STRATOFUSE® V

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 WERE PERFORMED USING ASEPTIC TECHNIQUES. THIS PRODUCT IS INTENDED FOR USE IN ONE PATIENT ON A SINGLE OCCASION ONLY.

Single Patient use. Do not re-use

Do not use if package is damaged

℞ only Prescription only

DESCRIPTION AND INDICATION FOR USE

STRATOFUSE® V, an Osteo Viable Matrix is a human tissue allograft consisting of cryopreserved cancellous and cortical bone matrix that is aseptically processed to preserve native factors that support bone repair. STRATOFUSE® V is a Human Cellular and Tissue Based Product (HCT/P) per 21 CFR Part 1271. This tissue form is limited to homologous use for the repair, replacement or reconstruction of bone defects on a single occasion by a licensed physician or surgeon.

DONOR SCREENING AND TESTING (SUMMARY OF RECORDS)

STRATOFUSE® V 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 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.

STRATOFUSE® V 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, Gentamicin, Vancomycin HCl, Amphotericin B, and hydrogen peroxide are all used for manufacturing of the allografts and trace amounts of these solutions may be present in the product.

WARNINGS AND PRECAUTIONS (Continued)

STRATOFUSE® V 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.

TRANSPORTATION, STORAGE AND HANDLING

STRATOFUSE® V 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.

STRATOFUSE® V bone allograft is supplied frozen and packaged in a sterile polycarbonate jar placed in a sterile outer peel pouch. The exterior surface of peel pouch is not sterile. Allograft volume is indicated on the package label.

STERILITY CONTROL

STRATOFUSE® V 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 STRATOFUSE® V 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. Using sterile surgical gloves; place the unopened jar into a sterile basin and fill with warm (approximately 37ºC) sterile saline to just below the jar lid. DO NOT submerge the jar lid.
4. Thaw STRATOFUSE® V for approximately 5-15 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.

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. In addition, an Allograft Usage Report is included with the allograft. The physician is to complete the report and affix one of the pre-printed labels to it. Scan and email the completed report to AllograftUsage@Aziyo.com.

ADVERSE REACTION

The physician must promptly report any adverse outcomes potentially attributable to STRATOFUSE® V to ChoiceSpine, LLC at Salessupport@choicespine.com or 865.243.3383.

Distributed by
ChoiceSpine, LLC
400 Erin Drive,
Knoxville, TN 37919
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FDA Registration No. 1000100754
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