



Cymetra® Micronized AlloDerm® Tissue

Instructions for Use



An Acelity Company

Processed from Donated Human Tissue
and Distributed by

LifeCell Corporation

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Description

Cymetra® Micronized AlloDerm® Tissue is micronized 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.

Regulatory classification

Cymetra® Micronized Tissue is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation. Cymetra® Micronized Tissue is processed and provided 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). 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 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.

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

Cymetra® Micronized AlloDerm® Tissue is intended for homologous use when transplanted into sub-epidermal spaces from which such tissue originates, for repair or replacement of damages or inadequate integumental tissues (e.g., correct soft-tissue defects, and depressed scars, or for replacement of integumental tissue lost through atrophy).

Each package of Cymetra® Micronized Tissue is intended for use in one patient, on a single occasion only.

Cymetra® Micronized Tissue is not intended for veterinary applications.

Contraindications

Cymetra® Micronized Tissue is contraindicated for use in any patient who is sensitive to polysorbate 20 or any of the antibiotics listed on the package.

DO NOT USE Cymetra® Micronized Tissue in the periocular, forehead or glabellar areas. If Cymetra® Micronized Tissue is used in these areas, there is a risk of the Cymetra® Micronized Tissue entering and occluding blood vessels supplying the eye through retrograde flow, resulting in vision impairment or blindness.

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, the Cymetra® Micronized AlloDerm® Tissue 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 the Cymetra® Micronized Tissue.

- **DO NOT RE-USE** Cymetra® Micronized Tissue.
- **DO NOT STERILIZE** Cymetra® Micronized Tissue.
- **DO NOT USE** Cymetra® Micronized Tissue if the foil pouch is perforated or torn. A damaged pouch may result in degradation or contamination of the product.
- **DO NOT USE** product after expiration date noted on label.
- The foil pouch that contains the Cymetra® Micronized Tissue is **NOT STERILE. 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, as well as nonvascular surgical sites, should be considered when selecting patients for implanting Cymetra® Micronized Tissue 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.

DO NOT USE the Cymetra® Micronized Tissue if prior to rehydration it is not uniformly white to buff in coloration.

DO NOT USE the Cymetra® Micronized AlloDerm® Tissue if it has discolored.

Use of Cymetra® Micronized Tissue is limited to specific healthcare professionals or practitioners (e.g., physicians).

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.

Failure to follow rehydration instructions may lead to sub-optimal results.

Aseptic technique must be adhered to throughout the procedure.

Cymetra® Micronized Tissue should be used within two hours following rehydration.

Use the supplied 23-gauge needle for implanting rehydrated Cymetra® Micronized Tissue. Use of a smaller gauge needle may increase the risk of the needle clogging.

If the needle should become clogged during insertion, replace with a fresh needle.

Gentle massage by the physician of the treated area is recommended during and following treatment to achieve symmetry. The patient should NOT massage the treated area. Transient swelling, redness and firmness can be expected to occur following treatment.

Adverse Reactions

Potential adverse reactions which may result from procedures associated with the application of Cymetra® Micronized AlloDerm® Tissue include, but are not limited to: wound or systemic infection; hypersensitive, allergic or other immune response; and rapid resorption of graft material.

Because Cymetra® Micronized AlloDerm® Tissue is placed into a superficial subdermal tissue plane, there is potential for swelling, bruising, pain or irritation during the immediate post-operative period. Skin redness, discoloration and herpetic lesions have been reported on rare occasions. These symptoms typically resolve without sequelae. In addition, lumpiness and a non-uniformity of contour may occur if care is not taken by the physician to evenly distribute the material during placement. Firmness of the treated site may occur within the first 4 months, but typically resolves without complication.

Adverse outcomes potentially attributed to Cymetra® Micronized Tissue must be reported promptly to LifeCell Corporation.

Storage

Refrigerate upon receipt between 1–10°C (34–50°F) in its original packaging. 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 Cymetra® Micronized Tissue is recorded on the outer package as a year (4 digits) and month (2 digits), the product expires on the last day of the month indicated. *Do not use product after expiration date.*

Expiration date printed on the labeling is valid as long as product is stored refrigerated and in an unopened foil bag.

How supplied

Cymetra® Micronized Tissue is supplied as a dried, acellular dermal particulate. The Cymetra® Micronized Tissue package includes standard disposable supplies to facilitate rehydration and delivery. Refer to product rehydration Instructions for contents.

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

Preparation instructions

Prepare treatment area for injection. If the injection site is susceptible to herpetic outbreak, the patient may be placed on prophylactic antiviral agents. See “Preparation for placement” for anesthetic options.

Instructions for optimal rehydration are separately enclosed in the Cymetra® Micronized AlloDerm® Tissue package. Failure to follow rehydration instructions may lead to sub-optimal results.

Preparation for placement

Cymetra® Micronized Tissue should be placed into a superficial sub-dermal tissue plane. Cymetra® Micronized Tissue has been formulated to a consistency that will easily pass through a 23-gauge needle. Use of a smaller gauge needle may increase the risk of the needle clogging. Preparation of the injection site can be achieved using a variety of approaches to help maximize patient comfort during and after the placement of tissue, including:

- Topical anesthetics such as lidocaine/prilocaine cream;
- Regional nerve block; and
- Lidocaine with epinephrine, or ice placed on the site 2-3 minutes prior to detection. (The use of lidocaine with epinephrine may alter the clinical endpoints of certain procedures such as laser resurfacing if concurrently performed.)

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

Contact LifeCell Customer Support at 908.947.1215 or 800.367.5737, or e-mail LifeCell at customersupport@lifecell.com for additional information, to place an order, or to report adverse reactions.

Cymetra® Micronized AlloDerm® Tissue is processed and distributed by LifeCell Corporation, One Millennium Way, Branchburg, NJ 08876 USA.

LifeCell Corporation holds Canadian CTO Registration No. 100128.

This product and certain methods are covered by U.S. and foreign patents and patents pending, including: US 7,358,284 and US 6,933,326.

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