

GRAFTJACKET™

Regenerative Tissue Matrix

(129016-2)

Wright Medical Technology, Inc.

5677 Airline Road

Arlington, TN 38002

901-867-9971

Processed from Donated

Human Tissue for Wright Medical

Technology, Inc. by LifeCell Corporation

DESCRIPTION:

The GRAFTJACKET™ Regenerative Tissue Matrix is processed from donated human skin supplied from U.S. tissue banks utilizing the guidelines of the American Association of Tissue Banks (AATB) and the Food and Drug Administration's (FDA) applicable rules and regulations. The allograft skin is minimally processed to remove epidermal and dermal cells through a patented method while preserving the remaining bioactive components and structure of dermis. The resulting allograft serves as a framework to support cellular repopulation and vascularization.

Histology and immunohistochemistry are performed on the GRAFTJACKET™ matrix to confirm the presence of intact basement membrane complex, retention of collagen, and an absence of cells. Microbiological cultures are performed on each lot to assure the absence of bacterial and fungal pathogens. Residual moisture of the GRAFTJACKET™ matrix is less than 5%.

REGULATORY CLASSIFICATION:

The GRAFTJACKET™ Regenerative Tissue Matrix is regulated by FDA as human tissue for transplantation. GRAFTJACKET™ matrix is processed in accordance with the FDA's requirements for the procurement and processing of banked human tissues (CFR Title 21, Part 1270 and 1271) and standards and guidelines of the AATB.

WARNING:

Processing of the tissue, laboratory testing, and careful donor screening minimize the risks of the donor tissue transmitting disease to the 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.

DONOR SCREENING AND TESTING:

Donor tissue undergoes several levels of testing and screening to assure its safety. Blood samples from each skin donor for the GRAFTJACKET™ matrix are screened by a certified laboratory [Clinical Laboratory Improvement Amendments of 1998] and found to be negative when tested for:

- Hepatitis B surface antigen (HBsAg);
- Antibody to hepatitis C (HCV);
- Antibody to human immunodeficiency virus (HIV) types 1 and 2;
- Antibody to human T-lymphotropic virus (HTLV) type I and II;
- Syphilis (RPR or VDRL).

All tests are FDA-licensed, except the Center for Disease Control (CDC)-approved syphilis tests. A licensed physician further determines donor suitability after review of all donor screening and testing records. Donor screening includes history (including medical and social) and physical examination, serology and microbiology, and cause of death. Samples of the donor skin are tested for and shown to be free of bacterial and fungal pathogens; normal non-pathogenic skin bacteria may be present. Existing tests cannot provide absolute assurance that human source material will not transmit disease.

INDICATIONS FOR USE:

The GRAFTJACKET™ matrix is used for the repair or replacement of damaged or inadequate integumental tissue.

CONTRAINDICATIONS:

Note to Surgeon: It is the responsibility of the physician to determine the appropriate size and thickness of GRAFTJACKET™ matrix for each application. GRAFTJACKET™ matrix should only be used where physical properties are appropriate.

The GRAFTJACKET™ matrix is contraindicated for use in any patient in whom soft tissue implants are contraindicated. These patients and conditions include:

- Patients diagnosed with autoimmune connective tissues diseases;
- Infected or nonvascular surgical sites, unless specifically prescribed by a physician;
- Sensitivity to specific antibiotics listed on the package;
- Any pathology that would limit the blood supply and compromise healing;
- Poor nutrition and/or poor general medical condition.

Ancillary agents or procedures that may cause inflammation at the treatment site should be avoided.

HOW SUPPLIED:

GRAFTJACKET™ Regenerative Tissue Matrix is packaged aseptically in a peel-pouch then freeze-dried and sealed within a foil bag in an inert atmosphere. Each package contains one sheet of the GRAFTJACKET™ matrix on a piece of an unattached, nonwoven printed backing. Approximate dimensions and average thickness ranges are indicated on the package label.

The GRAFTJACKET™ matrix is supplied only to licensed physicians or surgeons. This product is intended for single patient use only. **DO NOT STERILIZE. DO NOT REUSE.** LifeCell does not recommend sterilization of the GRAFTJACKET™ matrix by user facilities. Sterilization processes may result in structural damage and functional impairment of the tissue.

TRANSPORT AND STORAGE:

The GRAFTJACKET™ matrix is shipped at ambient temperature, and then refrigerated immediately upon receipt to maximize the shelf life. Store unopened GRAFTJACKET™ matrix between 1°-10° C (34° to 50° F). The expiration date for the GRAFTJACKET™ matrix is recorded on the foil bag. Proper stock rotation should be employed.

WARNING:

- If the outer foil bag has been perforated or torn in shipment or storage, then the enclosed GRAFTJACKET™ matrix should not be used. Damage to the foil bag may result in partial rehydration and oxidation of the enclosed GRAFTJACKET™ matrix. If the inner peel-pouch has been perforated, then the GRAFTJACKET™ matrix may have become contaminated and should not be used even if the outer foil pouch is intact;
- The inner pouch that contains the GRAFTJACKET™ matrix is **NOT STERILE. DO NOT PLACE THE INNER PACKAGE IN THE STERILE FIELD**
- The GRAFTJACKET™ matrix should be uniform in appearance and should be white or buff colored. **DO NOT USE** the GRAFTJACKET™ matrix if it has discolored or browned areas or if it is bent, broken or cracked. Every effort is made to ensure removal of all hair. If any hairs are present, remove them before implantation. If they cannot be easily removed, please notify Wright Medical Technology Customer Support (1-901-867-9971).
- Unused or expired product should be properly discarded.

POTENTIAL COMPLICATIONS:

- Wound or systemic infection
- Specific or nonspecific immune response: Hypersensitive, allergic or other immune response to the GRAFTJACKET™ matrix has not been seen in preclinical and clinical trials. However, because the GRAFTJACKET™ matrix is composed of proteins, proteoglycans, and other components of human tissue, the potential exists for such reactions.
- Resorption of the GRAFTJACKET™ matrix
- Non-integration of the GRAFTJACKET™ matrix into host tissue

Adverse outcomes potentially attributed to the GRAFTJACKET™ matrix must be promptly reported to Wright Medical Technology.

REHYDRATION INSTRUCTIONS:

Equipment required:

- 2 sterile dishes that can hold at least 100 ml of fluid (e.g., kidney dishes);
- At least 200 ml of rehydration fluid—100 ml sterile normal saline or sterile lactated Ringer's solution per dish/per sheet of GRAFTJACKET™ matrix;
- Sterile thumb forceps without teeth.

Step 1:

Tear open the foil bag at the notch and remove the inner peel-pouch containing the GRAFTJACKET™ matrix. Keep the peel-pouch out of the sterile field.

Step 2:

Open the peel-pouch and aseptically remove the tissue. **Do not peel off the backing at this point in the process.**

Step 3:

Place the tissue in the first dish in the sterile field.

Step 4:

Use 100 ml of fluid per sheet.

Step 5:

Submerge the tissue completely and soak for a minimum of 5 minutes. (The backing may float away from the tissue.) Using sterile gloves or forceps remove and discard the backing.

Step 6:

Transfer the tissue to the second dish filled with at least 100 ml of rehydration fluid per graft. Submerge completely and soak for an additional 5 minutes. Thicker grafts may take longer. Use the GRAFTJACKET™ matrix within 4 hours of rehydration.

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

Considerations:

- Prewarming the saline to room temperature will help the GRAFTJACKET™ matrix rehydrate faster; however, **do not heat the saline above 37° C**;
- If not completely rehydrated, the GRAFTJACKET™ matrix will appear uneven in thickness and have a mottled appearance;
- Animal studies have shown that implanting dry GRAFTJACKET™ matrix induces a mild inflammatory response;
- Antibiotics may be added to the second rehydration solution.

Inquiries:

Contact Wright Medical Technology Customer Support at 1-901-867-9971 for additional information, to place an order, or to report adverse reactions.

U.S. Patents No. 4,865,871, 5,024,830, and 5,366,616.

The GRAFTJACKET™ Regenerative Tissue Matrix is processed by LifeCell Corporation, One Millennium Way, Branchburg, NJ, 08876 U.S.A.

GRAFTJACKET™ is a trademark of Wright Medical Technology, Inc.