TheraFuze DBF® Fiber Boat™ INSTRUCTIONS FOR USE

Tissue ID Number:

Place Sticker Here

DESCRIPTION

TheraFuze DBF® Fiber Boat™ is derived from DONATED HUMAN TISSUES and processed using TheraCell, Inc.'s proprietary TheraFuze DBF® (Demineralized Bone Fiber) technology and is 100% DBF with no excipients. The tissue was prepared from a donor determined to be suitable for transplant by the Pinnacle Transplant Technologies (PTT) Medical Director based on the results of screening and testing. Recovery was performed using sterile surgical procedures and PTT's controlled tissue processing environment is designed to ensure tissue allograft quality and safety. PTT utilizes a proprietary series of disinfection soaks designed to significantly reduce bioburden prior to terminal sterilization via Gamma irradiation. This allograft was prepared from tissues which may have been treated with betadine, 70% isopropyl alcohol, Triton-X 100, hydrogen peroxide, hydrochloric acid, phosphate buffer solution, surfactant nonoxynol 9, and antibiotics (Polymyxin with Bacitracin) and may contain trace residuals of these agents. Caution should be exercised if the patient has a known sensitivity or allergy to any of these reagents.

STORAGE

TheraFuze DBF® Fiber Boat™ is Freeze-dried/lyophilized and can be stored at 15°C to 30°C until expiration date shown on allograft label.

INSTRUCTIONS FOR PREPARING ALLOGRAFT FOR ADMINISTRATION

1. Open carton and remove package.
2. Peel open pouches and hand over innermost container to sterile team member.
3. Tear open innermost packaging using tear-notch and remove tissue.
4. Fiber Boat™ can be rehydrated with saline, bone marrow aspirate or other fluids. It will rapidly absorb moisture and become pliable.
5. If desired autograft or other graft materials may be placed in the depression in the boat.
6. Place into graft site using standard procedures.
7. Once the container seal has been compromised, the tissue shall be either transplanted or otherwise discarded.

INDICATIONS AND USAGE

Fiber Boats may be used to fill defects in bone including those created surgically. Fiber Boats are intended to act as bone void fillers and may enhance the bone quality in compromised sites.

- Intended for use in one patient, on a single occasion only.
- Only qualified health care professionals (e.g. physicians, dentists, podiatrists, etc.) should transplant donated human tissue.
- Tissue may not be sterilized or re-sterilized.
- Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.
- PTT assumes no responsibility for the clinical use of this allograft tissue.
- Tissues may transmit infectious disease agents. Any adverse outcomes that may be attributable to the implantation of this allograft tissue must be reported to PTT as soon as possible.

DONOR SCREENING AND TESTING

TheraFuze DBF® Fiber Boat™ is processed for TheraCell, Inc. by Pinnacle Transplant Services (PTT).
PTT only accepts donors from federally designated Organ Procurement Organizations (OPOs) or qualified tissue recovery partners. As these organizations are focused primarily on organ donation and tissue recovery, PTT is responsible for donor screening, tissue processing, and distribution services for our partners. Each partner is routinely audited to guarantee their recovery practices meet current FDA regulations, AATB standards and PTT's own stringent guidelines. Prior to release for transplantation, each donor is subjected to a thorough suitability evaluation including review of the donors medical and social history, hospital records, infectious disease screening, autopsy report (if performed), and physical assessment. Testing* includes, but is not limited to, the following:

- HBsAg: Hepatitis B Surface Antigen
- HBcAb: Hepatitis B Core Antibody
- HCVAb: Hepatitis C Antibody
- HIV 1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O Antibody
- HCV NAT: Hepatitis C Virus
- HIV NAT: Human Immunodeficiency Virus
- HBV NAT: Hepatitis B Virus
- RPR/STS or Equivalent: Syphilis

* HTLV I/II testing may have been performed, if testing was performed results were found to be negative/nonreactive.

All required communicable disease tests are negative/nonreactive. 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 Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). Names and addresses of testing laboratories, and a listing of the documents reviewed as part of the relevant medical records are kept on file at PTT and are available to the End-User upon request, except such information that may infringe upon the confidentiality of the donor information.

Based on all the screening and testing results this donated human tissue has been determined to be suitable for transplant by the Medical Director and Quality Assurance.

TREATMENT WITH GAMMA IRRADIATION

Donor tissue is recovered using the safest recovery techniques and sterile equipment to minimize any potential bioburden. All PTT tissues are procured via a network of qualified and trained recovery partners, one of the most stringent screening and recovery protocols, tissue cleaning and validated sterilization processes, and a highly controlled processing environment, thus countering the risks of disease transmission at every step. Subsequently, all allografts are terminally sterilized using Gamma irradiation to ensure patient safety. The effects of low dose irradiation on the biological properties of human allograft tissues are not fully understood at this time.

PRECAUTIONS

Because of potential violations of sterility, this allograft must not be transplanted under the following conditions:

- The container in which the product is stored is damaged compromising packaging integrity.
- The tissue outer packaging is damaged or missing.
- The expiration date has been exceeded.
- The allograft is not labeled, or the label's information is damaged, defaced or illegible.
- The allograft has not been stored according to acceptable storage conditions outlined in this Package Insert.
- The allograft or package elements appear to be missing, damaged or tampered with.
- The product label or identifying barcode is severely damaged, illegible or missing.

If any of the aforementioned conditions exist or are suspected, please notify PTT immediately for resolution.

CONTRAINDICATIONS

No contraindications are known to exist. Trace amounts of Triton X-100, isopropyl alcohol, hydrogen peroxide, hydrochloric acid, phosphate buffered saline, betadine, surfactant nonoxynol 9, and antibiotics (Polymyxin with Bacitracin) may be present and caution should be exercised if the patient is allergic to any of these agents. A relative contraindication would include the presence of infection in the host bed where the allograft is implanted. Limitations of allografts may include slow and/or incomplete incorporation and/or resorption. Bacterial infection at the site of implantation may occur. This complication may not be apparent for long periods of time (6-24 months) after transplantation. Transmission of infectious disease is an inherent risk associated with human tissue allografts, despite rigorous donor selection and testing.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Inherent uncertainties exist 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 disease of unknown etiology;
- Transmission of known infectious agents including, but not limited to 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 Pinnacle Transplant Technologies immediately.

HCT/P TRACKING

Per 21 CFR 1271.290(e), documentation about the tissue disposition to enable tracking from the donor to the consignee or final disposition must be maintained. Joint Commission standard QC.5.310.7 requires 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, a Tissue Transplant Record (TTR) and preprinted labels are provided with every allograft. Record the patient information, the transplantation facility name and address, the allograft tissue identification information (using stickers) and comments regarding tissue on the TTR. Return the completed TTR to Pinnacle Transplant Technologies and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, a completed TTR with the allograft identification information and reason for discard needs to be returned to PTT.

TheraCell is committed to honoring the altruism of tissue donation. In accordance with this commitment, TheraCell may accept returned allografts for credit or exchange (less a handling fee) based on stringent criteria. The specific criteria for returning allograft tissue products ensure that the suitability of the graft is not compromised. Contact customerservice@theracellinc.com for assistance.

PROCESSING AND DONOR ELIGIBILITY DETERMINED BY:

Pinnacle Transplant Technologies
1125 W. Pinnacle Peak Rd Building #1
Phoenix, AZ 85027
(623) 277-5400

MARKETED AND DISTRIBUTED BY:

TheraCell Inc.
2021 Midwest Rd # 101, Oak Brook, IL 60523
(630) 953-9594
www.theracellinc.com

Disclaimer: It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant and that recipient records must be maintained for the purpose of tracing tissue post-transplantation. TheraCell and Pinnacle Transplant Technologies will not be liable for any damages, whether direct or indirect, special, incidental or consequential resulting from improper use of this allograft. The instructions for use are specific, and TheraCell and PTT waive all responsibility associated with mishandling, inappropriately storing and/or not taking proper precautions with the allograft tissue included with this insert.