V92™ FiberCell™ Cellular Bone Matrix

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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V92 FiberCell™ Cellular Bone Matrix is a bone allograft that consists of a bone particulate component, a bone gel component, and a cell component. The bone particulate and bone gel components are derived from mineralized and demineralized bone particulates.

V92 FiberCell™ Cellular Bone Matrix has been processed using aseptic techniques. The bone particulate and bone gel components of the allograft have been treated with an antimicrobial solution (containing Gentamicin and either Vancomycin or Bacitracin), hydrogen peroxide and hydrochloric acid solutions. Although the allograft was rinsed with sterile saline and (or) sterile water throughout processing, traces of the antibiotics, hydrochloric acid and hydrogen peroxide solutions may remain in the product. The bone particulate and bone gel components have been lyophilized and aseptically packaged in a tear pouch within a peel pouch configuration and frozen.

The cell component has been treated with an antimicrobial solution (containing Gentamicin and either Vancomycin or Bacitracin) and frozen with a 100% polyampholyte-based cryoprotectant. Although the allograft was rinsed with sterile saline and (or) sterile water throughout processing, traces of the antibiotics, hydrochloric acid and hydrogen peroxide solutions may remain in the product. The cell component has been aseptically packaged in a tear pouch within a peel pouch configuration.

All of the respective components of V92 FiberCell™ Cellular Bone Matrix have been packaged in one single outer container.

INTENDED USE
V92 FiberCell™ Cellular Bone Matrix is intended for use as a bone void filler.

CONTRAINDICATIONS
V92 FiberCell™ Cellular Bone Matrix is contraindicated in patients with known sensitivities to Gentamicin, Vancomycin, Bacitracin, hydrochloric acid, hydrogen peroxide or polyampholytes.

DONOR ELIGIBILITY
V92 FiberCell™ Cellular Bone Matrix 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 V92 FiberCell™ Cellular Bone Matrix 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). V92 FiberCell™ Cellular Bone Matrix 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 RE-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
V92 FiberCell™ Cellular Bone Matrix 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.

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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

V92 FiberCell™ Cellular Bone Matrix must be stored at -65˚C or colder. 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 THE CONTAINER SEAL HAS BEEN COMPROMISED, the allograft shall be either transplanted, if appropriate, or otherwise discarded.

ONCE OPENED, the allograft must be reconstituted and used within 4 hours of thawing.

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

Step 1: Prepare a sterile saline or sterile water bath for thawing of the cell vial(s) and bone gel jar.

Step 2: Remove the chevron peel pouch containing the bone gel jar from the outer container.

Step 3: Utilizing aseptic technique, peel open the chevron peel pouch containing the bone gel jar from the chevron end and present the inner pouch containing the bone gel jar to the operative field.

Step 4: Remove the bone gel jar from the inner pouch using standard aseptic technique.

Step 5: Place the bone gel jar in the bath until the contents of the bone gel jar have completely thawed.

Step 6: While the bone gel is thawing, remove the peel pouch containing the cell vial(s) from the outer container.

Step 7: Utilizing aseptic technique, peel open the chevron peel pouch containing the cell vial(s) from the chevron end and present the inner pouch containing the cell vial(s) to the operative field.

Step 8: Remove the cell vial(s) from the inner pouch using standard aseptic technique.

Step 9: Add sterile saline to the vial(s) containing the frozen cells according to Table 1.

Size	2.5 cc	5 cc	10 cc
Saline Volume per Vial	0.5 mL	1 mL	1 mL
Number of Vials	1	1	2

Table 1 –Formulation Guide

Step 10: Place the vial(s) containing the cell solution in the bath until the contents of the cell vial(s) have completely thawed.

Step 11: While the cell(s) and bone gel are thawing, remove the chevron peel pouch containing the bone particulate jar and spatula.

Step 12: Utilizing aseptic technique, peel open the chevron peel pouch from the chevron end and present the inner pouch containing the bone particulate jar and spatula to the operative field.

Step 13: Remove the bone particulate jar and spatula from the inner pouch using standard aseptic technique.

Step 14: After the contents of the cell vial(s) have completely thawed, carefully invert the cell vial(s) several times. Remove the liner from the inside of the bone particulate jar and pour the contents of the thawed cell vial(s) into the bone particulate jar.

Step 15: Using the spatula, mix the contents of the cell vial(s) and the bone particulate thoroughly.

Step 16: Cap the jar of the cell and bone particulate mixture until ready to prepare the final allograft in Step 20.

Step 17: Once the contents of the bone gel jar have thawed completely, remove the bone gel jar from the bath.

Step 18: Remove the bone gel from the jar and place on the palm of the hand.

Step 19: Using the spatula, press and spread the bone gel into the hand repeatedly until a smooth and homogenous texture is obtained.

Step 20: Transfer the mixture of bone particulate and cells onto the bone gel and fold the bone gel into the mixture thoroughly until uniform consistency is obtained.

Step 21: The prepared allograft should be placed back into the jar until ready for use and may be stored for 4 hours from time of initial cell thaw.

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 V92 FiberCell™ Cellular Bone Matrix 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

Returns will not be accepted for V92 FiberCell™ Cellular Bone Matrix.

Exclusively foot & ankle Paragon 28®

Distributed by:
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