LifeNet Health® Biologics

# ViviGEN® MIS Cellular Bone Matrix and Delivery System

## INSTRUCTIONS FOR USE

### DESCRIPTION

ViviGen Cellular Bone Matrix is a formulation of cryopreserved, viable cortical cancellous bone matrix and demineralized bone. ViviGen is processed from donated human tissue, resulting from the generous gift of an individual or his/her family, and 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). It arrives in a cryopreservative solution containing Dimethyl Sulfoxide (DMSO) and Human Serum Albumin (HSA). ViviGen is intended for repair or reconstruction of musculoskeletal defects. ViviGen is packaged and delivered to the recipient in LifeNet Health's ViviGen MIS Delivery System. This delivery system consists of a cannula for containing and delivering the allograft bone material to the surgical site, and a delivery dispenser and plunger to express the graft material from the cannula.

### DEVICE INDICATIONS FOR USE

The ViviGen MIS Delivery System is intended to be used for the delivery of hydrated allograft bone graft material to an orthopedic surgical site.

### CONTRAINDICATIONS

Contraindications include, but are not limited to:

- ViviGen MIS Delivery System is contraindicated for use in filling closed voids/bony defects where undesired pressurization may occur.
- Use of the allograft 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 of allograft in immune compromised patients.
- Stand-alone use of allograft in load-bearing applications.

### WARNINGS AND PRECAUTIONS

Delivery System Warnings and Precautions include but are not limited to:

- Federal law (USA) restricts this device for use by a licensed clinician only.
- Delivery dispenser and cannula must be assembled for proper use and delivery of allograft material.
- Use on a single occasion for a single patient only. Delivery System may not be re-used.
- Single patient use with graft delivery dispenser recommended not to exceed nine cannula.

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. The following are warnings and precautions related to the use of the delivered allograft bone graft material:

- Use on a single occasion for a single patient only
- Residual reagents including Gentamicin Sulfate, Meropenem, Vancomycin, Ciprofloxacin, Anidulafungin, 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

It is the responsibility of the end user to document and maintain storage at these conditions.

**ViviGen MIS:** After removal from the shipper, the prefilled cannula 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 ($LN_2$). Short-term (15 minutes maximum) temperature excursions up to -60°C due to cycling or opening of freezer doors are acceptable.
**Delivery Dispenser:** Store at ambient room temperature. (15-30°C)

### 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).

### TISSUE QUALITY CONTROL TESTING

- Finished cryopreserved 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.

### TISSUE 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 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.

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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 PROPERTIES AND/OR PERFORMANCE.

Note: Assembly of separately packaged components is required. Both the pre-filled cannula and the delivery dispenser must be present in the operating room (O.R.) to successfully deliver ViviGen MIS graft material to the surgical site.

ViviGen MIS Cannula components (cannula and inner/outer pouches) are pre-sterilized prior to filling with allograft under aseptic conditions. ViviGen MIS Delivery Dispenser is packaged in double, inner and outer, sealed trays and is provided sterile.

## VIVIGEN MIS CANNULA – FROM FREEZER TO OPERATING ROOM

Multiple cannula(s) may be necessary to deliver adequate graft material during a procedure. Please identify the number of cannula that will be necessary prior to beginning the thawing procedure outlined below. Do not remove ViviGen MIS cannula(s) from the freezer until ready to begin thawing. Remove 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 three 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 FOR THAWING CANNULA:

- 1 sterile basin
- Warm (35°C to 39°C) sterile isotonic solution
- 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 pouches from cardboard box. Open outer peel pouch and aseptically present the inner pouch directly to a Sterile Team Member.

### STEP THREE:

Sterile Team Member: Place pouch in warm sterile isotonic solution.

### STEP FOUR:

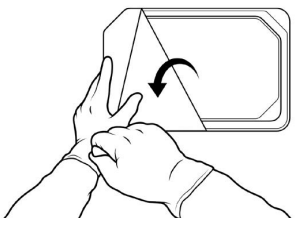
Continue thawing until the contents of the pouch are thawed, no more than 5 minutes. Remove the ViviGen pouch from the sterile isotonic solution and place on sterile field away from hot O.R. lights.

*NOTE: ViviGen can remain thawed in pouch for a maximum of 2 hours*

## DELIVERY SYSTEM – ASSEMBLY AND ALLOGRAFT DELIVERY

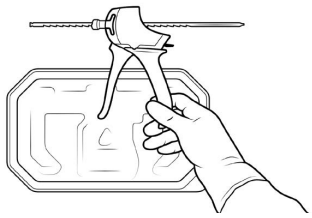
### STEP ONE:

Non-sterile Team Member: Remove delivery dispenser tray from box, open outer tray peel and aseptically present inner tray directly to a Sterile Team Member.



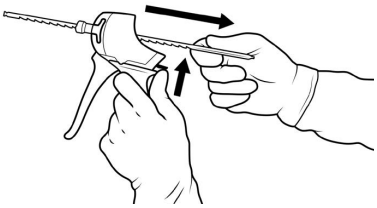
### STEP TWO:

Sterile Team Member: Open inner tray consisting of the delivery dispenser and plunger and remove the components.



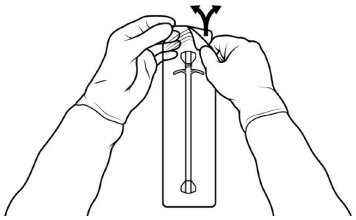
### STEP THREE:

Release the dispenser plunger by lifting the black release latch and pull the plunger to its rearmost position.



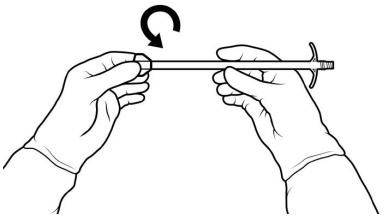
### STEP FOUR:

Open peel pouch containing thawed ViviGen MIS cannula.



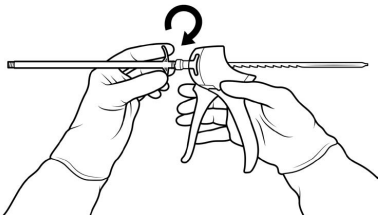
### STEP FIVE:

Unscrew and remove both caps from the cannula.



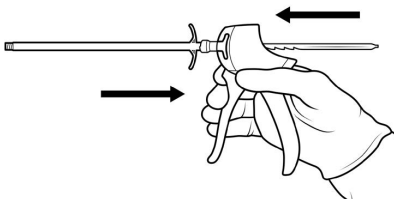
### STEP SIX:

Attach the cannula by screwing the proximal end that has a T shape or wings firmly onto the dispenser.



### STEP SEVEN:

The delivery system is now ready to be used. Pull the trigger repeatedly to dispense graft material to the desired implantation site.



### STEP EIGHT:

To remove empty cannula, release the dispenser plunger by lifting the black release latch and pull the plunger to its rearmost position. Unscrew the empty cannula and discard. Repeat assembly and delivery steps four through six when using multiple cannula during a procedure.

Manufactured by: LifeNet Health, 1864 Concert Drive, Virginia Beach, Virginia, 23453 USA
Source Establishment: LifeNet Health CTO #100038

For patent information, please visit: www.lifenethealth.org/patents



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