Medtronic

GRAFTON®

Demineralized Bone Matrix

DATA

FIBERS

FORMS

Data

GRAFTON® Demineralized Bone Matrix Has More Peer-reviewed Studies Than Any of the Major Competitors in DBM on the Market*

» Over 70 studies published in peer-reviewed journals.

» Peer-reviewed studies on spine, neurosurgery, orthopedic trauma and reconstruction surgery, and craniomaxillofacial surgery.

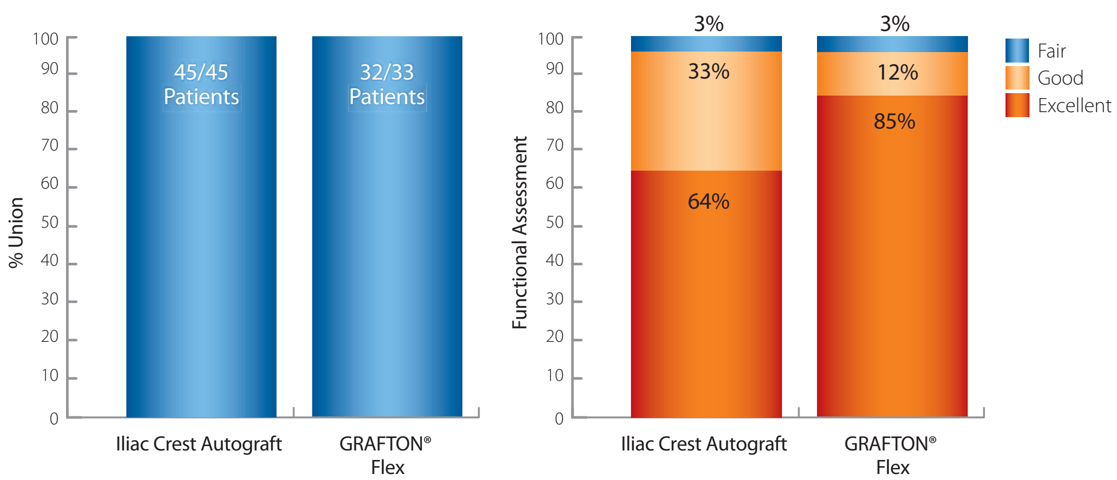
» Demonstrated 20 years of clinical history in nearly 1 million procedures worldwide.**

*Based on a Pub-Med search on 11/30/11 with keywords, Grafton, DBX, Accell, and Osteosponge.
**Based on internal sales data.

Shown to Be as Effective as Iliac Crest in Peer-Reviewed Clinical Studies

JBJS, Plate fixation of ununited humeral shaft fractures: effect of type of bone graft on healing. 2006;88-A(7):1442-1447. Hierholzer, C, Sama, D, Helfet, DL, et al.

78 Patient Retrospective Cohort Series with Minimum One-Year Follow-Up



» GRAFTON® Flex was successful for graft augmentation in the treatment of humeral nonunion and delayed unions without the need to recover iliac crest autograft and the associated donor site morbidity.

» 44% of the patients treated with iliac crest autograft had minor to major donor site morbidity.

» Patients treated with GRAFTON® Flex showed statistically better (p=0.04) elbow scores.

DATA

DATA

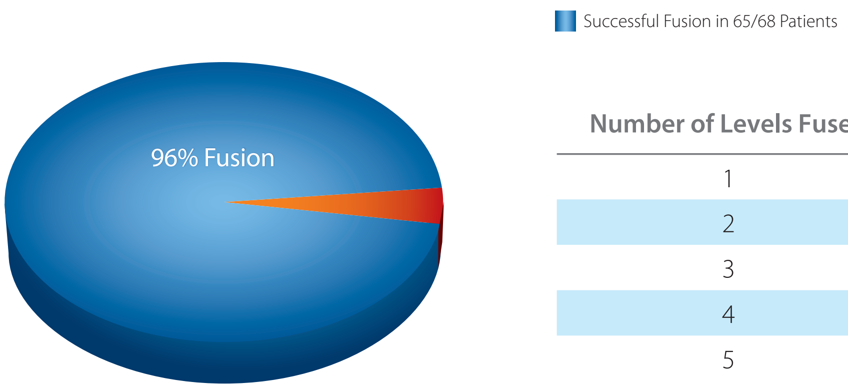
Data *continued*

Shown to Be Effective in Peer-Reviewed Clinical Studies

Neurosurg Q, **Safety and efficacy of demineralized bone matrix used in posterolateral lumbar spine fusion.** 2006;16(1):35-39. Bose B

68 Patient Retrospective Review with Minimum One-Year Follow-Up

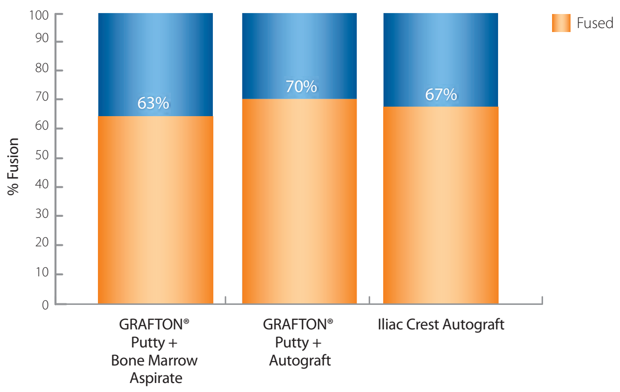
» GRAFTON® Flex demonstrated 96% successful fusion (65/68 patients)



Number of Levels Fused	Patients
1	24
2	29
3	10
4	3
5	2

Orthopedics, **Demineralized bone matrix composite grafting for posterolateral spinal fusion.** 2007; 30(7):567-70. Vaccaro, AR, Stubbs, HA, and Block, JE

73 Patient Prospective Clinical Series with 24 Months of Radiographic Follow-Up



» Fusion rates were statistically equivalent (p=0.0875) between GRAFTON® Putty groups and the Iliac Crest group

Fibers

Most demineralized bone products on the market are made with particles, created by grinding the bone into a powder and then demineralizing it. Bone fibers are created by a unique milling technique, and they produce a greater osteoconductive structure.

Medtronic (Osteotech, Inc.) holds the patents on this proprietary bone fiber technology, and is the only manufacturer to offer products containing bone fibers.

Exclusive Proprietary Fiber Technology

» Patented fiber technology offers enhanced osteoconductive scaffold[8]

Particle-based DBM

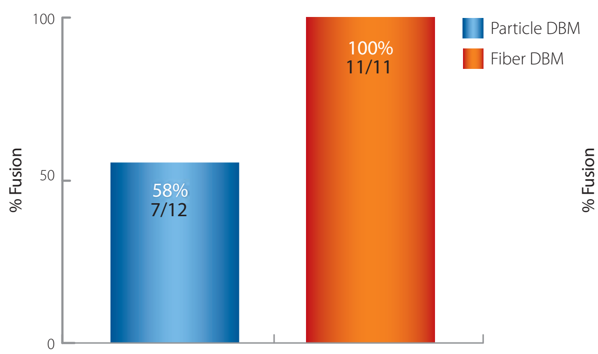
Fiber-based DBM

Fibers *continued*

Why are Fibers Better?

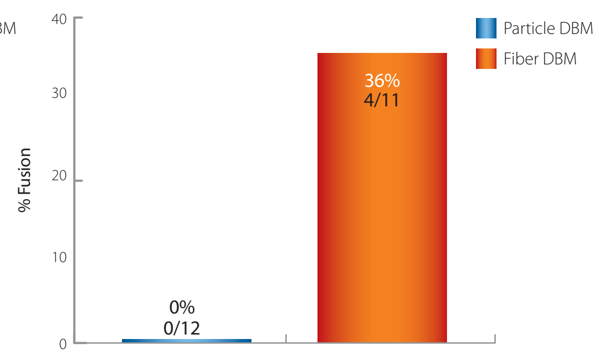
SPINE, **New Formulations of Demineralized Bone Matrix as a More Effective Graft Alternative in Experimental Posterolateral Lumbar Spine Arthrodesis.** 1999;24(7):637-645. Martin GJ, Boden SD, Titus L, and Scarborough, NL.[8]

Fusion Rate in Preclinical Model
(Osteoinductive and Osteoconductive)



(3.0ml of DBM with no enhancements)

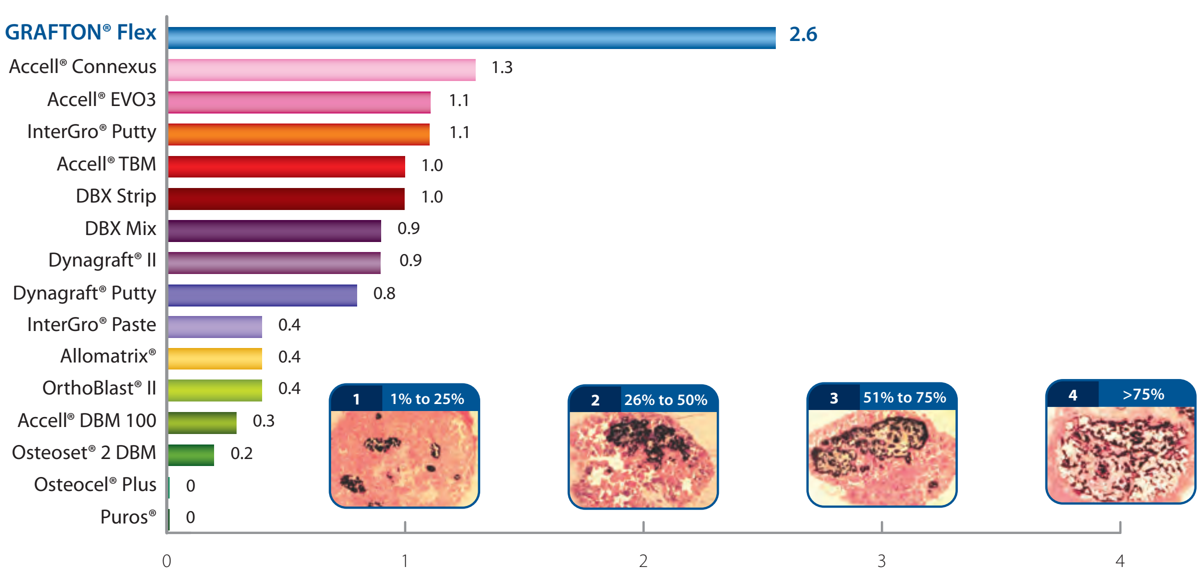
Fusion Rate in Preclinical Model
(Osteoconductive Only)



(Devitalized fibers and particles only with growth factors removed)

» Fiber-based DBM is a more effective osteoconductive structure than Particle-based DBM[8].

Demonstrated the Most Osteoinductive Demineralized Bone Matrix (Pre-Clinical Model)[6–7]



Osteoinductivity Score/Histology of New Bone Formation

Animal testing is not necessarily indicative of human clinical outcome.

Forms

Common Uses

GRAFTON® Demineralized Bone Matrix is a bone graft extender, bone graft substitute, and bone void filler in bony voids or gaps of the skeletal system (i.e. spine, pelvis, extremities) not intrinsic to the stability of the bony structure.

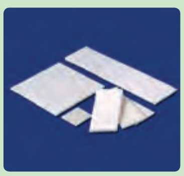
Contraindicated for use in the presence of infection at the transplant site.

Preformed Fiber Technology

GRAFTON® A-FLEX® Graft DBM

GRAFTON® A-FLEX® Graft DBM is a flexible formulation of GRAFTON® Demineralized Bone Matrix with a radial cleave that allows for customization.

Common Uses: Pelvis



GRAFTON® Flex

GRAFTON® Flex is a flexible sheet that can be applied whole, or cut into strips or smaller pieces.

Common Uses: Trauma, Extremities

GRAFTON® Matrix

GRAFTON® Matrix has a unique trough-like design that allows for use with allograft/autograft bone. Two grafts per package.

Common Uses: Spine

GRAFTON® Strips

GRAFTON® Strips are long, narrow strips of demineralized bone matrix that overlap for contiguous bone graft contact. Two grafts per package.

Common Uses: Spine

Fiber Technology

GRAFTON® CRUNCH® Graft DBM

GRAFTON® CRUNCH® Graft DBM is a ready-to-use mixture of demineralized bone fibers and demineralized cortical bone chips that packs into bone defects.

Chip Size: 2mm-4mm

Common Uses: Spine, Trauma, Pelvis, Extremities

GRAFTON® Putty

GRAFTON® Putty consists of demineralized bone fibers and can be mixed with either allograft or autograft bone.

Common Uses: Spine, Trauma, Pelvis, Extremities

Large Defect

Small Defect

GRAFTON® Orthoblend—Large Defect
GRAFTON® Orthoblend—Small Defect

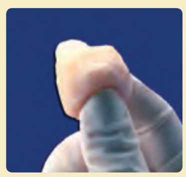
GRAFTON® Orthoblend, available in two distinct formulations, combines demineralized bone fibers with cancellous chips or crushed cancellous chips.

LG Chip Size: 2mm-10mm

SM Chip Size: 0.1mm-4mm

Common Uses: Spine, Trauma, Pelvis, Extremities

Injectable (Non-Fiber)



GRAFTON® Paste

GRAFTON® Paste is moldable and can be mixed with allograft or autograft bone.

Common Uses: Spine, Trauma, Pelvis, Extremities

GRAFTON® Gel

GRAFTON® Gel can be injected percutaneously and can be mixed with cancellous chips.

Common Uses: Trauma, Extremities

Ordering Information

Part Number	Description	Size
"X"42160	GRAFTON® A-FLEX® DBM	6 cm (Diameter)
"X" 42090	GRAFTON® Flex	1.5cm × 1.5cm
"X" 42110	GRAFTON® Flex	2.5cm × 5cm
"X" 42100	GRAFTON® Flex	2.5cm × 10cm
"X" 42210	GRAFTON® Matrix (2)	2.5cm × 5cm
"X" 42200	GRAFTON® Matrix (2)	2.5cm × 10cm
"X" 42275	GRAFTON® Strips (2)	1cm × 10cm
"X" 42280	GRAFTON® Strips (2)	1cm × 20cm
"X" 44105	GRAFTON® CRUNCH® DBM	5cc Jar
"X" 44115	GRAFTON® CRUNCH® DBM	15cc Jar
"X" 43101	GRAFTON® Putty	.5cc Jar
"X" 43102	GRAFTON® Putty	1cc Jar
"X" 43103	GRAFTON® Putty	2.5cc Jar
"X" 43105	GRAFTON® Putty	5cc Jar
"X" 43110	GRAFTON® Putty	10cc Jar
"X" 44125	GRAFTON® Orthoblend—Large Defect	5cc Jar
"X" 44135	GRAFTON® Orthoblend—Large Defect	15cc Jar
"X" 44145	GRAFTON® Orthoblend—Small Defect	5cc Jar
"X" 44150	GRAFTON® Orthoblend—Small Defect	10cc Jar
"X" 45001	GRAFTON® Paste	1cc Syringe
"X" 45005	GRAFTON® Paste	5cc Syringe
"X" 45010	GRAFTON® Paste	10cc Syringe
"X" 41110	GRAFTON® Gel	.5cc Syringe
"X" 41120	GRAFTON® Gel	1cc Syringe
"X" 41130	GRAFTON® Gel	5cc Syringe
"X" 41150	GRAFTON® Gel	10cc Syringe

"X" is a placeholder for the prefix that will be assigned by the Customer Service Representative.

References

1. Khan SN, Fraser JF, Sandhu HS, Cammisa FP, Girardi FP, Lane JM. Use of osteopromotive growth factors, demineralized bone matrix, and ceramics to enhance spinal fusion. *J Am Acad Orthop Surg*. 2005;13(2):129-137.

2. Cammisa FP, Lowery G, Garfin SR, Geisler FH, Klara PM, McGuire RA, Sassard WR, Stubbs HA, Block JE. Two-year fusion rate equivalency between GRAFTON® DBM Gel and autograft in posterolateral spine fusion. *Spine*. 2004;29(6):660-666.

3. Vaccaro AR, Stubbs HA, Block JE. Demineralized bone matrix composite grafting for posterolateral spinal fusion. *Orthopedics*. 2007;30(7):567-570.

4. Kang J, An H, Hilibrand A, Yoon ST, Generelli J, Kavanagh E, Boden S. GRAFTON® and local bone has comparable outcomes to iliac crest bone in single level lumbar fusions. Abstract presented at the American Academy of Orthopaedic Surgeons Annual Meeting; 2008.

5. Peterson B, Whang PG, Iglesias R, Wang JC, Lieberman JR. Osteoinductivity of commercially available demineralized bone matrix. *J Bone Joint Surg Am*. 2004;86-A(10):2243-2250.

6. Data on File, Osteotech Inc.

7. Edwards JT, Diegmann MH, Scarborough NL. Osteoinduction of human demineralized bone: characterization in a rat model. *Clin Orthop Relat Res*. 1998;357:219-228.

8. Martin GJ, Boden SD, Titus L, Scarborough NL. New formulations of demineralized bone matrix as a more effective graft alternative in experimental posterolateral lumbar spine arthrodesis. *Spine*. 1999;24(7):637-645.

Indications

GRAFTON® Demineralized Bone Matrix can be used as a bone graft extender, bone graft substitute, and bone void filler to fill bony voids or gaps not intrinsic to the stability of the bony structure.

GRAFTON® Demineralized Bone Matrix
is derived from human tissue which was
generously donated so that others may benefit.

www.medtronic.ca

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www.myspinetools.com

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Medtronic