DBX® Inject
Demineralized Bone Matrix Putty

DESCRIPTION
DBX Inject tissue is DBX Putty. DBX Inject Demineralized Bone Matrix Putty includes a glass syringe pre-loaded with DBX Inject tissue and a separate, sterile plastic syringe. The plastic syringe may be used with a variety of Synthes cannula and tamps for delivery of DBX Inject directly into the operative site. DBX Inject tissue contains processed human bone that has been demineralized and combined with sodium hyaluronate, which is a naturally derived material not of animal origin that is both biocompatible and biodegradable. The combination of demineralized bone and sodium hyaluronate results in a putty-like consistency for ease and flexibility of use during surgical application.

OSTEOINDUCTIVE POTENTIAL
DBX Inject tissue is osteoinductive and has been shown to have osteoinductive potential in an athymic mouse model. Every lot of final DBX Inject tissue is tested in vivo or in an alkaline phosphate assay, which has been shown to have a positive correlation with the athymic mouse model, to ensure the osteoinductive potential of the final product. Standard testing performed in vivo or by the alkaline phosphate assay must prove positive for lot release. It is unknown how the osteoinductive potential, measured in vivo or by the alkaline phosphate assay, will correlate with clinical performance in human subjects.

INDICATIONS FOR USE
DBX Inject is intended for use as a Demineralized Bone Matrix for voids or gaps that are not attributable to the stability of the bony structure. DBX Inject is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. DBX Inject can be used as follows:

- Extremities
- Pterolateral spine
- Pelvis
- Ridge Augmentation
- Filling of extraction sites
- Craniofacial augmentation
- Mandibular reconstruction
- Repair of traumatic defects of the alveolar ridge, excluding maxillary
- Filling resection defects in benign tumors, benign cysts, or other osseous defects in the alveolar ridge wall
- Filling of cystic defect
- Filling of lesions of periodontal origin
- Filling of defects of midfacial origin

ADVERSE EFFECTS
Possible adverse effects of using DBX Inject include, but are not limited to:
- Potential loss of contour of maxillofacial skull
- Infection of soft tissue and/or bone (osteomyelitis)
- Fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Hypercalcemia or transient hypercalcemia
- Fracture of the newly formed bone
- Disease transmission and undesirable immune response

Within the United States: Adverse outcomes attributable to the tissue must be promptly reported to your local representative.

CAUTIONS
Do not sterilize. Do not freeze. DBX Inject tissue may extrude into facial soft tissue. Trace amounts of Gentamicin may be present. Tissue is exposed to processing solutions that may contain detergents and alcohol. Trace amounts of processing solution may remain. Caution should be exercised if the patient is allergic to any of these substances. NOTE: No β-lactam antibiotics are used during the processing of tissue in DBX Inject products.

Extensive medical screening procedures have been used in the selection of all tissue donors for DBX Inject. Transmission of infectious diseases may occur despite careful donor selection and laboratory testing, including serology and nucleic acid testing (NAT). Bacterial infection at the site of grafting may occur.

In Vivo Processing and Packaging
DBX Inject Tissue is Not Terminally Sterilized.

The Provided Plastic Syringe Is Terminally Sterilized By Gamma Radiation.

This tissue was recovered from a deceased donor from whom legal authorization or consent has been obtained. This recovery was performed using aseptic techniques. Processing and packaging were performed under aseptic conditions. Terminal sterilization agents were not used in the process.

CONTRAINDICATIONS
DBX Inject is NOT intended to provide structural support of the bone during the healing process. DBX Inject is also contraindicated for incomplete skull growth.

DBX Inject Tissue Components
- Bone Particle Diameter
  - 212 – 850 μm
- Sodium hyaluronate content (by weight in solution)
  - 4%
- Bone content (by weight)
  - 31%

Some tissues are treated with low-dose gamma radiation. For these tissues the container label will state, “Treated with Gamma Radiation.” Samples from each donor lot of DBX Inject tissue were tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests. The provided plastic syringe is terminally sterilized by gamma radiation.

INSTRUCTIONS FOR USE
DBX Inject includes a glass syringe pre-loaded with DBX Inject tissue and a separate, sterile plastic syringe. The plastic syringe may be used with a variety of tamps and cannulas for delivery of DBX Inject directly into the operative site.

THE GLASS SYRINGE IS NOT AN APPLICATOR. Care should be taken to apply gentle, even force to the plunger when extruding DBX Inject tissue from the syringe. Extreme force applied to the plunger may cause the glass syringe to break. DBX Inject is composed of Demineralized Bone Matrix and sodium hyaluronate. The demineralized bone allograft in this product is prepared from tissue procured from a deceased donor using aseptic surgical techniques. The bone used in DBX Inject is cortical bone. These tissues were treated with Gentamicin and were cleaned using ethanol and washed with purified water. The bone was demineralized using hydrochloric acid. The demineralized bone was then lyophilized to a controlled moisture content. The demineralized bone was combined with sterile-filtered sodium hyaluronate prior to packaging. Sodium hyaluronate is a naturally derived material that is biocompatible and biodegradable. The sodium hyaluronate is mixed in a phosphate buffered saline and is added to the demineralized bone to aid in maintaining physiological pH as well to improve the handling characteristics of demineralized bone.


Definitions of Label Symbols

Consult instructions for use
Do Not Reuse

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Processed by: mtfbiologics

Donor blood samples taken at the time of recovery were tested by a facility that is CLIA certified and registered with the FDA. The donor blood samples were tested for:
- Hepatitis B surface antigen
- Hepatitis B core antibody
- Hepatitis C antibody
- HBV (NAT)
- HIV-1/2 antibody
- Syphilis
- HIV-1 (NAT)
- HCV (NAT)

Additional testing of SARS-CoV-2, HTLV 1 & 2 and/or West Nile Virus (as applicable) may also have been performed. All infectious disease test results passed acceptability for screening. This allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, consent, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria currently at the time of procurement, have been met. This tissue is suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, as applicable. All procedures for donor screening, serologic and microbiologic testing, meet or exceed current standards established by the American Association of Tissue Banks.

VIRAL CLEARANCE AND INACTIVATION

A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing method for a wide spectrum of potential human viruses. The DBX process further reduces the risk of viral contamination beyond donor testing and screening procedures.

PACKAGING & LABELING

DBX Inject tissue is aseptically packaged in a sterilized glass syringe. The syringe containing DBX Inject tissue is inside two plastic trays, each sealed with foil lids. The outer tray is labeled and then put in a box.

A separate, sterile plastic syringe is provided in every box of DBX Inject. The syringe is packaged in a plastic tray inside a Tyvek pouch. The outer pouch is labeled and placed in the same shelf box as the DBX Inject tissue pre-loaded in the glass syringe. This allograft or plastic syringe must not be used under any of the following circumstances:
- If the container seal is damaged or not intact or has any physical damage;
- If the container label or identifying bar code is severely damaged, not legible or is missing;
- If the expiration date shown on the container label has passed.

STORAGE

Store DBX Inject at ambient temperature. No refrigeration or freezing is required. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant.

PATIENT RECORD

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post-transplantation. A TissueTrace® Tracking Form and peel-off stickers have been included with each package of tissue. The serial number and the tissue description have been preprinted on the peel-off stickers. Please record the patient ID, name and address of the transplant facility, allograft tissue information (using the peel-off stickers), and comments regarding the use of the tissue on the TissueTrace Tracking Form. Alternatively a system for electronic submission may be used and sent to MTFJTC®Screis.com. Within the United States: Once completed, the bottom page of the form should be returned to MTF using the self-addressed mailer. Copies of this information should be retained by the transplant facility for future reference. Outside of the United States: Once completed, the bottom page of the form should be returned to the local allograft representative or provider. Copies of this information should be retained by the hospital for future reference.

Reference: Current MTF policies and procedures are in compliance with current FDA, AABB and other regulatory requirements.

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All recovery, processing and distribution costs were paid for by MTF, a non-profit organization. CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.

MTF tissue forms and products are protected by one or more issued or licensed United States patents. A list of patents on available tissues and related technologies may be found on the MTF web site www.mtf.org/patents.

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