

ViviGen[®] MIS

Cellular Bone Matrix and Delivery System



Surgical Technique Guide

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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. It is a 361 Human Cells, Tissues, and Cellular and Tissue-based Product (HCT/P) as defined by the U.S. Food and Drug Administration in 21 CFR 1271.10. 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 MIS is packaged and delivered to the recipient in LifeNet Health's MIS delivery system. This delivery system consists of a cannula for containing and delivering the allograft bone graft material to the surgical site, and a delivery dispenser with 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 allograft in any patient who has a known or suspected allergy to any of the antibiotics and/or processing 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 cannulae.

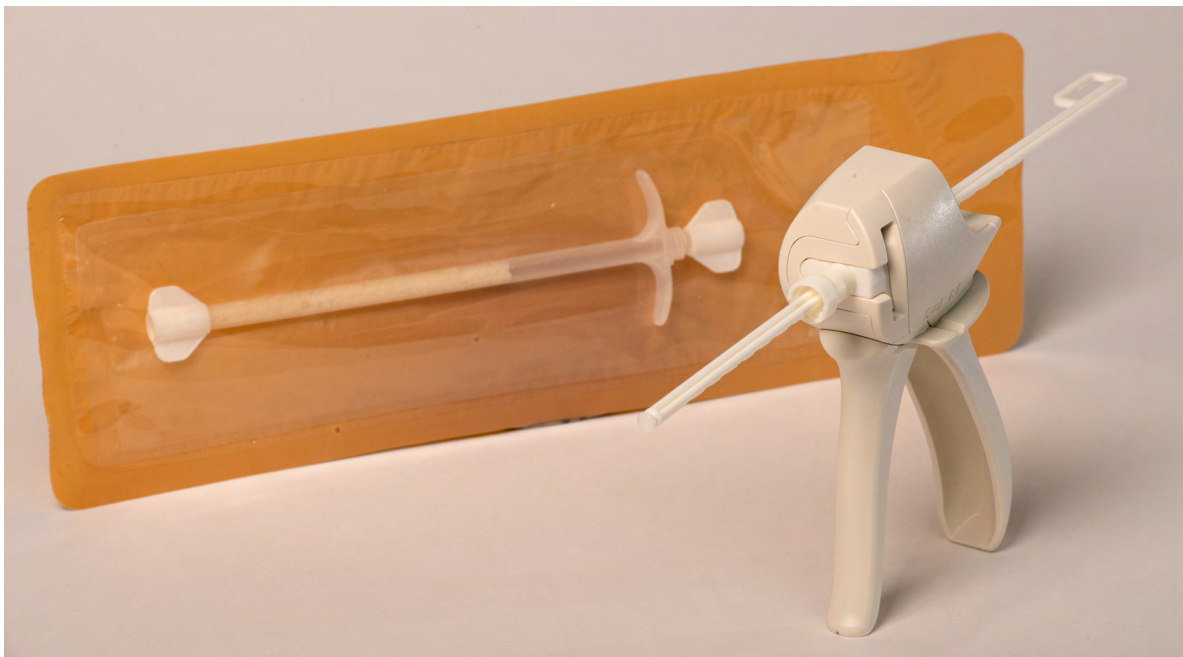
LifeNet Health employs stringent guidelines regarding donor tissue, processing treatment, and laboratory testing to reduce the risk of infectious agent transmission. As with any donor tissue, the potential for transmission of infectious agents exists. The following are warnings and precautions related 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, 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 storage requirements.
- Do not refreeze after thawing.

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ViviGen MIS is available as a procedurally focused bone grafting kit. The kit components consist of cryopreserved cannula and a separately packaged, sterile delivery dispenser. The following kit configurations are available to order. Both components—cannula and dispenser—are necessary to successfully extrude the tissue to the orthopedic surgical site.

Item Number	Description
BL-1900-KT3	Bilateral MIS Bone Grafting Kit
BL-1900-001	x3 Pre-filled Cannulae
BL-1900-GUN	x1 Delivery Dispenser
BL-1900-KT2	Unilateral MIS Bone Grafting Kit
BL-1900-001	x2 Pre-filled Cannulae
BL-1900-GUN	x1 Delivery Dispenser



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Procedurally Focused Solution

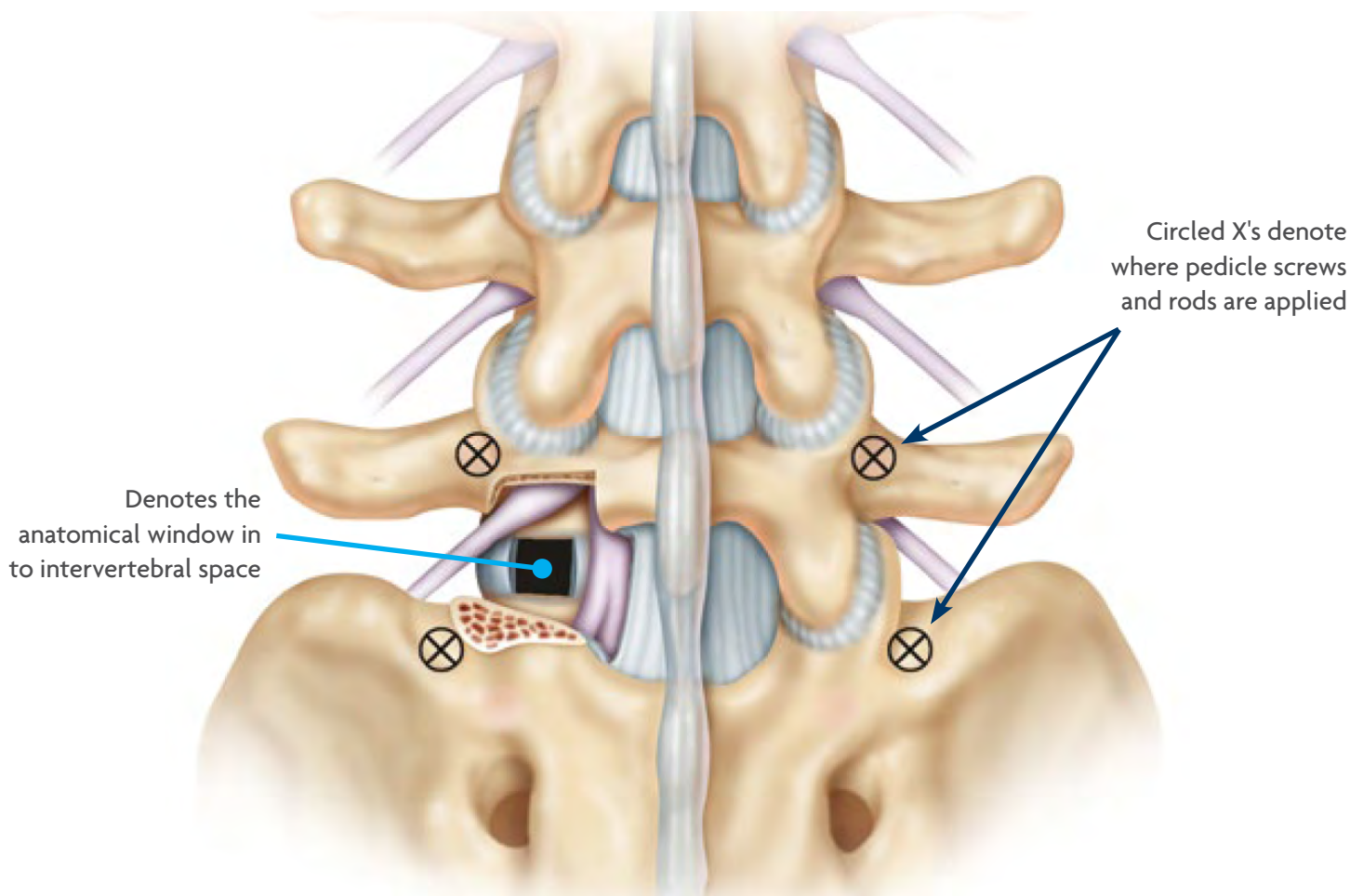
The kit components are configured to provide adequate bone graft material for the MIS Transforaminal Lumbar Interbody Fusion (TLIF) procedure. This procedure is typically performed through a small incision with an MIS-style retractor or tube. The AO Spine Foundation has an educational step-by-step guide highlighting the key steps in a MIS TLIF procedure.¹

Unilateral MIS Bone Grafting Kit

The unilateral kit provides two pre-filled cannulae for delivering ViviGen into the anterior portion of the intervertebral space.

Bilateral MIS Bone Grafting Kit

The bilateral kit provides three pre-filled cannulae. Two are still intended for delivering ViviGen into the intervertebral space. The third cannula provides graft material to be applied for posterolateral fusion of the contralateral side where pedicle screws and rods are typically applied.²



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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 graft material to the surgical site.

ViviGen MIS cannula is packaged in pre-sterilized cannula within pre-sterilized inner/outer pouches.

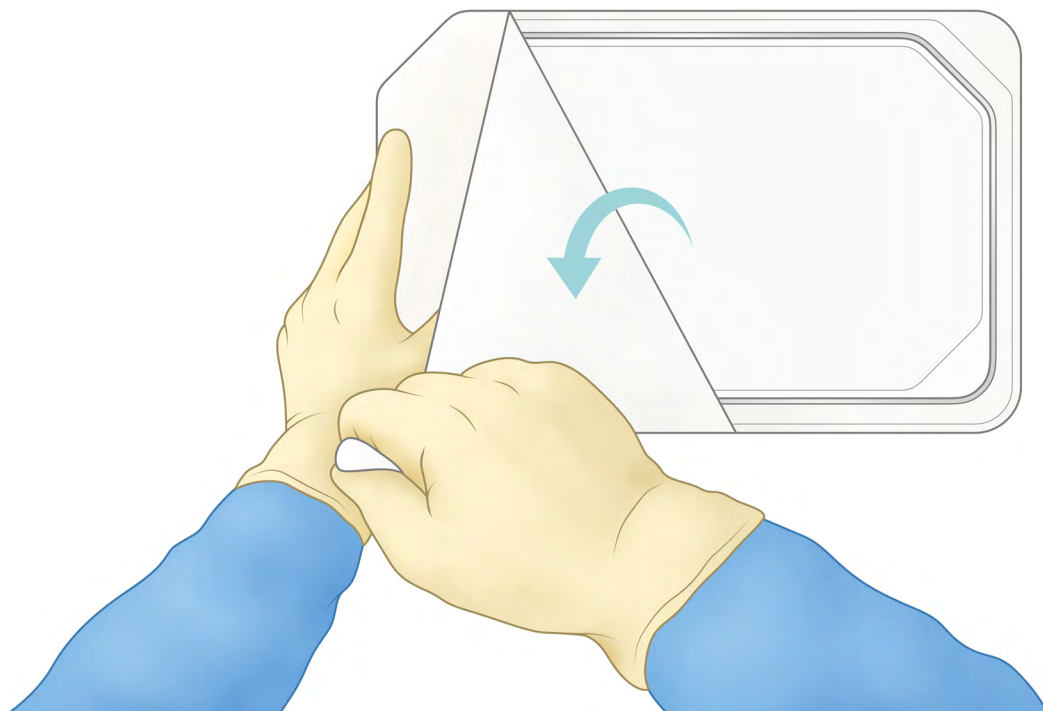
ViviGen MIS Delivery Dispenser is packaged in a double, inner and outer, sealed trays and is provided sterile.

Please refer to the Instructions for Use (IFU) for storage, thawing, and preparation steps

DELIVERY SYSTEM – ASSEMBLY AND ALLOGRAFT DELIVERY

STEP ONE:

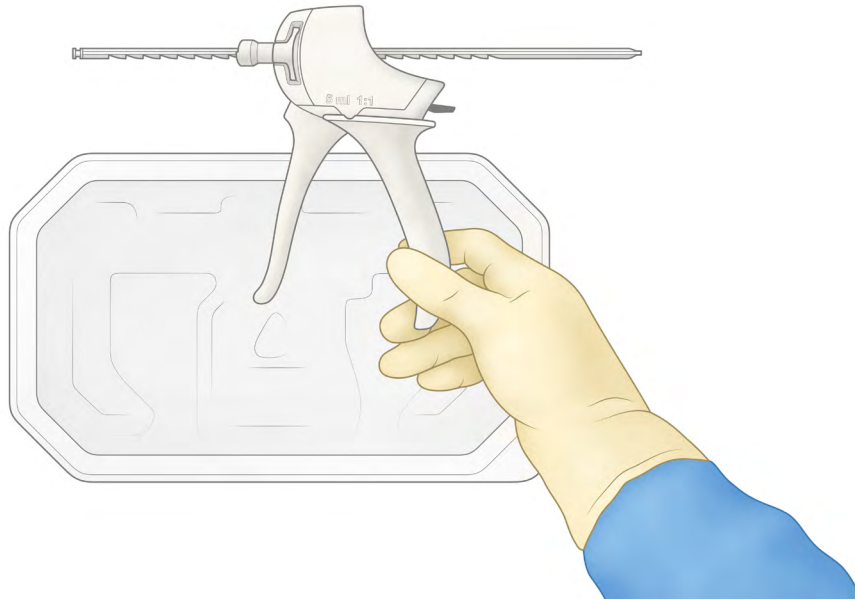
Non-Sterile Team Member: Remove delivery dispenser tray from box, open outer tray peel and aseptically present inner tray directly to a Sterile Team Member.



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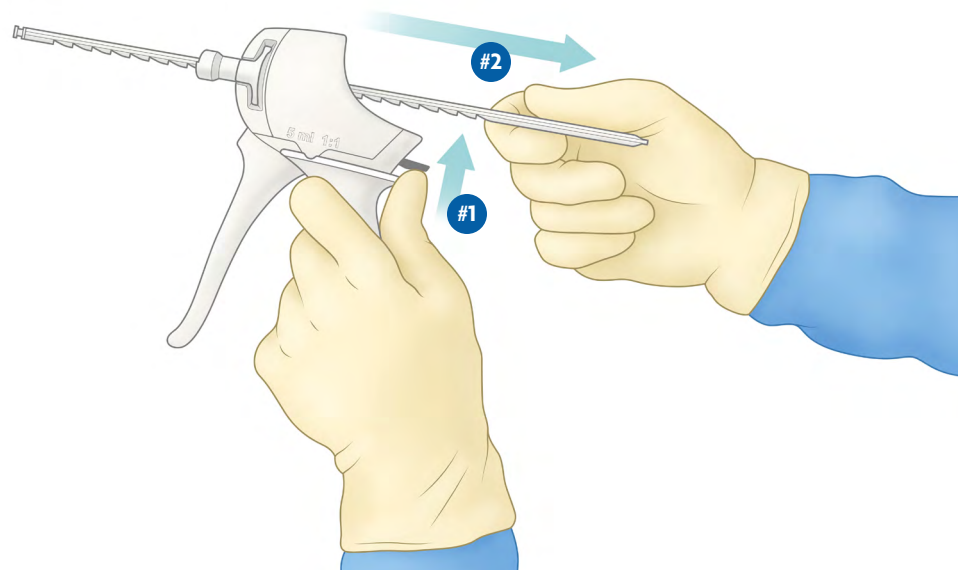
STEP TWO:

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



STEP THREE:

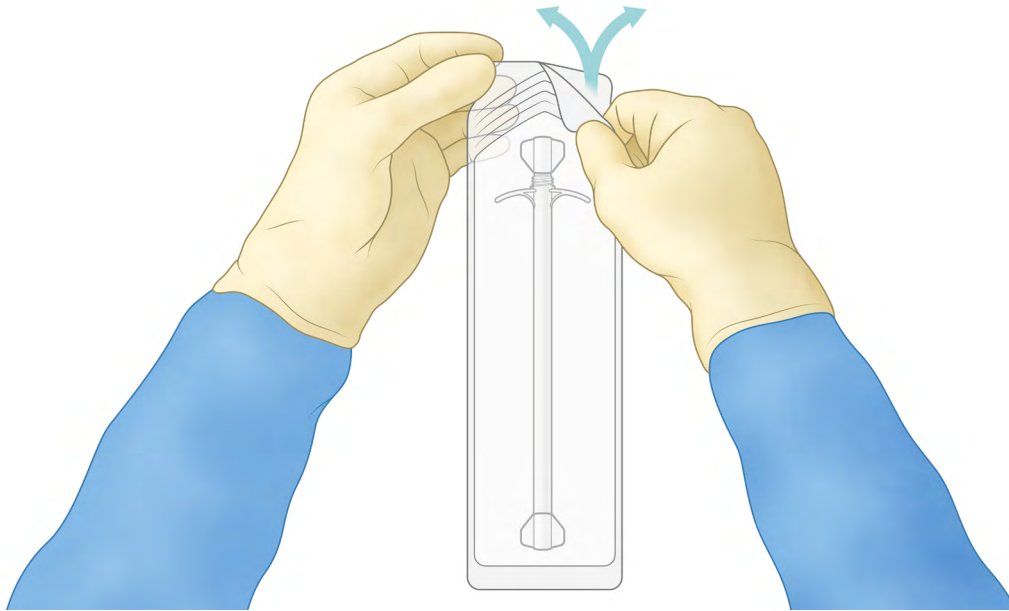
Release the dispenser plunger by lifting the black release latch #1 and pulling the plunger to its rearmost position #2. The dispenser has a stop and the plunger will not fall out at the rearmost position.



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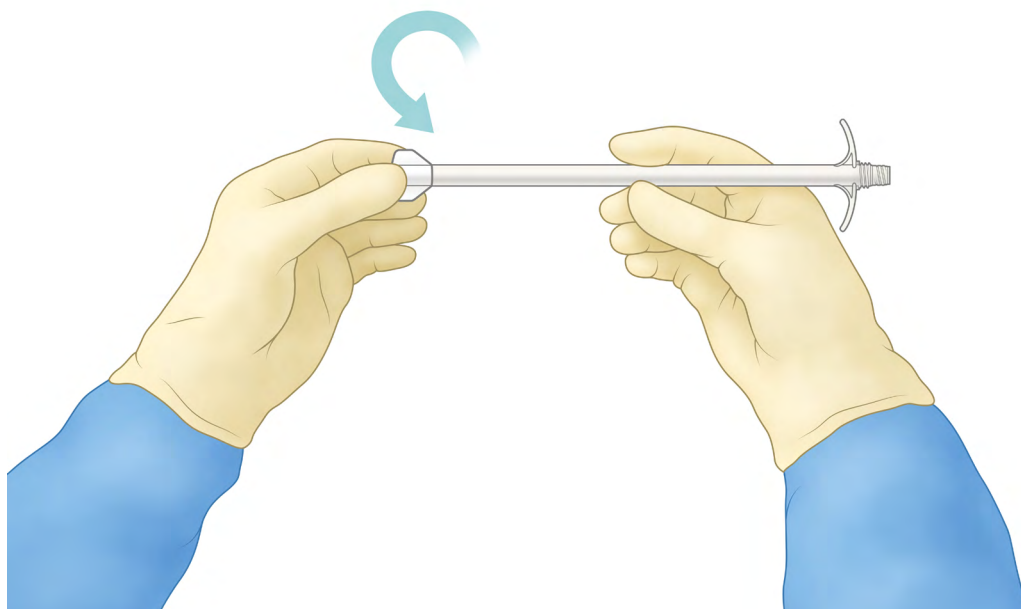
STEP FOUR:

Open peel pouch containing thawed ViviGen MIS cannula.



STEP FIVE:

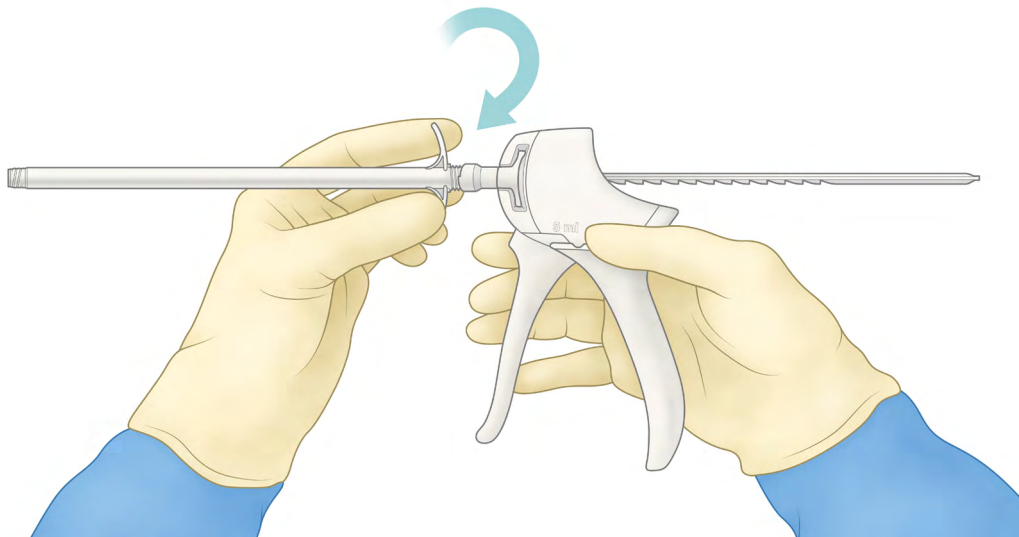
Unscrew and remove both caps from the cannula.



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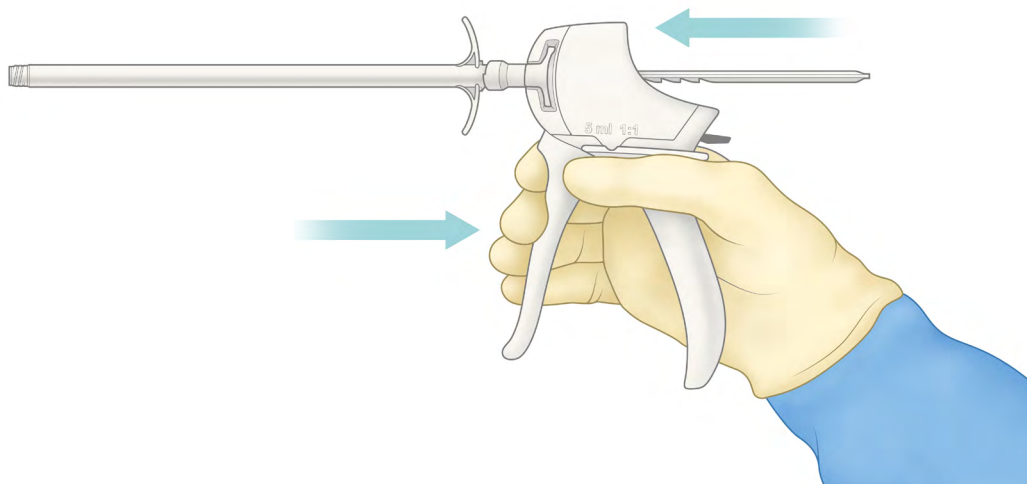
STEP SIX:

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 use. Pull the trigger repeatedly to dispense graft material to the desired implantation site. The plunger can be quickly advanced to contact tissue by pushing from the back.



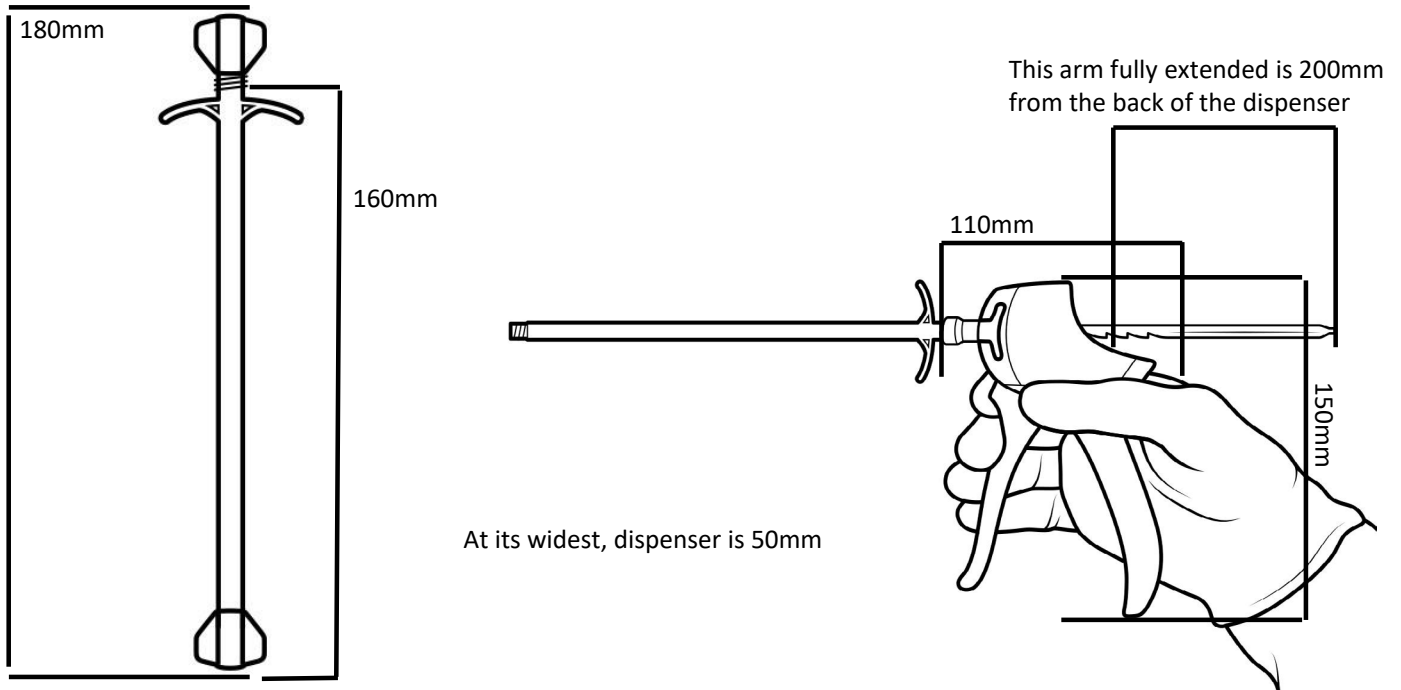
STEP EIGHT:

To remove an empty cannula, release the dispenser plunger by lifting the black release latch and pulling the plunger to its rearmost position. The plunger will not fall out at the rearmost position. Unscrew the empty cannula and discard. Repeat steps four through seven when using multiple cannulae during a procedure.

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VIVIGEN MIS SPECS AND MEASUREMENTS

Drawings not to scale.



REFERENCES:

1. Härtl R, Gelb D. Step-by-Step Guide: Key Steps in a MIS TLIF Procedure. AO Spine.
2. CONCORDE Interbody System for Transforaminal Lumbar Interbody Fusion (TLIF) Surgical Technique. DePuy Synthes Spine. 098052-180831 09/18

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