DESCRIPTION AND INDICATION FOR USE
MEDLINEUNITE® ACTI™ 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. MEDLINEUNITE® ACTI™ is supplied by Medline Industries Inc. and is processed and prepared by Aziyo Biologics. MEDLINEUNITE® ACTI™ 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. MEDLINEUNITE® ACTI™ 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)
MEDLINEUNITE® ACTI™ 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
Donor eligibility determination was made by Aziyo Biologics in accordance with the Clinical Laboratory

STERILITY CONTROL
MEDLINEUNITE® ACTI™ 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
MEDLINEUNITE® ACTI™ 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.

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 MEDLINEUNITE® ACTI™ 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. MEDLINEUNITE® ACTI™ should be transplanted within two hours of thawing and all unused product must be discarded.

CONTINUES ON BACK
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 MEDLINEUNITE® ACTIVI™ 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.