Human Hypothermic Dehydrated BioCartilage 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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BioCartilage is a dehydrated cartilage allograft, and has been processed using aseptic techniques. The allograft has been treated with an antimicrobial solution (containing Gentamicin and either Vancomycin or Bacitracin), and has been subjected to hypothermic dehydration. BioCartilage has been aseptically packaged in a tear pouch within a chevron peel pouch configuration and secured in an outer container.

INTENDED USE

BioCartilage is intended for use as an articular cartilage defect filler.

CONTRAINDICATIONS

BioCartilage is contraindicated in patients with known sensitivities to Gentamicin, Vancomycin, Bacitracin, and hydrogen peroxide.

DONOR ELIGIBILITY

BioCartilage was recovered from a qualified donor 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 donor has been screened and tested for communicable disease risks and other exclusionary medical conditions. The results of the donor screening and testing has been reviewed by the Medical Director (or licensed physician designee) of UMTB Biomedical, Inc. and the donor has 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 donor of BioCartilage has 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). BioCartilage was 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.

PRECAUTIONS

BioCartilage was 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

BioCartilage 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 pouch integrity has been compromised.

ONCE OPENED, the allograft must be reconsitituted and used within 2 hours.

THE OUTERMOST POUCH IS NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

ONCE THE INNER POUCH SEAL HAS BEEN BROKEN, THE GRAFT MUST BE TRANSPLANTED (if appropriate) OR DISCARDED.

The allograft is aseptically packaged in a plastic container, one tear pouch and one chevron peel pouch.

Step 1: Utilizing aseptic technique, peel open the outer peel pouch from the chevron end and present packaged graft to the sterile field.
Step 2: Place the packaged graft into a small basin on the sterile field, locate the tear notch and tear open.
Step 3: Remove the container from the inner pouch and unseal the container.
Step 4: Transfer the graft into a sterile basin and add an autologous blood solution; mix thoroughly (see Table 1 for suggested volume). Additional amounts of the autologous blood solution may be added and mixed with the allograft until a desired consistency is achieved. The autologous blood solution may consist of blood, plasma, platelet rich plasma, bone marrow, or other specific blood component(s) as deemed necessary by the clinical use requirements.
Step 5: Once completely reconstituted, the graft is ready to use. (It is advisable to implant the graft within 1-hour post-reconstitution.)

Table 1	
Volume of Cartilage	Volume of Autologous Fluid
1.0 cc	0.80 cc
0.75 cc	0.60 cc

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 BioCartilage should be promptly reported to UMTB Biomedical, Inc. at (888) 684-7783. Any other complaints should be promptly reported to Arthrex, Inc. at (800) 934-4404.

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 Arthrex, Inc. prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.

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