# BEAST 100™ ALLOGRAFT

*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

## QUALITY ASSURANCE STATEMENT AND PREPARATION FOR USE INSTRUCTIONS

**80-147 01 05/2016**
**P01-IFU-0006 RevA**

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 processed 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

BEAST 100™ Allograft 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 (CMS). 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 |

*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 performed 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.

| | |
|---|---|
| -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) |

3. The accompanying allograft has been subjected to **microbiologic studies** at each phase of development: recovery and final packaging.
4. The components of this allograft have positive OsteoInductive (01) testing results.
5. There are no known contraindications.

**The tissue was 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. As with any surgical procedure, the potential for infection exists.*

**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 FREEZE DRIED ALLOGRAFT**

The allograft is provided in a sterile syringe, which is sealed in its packaging container. The allograft must be stored at ambient temperature. It is the responsibility of the end-user to store tissues in appropriate storage conditions prior to further distribution or transplant. The allograft is ready for use and thus, does not require thawing or mixing. Once the inner package seal is broken, the allograft must be used within 24 hours. The allograft is intended for single patient use only.

*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**

The allograft is provided in a sterile syringe and aseptically packaged in one tear-pouch and one peel pouch and secured in an outer packaging to ensure allograft integrity. THE INNER POUCH IS CONSIDERED STERILE.

1. Remove the graft from the outer packaging.
2. Inspect the pouch packaging. DO NOT USE if the packaging is damaged, if elements are missing or appear to have been tampered with, if the labeling is illegible, or if the expiration date occurs in the past.
3. Utilizing aseptic technique, from the chevron end, peel open the outer peel pouch and present the inner pouch to the sterile field.
4. Locate the tear notch on the inner pouch and tear open.
5. Remove cap from syringe tip or remove the syringe end cap completely.
6. Apply pressure to the plunger to extrude the allograft.
7. Mold into desired shape and press into defect.

**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. If for any reason tissue must be returned, a return authorization is required from Paragon 28 Customer Service prior to shipping. If the plastic packaging surrounding the graft has been opened or compromised, returns will not be accepted. It is the responsibility of the health care institution returning the tissue to adequately package and label the tissue for return shipment.

**ORDERS AND INQUIRIES**

For additional information about BEAST 100™ Allograft or to place an order, contact Paragon 28 Customer Service at:

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FAX: (888) 728-1220
info@paragon28.com

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