

GRAFTJACKET[®]

REGENERATIVE TISSUE MATRIX

Instructions for Use

Wright Medical Technology
1023 Cherry Road
Memphis, TN 38117
USA
1-800-238-7117

Processed from Donated Human
Tissue for Wright Medical Technology
by LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876-3876

DESCRIPTION

GRAFTJACKET® Regenerative Tissue Matrix 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.

The GRAFTJACKET® matrix is white to buff colored and is uniform in appearance. The GRAFTJACKET® matrix has a distinct basement membrane and dermal surface. (See *ORIENTATION*.)

REGULATORY CLASSIFICATION

GRAFTJACKET® Regenerative Tissue Matrix is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation. GRAFTJACKET® matrix 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). The tissue processor 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.

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

GRAFTJACKET® matrix is used to provide supplemental support, protection, and reinforcement of tendon and ligamentous tissue; to be used as a periosteal patch or covering; or for protection and support of bone and tendons in foot & ankle and hand surgery.

Each package of GRAFTJACKET® matrix is intended for use in one patient, on a single occasion only.

GRAFTJACKET® matrix is not intended for veterinary applications.

CONTRAINDICATIONS

GRAFTJACKET® matrix 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, the GRAFTJACKET® matrix 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 GRAFTJACKET® Regenerative Tissue Matrix.

- **DO NOT STERILIZE** GRAFTJACKET® matrix.
- **DO NOT USE** GRAFTJACKET® matrix 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.
- **DO NOT USE** product after expiration date noted on label.
- The inner (Tyvek®) pouch that contains the GRAFTJACKET® matrix is NOT STERILE; **DO NOT PLACE THE INNER (Tyvek®) POUCH IN THE STERILE FIELD.**
- Transfer GRAFTJACKET® matrix from packaging aseptically. **DO NOT PLACE** either the foil bag or the inner (Tyvek®) pouch in the sterile field. (See *INSTRUCTIONS FOR REHYDRATION.*)

PRECAUTIONS

It is the responsibility of the physician to determine the appropriate size and thickness of GRAFTJACKET® matrix for each application.

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 GRAFTJACKET® matrix as such conditions may compromise successful clinical outcome.

Use of GRAFTJACKET® matrix is limited to specific health professionals (e.g., physicians).

Whenever clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken.

Prior to rehydration **DO NOT BEND** because this may cause the GRAFTJACKET® matrix to fracture. **DO NOT USE** the GRAFTJACKET® matrix if it is broken or cracked.

DO NOT USE the GRAFTJACKET® matrix if prior to rehydration it is not uniformly white to buff in coloration.

DO NOT USE the GRAFTJACKET® matrix if it has discolored or browned areas.

Normal rehydration of GRAFTJACKET® matrix is usually accomplished in 10–40 minutes, depending on thickness. Thick grafts may take up to 60 minutes or longer to completely rehydrate.

If any hair is visible, remove before implantation.

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 GRAFTJACKET® matrix must be reported promptly to Wright Medical Technology.

STORAGE

Store product 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 GRAFTJACKET® regenerative tissue matrix is recorded on the outer package as year (4 digits) and month (2 digits) and expires on the last day of the month indicated.

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

GRAFTJACKET® matrix is packaged aseptically in an inner (Tyvek®) pouch and sealed in an outer foil bag that may be placed into a box carton. GRAFTJACKET® matrix is supplied with or without a printed paper backing depending on size, (e.g., GRAFTJACKET® SLR matrix and GRAFTJACKET® MAXSTRIP matrix do not have a paper backing). Average product thickness range and approximate 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

Normal rehydration of GRAFTJACKET® matrix is usually accomplished in 10–40 minutes, depending on thickness. Thicker grafts may take up to 60 minutes or longer to completely rehydrate. When preparing to use GRAFTJACKET® matrix in the operating room, the following rehydration procedure should begin early enough to allow for adequate rehydration prior to intended implantation (See rehydration table on page 5).

Equipment required

- 2 sterile dishes large enough to accommodate the GRAFTJACKET® matrix without bending
- Sterile normal saline or sterile Lactated Ringer's solution that is sufficient to completely submerge the graft
- Sterile atraumatic forceps

Rehydration Steps

Step 1

Tear open the foil bag at the notch and remove the inner (Tyvek®) pouch.

Keep both the foil bag and the inner (Tyvek®) pouch OUT of the sterile field.

Step 2

Peel open the inner (Tyvek®) pouch and aseptically remove the tissue. If a backing is present, **do not peel backing at this point in the process.**

Note: GRAFTJACKET® SLR matrix AND GRAFTJACKET® MAXSTRIP matrix do not have a paper backing.

Step 3

Place the tissue in the first dish in the sterile field. Submerge the tissue completely and soak for a minimum of 5 minutes or until the paper backing separates from the GRAFTJACKET® matrix.

Step 4

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.

Step 5

Submerge completely and soak until the tissue is fully rehydrated (thicker grafts may take up to 60 minutes or longer).

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

Important: Use GRAFTJACKET® matrix within 4 hours of rehydration.

Approximate Rehydration Times

GRAFTJACKET® Matrix Product	1st Wash	2nd Wash
Standard and Low Profile	5 minutes	5–10 minutes
Maximum Force, MaxStrip and SLR	5 minutes	Up to 30 minutes
MaxForce Extreme	5 minutes	Up to 60 minutes or longer

Tips

- Keep GRAFTJACKET® matrix fully submerged by weighing it down (e.g., with sterile forceps).
- Warming saline up to 37°C and using gentle movement of GRAFTJACKET® matrix in the solution speeds the rehydration process. However, do not heat saline above 37°C.
- When rehydrating multiple pieces, ensure the pieces are not overlapping or clumping together as this may slow the rehydration process. Use multiple bowls for each rinse step, if necessary.

- If you are having a problem with rehydration, gently wipe/rub both sides of the GRAFTJACKET® matrix, using a sterile gloved hand, to remove any excess cryo-protectant that may be creating a barrier between the GRAFTJACKET® matrix and the rehydration fluid.

Considerations

If not completely rehydrated, GRAFTJACKET® matrix will appear to be of uneven thickness and have a mottled appearance.

Antibiotics may be added to the second rehydration solution.

Orientation

The GRAFTJACKET® matrix has a distinct basement membrane (upper) and dermal surface (lower). 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.

Prominent Physical Distinguishing Characteristics

BASEMENT MEMBRANE SIDE	DERMAL SIDE (Place facing most vascular tissue)
Dull	Shiny
Rough (Tactile)	Smooth (Tactile)
Buff-Colored	White Color
Repels Blood	Absorbs Blood

Additional procedures 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 where the blood has been absorbed into the graft, whereas the basement membrane side will appear pink.

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 Wright Medical Technology.

INQUIRIES

Contact Wright Medical Technology Customer Service 1-800-238-7117 for additional information, to place an order, or to report adverse reactions.

GRAFTJACKET® Regenerative Tissue Matrix is processed by LifeCell Corporation, One Millennium Way, Branchburg, NJ, 08876 USA.

LifeCell Corporation holds Canadian CTO Registration # 100128.

This product and certain methods are covered by U.S. and foreign patents and patents pending, including: US 8,323,352; US 8,007,531; and US 7,476,249

GRAFTJACKET is a registered trademark of Wright Medical Technology.

Tyvek is a registered trademark of DuPont.

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