PACKAGE INSERT

GRAFTJACKET NOW™
Regenerative Tissue Matrix

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES. IT IS INTENDED FOR SINGLE PATIENT, SINGLE USE ONLY.

This package contains an HCT/P (Human Cells, Tissues, and Cellular and Tissue Based Products) / CTO (Human Cell, Tissue, Organ) as defined by US Food and Drug Administration (FDA) 21 CFR Part 1271 and the Health Canada Cells, Tissues and Organs for Transplantation Regulations. All tissue has been collected, processed, stored and distributed according to the Standards for Tissue Banking of the American Association of Tissue Banks (AATB), the US FDA regulations, and the Health Canada CTO Regulations and associated Standards (when applicable).

DESCRIPTION / USE

GRAFTJACKET NOW ™ Acellular Dermal Matrix (ADM) is a human dermal allograft that has been decellularized while preserving the natural biologic components and structure of the dermal matrix. GRAFTJACKET NOW ™ ADM tissue is provided in a single patient use package in sterile water, and has been terminally sterilized using electron beam irradiation.

GRAFTJACKET NOW ™ ADM may be used for the repair or replacement of damaged or inadequate integumental tissue or for other homologous uses.

GRAFTJACKET NOW ™ ADM is supplied in multiple sizes for use by licensed clinicians (i.e. physicians, physician's assistants, nurse practitioners). All tissue is processed and packaged using aseptic technique.

It is the responsibility of the tissue dispensing service and end user (facility/clinician) to maintain the product under appropriate conditions prior to use.

CONTRAINDICATIONS

Patients exhibiting autoimmune connective tissue disease and the presence of gross infection at the transplantation site are contraindications for the use of GRAFTJACKET NOW™ ADM.

PRECAUTIONS

- **Restricted to use by a licensed clinician.**
- **Trace amounts of Vancomycin, Streptomycin, and Amphotericin may be present and caution should be exercised if the recipient is allergic to these antibiotics. NOTE**: No β-lactam antibiotics are used during the processing of GRAFTJACKET NOW™ ADM.
- Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for implantation of GRAFTJACKET NOW ™ ADM.
- GRAFTJACKET NOW™ ADM must be used prior to the expiration date.
- Do not use if the packaging has been damaged and/or the product has been contaminated. In the event of contamination, discard the product. Damaged packaging should be returned to Wright Medical.
- Appropriate placement and/or fixation are critical factors in the avoidance of potentially adverse effects.
- As with all biological products, the tissue in GRAFTJACKET NOW™ ADM has the potential to transmit infectious agents despite processing treatments, extensive donor screening, tissue selection and laboratory tests.
- As with any surgical procedure, the possibility of infection exists.
- Although the production technique is designed to eliminate antigenic properties of the product, the possibility of such a reaction is present.

WARNINGS

- **Human tissue has the potential to transmit infectious agents.** Donor screening, processing treatments and laboratory testing follow stringent specifications to reduce the risk of infectious agent transmission.
- Do not use if the expiration date has been exceeded or if there is evidence of defects in package or label integrity.
- Do not re-sterilize.
- It is the responsibility of the hospital or clinician to maintain tissue for transplantation according to recommended storage conditions. Do not use if tissue has not been stored according to the recommended STORAGE instructions.

ATTENTION

- Patients receiving any allografts in a surgical procedure should be appropriately informed of the risk associated with these grafts.

POTENTIAL COMPLICATIONS/ADVERSE REACTIONS

Inherent uncertainty exists in medical and social histories and laboratory testing which may not detect known or unknown pathogens. Therefore, the following complications may occur with tissue transplantation:

- Loss of integrity of transplanted tissue with resorption, disintegration, and associated loss of continuity.
- Immune response to transplanted tissue.
- Transmission of known pathogens including Hepatitis B or C, Human T-cell Leukemia / Lymphotropic Virus, Human Immunodeficiency Virus 1 & 2, syphilis or bacteria.
- Transmission or causation of diseases of unknown etiology and characteristics.
- Additional potential complications include, but are not limited to the following: seroma, dehiscence, or sloughing of the graft.
- Adverse outcomes or reactions potentially attributable to the product must be reported promptly to the distributor. Notify Wright Medical immediately for return authorization if any dissatisfaction with the product performance or packaging occurs.

DONOR ELIGIBILITY

Donor eligibility (screening and testing) is performed in accordance with US FDA regulations, AATB Standards, and Health Canada CTO regulations. Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation. Donor eligibility determination has been made by an AlloSource Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon request.

SEROLOGICAL TESTING

Communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493. The testing was conducted using FDA licensed, approved, or cleared donor screening tests for cadaveric specimens where applicable. The records of this testing are maintained at AlloSource at the address listed at the bottom of this document. The following required testing was performed and found to be negative or non-reactive:

- Antibody to Human Immunodeficiency Virus 1 & 2 (HIV 1 & 2)
- Human Immunodeficiency Virus Type 1 (HIV-1 NAT)
- Antibody to Hepatitis C (HCV)
- Hepatitis C Virus (HCV NAT)
- Hepatitis B Core IgG/IgM Antibody (HBcAb)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Virus (HBV NAT)
- Rapid Plasma Reagin or Serologic Test For Syphilis (RPR or STS)

Additional tests including, but not limited to Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II) may have been performed at the time of donor screening, and were found to be acceptable for transplantation. A list of additional communicable disease test(s) performed may be provided upon request.

MICROBIAL TESTING

Tissue is subjected to microbiological testing in the course of processing and must be free of specific aerobic/anaerobic microorganisms and fungal contaminants whose presence would preclude tissue from processing or transplantation.

MEDICAL DIRECTOR ASSESSMENT

Donor eligibility determination is made by the AlloSource Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon written request.

STORAGE

Tissue is packaged in sterile water and should be stored at ambient temperature. **DO NOT REFRIGERATE, FREEZE OR EXPOSE TO EXTREME HEAT.** Tissue shelf life as listed on the product label is 2 years.

As with all biological materials, some variations in the product should be expected, such as in appearance and in handling.

Do not use any tissue if the expiration date has been exceeded of if there is evidence of defect in the package or label integrity.

DIRECTIONS FOR HANDLING AND PREPARATION

These instructions are intended as guidelines for the use of GRAFTJACKET NOW™ ADM as a part of established surgical techniques. They are not intended to replace or change standard procedures or institutional protocols or practices.

All preparation should be performed using aseptic technique to minimize the risk of post-operative complications. Once the packaging has been opened, maintain tissue in moist gauze until ready for application.

NOTE: Tissue must be used for the surgical event for which it was prepared or otherwise DISCARDED.

PREOPERATIVE PREPARATION

Graft is packaged in two pouches, with the inner-most pouch containing the graft between two pieces of sterile gauze backing. Some smaller sizes of GRAFTJACKET NOW™ ADM use two different sizes of gauze backing to assist in application and orientation of the tissue. Larger sizes of GRAFTJACKET NOW™ ADM use two of the same size gauze backing. Application and Orientation preparation of the size variations is described below.

Peel open outer pouch and introduce inner-most pouch into sterile field. Use sterile scissors when opening inner pouch.

IMPORTANT NOTE: The strips of sterile gauze **MUST NOT BE IMPLANTED** with the tissue graft. Ensure that the gauze strips have been separated from the graft during the immersion process.

APPLICATION of GRAFTJACKET NOW™ ADM (4cm x 12cm or larger) With Same Size Gauze Backing

Using atraumatic forceps, remove GRAFTJACKET NOW™ ADM from the inner pouch and immerse the graft and its gauze in a sterile saline bath. Lightly agitate for approximately 10-15 seconds until the gauze layers have fully separated from the tissue.

Keep the graft moist until ready for application. Remove the graft from the saline bath.

Trim GRAFTJACKET NOW™ ADM to the proper size (as needed) and surgically secure.

APPLICATION of GRAFTJACKET NOW™ ADM (2cm x 12cm or smaller) With Different Size Gauze Backing

Using atraumatic forceps, remove GRAFTJACKET NOW™ ADM from the inner pouch. Rinse the graft with sterile saline solution prior to application.

Remove and discard the larger gauze backing. The larger gauze backing covers the "dermal" side, which is to be placed in contact with the surgical site.

Remove and discard the smaller gauze backing from the graft. Keep the graft moist until ready for application.

Trim GRAFTJACKET NOW™ ADM to the proper size (as needed) and surgically secure.

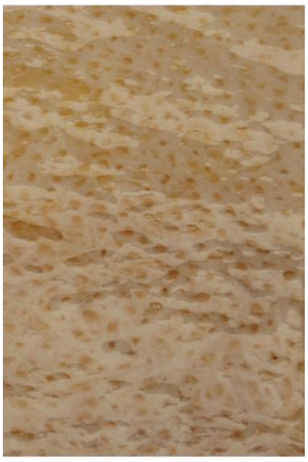
ORIENTATION OF THE TISSUE (See Photos)

GRAFTJACKET NOW™ ADM has two distinct sides, the "dermal" side and the "basement membrane" ("epidermal") side. The dermal side is shiny, appears with a deep pore-like pattern and absorbs blood. The basement membrane side is duller, without the pore-like pattern, and repels blood.

As further confirmation, a drop of blood may be placed on both sides of the graft, and the graft rinsed with sterile saline. Where the blood contacts the surface, the dermal side will appear red, whereas the basement membrane side will appear pink.

When applied to the surgical site in an implant procedure, the dermal side should be placed against the most vascular tissue, with the basement membrane side facing away.

Basement Membrane Layer
(top side)



Dermal Layer
(bottom side)

RECORD KEEPING & RECIPIENT TRACING

Regulatory bodies such as the US FDA and Health Canada require that allograft tissue be traceable from the donor to the recipient. The tissue bank (source establishment) is responsible for traceability from the donor to the consignee (transplantation facility, clinician or hospital), and the transplantation facility is responsible for traceability to the recipient. A *Transplantation Record & Feedback Form* and pre-printed peel-off labels are included with each package of tissue. The lot number provided on the labels contains the donor identification number and graft serial number. Record patient identifier, the transplantation facility name and address, the allograft tissue identification information (using the peel-off stickers) and comments regarding the use of the tissue on the *Transplantation Record & Feedback Form*. Return the completed form to AlloSource and retain a copy in the patient medical record. If the tissue has been discarded, please return the *Transplantation Record & Feedback Form* to AlloSource with the graft identification information and reason for discard.

Table of symbols that may appear on labeling:

Symbol	Meaning
REF	Catalog Number
LOT	Batch Code
STERILE R	Sterilized using radiation
	Caution, consult accompanying documents
	Do not re-use
	Temperature Limitation
	Use By Date
Rx Only	Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician
	Manufacturer

CONTACT INFORMATION

Please contact Wright Medical at 901.867.9971
to promptly report any unanticipated or adverse events, or should you require further information.

Manufactured for:

WRIGHT™
FOCUSED EXCELLENCE

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Health Canada CTO Registration Number 100137
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Processed by:

AlloSource®

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800.557.3587 (toll free)
Health Canada CTO
Registration Number 100134

Accredited Member of the American Association of Tissue Banks

For end users in Canada,
affix chart label here for Donor Identification Code and Expiration Date per CTO regulations 31.3 and 31.20.