Instructions for Use
DESCRIPTION
AlloDerm® Regenerative Tissue Matrix Ready To Use (referred to herein as “AlloDerm® Ready To Use”) is donated allograft human dermis, processed to remove cells while preserving biologic components and structure of the dermal matrix. AlloDerm® Ready To Use is white to buff colored and is uniform in appearance. All labeled dimensions are at nominal values only.

REGULATORY CLASSIFICATION
AlloDerm® Ready To Use is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation. AlloDerm® Ready To Use is processed and marketed in accordance with the FDA’s requirements for banked human tissue (21 CFR, Part 1271) and Standards for Tissue Banking of the American Association of Tissue Banks (AATB). AlloDerm® Ready To Use is compliant with the AATB Standards for Tissue Banking and the state guidelines of California, Florida, New York, Maryland, and Illinois.

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 declares 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 according to FDA regulations and AATB standards. 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.

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® Ready To Use 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® Ready To Use is intended for use in one patient, on a single occasion.

AlloDerm® Ready To Use is not indicated for use as a dural substitute.

CONTRAINDICATIONS
AlloDerm® Ready To Use 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® Ready To Use 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® Ready To Use.

DO NOT re-sterilize AlloDerm® Ready To Use. Discard all open and unused portions of the product.

DO NOT use if the outer pouch is opened or damaged.

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

Transfer AlloDerm® Ready To Use from the outer foil pouch aseptically. DO NOT place the outer 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® Ready To Use as such conditions may compromise successful implantation.
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® Ready To Use 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® Ready To Use should be hydrated and moist when the package is opened. If AlloDerm® Ready To Use is dry, DO NOT use.

Use of AlloDerm® Ready To Use is limited to specific health professionals (e.g., physicians, dentists, and/or podiatrists).

ADVERSE EFFECTS
Potential adverse effects which may result from placement of a tissue implant include, but are not limited to the following: wound or systemic infection; seroma; dehiscence; hypersensitive, allergic or other immune response; sloughing or failure of the graft; and disease transmission.

Adverse outcomes potentially attributed to AlloDerm® Ready To Use must be reported promptly to LifeCell at 1-908-947-1215 or by fax at 1-908-947-1089.

STORAGE
Store product at room temperature in its original packaging. 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 pouch.

HOW SUPPLIED
AlloDerm® Ready To Use undergoes a terminal sterilization process that includes electron beam irradiation, is sterile to a Sterility Assurance Level (SAL) of 10⁻³, and is supplied sealed in an inner foil pouch, which is enclosed within an outer foil pouch. Product thickness category 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.

RECOMMENDED INSTRUCTIONS FOR PREPARING ALLODERM® READY TO USE FOR SURGICAL USE

These recommendations are designed to serve only 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® Ready To Use.

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® Ready To Use

PREPARATION INSTRUCTIONS
1. Open the carton and remove the foil pouch.
2. Peel open the outer foil pouch and remove the inner foil pouch using aseptic technique. The inner foil pouch is sterile and may be placed directly into the sterile field.
3. Open the inner pouch carefully and aseptically remove the tissue. Always use sterile gloved hands or forceps when handling AlloDerm® Ready To Use.
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® Ready To Use 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.

SUGGESTED INSTRUCTIONS FOR POST-MASTECTOMY BREAST RECONSTRUCTION

Your LifeCell™ representative can help with the appropriate size selection.

AlloDerm® Ready To Use placement

• Center over inframammary fold arc.

Anchoring AlloDerm® Ready To Use

• Suture inferior border to chest wall tissue, not to skin flap.
• Ensure no gaps when suturing superior border of AlloDerm® Ready To Use to pectoralis major muscle.

Pectoralis major muscle placement

• Bring muscle over prosthesis as far inferolaterally as possible without overstretching it.
• Position muscle below incision site.

Prolonged use of drains

• Two drains are recommended: one between the breast implant and the AlloDerm® Ready To Use and one between the AlloDerm® Ready To Use and the skin flap. If only one drain is utilized, place it between the AlloDerm® Ready To Use and the skin flap.

• Leave drains in until output is 30 ml or less per drain, per 24-hour period, for three consecutive days.

Extent of expansion

• Expand intraoperatively as much as skin flap and AlloDerm® Ready To Use will comfortably tolerate.

SUGGESTED INSTRUCTIONS FOR HERNIA REPAIR

Your LifeCell™ representative can help with the appropriate size selection.

Minimize bioburden

• Prior to AlloDerm® Ready To Use 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® Ready To Use 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® Ready To Use at least 3–5 cm or as far in as required to reach healthy tissue.

Establishing appropriate tension

• Suture AlloDerm® Ready To Use 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.
**When used with vacuum-assisted closure device**

- Place a non-adherent dressing on top of AlloDerm® Ready To Use 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® Ready To Use.

**TISSUE TRANSPLANT RETURN RECORD**

The Tissue Transplant Return Record (TTRR) is attached to the outer pouch. Please separate the TTRR from the outer pouch and follow the directions provided on the form for completion and return to LifeCell Corporation.

**INQUIRIES**

Contact LifeCell™ Customer Support at 1-908-947-1215 or 1-800-367-5737, or e-mail LifeCell™ at customersupport@lifecell.com for additional information, to place an order, or to report adverse reactions.

AlloDerm® Ready To Use is processed and distributed by LifeCell Corporation, One Millennium Way, Branchburg, NJ 08876 USA.

LifeCell Corporation holds Canadian registration No. 100128.

This product and certain methods are covered by U.S. and foreign patents and patents pending.

AlloDerm is a registered trademark of LifeCell Corporation.