V92™ CELLULAR BONE MATRIX

DISTRIBUTED BY:
PARAGON 28, INC.
4B INVERNESS CT. E, STE 280
ENGLEWOOD, CO 80112
TEL: (888) 728-1888 | FAX: (888) 728-1220
www.paragon28.com

PROCESSED BY:
UMTB BIOMEDICAL INC
1951 NW. 7th AVENUE SUITE 20
MIAMI, FLORIDA USA 33136
TEL: (888) 6[illegible]-7783 | FAX: (305) 356-0900
www.umtb.com

QUALITY ASSURANCE STATEMENT AND PREPARATION FOR USE INSTRUCTIONS

80-118 01 12/2015

The enclosed tissue is for single patient use only. There is no charge for the tissue. Accompanying charges cover excision and processing expenses.

The enclosed donated human-tissue allograft distributed by Paragon 28, Inc. and manufactured by UMTB Biomedical, Inc. is for use by, or on order for, a licensed physician. The tissue was recovered and processed aseptically, following rigorous and technical quality assurance standards, in a controlled environment. The donor and donor tissue have been subjected to extensive biological and medical screening to guard against the possibility of recipient exposure to or transmission of, infectious processes such as HIV, Hepatitis, or exclusionary medical conditions. These screening procedures are performed in accordance with standards, regulations, statutes and/or directives of the American Association of Tissue Banks (AATB)[1], the U.S. Food and Drug Administration (FDA)[2], State Licensing Agencies[3,4,5,6,7], the European Union[9], and Health Canada[10]. Additional infectious disease testing and screening in excess of the requirements by the AATB and FDA may have been completed. Data has been reviewed by a Medical Director or Associate Medical Director (licensed physician) of UMTB Biomedical, Inc. and the allograft has been deemed suitable for transplantation.

APPLICATIONS FOR USE

This tissue is restricted to homologous use as a bone void filler. This tissue is for single patient use only and is restricted to use by a licensed physician.

DONOR SCREENING & TESTING

1. A qualified donor blood sample was tested using test kits licensed (if available) for donor screening by a laboratory certified/registered to perform such testing in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and FDA. All required infectious disease tests listed below were found to be **nonreactive or negative**.

TEST	SYMBOL
-Human Immunodeficiency Virus (HIV)	
HIV-1/2 Antibodies	HIV-1/2-Ab
Nucleic Acid Test for HIV-1 RNA	HIV-1 NAT
-Hepatitis B Virus (HBV)	
HBV Surface Antigen	HBsAg
HBV Core Antibody (IgG & IgM)	HBcAb
Nucleic Acid Test for HBV DNA (if applicable)	HBV NAT
-Hepatitis C Virus (HCV)	
HCV Antibody	HCVAb
Nucleic Acid Test for HCV RNA	HCV NAT
-Human T Cell Lymphotrophic Virus I/II (if applicable)	
HTLV-I/II Antibody	HTLV-I/II-Ab*
-Syphilis – Rapid Plasma Reagin Screen	RPR**
or	
T. Pallidum IgG	T. pallidum IgG
-Cytomegalovirus	CMV (IgM)

*Tissues from a donor with a reactive result for the HTLV-I/II Antibody test are cleared for transplantation use only when the result from a confirmatory assay is nonreactive.

**Tissues from a donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, are cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

2. Non-required screening tests for exposure to other viruses or parasites such as those listed below may have been completed on the donor by other agencies involved in the donation process. A negative/nonreactive result is not required for these tests; however, all donors are evaluated on a case-by-case basis by the Medical Director or Associate Medical Director.

-Epstein Barr Virus	EBV Ab (IgG & IgM)
-Toxoplasma gondii	Toxoplasma Ab (IgG & IgM)
-Trypanosoma cruzi	T. cruzi Ab (IgG & IgM)

3. Donors may undergo additional medical evaluation and screening for non-specific infections, malignancies, and exclusionary medical conditions via autopsies performed by a licensed pathologist.
4. The accompanying allograft has been subjected to extensive **microbiologic studies** at each phase of development: recovery, processing, and final packaging.
5. There are no known contraindications.

The tissue and cells were exposed to Gentamicin and either Vancomycin or Bacitracin. Although the allograft was rinsed with sterile saline and (or) sterile water throughout processing, traces of the antibiotics, Hydrochloric Acid, Hydrogen Peroxide, and Phosphate Buffer solutions may remain in the product. Individuals with known sensitivities to any of these agents should not receive this allograft.

Although all efforts have been made to ensure the safety of the allograft, current technologies may not preclude the transmission of all diseases.

Any adverse outcomes potentially attributable to the tissue must be reported immediately to UMTB Biomedical, Inc. at the telephone number indicated above.

OVER

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.

INSTRUCTIONS FOR USE

1. Prepare a 37°C ± 2°C sterile saline or sterile water bath for thawing the cell vial(s). The prepared room temperature irrigation bath can also be used.
2. Open the box for the cells and retrieve the pouch containing the cell vial(s).
3. Open the outer pouch and present the inner pouch containing the cell vial(s) to the sterile field.
4. Remove the cell vial from the inner pouch using standard sterile technique.
5. Add sterile saline to the vial(s) containing the frozen cells; refer to the table below for specific amounts for each size. Place the vial(s) containing the cell solution upright in the bath until the contents of the cell vial(s) have completely thawed.

Size	2.5 cc	5 cc
Amount Per Vial	1.5 mL	3 mL
Number of Vials	1	1

6. Open the box for the microparticulate bone and retrieve the pouch containing the microparticulate jar.
7. 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 using standard sterile technique.
9. After the contents of the cell vial(s) have completely thawed, carefully invert the cell vial(s) several times. Remove the liner from the inside of the microparticulate jar and pour the contents of the thawed cell vial(s) into the microparticulate jar.
10. Mix the contents of the cell vial(s) 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.

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 e-mail to turs@umtb.com or Fax to (888) 630-4321.

COMPLAINTS AND RETURNS

Complaints should be reported to Paragon 28, Inc. at TEL (888)-728-1888 in a timely manner. Returns will not be accepted .

References

1. Standards for Tissue Banking; American Association of Tissue Banks, 13th Edition, Issued February 29, 2012. **(Accredited)**
2. Code of Federal Regulations, Title 21 Part 1271 – Donor Eligibility and Good Tissue Practice (GTP) regulations for Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps), U.S. Food and Drug Administration, Final Rule, April 1, 2010. **(Registered)**
3. Florida Administrative Code Chapter 59A, Regulations of the Agency for Health Care Administration of the State of Florida, 2008. **(Certificate Issued)**
4. Part 52 of Title 10 (Health) of the Official Compliance of Codes, Rules & Regulations of the State of New York, February 24, 2007. **(Licensed)**
5. Title 10 Subtitle 50 Chapter 01 of the Official Compliance Codes, State of Maryland Department of Health and Mental Hygiene, December 1999. **(Permit Issued)**
6. Chapter 4.1 & Chapter 4.2 of the California Health and Safety Code, State of California Department of Health Services, January 2011. **(Licensed)**
7. Chapter 28 of Title 16 Health and Safety Delaware Code, February 22, 2011. **(Registered)**
8. Accreditation Program: Hospital Transplant Safety, The Joint Commission on Accreditation of Healthcare Organizations, 2008. **(Licensing Not Applicable)**
9. Commission Directive 2006/17/EC of 8 February 2006; Directive 2004/23/EC, Official Journal of the European Union, February 2006. **(Pending Registration)**
10. SOR/2007-118, Safety of Human Cells, Tissues and Organs for Transplantation Regulations of the Food and Drugs Act, Minister of Justice of Canada, December 2012. **(Registered)**

DISTRIBUTED BY:
PARAGON 28, INC.
4B INVERNESS CT. E, STE 280, ENGLEWOOD, CO 80112
TEL: (888) 728-1888 | FAX: (888) 728-1220
www.paragon28.com

PROCESSED BY:
UMTB BIOMEDICAL, INC.
1951 N.W. 7TH AVENUE, SUITE 200, MIAMI, FLORIDA USA 33136
TEL: (888) 684-7783 | FAX: (305) 356-0900
www.umtb.com

80-118 01 12/2015
P01-IFU-0003 RevA

V92™ CELLULAR BONE MATRIX

DISTRIBUTED BY:
PARAGON 28, INC. Paragon
4B INVERNESS CT. E, STE 280
ENGLEWOOD, CO USA 80112
TEL: (888) 728-1888 | FAX: (888) 728-1220
www.paragon28.com

PROCESSED BY:
UMTB BIOMEDICAL INC.
1951 N.W. 7th AVENUE, SUITE 200
MIAMI, FLORIDA USA 33136
TEL: (888) 684-7783 | FAX: (305) 356-0900
www.vivex.com

QUALITY ASSURANCE STATEMENT AND
PREPARATION FOR USE INSTRUCTIONS

80-118 02 02/2016

The enclosed tissue is for single patient use only. There is no charge for the tissue. Accompanying charges cover excision and processing expenses.

The enclosed donated human-tissue allograft distributed by Paragon 28, Inc. and manufactured by UMTB Biomedical, Inc. is for use by, or on order for, a licensed physician. The tissue was recovered and processed aseptically, following rigorous technical and quality assurance standards, in a controlled environment. The donor and donor tissue have been subjected to biological and medical screening to guard against the possibility of recipient exposure to, or transmission of, infectious processes such as HIV, Hepatitis, or exclusionary medical conditions. Data has been reviewed by a Medical Director or Associate Medical Director (licensed physician) of UMTB Biomedical, Inc. and the allograft has been deemed suitable for transplantation.

APPLICATIONS FOR USE

This tissue is restricted to homologous use as a bone void filler. This tissue is for single patient use only and is restricted to use by a licensed physician.

DONOR SCREENING & TESTING

1. A qualified donor blood sample was tested using test kits licensed (if available) for donor screening by a laboratory certified/registered to perform such testing in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicaid and Medicare Services. All required **infectious disease tests** listed below were found to be **nonreactive or negative.**

TEST	SYMBOL
-Human Immunodeficiency Virus (HIV)	
HIV-1/2 Antibodies	HIV-1/2-Ab
Nucleic Acid Test for HIV-1 RNA	HIV-1 NAT
-Hepatitis B Virus (HBV)	
HBV Surface Antigen	HBsAg
HBV Core Antibody (IgG & IgM)	HBcAb
Nucleic Acid Test for HBV DNA (if applicable)	HBV NAT
-Hepatitis C Virus (HCV)	
HCV Antibody	HCVAb
Nucleic Acid Test for HCV RNA	HCV NAT
-Human T Cell Lymphotrophic Virus I/II (if applicable)	
HTLV-I/II Antibody	HTLV-I/II-Ab*
-Syphilis – Rapid Plasma Reagin Screen	RPR**
or	
T. Pallidum IgG	T. pallidum IgG
-Cytomegalovirus	CMV (IgM)

*Tissues from a donor with a reactive result for the HTLV-I/II Antibody test are cleared for transplantation use only when the result from a confirmatory assay is nonreactive.

**Tissues from a donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, are cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

2. Non-required screening tests for exposure to other viruses or parasites such as those listed below may have been completed on the donor by other agencies involved in the donation process. A negative/nonreactive result is not required for these tests; however, all donors are evaluated on a case-by-case basis by the Medical Director or Associate Medical Director.

-Epstein Barr Virus	EBV Ab (IgG & IgM)
-Toxoplasma gondii	Toxoplasma Ab (IgG & IgM)
-Trypanosoma cruzi	T. cruzi Ab (IgG & IgM)

3. Donors may undergo additional medical evaluation and screening for non-specific infections, malignancies, and exclusionary medical conditions via autopsies performed by a licensed pathologist.
4. The accompanying allograft has been subjected to **microbiologic studies** at each phase of development: recovery and final packaging.
5. There are no known contraindications.

The tissue and cells were exposed to Gentamicin and either Vancomycin or Bacitracin. Although the allograft was rinsed with sterile saline and (or) sterile water throughout processing, traces of the antibiotics, Hydrochloric Acid, Hydrogen Peroxide, and Phosphate Buffer solutions may remain in the product. Individuals with known sensitivities to any of these agents should not receive this allograft.

Although all efforts have been made to ensure the safety of the allograft, current technologies may not preclude the transmission of all diseases.

Any adverse outcomes potentially attributable to the tissue must be reported immediately to UMTB Biomedical Inc. at the TEL (888) 684-7783.

OVER

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.

INSTRUCTIONS FOR USE

1. Prepare a 37°C ± 2°C sterile saline or sterile water bath for thawing the cell vial(s). The prepared room temperature irrigation bath can also be used.
2. Open the box for the cells and retrieve the pouch containing the cell vial(s).
3. Open the outer pouch and present the inner pouch containing the cell vial(s) to the sterile field.
4. Remove the cell vial(s) from the inner pouch using standard sterile technique.
5. Add sterile saline to the vial(s) containing the frozen cells; refer to the table below for specific amounts for each size. Place the vial(s) containing the cell solution upright in the bath until the contents of the cell vial(s) have completely thawed.

Size	1 cc	2.5 cc	5 cc	10 cc
Amount Per Vial	0.6 mL	1.5 mL	3 mL	3 mL
Number of Vials	1	1	1	2

6. Open the box for the microparticulate bone and retrieve the pouch containing the microparticulate jar.
7. 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 using standard sterile technique.
9. After the contents of the cell vial(s) have completely thawed, carefully invert the cell vial(s) several times. Remove the liner from the inside of the microparticulate jar and pour the contents of the thawed cell vial(s) into the microparticulate jar.
10. Mix the contents of the cell vial(s) 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.

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 e-mail to turs@umtb.com or Fax to (888) 630-4321.

COMPLAINTS AND RETURNS

Complaints should be reported to Paragon 28, Inc. at TEL (888)-728-1888 in a timely manner. Returns will not be accepted.

DISTRIBUTED BY:

PARAGON 28, INC.
4B INVERNESS CT. E, STE 280, ENGLEWOOD, CO USA 80112
TEL: (888) 728-1888 | FAX: (888) 728-1220
www.paragon28.com

PROCESSED BY:

UMTB BIOMEDICAL, INC.
1951 N.W. 7TH AVENUE, SUITE 200, MIAMI, FLORIDA USA 33136
TEL: (888) 684-7783 | FAX: (305) 356-0900
www.vivex.com

V92™ Cellular Bone Matrix

DONATED HUMAN TISSUE

RESTRICTED TO USE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PROFESSIONAL (physician, dentist, podiatrist, optometrist, nurse practitioner or physician assistant).

80-118 03 12/2016
P01-IFU-0003 RevC

V92 Cellular Bone Matrix is a bone allograft that consists of a bone particulate component and a cell component. The bone particulate component is derived from mineralized and demineralized bone particulates.

V92 Cellular Bone Matrix has been processed using aseptic techniques. The bone particulate component of the allograft has been treated with an antimicrobial solution (containing Gentamicin and either Vancomycin or Bacitracin), hydrogen peroxide, and hydrochloric acid solutions. Although the allograft was rinsed with sterile saline and (or) sterile water throughout processing, traces of the antibiotics, hydrochloric acid, and hydrogen peroxide solutions may remain in the product The bone particulate component has been lyophilized and aseptically packaged in a tear pouch within a peel pouch configuration and frozen.

The cell component has been treated with an antimicrobial solution (containing Gentamicin and either Vancomycin or Bacitracin) and frozen with a 100% polyampholyte-based cryoprotectant. The cell component has been aseptically packaged in a tear pouch within a peel pouch configuration.

All of the respective components of V92 Cellular Bone Matrix have been packaged in one single outer container.

INTENDED USE
V92 Cellular Bone Matrix is intended for use as a bone void filler.

CONTRAINDICATIONS
V92 Cellular Bone Matrix is contraindicated in patients with known sensitivities to Gentamicin, Vancomycin, Bacitracin, hydrochloric acid, hydrogen peroxide or polyampholytes.

DONOR ELIGIBILITY
V92 Cellular Bone Matrix is recovered from qualified donors and processed using aseptic techniques in accordance with federal, state, and/or international regulations and to the standards of the American Association of Tissue Banks. The donors have been screened and tested for communicable disease risks and other exclusionary medical conditions. The results of these donor screenings and testing have been reviewed by the Medical Director (or licensed physician designee) of UMTB Biomedical, Inc. and the donors have been deemed suitable for transplantation.

Communicable disease testing was performed by an FDA-registered laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions. Results from the following infectious disease tests were found to be nonreactive or negative:

Human Immunodeficiency Virus (HIV)
HIV-1/2 Antibodies (HIV-1/2-Ab)
Nucleic Acid Test for HIV-1 RNA (HIV-1 NAT)
Hepatitis B Virus (HBV)
HBV Surface Antigen (HBsAg)
HBV Core Antibody (IgG & IgM) (HBcAb)
Nucleic Acid Test for HBV DNA (if performed) (HBV NAT)
Hepatitis C Virus (HCV)
HCV Antibody (HCVAb)
Nucleic Acid Test for HCV RNA (HCV NAT)
Human T Cell Lymphotrophic Virus I/II* (if performed)
HTLV-I/II (Antibody HTLV-I/II-Ab)
Syphilis**
Rapid Plasma Reagin (RPR) Screen
T. Pallidum IgG

*A donor with a reactive result for the HTLV-I/II Antibody test is suitable for use only when the result from a confirmatory assay is nonreactive.
**A donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, is suitable for use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

Screening tests for exposure to other viruses or parasites such as those listed below may have been completed. A negative/nonreactive result is not required for these tests, however, all results are evaluated on a case-by-case basis by the Medical Director (or licensed physician designee).

Cytomegalovirus
CMV Ab (IgG & IgM)
Epstein Barr Virus
EBV Ab (IgG & IgM)
Toxoplasma gondii
Toxoplasma Ab (IgG & IgM)
Trypanosoma cruzi
T. cruzi Ab (IgG & IgM)

WARNINGS
The donors of V92 Cellular Bone Matrix have been screened and tested for relevant communicable diseases and disease agents in compliance with the FDA regulations relating to human cells, tissues, and cellular and tissue-based products (21 CFR part 1271). V92 Cellular Bone Matrix was processed using aseptic techniques and microbiologically tested. Although all efforts have been made to ensure the safety of the allograft, there is no assurance that this allograft is free from all infectious diseases or microbial contamination.

DO NOT RE-FREEZE the allograft by any method.

FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY.

DO NOT STERILIZE the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide or other chemical sterilants may render the allograft unfit for use.

PRECAUTIONS
V92 Cellular Bone Matrix was processed and packaged using aseptic techniques and must be handled in an aseptic manner to prevent contamination.

80-118 03 12/2016
P01-IFU-0003 RevC

ADVERSE EVENTS

Allogeneic cells or tissues can induce an immunologic response in the recipient. The possibility that a patient may develop alloantibodies should be considered for any patient who might be a future recipient of allograft tissue or cells.

Possible adverse events may include: immunologic response, transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, hepatitis, syphilis, or microbial contaminants.

STORAGE

V92 Cellular Bone Matrix must be stored at -65˚C or colder. It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use and to track expiration dates accordingly. Appropriate inventory control should be maintained so that the allograft with the earlier expiration date is preferentially used and expiration is avoided.

ALLOGRAFT PREPARATION

DO NOT USE THE ALLOGRAFT if the pouch integrity has been compromised.

ONCE THE CONTAINER SEAL HAS BEEN COMPROMISED, the allograft shall be either transplanted, if appropriate, or otherwise discarded.

ONCE OPENED, the allograft must be reconstituted and used within 4 hours of thawing.

THE CHEVRON PEEL POUCHES ARE NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

Step 1: Prepare a sterile saline or sterile water bath (37°C +/- 2°C or ambient temperature) for thawing the cell vial(s).

Step 2: Remove the chevron peel pouch containing the cell vial(s) from the outer container.

Step 3: Utilizing aseptic technique, peel open the chevron peel pouch containing the cell vial(s) from the chevron end and present the inner pouch containing the cell vial(s) to the operative field.

Step 4: Remove the cell vial(s) from the inner pouch using standard aseptic technique.

Step 5: Add sterile saline to the vial(s) containing the frozen cells according to Table 1:

Size	1 cc	2.5 cc	5 cc	10 cc
Saline Volume per Vial	0.6 mL	1.5 mL	3 mL	3 mL
Number of Vials	1	1	1	2

Table 1 –Formulation Guide

Step 6: Place the vial(s) containing the cell solution in the bath for 3-5 minutes or until the contents of the cell vial(s) have completely thawed (i.e. cells are in a liquid state with no visible crystals remaining).

Step 7: While the cell(s) vials are thawing, remove the chevron peel pouch containing the bone particulate jar and spatula.

Step 8: Utilizing aseptic technique, peel open the chevron peel pouch from the chevron end and present the inner pouch containing the bone particulate jar and spatula to the operative field.

Step 9: Remove the bone particulate jar and spatula from the inner pouch using standard aseptic technique.

Step 10: After the contents of the cell vial(s) have completely thawed, carefully invert the cell vial(s) several times. Remove the liner from the inside of the bone particulate jar and pour the contents of the thawed cell vial(s) into the bone particulate jar.

Step 11: Using the spatula, mix the contents of the cell vial(s) and the bone particulate thoroughly.

Step 12: The jar containing the prepared allograft should be capped until ready for use and may be stored for 4 hours from time of initial cell thaw.

RECIPIENT INFORMATION

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide UMTB Biomedical, Inc. with information pertaining to the traceability of the allograft used. For this purpose, the postage paid Tissue Utilization Report (TUR) card is provided with the allograft. Once the allograft is used, 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 e-mail to turs@umtb.com, or fax to (888) 630-4321.

ADVERSE OUTCOME AND COMPLAINT REPORTING

Adverse outcomes potentially attributable to V92 Cellular Bone Matrix should be promptly reported to UMTB Biomedical, Inc. at (888) 684-7783. Any other complaints should be promptly reported to Paragon 28, Inc. at (855) 786-2828.

RETURNED GOODS POLICY

Returns will not be accepted for V92 Cellular Bone Matrix.

Exclusively foot & ankle Paragon 28®

Distributed by:
Paragon 28, Inc.
4B Inverness Ct. E, Suite 280
Englewood, Colorado USA
TEL: (855) 786-2828
FAX: (888) 728-1220
www.paragon28.com

Manufactured by:
UMTB Biomedical, Inc.
1951 N.W. 7th Avenue, Suite 200
Miami, Florida USA 33136

80-118 03 12/2016
P01-IFU-0003 RevC