PACKAGE INSERT
PREPARATION INSTRUCTIONS

3D Profuse® Bioscaffold in VIP

All tissue has been collected, processed, stored and distributed according to the Standards for Tissue Banking of the American Association of Tissue Banks (AATB) and Food and Drug Administration (FDA) regulations.

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

INTRODUCTION:

Alphatec Spine, Inc., an FDA registered distributor of musculoskeletal tissue, has contracted with AlloSource®, an FDA registered tissue bank, for the procurement and processing of donated human musculoskeletal tissue for transplantation. AlloSource adheres to FDA regulations regarding current good tissue practices per 21 CFR part 1271, and is accredited by the American Association of Tissue Banks (AATB).

Alphatec recognizes the selfless gifts each donor family makes in their time of grief and encourages all who have a role in the transplantation of these gifts to keep in mind the spirit in which these precious gifts were given.

DESCRIPTION / USE:

3D Profuse® Bioscaffold in Vacuum Infusion Packaging (VIP) is an aseptic cancellous demineralized bone scaffold that may be used in a variety of orthopedic, neurosurgical, reconstructive or periodontal procedures. 3D Profuse® Bioscaffold in VIP is an osteoconductive scaffold with osteoinductive potential for rapid bone ingrowth, and is processed to provide compressive/expansive properties for maximum contact. 3D Profuse® Bioscaffold in VIP is aseptically processed and packed, and is preserved by lyophilization. 3D Profuse® Bioscaffold in VIP is supplied in a range of sizes for surgical use by licensed clinicians (i.e., physicians, dentists, oral surgeons, physician's assistants, nurse practitioners).

CONTRAINDICATIONS:

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

PROCESSING:

Processing is performed in a controlled, aseptic environment. This aseptic handing of the tissue occurs throughout recovery and processing, and is verified by microbiological cultures taken during recovery or at the pre-processing stage, during processing, and again at the time of final packaging. No tissue is released for transplantation unless the processing and final culture results support no bacterial growth.

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 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.

PRECAUTIONS:

- Restricted to use by a licensed clinician.
- Trace amounts of Polymyxin B sulfate and/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)
- Hepatitis B Virus (HBV NAT) (as required)
- 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.

TISSUE STORAGE AND PREPARATION:

GRAFT PREPARATION INSTRUCTIONS ARE INTENDED AS GUIDELINES AS PART OF ESTABLISHED SURGICAL TECHNIQUES; THEY ARE NOT INTENDED TO REPLACE OR CHANGE STANDARD PROCEDURES OR INSTITUTIONAL PROTOCOLS.

It is the responsibility of the hospital to maintain freeze-dried tissue at room temperature prior to use. DO NOT FREEZE. These freeze-dried allografts have been sealed under vacuum. Once the expiration date on the label has been reached, the allograft must be discarded. Each allograft is intended for single patient use, on a single occasion only. Do not use if package integrity has been violated. This allograft is aseptically processed and may not be sterilized.

Prior to surgery, **using aseptic technique** carefully follow the tissue preparation steps as described below:

1. Remove the pouch from the outer box.
2. Open the pouch and deliver inner package to the sterile field.
3. Deliver a sterile syringe and sterile needle to the sterile field. It is recommended that the needle be non-coring or beveled and be between 18 and 21 gauge.
4. Draw sterile saline or other isotonic fluid of choice into the syringe and safely attach the needle to the syringe.
5. Locate the septum directly over the vacuum chamber.
6. Carefully insert the needle directly into the septum, making sure the needle enters the vacuum chamber, but does not penetrate through the bottom of the tray. **Once the container has been compromised, the allograft shall be transplanted or discarded.**
7. Allow the graft to absorb the fluid for at least 30 seconds. Remove and discard the needle appropriately.
8. Remove the lid to expose the allograft.
9. Prepare the graft for implantation according to the appropriate surgical technique.

Rehydrated allografts may not be returned.

RECORD KEEPING:

The FDA requires that allograft tissue be traceable from the donor to the recipient. The transplantation facility (clinician or hospital) is responsible for traceability of the tissue post transplantation. A Transplantation Record & Feedback Form and preprinted 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 Alphatec Spine and retain a copy in the patient medical record. If the tissue has been discarded, please return the Transplantation Record & Feedback Form to Alphatec Spine with the graft identification information and reason for discard.

CONTACT INFORMATION

Please contact Alphatec Spine at 800.922.1356 or 760.431.9286 to promptly report any unanticipated or adverse events or should you require further information

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