graftjacket®

regenerative tissue matrix

for wounds

instructions for use

Processed from Donated Human Tissue by LifeCell Corporation for KCI USA, Inc.

KCI®

marketed by
KCI USA, Inc.
San Antonio, TX 78219
USA
800.275.4524
www.kci1.com
www.graftjacketbykci.com

distributed and manufactured by
LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876 USA

Product of USA

description

Graftjacket® regenerative tissue matrix for wounds 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.

Graftjacket® matrix is white to buff colored and is uniform in appearance. Graftjacket® matrix has a distinct basement membrane (upper) and dermal surface (lower). (See **orientation** in the **instructions for rehydration** section.) Graftjacket® matrix is fenestrated (1:1 ratio) and thin.

regulatory classification

Graftjacket® matrix is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation. Graftjacket® matrix is processed and marketed in accordance with the FDA's requirements for banked human tissue (21 CFR, Part 1270 and Part 1271) and *Standards for Tissue Banking* of the American Association of Tissue Banks (AATB). Graftjacket® matrix 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. Donor screening and testing is performed on all tissue donors according to FDA regulations and AATB standards. Refer to *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® regenerative tissue matrix for wounds provides a scaffold for the body's repair or replacement of damaged or inadequate integumental tissue, such as diabetic foot ulcers, venous leg ulcers, pressure ulcers, or for other homologous uses of human integument.

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

contraindications

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

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, 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 Graftjacket® 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 PLACE EITHER THE FOIL BAG OR THE INNER (TYVEK®) POUCH IN THE STERILE FIELD.
The inner (Tyvek®) pouch that contains the Graftjacket® matrix is **NOT STERILE**.

(See the **instructions for rehydration** section.)

Transfer Graftjacket® matrix from packaging aseptically.

precautions

It is the responsibility of the physician to determine the appropriate size 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 application of Graftjacket® matrix as such conditions may compromise successful application. Additionally, users should assess the appropriateness of using the Graftjacket® matrix in patients diagnosed with autoimmune connective tissue disease.

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

Use of Graftjacket® matrix is limited to trained healthcare professionals (e.g., physicians and / or podiatrists).

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

DO NOT BEND prior to rehydration 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 10-15 minutes. If any hair is visible, remove before application.

Unused or expired product should be discarded according to local institutional requirements.

adverse effects

Potential adverse effects which may result from placement of an application of Graftjacket® matrix include, but are not limited to: wound or systemic infection; dehiscence;

hypersensitive, allergic or other immune response; sloughing or failure of the graft; and disease transmission.

Adverse outcomes potentially attributed to Graftjacket® matrix must be reported promptly to KCI. See Customer Contact Information on the back of this IFU.

storage

Upon receipt, store at room temperature. The expiration date for the Graftjacket® 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. **Do not use product after 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

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 on a printed paper backing. Approximate size is clearly marked on the label of the outer foil pouch.

use with V.A.C.® Therapy

V.A.C.® Therapy can be used prior to the application of Graftjacket® matrix to prepare the wound bed for grafting. V.A.C.® Therapy can also be used to bolster the graft after the application of Graftjacket® matrix. Please refer to the instructions for use accompanying V.A.C.® Therapy System products and the V.A.C.® Therapy Clinical Guidelines found on www.kci1.com for important safety information and instructions on how to apply V.A.C.® Therapy for these purposes.

instructions for rehydration

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

Normal rehydration of Graftjacket® matrix is usually accomplished in 10-15 minutes. When preparing to use Graftjacket® matrix the following rehydration procedure should begin early enough to allow for adequate rehydration prior to intended application.

Equipment required

- Two 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 inner (Tyvek®) pouch OUT of the sterile field.**

Step 2: Peel open the inner (Tyvek®) pouch and aseptically remove the tissue. **Do not peel backing at this point in the process.**

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.

Approximate rehydration time is 5 minutes for the first bath and 5 –10 minutes for the second bath.

When Graftjacket® matrix is fully rehydrated, it is soft and pliable throughout. At this stage, it is ready for application to the surgical site.

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

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

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.

Prominent physical distinguishing characteristics

basement membrane side	dermal side (place against the wound bed)
Dull	Shiny
Rough (tactile)	Smooth (tactile)
Buff-color	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 these *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.

customer contact information

Contact KCI USA Customer Support at 800.275.4524, for additional information, to place an order, or to report adverse reactions.

Marketed by KCI USA, Inc., San Antonio, TX 78219 USA

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