GRAFTJACKET® XPRESS

Flowable Soft Tissue Scaffold

Instructions for Use

Marketed by:

KCI®

KCI USA, Inc.
www.KCI1.com

Distributed & Manufactured by:

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876 USA
800.275.4524

Processed from Donated Human Tissue by LifeCell Corporation

DESCRIPTION

GRAFTJACKET® Xpress *Flowable Soft Tissue Scaffold* is micronized 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

GRAFTJACKET® Xpress Scaffold is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation. GRAFTJACKET® Xpress Scaffold is processed and marketed in accordance with the FDA's requirements for banked human tissue (21 CFR, Part 1270 and 1271) and Standards for Tissue Banking of the American Association of Tissue Banks (AATB). GRAFTJACKET® Xpress Scaffold 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 declare 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 the *Summary of Records* label provided with each package 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® Xpress Flowable Soft Tissue Scaffold supports the body's repair of damaged or inadequate integumental tissue, such as deep dermal wounds or diabetic ulcers.

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

CONTRAINDICATIONS

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

Because of the particle size, GRAFTJACKET® Xpress Scaffold should not be used in the periocular, forehead or glabellar areas.

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® Xpress Scaffold 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® Xpress Flowable Soft Tissue Scaffold.

- **DO NOT RE-USE** GRAFTJACKET® Xpress Scaffold.
- **DO NOT STERILIZE** GRAFTJACKET® Xpress Scaffold.
- **DO NOT USE** GRAFTJACKET® Xpress Scaffold if the foil pouch is perforated or torn. A damaged pouch may result in degradation or contamination of the product.
- The foil pouch that contains the GRAFTJACKET® Xpress Scaffold is NOT STERILE. **DO NOT PLACE** the foil pouch in the sterile field. (*See PREPARATION INSTRUCTIONS*.)

PRECAUTIONS

It is the responsibility of the physician to determine the appropriate amount of GRAFTJACKET® Xpress Scaffold 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® Xpress Scaffold as such conditions may compromise successful implantation. Additionally, users should assess the appropriateness of using the GRAFTJACKET Xpress Scaffold in patients diagnosed with autoimmune connective tissue disease.

Use of GRAFTJACKET® Xpress Scaffold is limited to specific health professionals (e.g., physicians and/or podiatrists).

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 GRAFTJACKET® Xpress Scaffold if prior to rehydration it is not uniformly white to buff in coloration.

DO NOT USE the GRAFTJACKET® Xpress Scaffold if it has discolored.

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

ADVERSE EFFECTS

Potential adverse effects which may result from placement of an implant or graft include, but are not limited to the following: wound or systemic infection; hypersensitive, allergic or other immune response; rapid resorption of graft material; and disease transmission.

Adverse outcomes potentially attributed to GRAFTJACKET® Xpress Scaffold must be reported promptly to LifeCell Corporation.

STORAGE

Refrigerate upon receipt between 1 – 10°C (34 – 50°F). The expiration date for the GRAFTJACKET® Xpress Scaffold 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 refrigerated and in an unopened foil bag.

HOW SUPPLIED

GRAFTJACKET® Xpress Scaffold is supplied as a dried, acellular dermal particulate in a syringe. Each package contains one 5 cc syringe with the GRAFTJACKET® Xpress Scaffold packaged in a foil pouch. The GRAFTJACKET® Xpress Scaffold package includes standard disposable supplies to facilitate rehydration and delivery. These include: a sterile 3 cc syringe, a sterile 23 gauge needle, a sterile 1-1/4 18-Gauge OPTIVA® I.V. catheter, and a sterile syringe adapter with double female luer locks.

PREPARATION INSTRUCTIONS

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 optimal rehydration of GRAFTJACKET® Xpress Scaffold are separately provided in the product carton.

GRAFTJACKET® Xpress Scaffold has been formulated to a consistency that will pass through an 18-Gauge OPTIVA® I.V. catheter, included in the accessory kit.

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

GRAFTJACKET® Xpress *Flowable Soft Tissue Scaffold* is processed by LifeCell Corporation, One Millennium Way, Branchburg, NJ, 08876 USA.

LifeCell Corporation holds Canadian registration No. 100128.

GRAFTJACKET® is a registered trademark of Wright Medical Technology.

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