ViviGen®

Cellular Bone Matrix

FEDERAL LAW (USA) RESTRICTS THIS ALLOGRAFT FOR USE BY A LICENSED CLINICIAN ONLY.

DESCRIPTION

ViviGen Cellular Bone Matrix is a formulation of cryopreserved viable cortical cancellous bone matrix and demineralized bone. ViviGen is a Human Cells, Tissues, and Cellular and Tissue-based Product (HCT/P) as defined by the U.S. Food and Drug Administration in 21 CFR 1271.3(d). ViviGen meets the criteria set out in 21 CFR 1271.10 for regulation solely under section 361 of the Public Health Service Act. ViviGen was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. In addition, this allograft is packaged in pre-sterilized inner and outer pouches and arrives in a cryopreservative solution containing Dimethyl Sulfoxide (DMSO) and Human Serum Albumin (HSA).

INDICATIONS FOR USE

ViviGen is intended for repair, or reconstruction of musculoskeletal defects.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Use in any patient who has a known or suspected allergy to any of the antibiotics and/or reagents listed under the Warnings and Precautions section of this document
- Use in immune compromised patients
- Stand-alone use in load-bearing applications

WARNINGS AND PRECAUTIONS

- LifeNet Health employs stringent guidelines regarding donor tissue, processing treatment, and laboratory testing to reduce the risk of infectious agent transmission. As with any donor tissue, the potential for transmission of infectious agents exists.
- Use on a single occasion for a single patient only
- Residual reagents including Gentamicin Sulfate, Meropenem, Vancomycin, Dimethyl Sulfoxide (DMSO), and Human Serum Albumin (HSA) may be present.
- Do not use past expiration date or if package or label integrity has been compromised or damaged.
- Do not sterilize.
- Do not use if tissue has not been stored according to the recommended storage requirements.
- Do not refreeze after thawing.

STORAGE REQUIREMENTS

After removal from the shipper, ViviGen must be stored **immediately** in its original packaging at -70°C or colder until ready for use. Do not store in liquid phase of the Liquid Nitrogen (LN2). ViviGen packaging is designed to protect the graft from short-term (15 minutes maximum) temperature excursions up to -60°C due to cycling or opening of freezer doors. It is the responsibility of the end user to document and maintain the storage at these conditions.

POTENTIAL ADVERSE EVENTS

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions.

Potential adverse events or outcomes include, but are not limited to: disease transmission, infection, allograft tissue rejection, allergic reaction to residual reagents, re-operation, and/or death.

Promptly report any adverse event(s) or outcome(s) potentially attributable to ViviGen (See COMPLAINTS AND RETURNS section).

QUALITY CONTROL TESTING

- Finish product passes USP‹71› Sterility Tests.
- Each lot is tested to contain › 16,000 viable bone cells per cubic centimeter (cc) post thaw.
- Calcium content in demineralized bone is measured to ensure average residual calcium levels are in an optimal range.

TRACEABILITY

It is the responsibility of the end-user to maintain recipient records for the purpose of tracking tissue post-implantation. As a courtesy to the end-user clinician or facility, LifeNet Health has enclosed a Graft Implant Tracking Card to assist in the post-implantation tracking. Please refer to the enclosed card for additional instructions.

COMPLAINTS AND RETURNS

For further information on returns or to report a complaint or adverse event, please contact your authorized distributor or LifeNet Health Client Services (available 24 hours a day) at 1-888-847-7831 (inside the U.S.) or 00+1-757-464-4761 ext. 2000 (outside the U.S.) and have the identification number available (see label).

WARRANTY STATEMENT

Due to the inherent variability of allograft tissue, biological and biomechanical properties cannot be guaranteed by LifeNet Health.

DONOR SCREENING AND TESTING

All donors have been screened and tissues recovered, processed, stored, tested, and distributed in accordance with current U.S. federal regulations as promulgated in 21 CFR 1270 and 1271, current Standards for Tissue Banking set forth by the American Association of Tissue Banks (AATB) and international laws and regulations as required.

This allograft was deemed suitable for implantation by LifeNet Health. A physician medical director evaluated the following donor variables to determine donor suitability: infectious disease test results, current donor medical history, behavioral risk assessment interview, physical assessment, relevant medical records, including previous medical history, laboratory test results, and autopsy or coroner reports (if performed).

All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U. S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR 493. Test methods that are FDA-licensed, approved, or cleared for donor screening are used as available. The following test criteria were met for the donor of this allograft.

Required Infectious Disease Testing	
Test	Acceptance Criteria
HBcAb: Hepatitis B Total Core Antibody	Negative/Non-Reactive
HBsAg: Hepatitis B Surface Antigen	Negative/Non-Reactive
HCV NAT: Hepatitis C Virus Nucleic Acid Test	Negative/Non-Reactive
HCVAb: Hepatitis C Antibody	Negative/Non-Reactive
HBV NAT: Hepatitis B Virus Nucleic Acid Test*	Negative/Non-Reactive
HIV-1 NAT: Human Immunodeficiency Virus Type 1 Nucleic Acid Test	Negative/Non-Reactive
HIV 1/2 Ab: Human Immunodeficiency Virus Types 1/2 Antibody	Negative/Non-Reactive
RPR/STS or Equivalent: Syphilis	Confirmatory Negative/ Non-Reactive
HTLV I/II Ab: Human T-Lymphotropic Virus Types I/II Antibody**	Negative/Non-Reactive

* Not required for donors recovered prior to December 16, 2016. Performed as required by international laws and regulations.

**Not required for donors recovered after March 31, 2010. Performed as required by International laws and regulations.

Graft Sizes		
ViviGen Formable® Cellular Bone Matrix		
BL-1600-001	Small	1.3cc
BL-1600-002	Medium	5.4cc
BL-1600-003	Large	11.0cc
BL-1600-004	X-Large	16.0cc

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INSTRUCTIONS FOR USE
IT IS IMPORTANT TO READ AND UNDERSTAND THE FOLLOWING INSTRUCTIONS PRIOR TO CLINICAL USE. IMPROPER PREPARATION TECHNIQUE MAY ADVERSELY AFFECT HANDLING PROPERTIES AND/OR PERFORMANCE.

FROM FREEZER TO OPERATING ROOM

Do not remove ViviGen from the freezer until ready to begin thawing. Remove ViviGen from freezer and use one of three transport options:

Option 1: Thermal Transporter (15 minute transport time)

- Place ViviGen in thermal transporter and close (transporter allows the transportation of up to two boxes)
- Thawing must begin within 15 minutes of removal from freezer

Option 2: Original ViviGen Shipper (14 minute transport time)

- Place ViviGen in original packaging inside shipper immediately after removal from freezer
- Firmly insert foam block on top of ViviGen package and transport to O.R.
- Thawing must begin within 14 minutes of removal from freezer

Option 3: Original Packaging (8 minute transport time)

- Transport ViviGen in its original packaging in a secondary container
- Thawing must begin within 8 minutes of removal from freezer

MATERIALS NEEDED:

- 2 sterile basins (1 for thawing, 1 for the bio-implant)
- Warm (35°C to 39°C) sterile isotonic solution
- 2 Luer-Lock syringes (10cc syringes for 1cc and 5cc sizes, 20cc syringes for 10cc and 15cc sizes)
- Sterile 5% Dextrose in Lactated Ringer's Solution (room temperature)
- Sterile Scissors
- Sterile Thermometer

THAWING INSTRUCTIONS

STEP ONE:
Pour at least 2 liters of warm sterile isotonic solution in a sterile basin; starting temperature must be between 35°C to 39°C.

Note: Starting temperature Does Not need to be maintained during the thawing process.

STEP TWO:
Non-Sterile Team Member: Remove peel pouch from cardboard box. Open peel pouch and aseptically present the ported graft pouch directly to a Sterile Team Member.

STEP THREE:
Sterile Team Member: Completely submerge ported graft pouch in warm sterile isotonic solution.

STEP FOUR:
Continue thawing until the contents of the pouch flow freely (no more than 5 minutes). Remove the ViviGen pouch from the sterile isotonic solution and place on sterile field away from hot O.R. lights. Do not open pouch or extract cryopreservation solution until ready to implant.

NOTE: ViviGen can remain thawed in pouch with cryopreservation solution for maximum of 2 hours

STEP FIVE:
When ready to implant, attach appropriate size Luer-Lock syringe to the port and extract the cryopreservation solution contained within the pouch. When extracting the cryopreservation solution, hold the pouch vertically with Luer-Lock facing up. This will prevent any small bone particulate from entering the port.

STEP SIX: (OPTIONAL)
After removing cryopreservation solution, there is an option to rinse the pouch contents with a Lactated Ringer's solution containing 5% dextrose using the following volumes (see chart below). Do not detach the syringe from the port. Manually mix the contents of the pouch and 5% dextrose in Lactated Ringer's solution by gently massaging the pouch.

ViviGen Volume	Rinse Volume
1cc or Small	7.5cc
5cc or Medium	7.5cc
10cc or Large	15cc
15cc or X-Large	15cc

The optional rinsing step is meant to reduce, not eliminate, the residual concentration of cryopreservative solution in the final packaging. Caution should be exercised in any patient who has a known or suspected allergy to the reagents in the cryopreservative solution.

STEP SEVEN: (OPTIONAL)
Extract the 5% dextrose in Lactated Ringer's solution and detach the Luer-Lock syringe. When extracting the rinsing solution, hold the pouch vertically with the Luer-Lock facing up. This will prevent any small bone particulate from entering the port.

STEP EIGHT:
When ready to implant cut off the non-ported end of the pouch and dispense bone matrix in a sterile basin.

STEP NINE:
Mix the bone matrix thoroughly to obtain a more homogenous combination before implanting.

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1-888-847-7831 (inside the U.S.)
+1-757-464-4761 (outside the U.S.)
www.LifeNetHealth.org
Source Establishment: LifeNet Health CTO #100038

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63-0146.09