DBX Demineralized Bone Matrix. The natural solution for bone grafting needs.

Safe donors

Careful processing

Quality allografts

SYNTHES®

MTF Musculoskeletal Transplant Foundation
the better approach

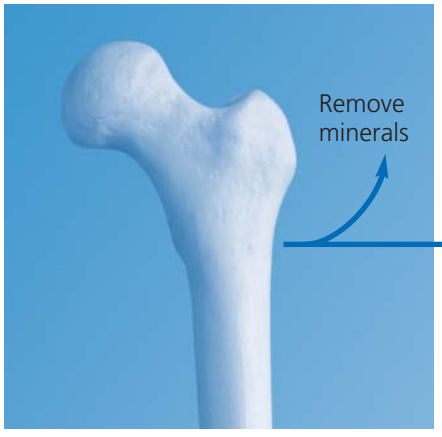
DBX Demineralized Bone Matrix. The natural solution for bone grafting needs.

DBX is demineralized bone matrix that has osteoinductive potential* and is osteoconductive. It is composed of demineralized bone from human donors in a biocompatible carrier.

The various tissue forms have been designed to meet surgical needs while maximizing the amount of bone delivered to the surgical site.

The demineralized bone powder is produced by the removal of minerals from cortical bone. DBX demineralized bone matrix is nonhemolytic, ensuring compatibility with the surrounding autogenous blood cells. The DBX formulation has been specifically designed to model the pH of human blood.

Cortical bone



Demineralized bone powder

Sodium hyaluronate carrier

DBX demineralized bone matrix

*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.

Indications and Contraindications

Indications
DBX 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 is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury.

Additionally, DBX Putty and Paste are intended for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oral/maxillofacial and dental intraosseous defects. DBX is for single-patient use only.

Contraindications*
DBX is not intended to provide structural support of the bone during the healing process. DBX is also contraindicated in the following circumstances:
– Incomplete 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
– Sepsis in or around the surgical site
– Inability to cooperate with and/or comprehend postoperative instructions

Indications for Use

	DBX Putty	DBX Inject	DBX Paste	DBX Mix	DBX Strip
Extremities	•	•	•	•	•
Spine				•	
Posterolateral spine†	•	•			•
Pelvis	•	•	•	•	•
Ridge augmentation	•	•	•		
Filling of extraction sites	•	•	•		
Cranium	•				
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	•	•	•		

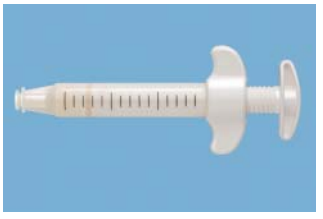
†DBX putty can be used as an extender in the spine with autograft. DBX can be used with bone marrow aspirate.

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

Excellent Handling Properties

DBX Putty
– Provides a moldable consistency
– Can be mixed with blood or bone marrow
– Composed of granulated cortical bone in sodium hyaluronate
– 31% bone content (by weight)

DBX Inject – DBX Putty with a delivery system
– Provides a moldable consistency direct from the delivery system
– Composed of granulated cortical bone in sodium hyaluronate
– Cannula and tamp available for more precise delivery (sold separately)
– 31% bone content (by weight)



DBX Paste
– Provides a flowable consistency
– Composed of granulated cortical bone in sodium hyaluronate
– 26% bone content (by weight)

DBX Mix
– Provides a morselized cortical-cancellous bone texture in sodium hyaluronate
– Eliminates or reduces the need to combine bone chips with DBM
– 35% bone content (by weight)

DBX Strip
– Provides a cohesive and flexible consistency in a preformed strip formulation
– Combined with sodium hyaluronate and gelatin
– 45% bone content (by weight)

All DBX formulations are designed to resist movement under irrigation while maintaining the physical integrity of the tissue form. Every lot of DBX undergoes strict release criteria testing. Sterility is tested per USP <71>. Each lot is also tested via an in vitro or in vivo assay for osteoinductive potential.

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.

Osteoinductive Potential

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

MTF utilizes the following methods to measure DBM osteoinductive potential prior to distribution:
– Athymic mouse muscle pouch assay
– Alkaline phosphatase assay

Athymic Mouse Test
The athymic mouse assay for in vivo osteoinductive potential is based upon the Urist[4] model and is designed to histologically confirm that DBX tissues have osteoinductive potential prior to distribution.

In this model, implantation of demineralized bone in the hamstring muscle pouch of an athymic mouse will result in ectopic bone formation if the bone has osteoinductive potential.

Alkaline Phosphatase (ALP) Test
ALP is an enzyme produced by bone growing cells during new bone formation. Demineralized bone will activate these bone growing cells, thus resulting in increased levels of the ALP enzyme. Correlations between the ALP levels and in vivo osteoinductivity scores from the athymic mouse model demonstrate that the ALP assay can be used as another means of measuring the osteoinductive potential of DBM tissue forms.[5]

Each lot of DBX is validated using one or both of these methods.

Important Factors of a Good DBM

Quality tissue
– MTF potential donors must pass through an extensive quality assurance process and comprehensive medical and social history check
– A team of medical/technical specialists evaluates all information, including test results, before the donor is released for processing
– MTF voluntarily exceeds both AATB and FDA screening criteria[6]

Careful processing
– To maintain biological integrity, MTF processes all tissue using aseptic techniques in ISO Class 4 (certified) clean rooms
– MTF tissue is not terminally sterilized

A good carrier
– Sodium hyaluronate is a polysaccharide formed by plasma membrane proteins in the human body
– Sodium hyaluronate naturally occurs in the human body in the joints, eyes, extracellular matrix of skin and musculoskeletal tissue
– Sodium hyaluronate plays an essential role in cell proliferation, migration and adhesion and has been correlated to angiogenesis[1,2]
– Sodium hyaluronate used in DBX is high-quality, medical grade sodium hyaluronate, ISO 13485 certified, produced through fermentation processes using Good Manufacturing Practice (GMP) guidelines

Quality control
– Every lot of DBX undergoes strict release criteria testing
– Each lot is also tested via an in vitro or in vivo assay for osteoinductive potential

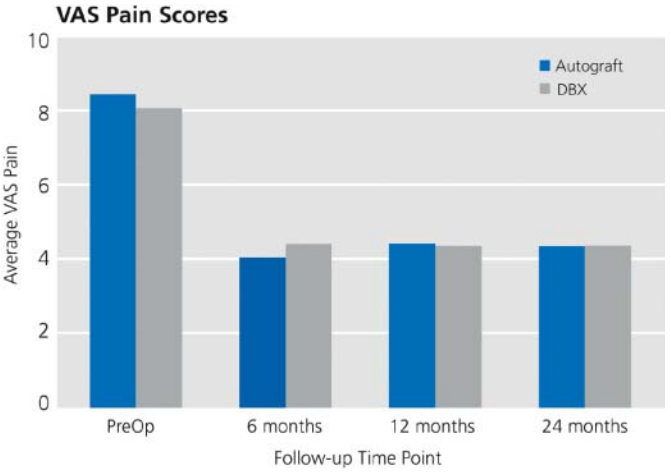
Scientific evidence
– Numerous studies have demonstrated the clinical effectiveness of MTF's demineralized bone matrix forms[7,8]

Clinical Studies

Study 1: DBX Putty plus autograft has been shown to be as effective as autograft alone

A mix of DBX Putty and autograft was shown to be as effective as autograft alone in a multicenter, randomized, controlled clinical study of patients undergoing posterolateral spine fusion for the treatment for degenerative disc disease (DDD).[7]

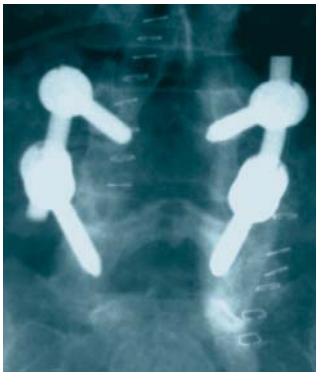
– Equivalent fusion rates were achieved:
  – DBX and autograft = 100% at 24 months
  – Autograft alone = 96% at 24 months
– Both groups exhibited significant decrease in VAS pain scores at 6 months relative to baseline that is sustained through 24 months
– The authors conclude that DBX Putty is at least as effective as autograft alone when used as a bone graft extender in the treatment of DDD via posterolateral spine fusion
– An equivalent fusion rate was achieved between the two groups at 24 months



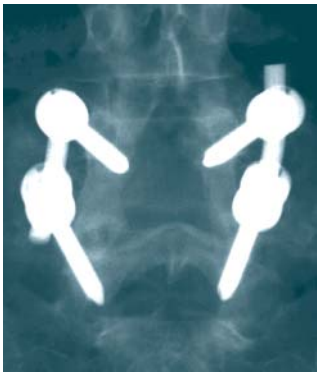
Average Visual Analog Scale (VAS) pain scores over time for autograft alone (Autograft) and DBX with autograft (DBX) treatment groups.

Study 2: DBX Putty effectively treats periodontal intraosseous defects

Intraosseous periodontal defects in systemically healthy patients were treated with either DBX putty or with demineralized freeze-dried bone allograft (DFDBA). Only sites with defects ≥ 3 mm in depth were considered. A statistical analysis was conducted at 6 months postoperative. Both groups of patients yielded significant improvements in percent bone fill, with 37% ± 18.5% bone fill achieved in patients treated with DFDBA and 50% ± 25% in case of patients treated with DBX.[8]



DBX group, 59-year-old woman at discharge showing an immature, disorganized bone graft



Same patient at 12 months, showing a fully matured fusion-mass with mineralized bone graft

Musculoskeletal Transplant Foundation (MTF)

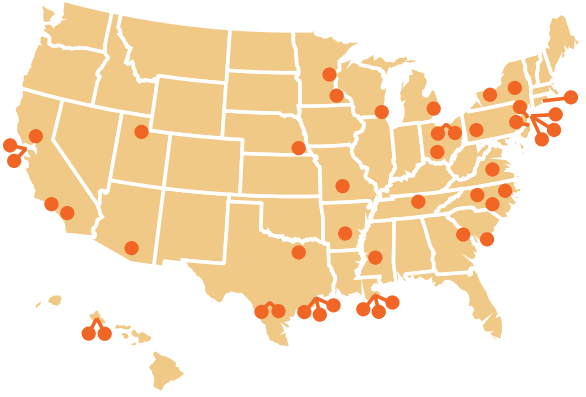
Synthes has partnered exclusively with the Musculoskeletal Transplant Foundation (MTF) for over 10 years to provide high quality tissue for patients. Although there are national standards for tissue banks, they only set a baseline for the industry. Beyond that, regulations leave a lot to interpretation, 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. Not all forms of human tissue are the same, nor should they be processed the same way. MTF has developed and validated several tissue cleaning technologies to provide safe and high quality allograft bone. Since MTF's inception, MTF has maintained an exemplary safety record distributing almost 4.2 million allografts from nearly 80,000 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

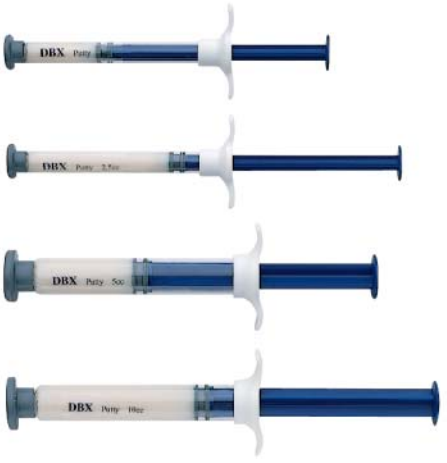
Product Information

DBX Demineralized Bone Matrix—Paste

	Volume (cc)
028005	0.5
028010	1.0
028050	5.0
028100	10.0

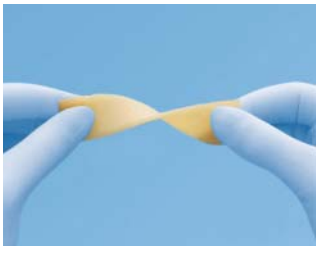
DBX Demineralized Bone Matrix—Putty

	Volume (cc)
038005	0.5
038010	1.0
038025	2.5
038050	5.0
038100	10.0



DBX Demineralized Bone Matrix—Strip

	Size (cm)	
048010	2.5 x 10	(Spine)
048125	2.5 x 5	(Trauma)
048150	5 x 5	(Trauma)



DBX Demineralized Bone Matrix—Mix

	Volume (cc)
058025	2.5
058050	5.0
058100	10.0
058200	20.0

DBX Demineralized Bone Matrix—Inject (Spine and Trauma only)

	Volume (cc)
068025	2.5
068050	5.0
068100	10.0

References

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