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RM -1499

READ BEFORE USING

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.

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.

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 osteoconductive 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 phosphatase 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 phosphatase assay must prove positive for lot release. It is unknown how the osteoinductive potential, measured *in vivo* or by the alkaline phosphatase 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 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:

Indications for Use
Extremities
Posterolateral spine
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 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 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 for incomplete skull growth.

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 MTF.** ***Outside of 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 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.

Caution should be taken for the following circumstances:

- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Pregnancy
- Hypercalcemia
- Renal-compromised patients
- History of or active Pott's disease
- Osteomyelitis at the surgical site
- Sepsis in or around the surgical site
- Inability to cooperate with and/or comprehend post-operative instructions

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 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.

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 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.
Warning: DBX Inject with or without a cannula is NOT a puncturing device. DBX Inject tissue should be extruded into the operative site after surgical approach from the sterile plastic syringe or cannula.

DBX Inject can be used alone or mixed with autogenous or allograft bone (1:1 ratio by volume), or with bone marrow aspirate (2.0 mL/2.8 g of DBX Inject or 2.0 cc/2.8 cc of DBX Inject).

NOTE: This allograft has been aseptically packaged into sterilized packaging components. To make ready for use, open the package using aseptic/sterile techniques.

Instructions for Opening the Packaging:

Extruding DBX Inject Tissue into the Plastic Syringe:
1. Peel back lid of outer tray of the DBX Inject tissue-filled glass syringe.
2. Pass inner tray to sterile field.
3. Peel open Tyvek pouch of the empty plastic syringe.
4. Pass inner plastic syringe tray into sterile field
5. Peel back foil lid of inner tray of the DBX Inject tissue-filled glass syringe and remove plastic snap lid from empty plastic syringe tray.
6. Remove syringes from inner trays.
7. Remove protective cap from the end of the glass syringe containing DBX Inject tissue and insert glass syringe tip into back of plastic syringe body.
8. Apply gentle, even force to the plunger to extrude DBX Inject tissue from the glass syringe into the plastic syringe.
9. Place the threaded plunger into the plastic syringe after it is filled with DBX Inject tissue.
Extruding DBX Inject Tissue from the Plastic Syringe into the Surgical Site:
1. Select appropriately sized tamp and cannula if desired.
2. Apply selected cannula to the tip of the plastic syringe.
3. Extrude DBX Inject tissue directly into the operative site with the plastic syringe.
4. Remove plastic syringe from cannula.
5. Insert tamp into cannula to deliver remaining DBX Inject tissue into operative site as needed.

Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste materials.

DONOR SCREENING & TESTING

Prior to donation, the donor's medical/social history is screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by the MTF Medical Board of Trustees.

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)

All infectious disease tests were negative. 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 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. 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 MTFTTC@Sceris.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, AATB and other regulatory requirements.

Definitions of Label Symbols


See IFU


Do Not Reuse

Processed by:

MTF Musculoskeletal Transplant Foundation

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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. Please note: Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.

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