



PACKAGE INSERT
ALLOPURE[®] + Allograft Bone Wedges
FUSIONFLEX[™] Demineralized Moldable Scaffold

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 Food and Drug Administration (FDA) Regulations, and the Health Canada Cells, Tissues and Organs for Transplantation (CTO) regulations.

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

DESCRIPTION / USE:

ALLOPURE[®] + Allograft Bone Wedges consist of both cancellous and cortical bone machined into a wedge shape. These wedges are intended to be used for the repair, replacement or reconstruction of musculoskeletal defects. This includes filling bone voids or gaps of the skeletal system (e.g. Evans and Cotton Osteotomies) that are not intrinsic to the stability of the bony structure. **ALLOPURE[®] + Allograft Bone Wedges** are supplied in a range of sizes.

FUSIONFLEX[™] Demineralized Moldable Scaffold consists of demineralized cancellous bone and is offered in a range of sizes. **FUSIONFLEX[™] Demineralized Moldable Scaffold** is a versatile bone scaffold designed to support bone regeneration for recipients in a variety of orthopedic procedures.

ALLOPURE[®] + Allograft Bone Wedges and **FUSIONFLEX[™] Demineralized Moldable Scaffold** are aseptically processed and packed, preserved by freeze drying, and terminally sterilized by gamma irradiation. The allografts are for surgical use by license clinicians.

CONTRAINDICATIONS:

The presence of infection at the transplantation site is a contraindication for use of musculoskeletal allografts.

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.

PRECAUTIONS:

- Restricted to use by a licensed clinician.
- Trace amounts of Polymyxin B sulfate or Bacitracin may be present and caution should be exercised if the recipient is allergic to these antibiotics.

DONOR ELIGIBILITY:

Donor eligibility (screening and testing) is performed in accordance with AATB standards and FDA 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 has been determined by an AlloSource[®] Medical Director.

SEROLOGICAL TESTING:

Communicable disease testing was performed by a laboratory registered with 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)
- 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 will be provided upon request.

MICROBIAL TESTING:

Tissue is subjected to microbiological testing at recovery and 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.

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 function or integrity of transplanted tissue with resorption, fragmentation, disintegration, and associated loss of continuity, displacement, bending or fracture.
- 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.

STORAGE:

Store freeze-dried allografts in a clean, dry environment at ambient temperature.

HANDLING:

CAUTION: All preparation should be performed using aseptic technique. Once the packaging has been opened, the tissue must either be transplanted or discarded.

PREPARATION:

1. Using aseptic technique, peel open outer package.
2. Introduce inner-most pouch into sterile field.
3. Place implant into a sterile bowl and reconstitute with sterile isotonic solution. At the surgeon's discretion, the following autologous fluids may also be used to hydrate the implant: blood, bone marrow aspirate and platelet rich plasma.
4. Hydrate for approximately 10 minutes before use.
5. Discard any unused implant in accordance with standard practice for disposal of human tissue.

INADEQUATE RECONSTITUTION MAY RESULT IN GRAFT BREAKAGE OR FRACTURE.

NOTE: Reconstituted grafts must be used for the surgical event for which they were reconstituted or otherwise must be DISCARDED.

RECORD KEEPING:

The FDA requires that allograft tissue be traceable from the donor to the recipient. The tissue bank is responsible for traceability from the donor to the consignee (transplantation facility), 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. Record the patient name or ID number, 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.

CONTACT INFORMATION

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



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Arlington, TN 38002
901.867.9971

Processed by:



6278 South Troy Circle
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800.557.3587 (toll free)
Health Canada CTO
Registration Number 100134

Symbol



RxOnly

Meaning

Sterilized by Irradiation

Federal law restricts this sale by or on the order of a licensed healthcare practitioner.

IMPORTED/DISTRIBUTED IN CANADA BY:

Wright Medical Technology Canada Ltd.
6581 Kitimat Road, Unit #8
Mississauga, Ontario
Canada, L5N3T5
Health Canada CTO
Registration Number 100137

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