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.

INDICATIONS FOR USE

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.

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.

FORMULATION

Paste and 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.

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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. Amounts of processing solutions 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.

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.