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Ossifuse® HSA

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IMPORTANT INFORMATION ON Ossifuse® HSA

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ALLOGRAFT TISSUE PACKAGE INSERT AND RECONSTITUTION INFORMATION

READ BEFORE USING
THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES. PROCESSING AND PACKAGING WERE ASEPTICALLY COMPLETED IN A CLEANROOM FACILITY. STERILIZATION VIA GAMMA IRRADIATION WAS USED IN THE PROCESS.

ENGLISH **IMPORTANT INFORMATION ON Ossifuse® HSA**

DESCRIPTION AND APPLICATIONS FOR USE
This information is for Ossifuse® High Surface Area (HSA) Fiber Bone Graft Putty, Strips, and Boats and Ossifuse® HSA Flowable. This processed human bone or soft tissue allograft is provided in a diverse range of sizes and shapes to be used at the discretion of qualified medical professionals (e.g. physicians, dentists and/or podiatrists) for various types of surgical procedures. It may be used independently or in combination with autologous tissue or other forms of allograft tissue.

REGULATORY CLASSIFICATION
This allograft is a human tissue product for transplantation. It is processed and distributed by Bone Bank Allografts, an American Association of Tissue Banks (AATB) accredited institution, in accordance with FDA requirements for Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271) and State regulations.

Caution: Federal Law restricts this product to sale by or on the order of a licensed practitioner. Human Tissue for transplant shall not be offered, distributed or dispensed for veterinary use.

DONOR RECOVERY AND SCREENING
After legal authorization or consent for donation is obtained, recovery of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments.

The allograft was prepared from a donor determined to be eligible based on the results of screening and testing. Blood samples from each donor are tested by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens under the 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). Test kits used are approved by the FDA for testing cadaveric specimens where applicable. Donor test results were shown to be negative or nonreactive for the following:

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- HIV1 Nucleic Acid Test (NAT)
- Hepatitis C Virus Antibody
- HCV Nucleic Acid Test (NAT)
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- HBV Nucleic Acid Test (NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay

The following test(s) may have also been performed and shown to be **negative or nonreactive**:

- Human T-Cell Lymphotropic Virus Type I and II Antibody (required for international)
- West Nile Virus Nucleic Acid Test (NAT)

The following test(s) may have also been performed. Positive or reactive results require further antibody testing and Medical Director review.

- Cytomegalovirus CMV Ab

Donor medical and social history, physical assessment, autopsy results (if performed), infectious disease testing, tissue cultures, cause of death and all other available medical records have been evaluated by a licensed physician and determined to meet all donor eligibility requirements for transplantation as required by the US FDA, other regulatory standards, and applicable State guidelines. All testing and medical release records are maintained by Bone Bank Allografts.

PROCESSING
Allograft tissues are processed in a controlled cleanroom environment using methods designed to prevent contamination and cross-contamination. Proprietary physiological buffers, acids, alcohols and surfactants are used during processing. Allograft tissue may contain traces of these processing agents. Antibiotics were not used in the processing of these allografts. Final allografts are sized and packaged according to approved specifications and procedures and are sterilized using gamma irradiation in accordance with ISO 11137 standards.

Allograft tissues will naturally vary in color from white to off-white, and yellow to pale yellow. Occasional dark spots or localized discoloration are normal occurrences.

WARNINGS AND PRECAUTIONS
Careful donor screening, laboratory testing, tissue processing, and gamma irradiation have been utilized to minimize the risk of transmission of relevant communicable diseases to the patient. As with any processed human donor tissue, this graft cannot be guaranteed to be free of all pathogens and may transmit infectious agents.

Possible complications may occur with any surgical procedure including, but not limited to pain, bacterial infection, hematoma, incomplete or lack of bony growth at treatment site, and/or immune rejection of the introduced tissue. As allografts are composed of proteins such as collagen, the potential for hypersensitivity, allergic reactions or other immune responses may exist.

Contraindications for the use of this allograft shall be determined by a licensed practitioner.

Trace amounts of Povidone-iodine, Vancomycin, Meropenem, and Amphotericin B may be present.

All adverse outcomes potentially attributed to the allograft must be promptly reported to Bone Bank Allografts and to the Distributor listed on the container label, if applicable.

This allograft is intended for single patient use only.
Do NOT reuse or sterilize.

Do Not Use This Allograft If:

1. Any of the package or allograft elements appear to be missing, tampered with or damaged.
2. Label or identifying bar code is severely damaged, illegible or missing.
3. Expiration date shown on the package label has passed.
4. Allograft has not been stored according to storage temperature requirements.
5. Allograft has been rehydrated and not used within 24 hours.

PACKAGING AND LABELING

Allografts are supplied freeze-dried or hydrated. Each allograft is identified by its own unique serial number and packaged in a two-layer pouch or tray configuration. Some allografts may also be placed in a syringe prior to packaging. If present, the tissue must be removed from the container prior to implantation.

The package container label includes graft details such as distributor name, address, phone number and allograft dimensions and/or volumes. **Contents of the package are sterile unless the package is opened or damaged.**

TRANSPORT, STORAGE AND EXPIRATION

Freeze-dried and hydrated tissues are shipped at ambient temperatures. Upon receipt the allograft should be removed from the shipping container and stored at room temperature (59–86°F or 15–30°C). No refrigeration is necessary.

See package label for expiration date.

It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain tissue intended for transplantation in the appropriate storage conditions prior to further distribution or transplant and to track expiration date accordingly.

USAGE INSTRUCTIONS

Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or properly discarded.

1. Open allograft packaging for use by following the below procedures. Use proper aseptic technique to open and deliver the allograft to the sterile field.

   Pouch packaging:

   a) Cut or tear open the non-sterile outermost moisture barrier and remove associated labeling materials.

   b) Peel open the outer pouch and deliver the innermost sterile sealed pouch containing the graft material to a sterile field.

   c) Peel open the sterile sealed pouch and deliver the graft to a sterile field.
   Vial Containers: Remove plastic cap and place the contents of the vial on the sterile field.

   Tray packaging:

   a) Peel open the non-sterile outermost tray and deliver the innermost sterile sealed tray containing the graft material to a sterile field.

   b) Peel open the sterile sealed tray and deliver the graft to a sterile field.

Note: Weight bearing tissues or allografts which will be cut, shaped, sutured, shall not have excessive force applied during manipulation or implantation.

If for any reason the graft is opened and not used, it should be disposed of properly in accordance with recognized local, state, and federal regulations for discarding medical waste material. Document the reason for non-use of the graft and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to the address listed.

Ossifuse® HSA BOATS, STRIPS, AND PUTTY

1. Immerse the allograft in sterile saline (0.9%), Lactated Ringer's, patient's blood/bone marrow aspirate, or other sterile isotonic solution for a minimum of 60 seconds.

   Note: Flexible partially demineralized cancellous sponge, cortical strip and cortical fiber allografts require a shorter rehydration time, and may be determined ready for use per surgeon's preference.

2. Extended rehydration time (up to 4 hours) is recommended for any tissue to be cut, shaped or wedged to reduce the chance of fracturing.
3. Allografts must be used within six (6) hours after rehydrating if the allograft is stored at room temperature. If refrigerated and stored between 2ºC and 8ºC within six hours after rehydrating, the allograft may be used within 24 hours (including rehydration time). Graft must be stored with proper precautions to prevent contamination.

Ossifuse® HSA FLOWABLE

1. Immerse the sealed syringe containing allograft in sterile saline (0.9%), Lactated Ringer's, or sterile water for a minimum of 90 seconds. The solution may be heated to 30°C ±3°C (range of 27–33°C or 80.6–91.4°F).
2. When ready to use, remove the syringe from the warming bath. Twist off butterfly cap and push the plunger to dispense the product.
3. If for any reason the graft is opened and not used, it should be disposed of properly in accordance with recognized local, state, and federal regulations for discarding medical waste material. Document the reason for non-use of the graft and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to the address listed.

PATIENT RECORD

Recipient records must be maintained for the purpose of tracking tissue post-transplant. ***IMPORTANT NOTICE TO END-USER:*** Please record this distinct graft identification code in your records and in the patient's medical record. It is also recommended that the following information be recorded in the patient's medical record:

1. Description of Tissue
2. Product Code
3. Expiration Date
4. Description of Procedure
5. Date and Time of Procedure
6. Surgeon Name
7. Any Other Pertinent Information

A Transplant Record has been included with each package of tissue. Please record the patient name, distinct graft identification code, date of birth, sex, name and address of the healthcare facility, name of the transplanting physician, date and type of surgery, name of the person filling out the Transplant Record and any comments. Once completed, the bottom copy of the Transplant Record should be returned to the address indicated. Copies of this information should be retained by the transplant facility for future reference.

DONOR ELIGIBILITY DETERMINATION AND PROCESSING BY:

Bone Bank Allografts
5335 Castroville Road
San Antonio, TX 78227
(800) 397-0088
FDA Registration FEI: 3000779542

All recovery, processing and distribution costs were reimbursed in part by Bone Bank Allografts in accordance with NOTA.