Organogenesis
FiberOS™
Demineralized Cortical Fiber Matrix

Organogenesis
Empowering Healing

Allograft Tissue Information and FiberOS Instructions for Use

Contents

This package contains human allograft tissue that is regulated as a human cells, tissues, and cellular and tissue-based product (HCT/P) as defined by 21 CFR Part 1271.

Description

FiberOS is a sterile, freeze-dried allograft consisting of donated demineralized cortical fibers, demineralized cortical powder, and mineralized cortical powder, processed by Xtant Medical. Xtant Medical is a for-profit tissue bank accredited by AATB and registered with the FDA.

Intended Use

FiberOS is an allograft intended for use as a bone void filler in bony voids or gaps.

CAUTION: This product is restricted to sale by or on the order of a physician or properly licensed practitioner.

Donor Screening for Tissue Procurement

Donor eligibility (screening and testing) is performed in accordance with US FDA regulations and AATB Standards. 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 is conducted by a licensed Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon written request. Donor eligibility was determined by one of the following establishments:

Xtant® Medical
664 Cruiser Lane
Belgrade, MT 59714
(888)886-9354

AlloSource®
6278 South Troy Circle
Centennial, CO 80111
(800)557-3587

The establishment responsible for donor eligibility can be identified via the donor number located on the product label. The first character "A" or "B" corresponds to AlloSource or Xtant Medical respectively.

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 Xtant Medical. The following required testing was performed and found to be negative or non-reactive;

- HBsAg (Hepatitis B Surface Antigen)
- HBcAb (Hepatitis B Core Total Antibody)
- HBV-NAT (Hepatitis B Nucleic Acid Test)
- HCV (Hepatitis C Antibody)
- HIV 1/2-Ab (Antibody to Human Immunodeficiency Virus Types 1 and 2)
- Syphilis
- HIV-1 NAT (HIV-1 Nucleic Acid Test)
- HCV NAT (HCV Nucleic Acid Test).
- HTLV I/II Ab

Additional tests 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.

STERILE R Sterilized using gamma irradiation

Processing

Technical Quality Assurance standards are rigorously maintained by Xtant Medical. Tissue is processed using aseptic techniques in a controlled, clean environment. This tissue is processed using some or all of the following agents: Gentamicin, PVP-Iodine, alcohol and surfactants. Although the tissue was rinsed with sterile water or sterile saline throughout the processing procedure, traces of the agents may remain. Final product is terminally sterilized using a validated gamma irradiation process.

Contraindications

- FiberOS is contraindicated for use in surgical implantation sites with active or latent infection.
- FiberOS is contraindicated for use as a standalone to provide structural support for load-bearing applications

Warnings & Precautions

As with all allogeneic materials, it is not possible to provide an absolute guarantee that no infectious disease will be transmitted. However, this risk is greatly reduced by using processing treatments shown to be capable of reducing this risk as well as the use of strict donor screening criteria, laboratory testing, processing using aseptic techniques, and terminal gamma irradiation of the final product.

- **Single patient, single use only**
- **Do not sterilize or re-sterilize**

Do not use if:
- the package integrity has been violated, opened, or damaged, or if mishandling has caused possible damage or contamination.
- any seal is broken or compromised.
- the expiration date has been exceeded.
- the tissue has not been stored in accordance with the storage instructions specified in this insert.

- Return all allografts with compromised or flawed packaging to Organogenesis, Inc.
- Recommended storage conditions and the maintenance of the tissue for transplantation are the responsibility of the hospital or clinician.
- The healthcare professional is responsible for informing the patient of risks associated with his/her treatment and the possibility of complications or adverse reactions.
- Caution should be exercised on patients with a known sensitivity or allergies to Gentamicin, PVP-Iodine, alcohol and surfactants.

Complications and Possible Adverse Effects

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

- Transmission of diseases of unknown etiology;
- Transmission of known infectious agents such as viruses, bacteria and fungi;
- Immune rejection of implanted HCT/P; or
- Loss of function and/or integrity of implanted HCT/P due to resorption, fragmentation, and/or disintegration

Report any adverse outcomes to Organogenesis Inc.

Tissue Preparation and Use

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgement concerning patient care.

Prior to surgery, carefully follow the tissue preparation steps as described below. The appropriate preparation method is dependent on the tissue type and packaging method described below. See product label for method in which tissue is supplied. It is recommended that all freeze-dried allografts be rehydrated in Lactated Ringers, Normal Saline, blood, or other normal physiologic solution containing antibiotics of the surgeon's preference. Antibiotic acceptability must be discussed with the surgeon to discern patient status regarding antibiotic sensitivity. It is the responsibility of the Distributor and/or End-User to maintain tissue at the appropriate storage conditions described below.

Non-Sterile Team Member

1. Visually inspect packaging and jar to ensure that it is intact and that its integrity has not been compromised. If the packaging and/or jar is damaged, the enclosed graft may be contaminated and should not be used.
2. Using aseptic technique, peel open the outer pouch and transfer the inner pouch containing the jar into the sterile field.

Sterile Team Member

1. Remove jar of FiberOS from the inner peel pouch.
2. Reconstitute tissue with the surgeon's fluid of choice. Add sufficient fluid to cover the graft. The graft may be reconstituted in the jar or removed to a separate basin in the operative field.
3. Gently mix for 30 – 60 seconds until completely hydrated. or until desired malleability is achieved. Due to biologic variability the reconstitution time for each graft will vary. Within a single graft some parts may rehydrate sooner than others.
4. Once rehydrated, allografts must be used immediately or discarded. **Do not return opened or reconstituted allografts to Organogenesis Inc.**

HCT/P Tracking

Organogenesis Inc. is required by 21 CFR 1271 to maintain documentation about the disposition of each tissue to enable tracking from the donor to the consignee or final disposition. Joint Commission standards require that "the organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities."

To comply with these requirements, Organogenesis Inc. provides an *Allograft Implant Record (AIR)* and preprinted labels with every graft. Record the patient information, the transplantation facility name and address, the allograft tissue identification information (using stickers) and comments regarding tissue on the AIR. Return the completed form to Organogenesis Inc. (address below) and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, the AIR completed with the allograft identification information and reason for discard needs to be returned to Organogenesis Inc.

Storage and Handling

It is the responsibility of the user facility and user clinician to maintain allograft tissue in appropriate storage conditions prior to transplant. It is the responsibility of the end user to document and maintain the HCT/P's in its original packaging between 15°C – 30°C (59°F – 86°F) until ready for use. After use, handle and dispose of all unused products and packaging in accordance with accepted medical practice and applicable local, state, and Federal laws and regulations. All freeze-dried allografts must be maintained between 15°C – 30°C (59°F – 86°F) prior to reconstitution. **DO NOT FREEZE.**

Return Policy

Please contact Customer Service at 1-888-432-5232 for information regarding Organogenesis's Tissue Return Policy.

Disclaimer

Organogenesis Inc. and Xtant Medical make no claims concerning the biologic or biomechanical properties of allograft tissue. All tissue has been collected, processed, stored and distributed according to nationally recognized standards and in compliance with the U.S. Food and Drug Administration requirements. Although efforts have been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease. Adverse outcomes potentially attributable to the tissue must be reported immediately to Organogenesis Inc.

Processed By:
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Fax: (406) 388-3380
Website: www.xtantmedical.com

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