HammerGraft™ Hammertoe Allograft

DONATED HUMAN TISSUE

RESTRICTED TO USE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PROFESSIONAL (physician, dentist, podiatrist, optometrist, nurse practitioner or physician assistant).

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The Hammertoe Allograft is derived from cortical bone. The allograft is aseptically recovered with consent from qualified donors, and is processed using aseptic techniques. The allograft is packaged in antibiotic-free hypertonic saline solution, and sealed in packaging consisting of one inner tear pouch and one outer chevron peel pouch. The allograft is secured in a sealed outer container to help ensure allograft integrity.

INTENDED USE

The Hammertoe Allograft is intended for use as a bone void filler.

CONTRAINDICATIONS

The Hammertoe Allograft has no known contraindications.

DONOR ELIGIBILITY

The Hammertoe Allograft is recovered from qualified donors and processed using aseptic techniques in accordance with federal, state, and/or international regulations and to the standards of the American Association of Tissue Banks. The donors have been screened and tested for communicable disease risks and other exclusionary medical conditions. The results of these donor screenings and testing have been reviewed by the Medical Director (or licensed physician designee) of UMTB Biomedical, Inc. and the donors have been deemed suitable for transplantation.

Communicable disease testing was performed by an FDA-registered laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions. Results from the following infectious disease tests were found to be nonreactive or negative:

Human Immunodeficiency Virus (HIV)
HIV-1/2 Antibodies (HIV-1/2-Ab)
Nucleic Acid Test for HIV-1 RNA (HIV-1 NAT)
Hepatitis B Virus (HBV)
HBV Surface Antigen (HBsAg)
HBV Core Antibody (IgG & IgM) (HBcAb)
Nucleic Acid Test for HBV DNA (if performed) (HBV NAT)
Hepatitis C Virus (HCV)
HCV Antibody (HCVAb)
Nucleic Acid Test for HCV RNA (HCV NAT)
Human T Cell Lymphotrophic Virus I/II* (if performed)
HTLV-I/II (Antibody HTLV-I/II-Ab)
Syphilis**
Rapid Plasma Reagin (RPR) Screen
T. Pallidum IgG

*A donor with a reactive result for the HTLV-I/II Antibody test is suitable for use only when the result from a confirmatory assay is nonreactive.
**A donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, is suitable for use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

Screening tests for exposure to other viruses or parasites such as those listed below may have been completed. A negative/nonreactive result is not required for these tests, however, all results are evaluated on a case-by-case basis by the Medical Director (or licensed physician designee).

Cytomegalovirus
CMV Ab (IgG & IgM)
Epstein Barr Virus
EBV Ab (IgG & IgM)
Toxoplasma gondii
Toxoplasma Ab (IgG & IgM)
Trypanosoma cruzi
T. cruzi Ab (IgG & IgM)

WARNINGS

The donors of the Hammertoe Allograft have been screened and tested for relevant communicable diseases and disease agents in compliance with the FDA regulations relating to human cells, tissues, and cellular and tissue-based products (21 CFR part 1271). The Hammertoe Allograft is processed using aseptic techniques and microbiologically tested. Although all efforts have been made to ensure the safety of the allograft, there is no assurance that this allograft is free from all infectious diseases or microbial contamination.

DO NOT FREEZE the allograft by any method.

FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY.

DO NOT STERILIZE the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide or other chemical sterilants may render the allograft unfit for use.

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PRECAUTIONS

The Hammertoe Allograft is processed and packaged using aseptic techniques and must be handled in an aseptic manner to prevent contamination.

ADVERSE EVENTS

Allogeneic cells or tissues can induce an immunologic response in the recipient. The possibility that a patient may develop alloantibodies should be considered for any patient who might be a future recipient of allograft tissue or cells.

Possible adverse events may include: immunologic response, transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, hepatitis, syphilis, or microbial contaminants.

STORAGE

The Hammertoe Allograft must be stored at ambient temperature 2˚C to 30 ˚C. It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use and to track expiration dates accordingly. Appropriate inventory control should be maintained so that the allograft with the earlier expiration date is preferentially used and expiration is avoided.

ALLOGRAFT PREPARATION

DO NOT USE THE ALLOGRAFT if the outer pouch integrity has been compromised.

ONCE THE OUTER CONTAINER SEAL HAS BEEN COMPROMISED, the allograft shall be either transplanted, if appropriate, or otherwise discarded.

ONCE OPENED, the allograft must be used within 24 hours.

THE OUTER CHEVRON PEEL POUCHES ARE NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

Step 1: Remove the outer chevron peel pouch containing the allograft from the outer container.

Step 2: Utilizing aseptic technique, peel open the outer chevron peel pouch from the chevron end and present the inner pouch to the operative field.

Step 3: Locate the tear notch on the inner pouch, and tear open. Place the allograft into a sterile basin. HYPERTONIC SALINE SOLUTION WILL EXPEL FROM THE INNER POUCH.

Step 4: Transfer the allograft into another basin containing fresh solution of choice. Antibiotics of the physician's preference may be added to the solution. The allograft is ready for use.

In the event that the allograft is not implanted within 2 hours, place the allograft into a sterile basin containing the solution of choice and cover and seal the basin with a sterile Vi-Drape or similar adhesive drape and double wrap the sealed basin with sterile waterproof wrappers. Store in the refrigerator at 1 to 10°C for no longer than 24 hours.

RECIPIENT INFORMATION

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide UMTB Biomedical, Inc. with information pertaining to the traceability of the allograft used. For this purpose, the postage paid Tissue Utilization Report (TUR) card is provided with the allograft. Once the allograft is used, peel off the small product labels provided on the product packaging and affix on the TUR card and applicable patient records. Complete the TUR card and mail to UMTB Biomedical, Inc., scan and e-mail to turs@umtb.com, or fax to (888) 630-4321.

ADVERSE OUTCOME AND COMPLAINT REPORTING

Adverse outcomes potentially attributable to the Hammertoe Allograft should be promptly reported to UMTB Biomedical, Inc. at (888) 684-7783. Any other complaints should be promptly reported to Paragon 28, Inc. at (855) 786-2828.

RETURNED GOODS POLICY

Due to the delicate biological nature of a processed allograft, it cannot be returned for credit. If for any reason the allograft must be returned, a return authorization is required from Paragon 28, Inc. prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.

Exclusively foot & ankle Paragon 28®

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