PUREBONE®
Demineralized Cancellous
STRIP

INSTRUCTIONS FOR USE

Caution: U.S. Federal Law restricts this tissue to sale by or on the order of a physician or hospital.

IMPORTANT PRODUCT INFORMATION
Please read before use

STERILE R
Sterilized by Radiation

2
Single Use Only

℞ only
Prescription Only

These instructions-for-use refer specifically to the Demineralized Cancellous Strip

The tissue was recovered from a deceased donor whose legal next-of-kin has given permission for the bone and connective tissue to be donated. Tissue recovery was performed using aseptic techniques. Once processed, the tissue is sterilized by gamma irradiation.

Description
The implant is composed of 100% human bone tissue and does not contain any additive or extrinsic carrier. The bone is demineralized using a simple process that has been validated to perform viral inactivation.
The demineralized cancellous strips are manufactured using cancellous bone.

Intended Use
The graft is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. It should be gently packed into bony voids or gaps of the skeletal system. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The graft provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process. It can be mixed with autogenous bone marrow prior to use at the physician's discretion.

Contraindications
Do not use the graft in the presence of any contraindication. The graft is contraindicated where the graft is intended as structural support in the skeletal system. Other conditions representing relative contraindication include:
- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- pregnancy
- uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- hypercalcemia, abnormal calcium metabolism
- existing acute or chronic infections, especially at the site of the operation
- inflammatory bone disease such as osteomyelitis
- malignant tumors
- severely impaired renal function

Warnings
The graft is sterilized by gamma irradiation. Content of package is STERILE unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded.
It is recommended to use the graft within one hour of opening the package.
Dosage is for SINGLE USE ONLY. Any attempt to re-sterilize or re-use may cause a loss of functionality or contaminate the graft.

While every effort has been made to ensure the quality of this allograft, no claims are made concerning its biological or biomechanical properties. As with any allograft, despite strict screening/testing procedures, this allograft has the potential to transmit infectious agents to the recipient.
This allograft may contain trace amounts of processing/cleaning agents such as iodine, ethanol, glycerol, or hydrogen peroxide.

Precautions
The graft is not intended for load-bearing uses. It is important to ensure that the area where the graft have been implanted be properly secured mechanically with rigid fixations to strengthen the surroundings. Attempts should not be made to modify the size of the graft or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. The effect of the graft on patients with the following conditions is unknown:
- documented renal disease
- pregnancy and nursing
- long-term infection
- metabolic bone disease
- radiation bone therapy
- cardiovascular disease precluding elective surgery.

The implant must be secured to prevent potential migration or embolization of the graft into the blood stream. The implants should only be used in surgical procedures where bone grafts are adequately contained.

Adverse Reactions
A graft may not elicit proper response from the recipient (e.g. fusion/union with adjacent tissue). It is possible for a host site to become infected. The graft may also lead to a deformity of the bone at the site. The graft may cause an inflammatory response. While efforts are made to ensure the safety of the tissue, current technologies may not preclude the transmission of disease, including hepatitis and HIV.

Reporting Adverse Reactions
The surgeon is responsible for reporting all adverse reactions potentially attributed to the allograft immediately following the occurrence. In such a case, contact BioStructures, LLC, at 949-553-1717.

Viral Inactivation
The processing methods were evaluated for their viral inactivation potential. A select panel of viruses representing various virus types, shapes and genomes were evaluated. The tests demonstrated suitable viral inactivation potential of the processing methods. The product is also terminally sterilized by gamma sterilization to also ensure its biological sterility.

Donor Selection
All donor tissue is recovered, processed and distributed according to standards established by the American Association of Tissue Banks. Donor screening exclusion criteria is performed via donor physical inspection, interview with a person who knew the donor, review of available medical records, and a review of autopsy findings (when applicable). Individuals considered to be at high risk for AIDS or hepatitis as defined by the FDA and CDC are excluded from donorship. Using FDA licensed test kits in a CLIA certified lab, a serum sample from the donor has passed a hemodilution review and tested non-reactive for the following:
- Human immunodeficiency virus antibody (anti-HIV1 and ant-HIV 2)
- Nucleic acid test (NAT) for HIV-1
- Hepatitis B surface antigen (HBsAg)
- Total antibodies to Hepatitis B core antigen (anti-HBc-total, IgG+IgM)
- Antibodies to the Hepatitis C virus (anti-HCV)
- Nucleic acid test (NAT) for HCV
- Rapid plasma reagin (RPR) or serological tests for syphilis (STS).

Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation.
Donor eligibility was performed by Tissue Banks International, 2597 Kerner Blvd., San Rafael, CA or Community Tissue Services, 349 S. Main St., Dayton, OH.

Preoperative Procedure
In the incidence of an open fracture, initial debridement and wound management should be performed. Exercise care to minimize periosteal stripping. Infections must be treated and sepsis eradicated prior to the graft procedure. Use prophylactic antibiotic coverage as appropriate.

Surgical Procedure
All procedures should be performed in the operative room under aseptic conditions. Open both outer and inner pouches. Open the container to dispense the graft. Follow accepted procedures for grafting with fixation. When excess fluid is present in the surgical field, the surgeon may use cauterization, suction, and application of bone wax (if needed) to reduce bleeding. Bone marrow aspirate can be added to the graft. The marrow aspirate is obtained by the standard bone

marrow collection techniques, and the donor sites include iliac crest, fracture, or other sites. Exercise care not to collect blood. If marrow from the fracture site is used, it is important that the marrow has not been contaminated. If the material is not positioned satisfactorily, remove the implant and start over with a new dose of the graft.

Storage Conditions

Optimal Storage Conditions: 15-30˚C (59-86F) in a secure and dry environment. DO NOT FREEZE. DO NOT EXPOSE TO EXCESSIVE HEAT. DBM will quickly lose functionality if exposed to temperature above 40°C (104F).

Shelf Life and Disposal

The expiration date is printed on the label. DO NOT USE AFTER THE EXPIRATION DATE. Packaging materials are recyclable. The graft comes sterile. Residual materials may be dispensed with other medical waste.

Tissue Tracing

It is the responsibility of the user surgeon to complete recipient records for the purpose of tracing tissue post transplant. Complete the enclosed *TRANSPLANT USAGE REPORT* in detail and return as indicated.

Other Information

The implants are packed individually in containers that are sealed in translucent double pouches within an additional box for transport and storage. The blocks come in a translucent pouch and included with this instructions-for-use leaflet are supplementary labels for patient documentation and a Transplant Usage Report for traceability.

Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of the graft, and for the choice of post-operative follow-up procedures rests entirely with the physician. In case of complaint or for further information on the product and its uses, please contact Berkeley Advanced Biomaterials and/or BioStructures, LLC at the address printed on this leaflet.

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