ViviGen® Cellular Bone Matrix
ViviGen Formable™ Cellular Bone Matrix

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:

1

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.

2

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.

3

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

4

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.

5

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.

6 (Optional*)

After removing cryopreservation solution, 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 and 5% Dextrose in Lactated Ringer's Solution by gently massaging the pouch.

7 (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.

8

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

9

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

Transportation Methods from -70 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

Rinsing Volume (Step 6)

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 DMSO in the final packaging. Caution should be exercised in any patient who has a known or suspected allergy to DMSO.

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