DBX® Inject.™ Demineralized Bone Matrix with Delivery System.

Technique Guide

SYNTHES®

MTF Musculoskeletal Transplant Foundation
the better approach

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DBX® Inject.™ Demineralized bone matrix with delivery system.

The DBX® Inject™ Putty package contains a glass syringe preloaded with DBX® Putty and a separate plastic delivery syringe. When the DBX Putty is transferred from the glass syringe to the delivery syringe, it becomes DBX Inject Putty.

When using the delivery syringe, DBX Inject Putty may be extruded directly into the operative site. The delivery syringe may be used with a variety of tamps and cannulas, provided separately, but also can be used alone.

Caution: The glass syringe is not an applicator and should not be used to deliver tissue to the operative site.

DBX Putty is demineralized bone matrix that has osteoinductive potential* and is osteoconductive. It is composed of demineralized bone from human donors in a biocompatible carrier and provided in various forms to meet surgical needs. The demineralized bone powder is produced by the removal of minerals from cortical bone.

The DBX Putty carrier, sodium hyaluronate, is a naturally derived material that is biocompatible and biodegradeable, similar to the naturally occurring hyaluronate found in the human body.

DBX Putty demineralized bone matrix is nonhemolytic, ensuring compatibility with the surrounding autogenous blood cells.

*Note: It is unknown how the osteoinductive potential, measured in the athymic mouse model or the alkaline phosphatase assay, will correlate with clinical performance in human subjects.

DBX® Putty
- Demonstrated bone formation
- Osteoconductive and osteoinductive potential
- Biocompatible – inert carrier, pH-balanced, nonhemolytic
- Exemplary safety – AATB-accredited tissue bank, viral inactivation, NAT-tested
- Stays in place – resists movement under irrigation, maintains physical integrity
- Ready to use, with no mixing or thawing required

Delivery system
- Delivery syringe provides tactile feedback allowing consistent and controlled delivery
- Optional delivery cannula can be attached to the syringe, for more precise application and access to remote sites
- Tamp is provided with delivery cannula to extrude remaining material from cannula

DBX Putty glass syringe


Delivery syringe body


Delivery syringe plunger


Cannula


Tamp

DBX Inject.™ Demineralized bone matrix with delivery system.

Carrier characteristics

Sodium hyaluronate is a polysaccharide which occurs naturally in the human body. It plays an essential role in cell proliferation, migration and adhesion, and has been correlated to angiogenesis.[1,2] It also confers positional stability to the tissue.[3]

Sodium hyaluronate is proven to be safe.[2] The DBX® Putty carrier, sodium hyaluronate, is similar to the naturally occurring hyaluronate found in the body. MTF uses high-quality medical grade sodium hyaluronate, produced through fermentation processes under good manufacturing practice (GMP) guidelines.

The DBX Putty formulation has been specifically designed to have the physiological normal pH of 7.2, similar to human blood.

1. Alicia Orlidge and Patricia D'Amore. "Cell Specific Effects of Glycosamino-glycans on the attachment and Proliferation of Vascular Wall Components." *Microvascular Research*. 31: S41–S43, 1986.
2. J.R.E. Fraser and T.C. Laurent. "Turnover and Metabolism of Hyaluronan." *The Biology of Hyaluronan*. Evered D. and Whelan J., eds. Wiley, Chichester (Ciba Foundation Symposium 143) S41–S59, 1989.
3. Arthur Gertzman, Moon Hae Sunwoo. "A Pilot Study Evaluating Sodium Hyaluronate as a Carrier for Freeze-dried Demineralized Bone Powder." *Cell and Tissue Banking*. 2: S87–S94, 2001.

Demonstrated bone formation

Osteoinductive potential

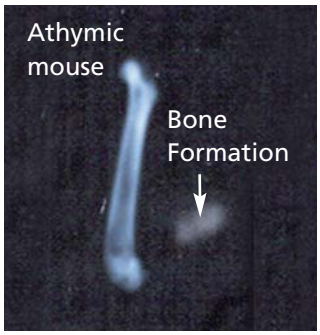
– Each lot of DBX® Putty is validated in vivo or in vitro to verify its osteoinductive potential.

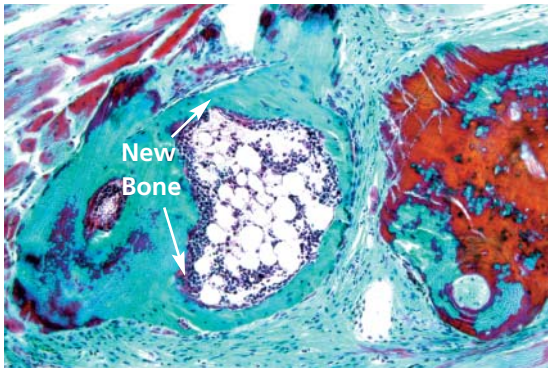
Osteoconductivity

– The variety of DBM particle sizes provides an osteoconductive matrix.

Histologic verification—Osteoinductivity study

An athymic mouse study, based on the Urist intramuscular model, confirmed histologically that DBX Putty has osteoinductive potential.[4]





Bone content of DBX Putty

% Bone (by weight)	31%
Bone Particle Diameter	212–850 µ

Notes:

High demineralized bone content maximizes the amount of bone placed in the surgical site.

Animal test results may not necessarily be indicative of clinical performance.

4. M. Urist. "Bone Formation by Autoinduction." *Science*. 1965; 150: 893–899.

Indications and Contraindications

Indications

DBX® Inject™ Putty 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 Inject Putty is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury.

DBX Inject Putty can be used alone in the posterolateral spine. DBX Inject Putty can also be used as an extender in the spine with autograft or allograft. DBX Inject Putty can be used with bone marrow. DBX Inject Putty is for single patient use only.

DBX Inject Putty can be used alone in the pelvis and extremities. DBX Inject Putty can also be used as an extender in the pelvis and extremities with autograft or allograft. DBX Inject Putty can be used with bone marrow. DBX Inject Putty is for single patient use only.

Contraindications*

DBX Inject Putty is not intended to provide structural support of the bone during the healing process. DBX Inject 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 Pott's disease
- Osteomyelitis at the surgical site
- Inability to cooperate with and/or comprehend postoperative instructions

* Please see the Directions for Use for complete description of indications, contraindications, warnings, and precautions.

1
Planning

Select the appropriate volume of DBX® Inject™ Putty and appropriate cannula and tamp size for the procedure.

Note: A cannula and tamp is not necessary if delivering material directly from the delivery syringe. The glass syringe is not an applicator.

2

Open outer tray

Using aseptic technique, remove the inner tray containing DBX® Putty from the outer tray by peeling back the foil lid.

Note: DBX Putty is aseptically packaged into a sterile tray.

3

Open inner tray

Remove the glass syringe containing DBX® Putty from the package by peeling back the foil lid of the inner tray.

Caution: DBX Putty should not be extruded into the operative site from the glass syringe. Material should be dispensed into the delivery syringe or extruded into a sterile basin.

Take care when opening the DBX Putty package to avoid dropping the glass syringe.

4

Transfer DBX® Putty to delivery syringe

Remove the cap from the glass syringe and place the open end into the back of the delivery syringe body.

Take care to apply gentle, even force to the plunger when extruding DBX Putty from the glass syringe. Extreme force applied to the plunger may cause the glass syringe to break.

Dispense all the DBX Putty by backfilling the delivery syringe body.

Remove and dispose of the glass syringe appropriately.

5

Insert plunger and deliver material

Once the DBX® Putty has been transferred completely into the delivery syringe body, place the threaded plunger into the delivery syringe body.

Note: Delivery to the operative site can be achieved directly from the delivery syringe, or a cannula can be attached to the delivery syringe for more precise application or access to remote areas.

When the DBX Putty is transferred from the glass syringe to the delivery syringe, it becomes DBX® Inject™ Putty.

5. Insert plunger and deliver material continued

Small volumes of DBX® Inject™ Putty may be delivered with precise control by rotating the threaded plunger in a clockwise direction. Each full rotation of the plunger results in the delivery of 0.5 cc of tissue.

Large volumes of DBX Inject Putty may be delivered at a faster rate by advancing the threaded plunger into the syringe. Each click indicates that 0.5 cc of tissue has been dispensed.

Caution: If resistance is encountered, pull the threaded plunger back slightly and rotate the knob one-half (1/2) turn counterclockwise to relieve the pressure, then continue delivery.

Calibration marks on the delivery syringe are in 1 cc increments.

6

Attach delivery cannula (optional)

Using aseptic technique, peel open the cannula and tamp packaging and remove the cannula and tamp. Attach the cannula to the delivery syringe by fully inserting it into the tip and rotating one-quarter (1/4) turn clockwise to lock into place.

6. Attach delivery cannula (optional) continued

With the cannula securely attached, begin delivery of DBX® Inject™ Putty as described in Step 5.

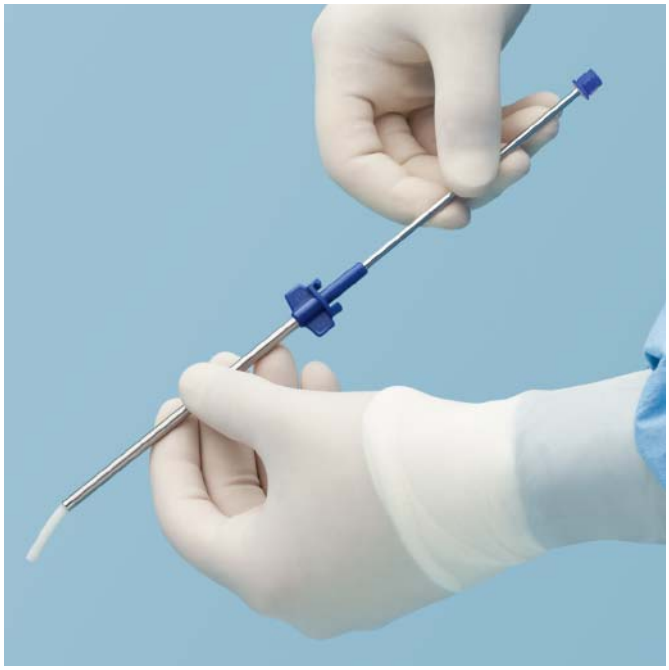
Notes:
Always use a backfill technique. Begin injection or delivery and slowly withdraw the cannula as fill is achieved.

DBX Inject Putty with or without cannula is NOT a puncturing device. DBX Inject Putty should be extruded into operative site after surgical approach from the sterile plastic syringe or cannula.

7

Insert tamp

To deliver remaining DBX® Inject™ Putty in the cannula, remove the cannula from the delivery syringe and insert the tamp through the cannula.



Musculoskeletal Transplant Foundation (MTF)

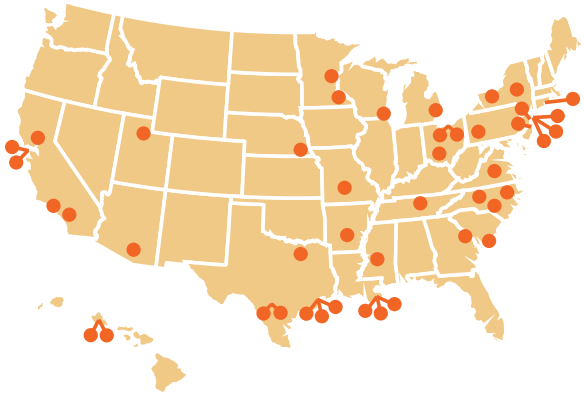
Synthes has partnered exclusively with the Musculoskeletal Transplant Foundation (MTF) for over 10 years to provide high quality tissue for patients. Although there are national standards for tissue banks, they only set a baseline for the industry. Beyond that, regulations leave a lot to interpretation, so standards vary significantly from tissue bank to tissue bank. MTF offers safe allografts processed from among the most carefully selected donors.

Directed by Surgeons
MTF utilizes a Medical Board of Trustees comprised of more than forty surgeons from world-renowned academic institutions. MTF's board sets standards, which are among some of the most stringent in the industry.

Selecting the Ideal Donor
MTF's extensive network of participating organ procurement organizations ensures that MTF has access to a broad selection of qualified donors. MTF holds itself to stringent standards for donor selection and processing criteria. MTF defers more donors than they accept.

Preserving and Protecting Tissue Integrity
MTF's approach ensures a high level of safety, without compromising biological and mechanical integrity. MTF has developed and validated several tissue cleaning technologies to provide safe and high quality allograft bone. Allograft bone processed by MTF may result in improved incorporation in humans when compared to allograft bone processed from other sources based on results of in vivo testing*. Since MTF's inception, MTF has maintained an exemplary safety record distributing more than 5 million allografts from more than 90,000 donors.

MTF's standards are set by their Medical Board of Trustees — more than 40 surgeons from world-renowned academic institutions.



MTF Donor Deferral Rate

*Dunn M.G, 2008. "Effect of Allograft Bone Processing on Structural Cortical Grafts: A Comparison of three proprietary processing Methods."

Product Information

DBX® Inject™ Demineralized Bone Matrix

	Volume (cc)
068025	2.5
068050	5.0
068100	10.0

Delivery Cannulas and Tamps, sterile (1 ea./pkg.)

	(Trauma)
03.702.400.97S	8 gauge x 10 cm
03.702.403.97S*	8 gauge x 19 cm
03.702.401.97S	10 gauge x 10 cm
03.702.402.97S	12 gauge x 5 cm

	(Spine)
03.702.400.99S	8 gauge x 10 cm
03.702.403.99S*	8 gauge x 19 cm

* Recommended for use with paste only.

Note: For additional information, please refer to the package insert or www.e-ifu.com.

For detailed cleaning and sterilization instructions, please refer to www.depuysynthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.

Some devices listed in this technique guide may not have been licensed in accordance with Canadian law and may not be for sale in Canada.
Please contact your sales consultant for items approved for sale in Canada.

DePuy Synthes

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Available through
Synthes USA Products, LLC
1302 Wrights Lane East
West Chester, PA 19380

Synthes GmbH
Luzernstrasse 21
4528 Zuchwil, Switzerland

To order (USA): 800-523-0322
To order (Canada): 844-243-4321

Note: For recognized manufacturer, refer to the product label.

www.depuysynthes.com

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MTF tissue forms & products are protected by one or more issued or licensed US patents. A list of patents on available tissues and related technologies may be found on the MTF Website www.mtf.org.

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