Demineralized Bone Matrix
Renal-compromised patients
Fever
Fracture of the newly formed bone
DBX Putty may extrude into facial soft tissue.
History of or active Pott’s disease
Inability to cooperate with and/or comprehend post-operative

USED IN THE PROCESS.
Severe vascular or neurological disease
212 – 850
Incomplete bone ingrowth, delayed union or non-union
Pregnancy
NOT
Adverse outcomes attributable to the tissue must
4%
Severe degenerative bone disease
Disease transmission and undesirable immune response
Incomplete maxillofacial skull growth
Osteomyelitis at the surgical site
Hypercalcemia or transient hypercalcemia
Adverse
Sepsis in or around the surgical site
Uncontrolled diabetes
Infection of soft tissue and/or bone (osteomyelitis)
Putty is osteoconductive, and has been shown to have osteoinductive
Fever
intraosseous defects including:
INDICATIONS FOR USE
Correlate with clinical performance in human subjects.
measured in the athymic mouse model or the alkaline phosphatase assay, will
positive for lot release. It is unknown how the osteoinductive potential,
performed in an athymic mouse or alkaline phosphatase assay must prove
to ensure the osteoinductive potential of the final product. Standard testing
has been shown to have a positive correlation with the athymic mouse model,
well as to improve the handling characteristics of demineralized bone.
DESCRIPTION
DBX Demineralized Bone Matrix Putty is 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 or textured consistency for ease and
flexibility of use during surgical application.
OSTEOINDUCTIVE POTENTIAL
DBX Putty is osteoconductive, and has been shown to have osteoinductive
potential in an athymic mouse model. Every lot of final DBX Putty product is
tested in an athymic mouse model 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 an athymic mouse or alkaline phosphatase assay must prove
positive for lot release. It is unknown how the osteoinductive potential,
maintained in the athymic mouse model or the alkaline phosphatase assay, will
correlate with clinical performance in human subjects.
INDICATIONS FOR USE
DBX Putty is intended for the augmentation of deficient maxillary and
mandibular alveolar ridges and the treatment of oral/maxillofacial and dental
intraosseous defects including:
-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 bone tumors, benign cysts or other
osseous defects in the alveolar ridge wall
DBX Putty can be used with autograft or bone marrow aspirate. DBX Putty is
for single patient use only.
CONTRAINDICATIONS
DBX Putty is NOT intended to provide structural support of the bone during the
healing process. DBX Putty is also contraindicated in the following circumstances:
- Incomplete maxillofacial skull growth
- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Hypercalcemia
- Renal-compromised patients
- History of or active Poti’s disease
- Osteomyelitis at the surgical site
- Sepsis in or around the surgical site
- Inability to cooperate with and/or comprehend post-operative
instructions
ADVERSE EFFECTS
Possible adverse effects of using DBX Putty 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. DBX Putty may extrude into facial soft tissue.
Trace amounts of Gentamicin antibiotic, Polysorbate-80, Ethanol, Methanol,
Isopropanol, and Hydrogen Peroxide may be present. 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.
DEVICE INFORMATION
DBX Putty 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 the
Putty is cortical bone. These tissues were treated with Gentamicin and were
cleaned using ethanol and washed with purified water. The bone was
deminalerized 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
as well as to improve the handling characteristics of demineralized bone.

<table>
<thead>
<tr>
<th>DBX Putty Components</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone Particle Diameter</td>
<td>212 – 850 µm</td>
</tr>
<tr>
<td>Sodium hyaluronate content (by weight in solution)</td>
<td>4%</td>
</tr>
<tr>
<td>Bone content (by weight)</td>
<td>31%</td>
</tr>
</tbody>
</table>

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

This Tissue Was Recovered From a Deceased Donor Whose Legal Next-of-Kin Has Given Permission for the Bone and Connective Tissue to be Donated. This Recovery Was Performed Using Aseptic Techniques. Processing and Packaging Were Performed Under Aseptic Conditions. Terminal Sterilization Agents Were Not Used in the Process.
INSTRUCTIONS FOR USE

DBX Putty 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 Putty from the syringe. Extreme force applied to the plunger may cause the glass syringe to break.

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 back lid of outer tray.
2. Pass inner tray to sterile field.
3. Peel back lid of inner tray.
4. Remove syringe from inner tray.
5. Remove protective cap from end of syringe.
6. Extrude DBX Putty into a sterile basin.
7. Shape and use DBX Putty as per surgeon’s preference.

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

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 CLIA licensed facility for:

- Hepatitis B surface antigen
- Hepatitis B core antibody
- Hepatitis C antibody
- HIV-1/2 antibody
- Syphilis
- HIV -1 (NAT)
- HCV (NAT)

The results of all serological testing 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 Putty is aseptically packaged in a sterilized syringe. The syringe containing DBX Putty is inside two sterilized plastic trays, each sealed with foil lids. The outer tray is labeled and then put in 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 Putty 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. This will allow MTF to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action. 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.

Definitions of Label Symbols

- See IFU
- Do Not Reuse

Processed by:
MTF 125 May Street
Edison, NJ 08837
USA

Within the United States: 1.800.433.6576
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.

These tissue forms may be covered by one or more of the following US Patents:
- US 5,284,655; US 5,290,558; US 5,728,159; US 6,025,538; US 6,030,635; US 6,111,164; US 6,432,436; US 6,437,018; US 6,448,375; US 6,544,599; US 6,911,212; US 7,019,192; and US 7,045,141; Other patents pending.

DBX® is a registered trademark of MTF.

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