STERILE HUMAN ALLOGRAFT
INSTRUCTIONS FOR USE
FUSEPURE™ DBM PUTTY

DESCRIPTION

FusePure™ Plus DBM Putty is a versatile and manageable bone putty that is derived from 100% donated human tissue, eliminating the need for an extrinsic synthetic carrier. This product can be stored at 15-30˚C or 59-86˚F and is ready for immediate use.

This unit of allograft is derived from DONATED HUMAN TISSUES. The donor tissue was prepared by an accredited human tissue bank in the USA. The tissue is determined to be suitable for transplant by the tissue bank's Medical Director based on the results of screening and testing. Recovery was performed using industry standard procedures in a controlled tissue processing environment designed to ensure tissue allograft bio-implant quality and safety. The tissue bank utilizes a proprietary series of disinfection soaks validated to significantly reduce bioburden prior to terminal sterilization via electron beam 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

FusePure™ DBM Putty allografts can be stored at 15°C to 30°C until expiration date shown on allograft label.

INSTRUCTIONS FOR PREPARING ALLOGRAFT

1. Remove double-packaged allograft from box
2. Use standard sterile technique to open outer foil package and pass inner package to sterile field
3. In sterile field, open inner peel pouch and lay out contents
4. Keep dispenser capped when product is not in use
5. Remove cap from dispenser and dispense product as needed
6. Discard any unused product in accordance with standard hospital or clinical practice for disposal of human tissue
7. Once container seal has been compromised, tissue shall either be transplanted, if appropriate, or discarded

TREATMENT WITH ELECTRON BEAM RADIATION

Donor tissue is recovered using the safest recovery techniques and sterile equipment to minimize any bioburden contamination. All supplied 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 Electron Beam 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.

INDICATIONS AND USAGE

This allograft is indicated for use as an alternative to autograft in a number of orthopedic, spine and reconstructive applications including filling bone voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure.

- 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
- Fuse Medical and the processing tissue bank assume 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 Fuse Medical or the processing tissue bank as soon as possible.

DONOR SCREENING AND TESTING

The processing tissue bank 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, the tissue bank 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 the tissue bank's own stringent guidelines. Prior to release for transplantation, each donor is subjected to a thorough eligibility evaluation including review of the donor's 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 the processing tissue bank 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.

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
- If any of the allograft or package elements appear to be missing, damaged or tampered with
- If the product label or identifying barcode is severely damaged, illegible or missing
- If any of the aforementioned conditions exist or are suspected, please notify Fuse Medical and the tissue bank immediately for resolution.

CONTRAINDICATIONS, EFFECTS AND HAZARDS

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 include slow and/or incomplete incorporation and/or resorption which may be due to the difference in histocompatibility factors between the donor and recipient. 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. Transmissions of infectious disease may occur despite rigorous donor selection and testing.

FusePure™ DBM Putty is contraindicated where the allograft is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing relative contraindications include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Hypercalcemia
- Renal impairment
- Active or latent infection at the surgical site

COMPLICATIONS AND 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
- Loss of function and/or integrity of implanted HCT/P due to resorption, fragmentation, and/or disintegration.

Report any adverse outcomes to Fuse Medical or the tissue bank 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 Fuse Medical and the tissue bank 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.

RETURN POLICY

Fuse Medical does not accept the return of allograft products unless it is received damaged or defective. If you experience a problem with your allograft product, notify Fuse Medical immediately for a Returned Material Authorization (RMA) number at (469) 862-3030.

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. Fuse Medical and the processing tissue bank 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 Fuse Medical and the tissue bank waive all responsibility associated with mishandling, inappropriately storing and/or not taking proper precautions with the allograft tissue included with this insert.

Additional Information:

Comments, questions, or concerns regarding the use of this device should be directed to the following:

Website	www.FuseMedical.Com
Email	Info@FuseMedical.Com
Phone	469-862-3030
Postal	Attn: Customer Service CPM Medical Consultants, LLC 4343 Sigma Road, Suite 500 Farmers Branch, TX 75244
Website	www.FuseMedical.Com

fuse medical

Distributed By:
CPM Medical Consultants, LLC
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PROCESSING AND DONOR ELIGIBILITY DETERMINED BY

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