



Donor Screening and Processing

Materials have been recovered, screened, processed, packaged, labeled, stored, deemed suitable for transplant and donor eligibility has been determined by Tissue Banks International NPC (2597 Kerner Blvd., San Rafael, CA). The tissue is shipped and distributed by Grand Biologics in compliance with GBI and TBI's Quality System, the American Association of Tissue Banks (AATB) Standards, the United States Food and Drug Administration (FDA) requirements, and all applicable current regulations for US State, US Federal and International Laws.

Donor eligibility determination includes donor physical examination, medical and social history interview medical records review and autopsy findings (when applicable). A blood sample collected from the donor at the time of recovery has passed a hemodilution review and tested negative or non-reactive for the following communicable disease agents:

- Human Immunodeficiency Virus types 1 & 2 antibody
- Hepatitis B surface antigen
- Hepatitis B core total antibody
- Hepatitis C Virus antibody
- Human T-lymphotropic Virus types 1 & 2 antibody
- Syphilis
- Human Immunodeficiency Virus type-1 NAT
- Hepatitis C Virus NAT

All serology testing indicated above is performed by a CLIA approved laboratory utilizing FDA-licensed test kits. The names and addresses of testing laboratories, the listing and interpretation of all communicable disease tests, a listing of the documents reviewed as part of the relevant medical records and the names of the persons determining the eligibility of this donor are on file at TBI-NPC and are available upon request.

The DBM has been processed aseptically from ground cortical/cancellous bone from the following specifications:

Particle Size Range	125 um – 850 um
Residual Calcium Level	< 8%
pH of DBM	6.5 – 7.5 (in aqueous solution)
Foreign Bodies	Not present on visual examination
Vial Size	1 cc or 60 cc
Fill Volumes	Nominal to deliver 1.0cc, 2.5cc, 5.0 cc and 10.0cc. Volume determined by measures provided by BAB
Osteoinduction	Osteoinduction assays must indicate > 10 units alkaline phosphatase per milligram protein in the 20 mg per well assay or in a < 20 mg per well assay

The DBM has been freeze-dried. For the 1cc and 5.0cc DBM products (5 mL bottle) and the 10cc DBM product (60 mL bottle), the vial is vacuum-sealed and single-pouched. The complete DBM unit is gamma irradiated at a target of 17-23 kGy. Each DBM unit is labeled on the pouch with a unique allograft number and is intended for single patient use on one occasion only. In addition, each vial will be supplied with six matching allograft specific labels for return cards and/or other documentation. Each pouched vial and extra label set will be delivered in individual boxes. Each shipment includes a packing list posting items in allograft number detail.