Step 1

Tear open the foil bag at the notch and remove the inner (Tyvek) pouch. (Keep both the foil bag and inner (Tyvek) pouch OUT of the sterile field.)

Peel open the inner (Tyvek) pouch and aseptically remove the tissue. **Do not peel printed paper backing at this point in the process.**

Submerge the tissue completely and soak for a minimum of 5 minutes or until the backing separates from the ALLODERM™ RTM.

Tip: Warming saline up to 37°C and using gentle movement of ALLODERM™ RTM in the solution speeds the rehydration process. However, do not heat saline above 37°C.

Tip: When rehydrating multiple pieces, ensure the pieces are not overlapping or clumping together as this may slow down the process. Use multiple bowls if necessary.

Tip: Keep ALLODERM™ RTM fully submerged by weighing it down, e.g., with sterile forceps.

Tip: If you are having a problem with rehydration, gently wipe/rub both sides of ALLODERM™ RTM, with a sterile gloved hand, to remove any excess cryoprotectant that may be creating a barrier between the ALLODERM™ RTM and the rehydration fluid.

Rehydration Step 2

Using a sterile gloved hand or forceps, remove and discard the backing once it separates from the tissue. Then, aseptically transfer the tissue to a second bath sufficiently filled with rehydration fluid.

Submerge completely and soak until the tissue is fully rehydrated (thicker grafts may take up to 40 minutes).

Tip: Keep ALLODERM™ RTM fully submerged by weighing it down, e.g., with sterile forceps.

When ALLODERM™ RTM is fully rehydrated, it is soft and pliable throughout. At this stage, it is ready for application to the surgical site. ALLODERM™ RTM may be aseptically trimmed to required dimensions.

Important: Use ALLODERM™ RTM within 4 hours of rehydration.

Considerations

If not completely rehydrated, ALLODERM™ RTM will appear to be of uneven thickness and have a mottled appearance.

Antibiotics may be added to the second rehydration solution.

Orientation

ALLODERM™ 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 to the wound bed in a grafting procedure, the dermal side should be placed against the wound bed, with the basement membrane side facing up. When applied as an implant, the dermal side should be placed against the most vascular tissue.

Procedure for determining orientation

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

Premeshed 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. Generally, correct orientation also may be determined by the blood test noted above.



SUGGESTED DRESSING INSTRUCTIONS FOR GRAFTING

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 procedures and techniques before using ALLODERM™ RTM.

After applying the ALLODERM™ RTM as described above, dress it with the following multilayered dressing (from the treated wound to the outside) to prevent surface desiccation, to prevent maceration, to provide a protection from shearing forces, and to provide a suitable microbial barrier.

Inner layer	Fine mesh gauze impregnated with bacitracin or other petrolatum-based antimicrobial ointment
Middle layer	Damp saline gauze wrap (a suitable antibiotic may be added to saline, if desired)
Outer layers	Dry gauze wrap followed by an elastic bandage or other wrap or splint

Considerations

- The dressings should not be saturated, as this may cause maceration of the ALLODERM™ RTM, resulting in poor autograft engraftment.
- The inner dressing of petrolatum-impregnated gauze must not be changed for at least 7 days. Optimum take of the ALLODERM™ RTM and overlying autograft requires that both remain undisturbed during this period to allow revascularization and reepithelialization.
- The 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 ointment-impregnated gauze or the composite graft.
- On or about Day 7, the inner layer may be removed. A generous application of petrolatum-based ointment prior to takedown will prevent adherence and stress to the grafted area. Saline soaks may be effective during dressing removal.
- It is normal for some areas of the ALLODERM™ RTM to appear white/yellow during this time period.
- Until the grafts are fully revascularized and reepithelialized, they should be re-dressed with antibiotic-impregnated fine mesh gauze or other nonadherent dressing. The damp saline layer may be eliminated at this time.
- On Day 7, the autograft may appear whiter than the surrounding epidermis and may only weakly adhere. This is normal.
- Occasionally, all or part of the autograft may come off with the dressing. This does not necessarily mean regrafting is required. Enough epidermal cells may have migrated from the autograft to the basement membrane to make regrafting unnecessary.
- With a meshed graft, the growth of epithelial cells under the thin dermal layer of the autograft may cause it to detach. However, the autograft may have already seeded the surface of the ALLODERM™ RTM with enough keratinocytes to provide partial covering. Careful examination of the surface will help determine if regrafting is needed.
- As the epidermis establishes over the entire ALLODERM™ RTM surface and keratinocytes differentiate to form a cornified layer, protective dressings may be eliminated. Once a cornified layer has been established (10 to 14 days), bathing with mild soaps and limited activity may commence.

SUGGESTED INSTRUCTIONS FOR HERNIA REPAIR

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 procedures and techniques before using ALLODERM™ RTM.

Minimize bioburden

Prior to ALLODERM™ 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.

Rehydration

Fully rehydrate ALLODERM™ RTM using the recommended two baths, warming the saline up to 37°C and keeping the ALLODERM™ RTM fully submerged (e.g., with sterile forceps). ALLODERM™ RTM can be shaped with sterile scissors or scalpel. When ALLODERM™ RTM is ready, store in the second saline wash until surgical site is prepared.

Important: Use ALLODERM™ RTM within 4 hours of rehydration.

Technique

Reapproximate rectus muscles back to midline whenever possible and use ALLODERM™ 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™ RTM at least 3–5 cm or as far in as required to reach healthy tissue.

Establishing appropriate tension

Suture ALLODERM™ 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 in until 30 ml or less is output per drain, per 24-hour period, for three consecutive days. This often takes about 3 weeks after surgery.

When used with vacuum-assisted closure device

Place a non-adherent dressing on top of ALLODERM™ RTM to prevent dryness and debridement of the graft when using vacuum-assisted negative pressure therapy. Ensure that there is an air-tight seal around the wound; any air leak may dry out the ALLODERM™ RTM.

TISSUE TRANSPLANT RETURN RECORD

The Tissue Transplant Return Record (TTRR) is attached to the *Instructions for Use*. Please separate the TTRR from the *Instructions for Use* and 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.

ALLODERM™ RTM is 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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Part No. 121P0541 Rev G

February 2020



121P0541REVG

