

# DBX Strip. Demineralized Bone Matrix.

Easy to use

Stays in position

Proven bone  
formation



# DBX Strip

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DBX Strip is part of the DBX family of tissue forms, which includes DBX Putty and Mix.

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## Features

### Easy to use

- Flexible and ready-to-use straight out of the package
- Easily cut and contoured to the surgical site
- Resists sticking and adhering to surgical gloves
- Long enough to address most two-level procedures

### Proven bone formation

- 45% demineralized bone by weight
- Osteoconductive and shown to have osteoinductive potential in the validated athymic mouse model\*
- Osteoinductivity testing is conducted on each lot. Only those tissues with an acceptable histological verification of bone growth are made available for distribution and implantation

### Biocompatible carriers

- Sodium hyaluronate is a naturally derived material that is biocompatible and biodegradable
- Porcine gelatin provides flexibility

### Stays in position

- Resists displacement and wash-away from irrigation



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## Osteoinductive potential

- Osteoconductive and shown to have osteoinductive potential in the validated athymic mouse model\*
- Every lot tested for osteoinductive potential via a validated model

\* It is unknown how osteoinductive potential, measured in the athymic mouse model, will correlate with clinical performance in human subjects.

# Indications

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## **Indications\*\***

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.

\*\*Refer to the package insert for complete listing of indications, contraindications, warnings and precautions.

# DBX Strip Animal Study

## “Posterolateral Lumbar Fusion with a Strip Formulation of DBM”

The purpose of this animal study was to evaluate the performance of a solid, one-piece flexible form of DBX, DBX Strip, in a single-level rabbit lumbar fusion model. Autograft was used as the control group, with DBX Strip alone and DBX Strip plus autograft used in the experimental groups.

- Rabbit model
- L5–L6 fusion
- 9-week study duration<sup>1</sup>



Group 1



Group 2



Group 3

	<b>Group 1</b>	<b>Group 2</b>	<b>Group 3</b>
Investigation (20 subjects/group)	1.4 g Autograft (Control)	2 DBX Strips (1 strip per side)	2 DBX Strips (1 strip per side) plus 1.4 g of Autograft
Fusion Percentage (%)	68.7%	100%	100%
Fusion determined by manual palpation (%)	37.5%	93.8%	100%
Bone Volume (mm <sup>3</sup> )	2142 ± 318 mm <sup>3</sup>	3132 ± 632 mm <sup>3</sup>	4181 ± 609 mm <sup>3</sup>

In vivo results may not necessarily be indicative of clinical performance.

<sup>1</sup> Y.S. Choi, B. Johnstone, J.U. Yoo. “Posterolateral Lumbar Fusion with a Strip Formulation of DBM.” Case Western Reserve University, Cleveland, OH. Unpublished investigation, 2005.

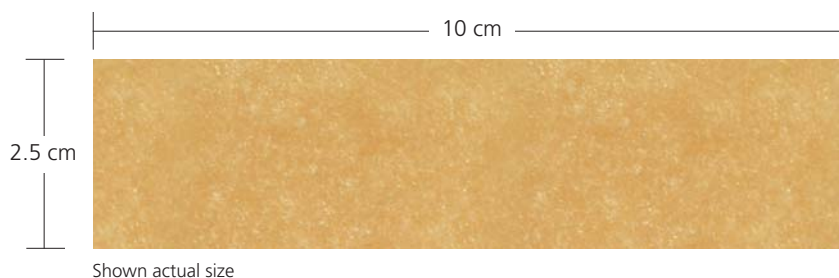
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**Conclusion**

The results of this study show that in animal testing, DBX Strip is highly osteoinductive by itself as well as when mixed with autograft. DBX Strip, both by itself and mixed with autograft, yielded higher fusion rates and remodeled bone volumes than did autograft alone.

# Product Information

048010 DBX Strip, 2.5 cm x 10 cm



## Also available from MTF

### 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—Inject

	Volume (cc)
068025	2.5
068050	5.0
068100	10.0



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

03.702.400.99S	8 gauge x 10 cm
03.702.403.99S	8 gauge x 19 cm



### DBX Demineralized Bone Matrix—Mix

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



# 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.

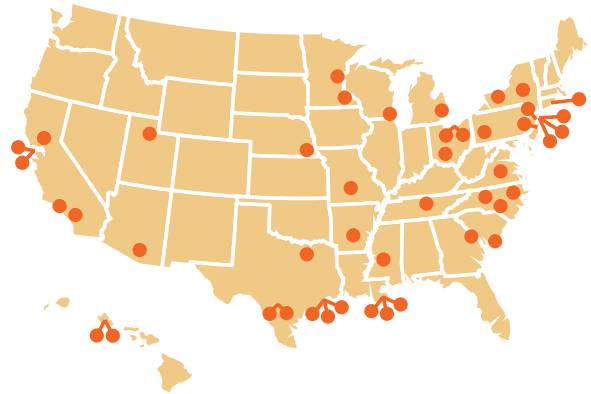
## Selecting the Ideal Donor

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 provided more than 5 million allografts from over 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.



*Available through*  
Synthes Spine  
1302 Wrights Lane East  
West Chester, PA 19380  
Telephone: (610) 719-5000  
[www.synthes.com](http://www.synthes.com)



*Processed by*  
Musculoskeletal Transplant  
Foundation  
125 May Street  
Edison, NJ 08837  
Telephone: (732) 661-0202  
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