DBX Inject™
Demineralized Bone Matrix Putty

DONATED HUMAN TISSUE

CAUTION: DEVICES ARE FOR SINGLE PATIENT USE ONLY. DBX Inject Tissue Is Aseptically Processed And Passes USP <71> Sterility Tests.


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 cannulas 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 osteoconductive and has been shown to have osteoinductive potential in an athymic mouse model. Every lot of final DBX Inject tissue was 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.

INDICATIONS FOR USE
DBX Inject is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic 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**
- **Posterior fat pad**
- **Pelvis**
- **Ridge Augmentation**
- **Filling of extraction sites**
- **Craniofacial augmentation**
- **Mandibular reconstruction**
- **Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture**
- **Filling of cystic defect**
- **Filling of lesions of periodontal origin**
- **Filling of defects of endodontic origin**

Lesions of periodontal origin
Filling of defects of endodontic origin

DBX Inject can be used as an extender in the spine, pelvis, and extremities with autograft or allograft. DBX Inject can be used with bone marrow aspirate. DBX Inject is for single patient use only.

CONTRAINdications
DBX Inject is NOT intended to provide structural support of the bone during the healing process. DBX Inject is also contraindicated in the following circumstances:

- Incomplete maxillofacial skull growth
- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Hypercalcaemia
- Renal-compromised patients
- History of or active Ptu’s disease
- Osteomyelitis at the surgical site
- Septis in or around the surgical site
- Inability to cooperate with and/or comprehend post-operative instructions

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
- Hypercalcaemia or transient hypercalcaemia
- 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 MTF. Outside of the United States: Adverse outcomes attributable to the tissue must be promptly reported to your local representative.

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 cannula 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 tissue may be extruded into a sterile basin or into the plastic syringe. For direct delivery to the operative site, the DBX Inject tissue must be transferred directly from the glass syringe into the plastic syringe.

CAUTIONS
Do not sterilize. DBX Inject tissue may extrude into facial soft tissue. Trace amounts of Gentamicin antibiotic, Polyorbate-80, Ethanol, Methanol, Isopropanol and Hydrogen Peroxide may be present. 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.

Outside medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening and Testing). Transmission of infectious diseases such as HIV or hepatitis, as well as a theoretical risk of the Creutzfeldt-Jakob (CJD) agent, may occur in spite of careful donor selection and serological testing.

Closed suction or drainage is recommended to prevent fluid accumulation in the wound.

DEVICE INFORMATION
DBX Inject tissue 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 asptic surgical techniques. The tissue 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 sterilized 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.

<table>
<thead>
<tr>
<th>DBX Inject Tissue Components</th>
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<tbody>
<tr>
<td>Bone Particle Diameter</td>
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<tr>
<td>Sodium hyaluronate content (by weight in solution)</td>
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<tr>
<td>Bone content (by weight)</td>
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Legal Next-of-Kin has given permission for the bone and connective tissue to be donated. This recovery was performed using aseptic techniques. Processing and packaging were performed under aseptic conditions. Terminal sterilization agents were not used in the process.

Caution should be exercised if the patient is allergic to any of these substances.
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 current 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; or
- 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. This will allow MTF to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action. 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. Within the United States: Once completed, the bottom page of the form should be returned to MTF using the self-addressed, postage paid mailer.

Definitions of Label Symbols

PI –70, Rev 5, 11/2011

PI – 70

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Outside the United States: 1.732.661.0202

Within the United States: 1.800.433.6576

Outside the United States: 1.732.661.0202

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.

These tissue forms are covered by the following US Patents: US 6,437,018; US 6,793,660; US 6,911,212; US 7,019,192.

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