PI –16, Rev 12, 08/2016
RM -796

READ BEFORE USING

DBX Strip®

DEMINERALIZED BONE MATRIX

DONATED HUMAN TISSUE

CAUTION: DEVICE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Passes USP <71> Sterility Tests.
DBX Strip Is 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 Strip is processed human bone that has been demineralized and combined with gelatin and sodium hyaluronate, which are naturally derived materials that are biocompatible and biodegradable. The sodium hyaluronate used in the manufacturing of DBX Strip is not of animal origin. The combination of demineralized bone, gelatin and sodium hyaluronate results in a strip formulation that is flexible and bendable as per the physician's preference.

OSTEOINDUCTIVE POTENTIAL

DBX Strip is osteoconductive and has been shown to have osteoinductive potential in an athymic mouse model. Every lot of final product is tested to ensure the osteoinductive potential of the final product. 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 Strip 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 Strip is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. It can be used in the pelvis, extremities, and the posterolateral spine for posterolateral spine fusion. DBX Strip, when used for posterolateral spine fusion, may be used with autograft. DBX Strip is for single patient use only.

CONTRAINDICATIONS

DBX Strip is NOT intended to provide structural support of the bone during the healing process. DBX Strip is contraindicated for incomplete skull growth.

ADVERSE EFFECTS

Possible adverse effects of using DBX Strip 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 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 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 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.

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 Strip is composed of Demineralized Bone Matrix, sodium hyaluronate, and gelatin. The demineralized bone allograft in this product is prepared from tissue procured from a deceased donor using aseptic surgical techniques. The bone used 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 and sterile gelatin 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 as 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 Strip were tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests.

INSTRUCTIONS FOR USE

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

1. Peel open Tyvek pouch
2. Pass inner foil pouch to sterile field
3. Peel open foil pouch
4. Remove DBX Strip
5. Implant as per surgeon's preference

DBX Strip may be rehydrated in saline for up to 10 minutes.

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 are 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 Strip process further reduces the risk of viral contamination beyond donor testing and screening procedures.

PACKAGING & LABELING

DBX Strip is aseptically packaged in a sterilized foil pouch. The pouch containing the DBX Strip is sealed and placed into a sterilized Tyvek pouch. The outer pouch is labeled and placed inside a box.

This allograft 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 Strip 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

125 May Street
Edison, NJ 08837
USA

Within the United States: 1.800.433.6576
Outside of 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.

MTF tissue forms and products are protected by one or more issued or licensed United States patents. A list of patents on available tissues and related technologies may be found on the MTF web site www.mtf.org.
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CTO: 100024