### Document Detail

**Review**

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**Closed Date:** 5/10/2022 1:55:48PM

**Review Purpose:** Document Approval-Package Insert

**Review Note:** SYSTEM AUTO CLOSE REVIEW

<table>
<thead>
<tr>
<th>Level</th>
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| 1     | Document Approver-Medical  
  Director Document  
  Approver-Medical Director | MAHLISE Emmanuel Mahlis | 08-May-2022 9:41 pm | MAHLISE |
|       | Document Approver-Marketing | FALLONK Kevin Fallon | 03-May-2022 1:32 pm | FALLONK |
|       | Document Approver-Regulatory | CARROLK Katrina Carroll | 02-May-2022 7:50 pm | CARROLK |
| 2     | Verify Training/Release  
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  Management Role | MOOREJ Joann Moore | 10-May-2022 1:55 pm | MOOREJ |

**Note To Approver:** See CC20220156 for change details

**Note From Approver:**

- Approved
- n/a
- approved
- No comment.
- Sign off to release
DBX® Demineralized Bone Matrix Paste & Mix

DONATED HUMAN TISSUE


DESCRIPTION
DBX Demineralized Bone Matrix Paste and DBX Demineralized Bone Matrix Mix are 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 paste-like or textured consistency (DBX Paste and DBX Mix, respectively) for ease and flexibility of use during surgical application.

OSTEOINDUCTIVE POTENTIAL
DBX Paste and DBX Mix are osteoconductive and have been shown to have osteoinductive potential in an athymic mouse model. Every lot of final DBX Paste and DBX Mix product is tested in vivo for osteoinductive potential. Standard testing performed in an athymic mouse model must prove positive for lot release. It is unknown how the osteoinductive potential, measured in the athymic mouse model, will correlate with clinical performance in human subjects.

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

- Indications for Use
  - Spine
  - Craniotomy
  - Ridge augmentation
  - Filling of extraction sites
  - Nasal septal augmentation
  - Mandibular reconstruction
  - Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular defects
  - Filling resorption defects in benign tumors, benign cysts, or other osseous defects in the alveolar ridge wall
  - Filling of cystic defect
  - Filling of lesions of paranasal sinus origin
  - Filling of defects of endosteal origin

DBX Paste and DBX Mix can be used with bone marrow aspirate. DBX Paste and DBX Mix are for single patient use only.

CONTRAINDICATIONS
DBX Paste and DBX Mix are NOT intended to provide structural support of the bone during the healing process. DBX Paste and DBX Mix are also contraindicated for incomplete skull growth.

ADVERSE EFFECTS
Possible adverse effects of using DBX Paste and DBX Mix include, but are not limited to:
- 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. 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 Paste and DBX Mix 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 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.

Closed suction or drainage is recommended to prevent fluid accumulation in the wound. Use caution in 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 Paste and DBX Mix are 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 the DBX Paste is cortical bone; DBX Mix is composed of 80% cortical bone and 20% cancellous 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.

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 Paste and DBX Mix were tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests.

INSTRUCTIONS FOR USE
DBX Paste is packaged in a glass syringe and must be extruded into a sterile basin, not directly into the operative site. THE SYRINGE IS NOT AN APPLICATOR. Care should be taken to apply gentle, even force to the plunger when extruding DBX Paste from the syringe. Extreme force applied to the plunger may cause the glass syringe to break. DBX Mix is packaged in a glass jar. Use the enclosed sterile spatula to remove DBX Mix from the jar. THE SPATULA IS NOT AN APPLICATOR.