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

MEDLINE**UNITE**® ACTI**VI**™ fiber viable bone matrix (FVBM) is a human tissue allograft consisting of cryopreserved cancellous and corticocancellous bone matrix that is aseptically processed to preserve native factors that support bone repair. MEDLINE**UNITE**® ACTI**VI**™ is supplied by Medline Industries Inc. and is processed and prepared by Aziyo Biologics. MEDLINE**UNITE**® ACTI**VI**™ 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 for repair, replacement or reconstruction on a single occasion by a licensed physician or surgeon. MEDLINE**UNITE**® ACTI**VI**™ can be used in orthopedic or reconstructive bone grafting procedures in combination with autologous bone or other forms of allograft bone, or alone as a bone graft.

DONOR SCREENING AND TESTING (SUMMARY OF RECORDS)

MEDLINE**UNITE**® ACTI**VI**™ 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.

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.

MEDLINE**UNITE**® ACTI**VI**™ is preserved in 5% dimethyl sulfoxide (DMSO) in a 0.9% sodium chloride solution. Povidone iodine, Dulbecco's phosphate buffered saline, 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

MEDLINE**UNITE**® ACTI**VI**™ is supplied ready to use and must be stored in its original packaging at -75°C (-103°F) or colder 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

MEDLINE**UNITE**® ACTI**VI**™ bone allograft is supplied frozen and packaged in a sterile polycarbonate jar placed in a sterile peel pouch. The exterior surface of the peel pouch is not sterile. Allograft volume is indicated on the package label.

LABELING SYMBOLS

MEDLINE**UNITE**® ACTI**VI**™ packaging labels uses symbols to convey specific meaning. These symbols and their use are defined within ISO 15223-1, unless stated otherwise. As a convenience, the symbols used with MEDLINE**UNITE**® ACTI**VI**™ labels and their meaning are defined below.

	Manufacturer
	Date of Manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial Number
	Sterilized using aseptic processing techniques
	Upper limit of temperature
	Do not re-use
	Consult instructions of use
Rx Only	Restricted use/Prescription only*
QTY	Number of packaged units**

**Symbol use not defined by ISO 15223-1. Its use is defined by 21 CFR 801 to express that the contents labeled as such are not safe except under the supervision of a practitioner licensed by law to direct its use, and hence for which "adequate directions for use" cannot be prepared.*

***Symbol not defined in any standard or regulation but is used to express the number of units packaged with the labeled volume.*

STERILITY CONTROL

MEDLINE**UNITE**® ACTI**VI**™ 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 MEDLINE**UNITE**® ACTI**VI**™ under the following conditions:

- The container and/or the outer pouch in which the allograft is stored are 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. Don sterile surgical gloves; place the unopened jar upright into a sterile basin, and fill with warm (approximately 37 ºC) sterile saline to just below the jar lid. DO NOT submerge the jar lid.
4. Thaw MEDLINE**UNITE**® ACTI**VI**™ for approximately 5-30 minutes, depending on allograft size.
5. 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. MEDLINE**UNITE**® ACTI**VI**™ 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.

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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 MEDLINE**UNITE**® ACTI**VI**™ to Medline Industries, Inc. at 1-800-Medline.

Marketed By:

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Phone: 1-800-MEDLINE

Manufactured By:

Aziyo Biologics, Inc.
880 Harbour Way S, Suite 100
Richmond, CA 94804
Phone: 800-922-3100

Remainder of document intentionally left blank.

FDA Registration No. 1000100754
Accredited by the AATB®