

Review

Build No.: 2

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

Review: Document Approval-Package Insert

Review Purpose: Document Approval-Package Insert

Review Note: SYSTEM AUTO CLOSE REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off Date</u>	<u>Sign-off By</u>
1	Document Approver-Medical Director Document Approver-Medical Director	MAHLISE Emmanuel Mahlis	08-May-2022 9:41 pm	MAHLISE

Note To Approver: See CC20220156 for change details

Note From Approver:Approved

1	Document Approver-Marketing Document Approver-Marketing	FALLONK Kevin Fallon	03-May-2022 1:32 pm	FALLONK
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Note To Approver: See CC20220156 for change details

Note From Approver:n/a

1	Document Approver-Regulatory Document Approver-Regulatory	CARROLK Katrina Carroll	02-May-2022 7:50 pm	CARROLK
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Note To Approver: See CC20220156 for change details

Note From Approver:approved

2	Verify Training/Release Authorization Verify Training/Release Authorization	TINKERD David Tinker	09-May-2022 11:46 am	TINKERD
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Note To Approver: Verify Training/Release Authorization
See CC20220156 for change details

Note From Approver:No comment.

3	Document Management Document Management Role	MOOREJ Joann Moore	10-May-2022 1:55 pm	MOOREJ
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Note To Approver: See CC20220156 for change details

Note From Approver:Sign off to release

READ BEFORE USING

**DBX® Demineralized Bone Matrix
Paste & Mix**

DONATED HUMAN TISSUE

**CAUTION: DEVICE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Passes USP <71> Sterility Tests.
DBX Paste and DBX Mix Are Not Terminally Sterilized.**

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 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	DBX Paste	DBX Mix
Extremities	√	√
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 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.

	DBX Paste	DBX Mix
Bone Particle Diameter	212 – 850 μm	≤ 6mm
Sodium hyaluronate content (by weight in solution)	2%	4%
Bone content (by weight)	26%	35%

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.**