graftjacket® Xpress

flowable soft tissue scaffold

for wounds

instructions for use

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

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

description

Graftjacket® Xpress flowable soft tissue scaffold (FSTS) 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

Graftjacket® Xpress FSTS is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation. Graftjacket® Xpress FSTS is processed and marketed 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). Graftjacket® Xpress FSTS 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 FSTS supports the body's repair of damaged or inadequate integumental tissue, such as deep dermal wounds or diabetic ulcers.

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

contraindications

Graftjacket® Xpress FSTS 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 Graftjacket® Xpress FSTS in the periocular, forehead or glabellar areas because of the particle size.

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 FSTS 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 FSTS.

DO NOT RE-USE Graftjacket® Xpress FSTS.

DO NOT STERILIZE Graftjacket® Xpress FSTS.

DO NOT USE Graftjacket® Xpress FSTS if the foil pouch is perforated or torn. A damaged pouch may result in degradation or contamination of the product.

DO NOT PLACE the foil pouch in the sterile field. The foil pouch that contains the Graftjacket® Xpress FSTS is **NOT STERILE**. (See the **preparation instructions** section.)

precautions

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

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

Whenever clinical circumstances require application 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 FSTS if prior to rehydration it is not uniformly white to buff in coloration.

DO NOT USE the Graftjacket® Xpress FSTS 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 application of Graftjacket® matrix include, but are not limited to: 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 FSTS must be reported promptly to KCI.

storage

Upon receipt, refrigerate at 1–10°C (34–50°F).
The expiration date for the Graftjacket® Xpress FSTS 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 refrigerated at 1–10°C (34–50°F) and in an unopened foil bag.

how supplied

Graftjacket® Xpress FSTS is supplied as a dried, acellular dermal particulate in a syringe. Each package contains one 5 cc syringe with the Graftjacket® Xpress FSTS packaged in a foil pouch. The Graftjacket® Xpress FSTS package includes standard disposable supplies to facilitate rehydration and delivery. These include: a sterile 3 cc syringe, a sterile 1-1/2 in 23 gauge needle, a sterile 1-1/4 in 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-application. Patient tracking labels are provided for convenience.

Instructions for optimal rehydration of Graftjacket® Xpress FSTS are separately provided in the product carton.

Graftjacket® Xpress FSTS has been formulated to a consistency that will pass through an 18-Gauge OPTIVA® I.V. catheter, included in the package.

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.

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LifeCell Corporation holds Canadian registration No. 100128.

Part No. 173P0024 Rev. B
Aug. 2012

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173P0024REVB