



V92™ is a viable allogeneic bone scaffold derived from bone marrow, in full compliance with FDA guidelines regarding human cells, tissues and cellular tissue-based products, and is intended for use in bone remodeling.

The scaffold is comprised of a proprietary blend of microparticulate cortical, cancellous and demineralized cortical allograft bone in optimum particle sizes ranging from 100-300 microns. Furthermore, V92™ processing preserves a cell population that includes marrow-isolated adult multilineage-inducible (MIAMI) cells. These primitive cells provide properties that in combination with the osteoinductive, osteoconductive, and osteogenic elements of the graft, enhance the patient's innate healing process.

V92™ provides the three key elements necessary for bone repair:

- Viable cells to support osteogenic healing processes
- Osteoinductive potential
- Three dimensional osteoconductive scaffold

Key Features:

- V92™ is an HCT/P 361 regulated viable allogeneic bone scaffold that is intended for use in bone remodeling
- Cell viability and functionality is preserved using a novel cryoprotectant that is free of exogenous proteins and DMSO
- Shelf life is 2 years from date of processing, stored at -65° to -80°C and shipped on dry ice
- Preparation time on back table is less than 20 minutes, and once prepared can sit for 2 hours without loss of cell viability or functionality
- V92™ is a safe, non-immunogenic alternative to autograft. Donors processed for V92™ undergo screening, testing and culturing that meet FDA guidelines

Tissue Tracking Instructions

It is the responsibility of the end-user or the clinician to provide UMTB Biomedical, Inc., with information pertaining to the traceability of the implanted tissue. For this purpose, the postage paid Tissue Utilization Report (TUR) card is provided with the allograft. Once the graft is implanted, peel off the small product labels provided on the product packaging and affix on the TUR card and applicable patient records. Complete the TUR card and mail to UMTB Biomedical, Inc., scan and email to turs@umtb.com or fax to 888.630.4321.

Complaints and Returns

Complaints should be reported to Paragon 28, Inc. at 888.728.1888.
Returns will not be accepted.

Ordering information:

ITEM NUMBER	PRODUCT DESCRIPTION
P01-V92-0100	V92 Cellular Bone Matrix 1.0 cc
P01-V92-0250	V92 Cellular Bone Matrix 2.5 cc
P01-V92-0500	V92 Cellular Bone Matrix 5.0 cc
P01-V92-1000	V92 Cellular Bone Matrix 10.0 cc

**To place an order, please contact:
info@paragon28.com**

4B Inverness Ct. E, Ste. 280
Englewood, CO 80112
888.728.1888 | www.paragon28.com



PROCESSED BY:
UMTB Biomedical, Inc.
1951 N.W. 7th Ave, Suite 200
Miami, FL 33136, U.S.A.
888.684.7783
305.356.0900 (fax)
umtb.com

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Caution: U.S. Federal Law restricts this device to sale by or on order of a physician.
P01-V92-SSPG RevA



PREPARATION GUIDE

Instructions for Use:

Storage requirements and preparation for use of V92™ Cellular Bone Matrix

The allograft has been cryopreserved and freeze-dried, sealed in its packaging container, and must be stored at -65°C or colder. It is the responsibility of the end-user to store the cells and tissue in appropriate storage conditions prior to further distribution or transplant. The allograft must be reconstituted prior to implantation. Once the inner package seal is broken, the allograft must be reconstituted and used within 2 hours of thawing. The allograft was processed and packaged aseptically and must be handled in an aseptic manner to prevent contamination.

Do not use if package integrity has been compromised.

Once the user breaks the seal, the graft must be transplanted (if appropriate) or discarded.

NOTE:

Implant within 2 hours of complete thawing of cell suspension and before expiration date on label. To prevent expiration, ensure adequate preparation time (up to 20 minutes).

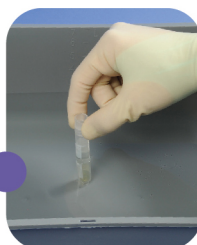
IMPORTANT:

Read the entire package insert (provided with the implant) before following this preparation guide.

For use in single patient, for a single procedure only.

- 1 Prepare a 37°C ± 2°C sterile saline or sterile water bath on the sterile field for thawing the cell vial. The prepared room temperature irrigation bath can also be used.
- 2 An unsterile member of the operating room team should open the box for the cells and retrieve the pouch containing the cell vial.
- 3 The unsterile team member will open the outer pouch and present the sterile inner pouch containing the cell vial to the sterile field.

- 4 Remove the cell vial from the inner pouch on the sterile field.
- 5 Place the vial containing the cell solution upright in the bath until the contents of the cell vial have completely thawed. Add sterile saline (3 mL to the 5 cc size, 1.5 mL to the 2.5 cc size) to the vial containing the frozen cells.
- 6 An unsterile member of the operating room team will open the box for the microparticulate bone and retrieve the pouch containing the microparticulate jar.



ON STERILE FIELD



- 7 This unsterile team member will open the outer pouch and present the inner pouch containing the microparticulate jar to the sterile field.
- 8 Remove the microparticulate jar from the inner pouch on the sterile field.
- 9 After the contents of the cell vial have completely thawed, carefully invert the cell vial several times. Remove the liner from the inside of the microparticulate jar and pour the contents of the thawed cell vial into the microparticulate jar.



ON STERILE FIELD



ON STERILE FIELD



ON STERILE FIELD

- 10 Mix the contents of the cell vial and the microparticulate bone thoroughly.
- 11 Cap the jar of prepared graft and allow to sit for 15 minutes.
- 12 The allograft is now ready for implantation. The reconstituted allograft must be transplanted within 2 hours of thawing.



ON STERILE FIELD



ON STERILE FIELD

