EXPONENT™
Demineralized Bone Matrix

TISSUE IN THIS PRODUCT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES. IT IS INTENDED FOR SINGLE PATIENT, SINGLE OCCASION ONLY.

Tissue in this product has been collected, processed, stored and distributed according to the Standards for Tissue Banking of the American Association of Tissue Banks (AATB) and Food and Drug Administration (FDA) Regulations.

CAUTION: Federal Law (U.S.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DESCRIPTION
Exponent™ Demineralized Bone Matrix is composed of human demineralized bone (DBM) mixed with resorbable carrier, carboxymethylcellulose (CMC). It is provided in a sterile, single patient use syringe.

INDICATIONS
Exponent™ Demineralized Bone Matrix is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is intended to be gently packed into bony voids or gaps of the skeletal system (posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

CONTRAINDICATIONS
- Active or latent infection in or about the surgical site
- Vascular disease
- Neurological disease
- Degenerative bone disease
- Uncontrolled diabetes
- Renal impairment

INSTRUCTIONS FOR USE
Keep the surgical site as dry as possible. Do not irrigate during or after placement of Exponent™ Demineralized Bone Matrix. Fluids such as water, saline solution or blood may alter the consistency or handling characteristics of Exponent™ Demineralized Bone Matrix. Irrigation of the graft site during or after graft placement may remove or displace graft materials.

Exponent™ Demineralized Bone Matrix requires no reconstitution prior to use. Also, kneading the Exponent™ Demineralized Bone Matrix may enhance the pliability and cohesiveness of the allograft.
1. Peel open outer pouch using proper sterile technique.
2. Pass sterile pouch into sterile field.
3. Peel open inner pouch and remove syringe.
4. Remove protective cap from syringe end and dispense.

Once the inner pouch has been opened, the tissue must either be transplanted, if applicable, or discarded.

Bone grafting procedures can experience extremely variable results. Factors to be considered in selecting the bone grafting material and the surgical technique to be utilized are as follows:

- Location of the defect
- Age of the patient
- Quality of the patient's bone
- Anticipated loading conditions
- Proximity of the graft to a suitable blood supply
- Elimination of gaps in the graft sites' ability to suitably stabilize the graft site
- Ability to achieve direct apposition of the graft to viable host bone

PREOPERATIVE PREPARATION
Preparation of the bone graft bed is important for graft incorporation and bone formation, as are other factors such as blood supply, source or marrow elements, loading, stability and absence of infection at the graft site. The volume of graft material used in each procedure is determined by the judgment of the clinician.

POSTOPERATIVE CARE
Standard postoperative practices should be followed, particularly as applicable to defects involving the use of fixation devices. The patient should be cautioned against early weight bearing and premature ambulation which could lead to loosening and/or failure of the fixators or loss of reduction. The length of time a defect should remain in a reduced state of loading is determined by the patient's physical condition and the complexity of the defect site. Do not remove hardware until the defect is healed.

SINGLE PATIENT USE
Each Exponent™ Demineralized Bone Matrix package is intended for single patient use only. To prevent cross-infection of graft recipients and graft contamination, do not use the contents of any Exponent™ Demineralized Bone Matrix package for multiple patients.

Exponent™ Demineralized Bone Matrix has been tested for sterility. Do not subject to additional disinfection or sterilization procedures. Empty Exponent™ Demineralized Bone Matrix packages and excess or unused Exponent™ Demineralized Bone Matrix should be disposed in accordance with recognized procedures for discarding medical waste material.

STORAGE
Store Exponent™ Demineralized Bone Matrix at room temperature (1º C to 30º C). No refrigeration or freezing is required. It is the responsibility of the tissue distributing service and user to maintain the product under appropriate conditions prior to use. The circulation (shelf-life) period is 2 years after the date of manufacture.

STERILIZATION
After the complete processing and packaging procedure, Exponent™ Demineralized Bone Matrix has been sterilized by electron beam irradiation. This product is for single use only and should not be re-sterilized and the product must not be used beyond the expiration date.

PRECAUTIONS
- In order to avoid the use of a potentially contaminated package of Exponent™ Demineralized Bone Matrix, it must not be used under any of the following conditions:
  - if any of the package or product elements appear to be missing, tampered with, or damaged
  - if the expiration date shown on the package label has passed
  - If any of the above conditions exists or are suspected, the package of Exponent™ Demineralized Bone Matrix should not be used.
- Please avoid pressurization in closed cavities which could produce fat embolization or embolization of device into blood stream and extrusion past treatment site which could damage surrounding tissues.
- Inflammation may be caused by bleeding and necrosis at surgical site or patient's constitution. Inflammation may be caused by the excessive use of bone void filler.
- The excess material from the defect site may invade the surrounding tissues and cause the tissues to be inflamed.
- Adverse Outcomes potentially attibutable to the tissue must be promptly reports to the tissue supplier.

ADVERSE EFFECTS
Possible adverse effects include but are not limited to:
-Wound complications including hematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery
-Fracture or extrusion of the product with or without generation of particulate devris
-Deformity of the bone at the site
-Incomplete or lack of osseous ingrowth into bone void, as is possible with any bone graft substitute

WARNINGS
As biological products, the tissue has the potential to transmit infectious agents in spite of processing treatments, donor screening, tissue selection and laboratory tests. To date, there have been no reports of experimental or clinical viral seroconversion using demineralized bone matrix. As with any surgical procedure, the possibility of infection exists.

PROCESSING
Exponent™ Demineralized Bone Matrix is banked human tissue that has been demineralized and combined with our own carrier using a process that results in an allograft with a putty-like consistency. These tissues were demineralized so that the resulting bone matrix has a calcium content of less than 8.0%. Material solution was combined with the demineralized bone matrix to form the final allograft product.

(Exponent™ Demineralized Bone Matrix tissue grafts are prepared via a proprietary processing service.)

TISSUE DONER SCREENING
Prior to donation the donor's medical/social history was screened for medical conditions or disease that would contraindicate the donation of tissue in accordance with the current standards established by the American Association of Tissue Banks (AATB).

Tissue cultures collected at recovery were further tested for:
- Microbial contaminants; aerobic
- Microbial contaminants; anaerobic
- Microbial contaminants; fungus

SEROLOGICAL TESTING
The following required testing was performed and found to be negative or non-reactive. HansBiomed Corp. screened and disposed of tissues that tested positive. Serological testing is performed using FDA-licensed test kit by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42CFR part 493, or that has met equivalent requirements as determined by the Center for Medicare and Medicaid Services (CMS).

- Antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2)
- Nucleic acid test (NAT) for HIV-1
- Hepatitis B surface antigen (HBsAg)
- Total antibodies to hepatitis B core antigen (anti-HBc-total, meaning IgG and IgM)
- Antibodies to the hepatitis C virus (anti-HCV)
- Nucleic acid test (NAT) for HCV
- Syphilis

RECIPIENT RECORD
The clinician or hospital is responsible for maintaining recipient records for tissue tracking purposes by international guidelines. Please complete the donor information form to the patient record for future reference and it should be returned to BioStructures.

Distributed by:

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