

ViBone

THIS PRODUCT IS MANUFACTURED FROM DONATED HUMAN TISSUE, RECOVERED FROM A SINGLE HUMAN DONOR WITH DOCUMENTED AUTHORIZATION FOR DONATION AND RECOVERY. THE TISSUE IS RECOVERED AND SUPPLIED FROM U.S. TISSUE BANKS ONLY. THE RECOVERY, PROCESSING AND PACKAGING WAS PERFORMED USING ASEPTIC TECHNIQUES.

DESCRIPTION AND INDICATION FOR USE

ViBone™ is a human tissue allograft consisting of cryopreserved bone matrix that is aseptically processed to preserve native factors that support bone repair. ViBone™ is a Human Cellular and Tissue Based Product (HCT/P) per 21 CFR Part 1271. Each allograft is restricted to homologous use for transplant in procedures on a single occasion by a licensed physician or surgeon.

DONOR SCREENING AND TESTING (SUMMARY OF RECORDS)

ViBone™ was prepared from a donor determined to be eligible by the Medical Director of Aziyo or physician designee based on the results of screening and testing. Donors are screened for high risk behavior and contraindications to transplant through medical/social history interview, review of medical records, physical assessment, and review of post mortem-examination results (when applicable). Tissue from this donor has passed bacteriological testing by a CLIA Certified Laboratory. Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with 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) and found to be negative or non-reactive for a minimum of:

- HIV type 1 and 2 antibody (HIV-1 & 2 Ab)
- HIV type 1 nucleic acid test using PCR and/or TMA format (HIV-1 NAT)
- Hepatitis B virus (HBsAg and HBV NAT)
- Hepatitis B core antibody total (HBcAb IgG/IgM or total)
- Hepatitis C virus (HCV Ab and HCV NAT)
- Syphilis by rapid plasma reagin (RPR) or other serological tests

Additional tests, including Human T-lymphotropic virus I/II, may have been performed at the time of screening, and results were found acceptable for transplantation. Any additional test(s) performed can be provided upon request. Donor eligibility determination was made by Aziyo Biologics in compliance with U.S. FDA regulations (21 CFR 1270 and 1271) and American Association of Tissue Banks® (AATB®) Standards. The Medical Director determined final eligibility and acceptability for transplantation after review of donor screening and testing records.

WARNINGS AND PRECAUTIONS

An allograft may not elicit proper response from the recipient (e.g. fusion/union with adjacent tissue). It is possible for a host site to become infected or the allograft may cause an inflammatory response. Current technologies may not preclude the transmission of infectious agents or disease, including hepatitis and HIV. ViBone™ is preserved in 5% dimethyl sulfoxide (DMSO) in a 0.9% sodium chloride solution. Povidone iodine, Dulbecco's phosphate buffered saline, sodium chloride irrigation solution, sodium phosphate, hydrochloric acid and hydrogen peroxide are all used for processing, preservation and storage of the allografts and trace amounts of these solutions may be present in the product.

TRANSPORTATION, STORAGE AND HANDLING

ViBone™ is supplied ready to use and must be stored in its original packaging at -75°C to -85°C (-103°F to -121°F) until prepared for use. It is the responsibility of the transplant facility or clinician to maintain the allograft intended for transplantation in the appropriate recommended storage conditions prior to transplant.

HOW SUPPLIED

ViBone™ bone allograft is supplied frozen and packaged in a polycarbonate jar placed in an outer peel pouch. The inner jar and allograft are sterile. The outer peel pouch is not sterile. Allograft volume is indicated on the package label.

STERILITY CONTROL

ViBone™ allografts have been processed under aseptic conditions to prevent contamination and cross contamination of the product. Destructive microbiological testing per USP <71> *Sterility Tests* is performed on samples from each lot and must show "No Growth" after a 14-day incubation in growth promoting media.

PRECAUTIONS

Inspect the integrity of the package upon receipt and before use. Do not use ViBone™ under the following conditions:

- The container in which the allograft is stored is damaged or the label has been damaged or defaced.
- The allograft expiration date has passed.
- Recommended storage conditions have not been maintained.

INSTRUCTIONS FOR USE

It is important to utilize aseptic techniques when unpacking the allograft.

1. Examine the labeling and outer peel pouch. Do not use if there is evidence that the integrity of the outer pouch has been compromised.
2. Aseptically present the inner jar onto a sterile field.
3. Place the unopened jar into a sterile basin and fill with warm (approximately 37°C) sterile saline to just below the jar lid.
4. Thaw ViBone™ for approximately 5-15 minutes.
5. Don sterile surgical gloves, remove the jar lid and remove the product from the jar.
6. The allograft tissue should be pliable. If the allograft is still frozen, warm by holding the allograft with sterile gloved hands until completely thawed and pliable.
7. ViBone™ should be transplanted within two hours of thawing and all unused product must be discarded. Product is intended for single use and should not be refrozen or sterilized.

TRACEABILITY

The FDA requires traceability from the donor to the recipient. The physician is responsible for completing the recipient records to ensure traceability. As a convenience, pre-printed peel-off labels are included with each allograft. Using the labels, record the allograft tissue identification information in the patient medical record.

ADVERSE REACTION

The physician must promptly report any adverse outcomes potentially attributable to ViBone™ to Aziyo at 800-922-3100.

Manufactured By:



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FDA Registration No. 1000100754

CTO Registration Certificate No. 100242

Accredited by the AATB®

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