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TENFUSE®

STERILE ALLOGRAFT

Wright Medical Technology Patent Pending

ALLOGRAFTS ARE PROVIDED FROM DONATED HUMAN TISSUE
ALLOGRAFT IS FOR SINGLE USE ONLY

THE TISSUE USED FOR PROCESSING WAS RECOVERED FROM A SINGLE HUMAN DONOR WITH DOCUMENTED CONSENT 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. THE OFFERED ALLOGRAFT IS TERMINALLY STERILIZED IN ITS FINAL PACKAGING.

DESCRIPTION

TENFUSE® machined, sterile bone matrix allografts are manufactured using Computer Numerically Controlled (CNC) machining technology for dimensional reproducibility and conforming fit within the bone space. The finished allograft is provided terminally sterilized, preserved in saline and ready for immediate use, with no reconstitution needed. The resulting allograft is restricted to homologous use for transplant in fusion surgical procedures.

INDICATIONS FOR USE

TENFUSE® machined, sterile bone matrix allografts are intended for transplant in small bone with fusion procedures. Each allograft package is intended for use in one patient, on a single occasion by a licensed physician or surgeon.

CONTRAINDICATIONS

Use of this allograft in patients exhibiting metabolic bone disorder/disease or evidence of necrosis is not recommended.

The enclosed allograft may contain trace amounts of processing agents listed in the Warnings section of the insert. The allograft should not be used in patients sensitive or allergic to these specific agents.

WARNINGS

Potential adverse effects that may result from placement of the TENFUSE® machined, sterile bone matrix allograft include, but are not limited to the following: surgical site or systemic infection; hypersensitivity; allergic or other immune response; failure to provide the desired mechanical support and/or breakage; failure to elicit the intended response (fusion/union with adjacent tissue) and disease transmission.

- Trace amounts of processing agents may include iodine, ethanol, hydrogen peroxide, Gentamicin or Vancomycin.
- Unused allograft, whole or partial may not be repackaged.
- Do not re-sterilize.
- Wright Medical Technology and Aziyo Biologics, Inc. make no claims regarding the biologic or biomechanical properties.

Extensive medical screening procedures have been used in the selection of all tissue donors for Aziyo Biologics, Inc. (see Donor Selection, Screening and Testing). Due to limitations in testing technology, testing and donor screening cannot totally eliminate the risk that human source material may transmit infectious agents or diseases, such as hepatitis and HIV.

Donor Selection, Screening and Testing (Summary of Records)

Aziyo Biologics, Inc. commitment to tissue safety begins with donor selection and screening. Potential donors are screened for high risk behavior and contraindications to transplant through medical/social history interview, review of medical records, assessment of the donor's body, and review of post mortem-examination results (when applicable).

All donors are subjected to communicable disease marker testing 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 surface antigen (HBsAg)
- 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. A list of additional test(s), if performed, can be provided upon request.

Tissue from this donor has passed bacteriological testing by a CLIA Certified Laboratory.

Donor eligibility determination made in compliance with U.S. Food and Drug Administration (FDA) regulations (21 CFR 1270 and 1271) and American Association of Tissue Banks (AATB) Standards. A Medical Director determines final eligibility and acceptability for transplantation after review of donor screening and testing records.

Transportation, Storage and Handling

TENFUSE® machined, sterile bone matrix allograft must be stored and handled as follows:

- The allograft is supplied ready to use, no rehydration is necessary.
- The allograft can be stored between 2°C and 40°C (36°F and 104°F) until prepared for use.
- The allograft must not be frozen.
- 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

TENFUSE® machined, sterile bone matrix allograft is supplied fully hydrated and terminally sterilized. The allograft is enclosed inside a sealed, sterile glass bottle filled with normal saline. The allograft and sealed bottle are then enclosed in a secondary outer pouch.

Sterility Control

TENFUSE® machined, sterile bone matrix allograft is provided sterile following an internationally recognized validation method and monitoring process, in combination with a proprietary irradiation system using gamma radiation from cobalt-60 source material, to a Sterility Assurance Level of 10^{-6}.

Precautions

TENFUSE® machined, sterile bone matrix allograft is considered sterile as long as the inner most packaging (bottle) is not opened or damaged. Inspect the integrity of the package upon receipt and before use. The allograft should not be used under any of the following circumstances:

- If the expiration date shown on the labeling has passed.
- If the inner most package, bottle seal integrity is damaged or compromised.
- If the labels or identifying barcodes are not legible or missing.
- Recommended storage conditions have not been maintained.

Instructions for Use

1. Examine the integrity of the package. Do not use if there is evidence that the inner most package is damaged or sterility has been compromised.
2. The outer pouch is not sterile. The inner bottle and allograft it contains are considered sterile, provided the packaging has not been compromised.
3. Aseptically present the bottle containing the allograft onto the sterile eld. Alternatively, if the pouch containing the bottle has been compromised, but

the bottle seal is still intact, the bottle can be opened as indicated below and the allograft aseptically presented onto the sterile field.
4. Remove the safety seal band/cap.
5. Remove the stopper. Pour the contents of the bottle into a sterile preparation basin on the sterile field. The allograft is ready to use and requires no further preparation.

NOTE: Once the bottle containing the allograft has been opened, the allograft must be implanted during that surgical procedure; otherwise the allograft must be discarded if not used.

Tissue Tracing

The FDA requires that allograft tissue be traceable from the donor to the recipient. An Allograft Usage Report and pre-printed peel-off labels are included with each package of tissue. Record the recipient name and medical record number, the hospital/surgery center name and address, the allograft tissue identification information (using the peel off stickers) and the use of the tissue on the Allograft Usage Report. Return the completed form to Wright Medical and retain a copy in the patient medical record. If the tissue has been discarded, please return the Allograft Usage Report to Wright medical along with the graft identification information and reason for discard.

Adverse Reactions

The physician is responsible for promptly reporting any adverse reaction that may be potentially attributable to the TENFUSE® machined, sterile bone matrix allograft to Wright Medical Technology by calling 800-238-7117.

Provided By:

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FDA Registration Number 1000100754.
CTO Registration Certificate Number 100242.

Aziyo Biologics, Inc. is accredited by the American Association of Tissue Banks (AATB).