HOSPITAL OVERVIEW
AND TECHNICAL ASSESSMENT

Grafton™ DBF Inject

TECHNOLOGY OVERVIEW

Grafton (Demineralized Bone Fiber) DBF Inject is a demineralized bone allograft consisting of demineralized cortical fibers derived from cadaveric donor. This graft comes pre-loaded in a syringe with minimally invasive accessories that allow the product to be delivered through most retractor systems and helps facilitate spine fusion procedures, as well as any bone voids where fusion/union is desired.

- Utilizes Grafton DBM technology
- 100% Allograft or HCT/P
- MIS (Minimally Invasive Surgery) disposable instruments included in every kit

Description

Grafton DBF Inject is a human allograft-based bone grafting product preloaded in an MIS graft delivery syringe. This allograft bone graft product is processed by removing the mineral, leaving only the organic portion of bone. The remaining organic portion is composed of demineralized cortical fibers that consist of collagen and native growth factors found within the collagen matrix. Grafton DBF is prepared via a proprietary processing method of Medtronic validated to consistently produce (Demineralized Bone Matrix) DBM that is osteoinductive in an athymic rat assay. Product and process consistency are confirmed via ongoing testing of Grafton™ DBF finished product for osteoinductivity in this validated athymic rat assay using a five-point linear scale (0,1,2,3,4) to score bone formation at 28 days post implantation.[1]

In addition to the osteoinductive properties of this graft, the fiber technology found in Grafton DBF Inject has shown enhanced osteoconductive properties when compared to particulate based DBM.[2]

Grafton DBF Inject can be used in orthopedic or reconstructive bone grafting procedures. The product can also be used in bone grafting procedures in combination with autologous bone or other forms of allograft bone, or alone as a bone graft.

Contraindications:

The Presence of infection at the transplant site is a contraindication for the use of this allograft.

Animal studies are not necessarily indicative of human clinical outcomes.

Medtronic
Further, Together

TECHNOLOGY OVERVIEW

Medtronic's processing facility, located in Eatontown, New Jersey, is accredited by the American Association of Tissue Banks (AATB), and is committed to providing quality and innovation in its various demineralized bone matrix tissue forms. We use our proprietary D-Min™ process to demineralize the allograft tissue that goes into the different Grafton DBM forms. Controls in the D-Min process eliminate many of the variables that can affect the osteoinductivity of demineralized bone matrix. Through a prospective randomized study of production allograft, we were able to validate that the D-Min process yields a consistently osteoinductive product.[3] Product processing consistency is confirmed via ongoing testing.†

GRAFTON DBM THE BONE GRAFT WITH PROVEN TECHNOLOGY RESULTING IN PROVEN BONE HEALING

Grafton DBM has over **25 years of clinical history.**

Grafton DBM has been used in over **1.5 million surgeries.**‡

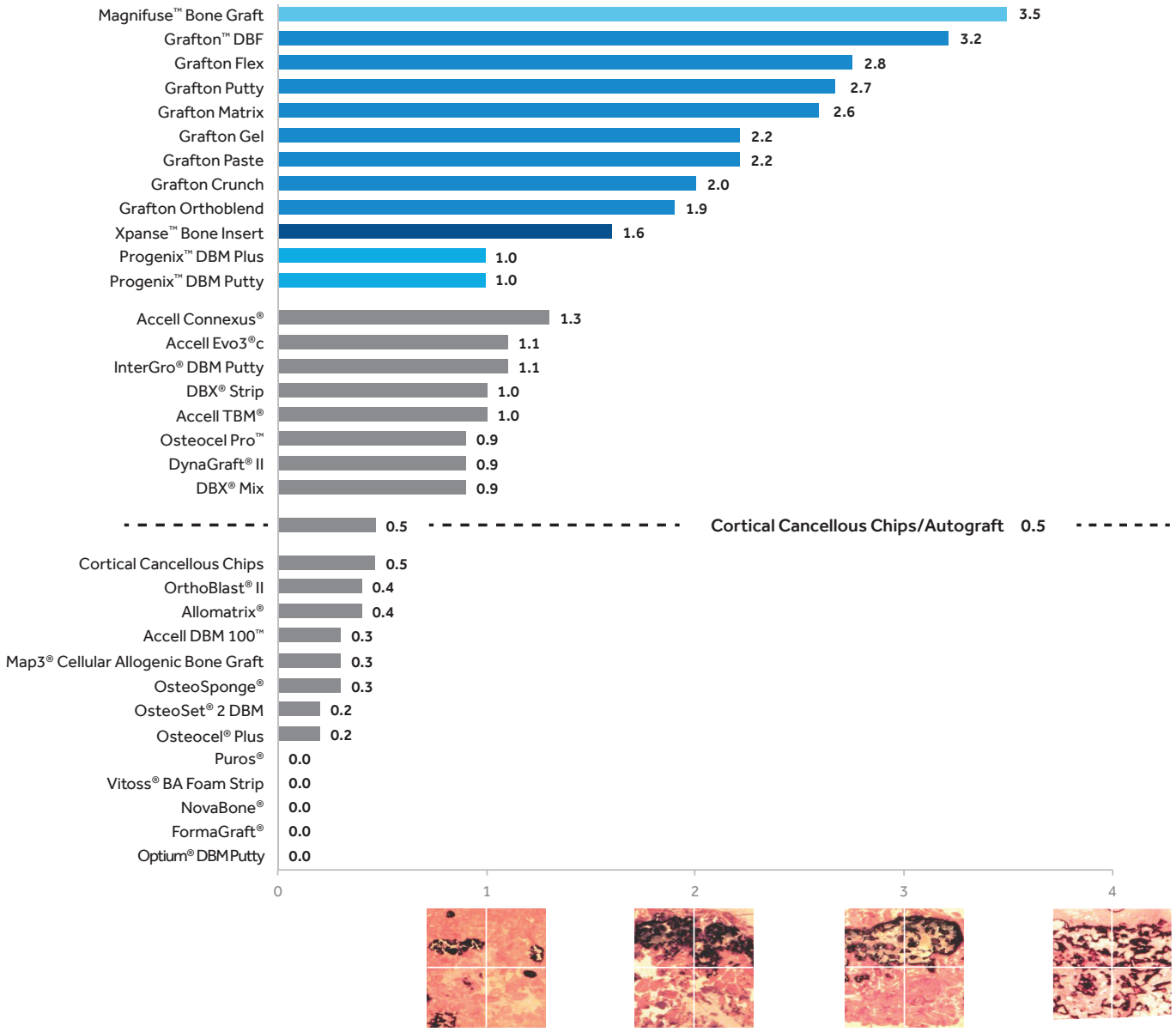
The fiber technology has demonstrated enhanced **osteoconductive** properties over particle based DBMs in preclinical studies.[2]

Our validated process consistently produces an **osteoinductive** finished allograft.[3†]

Proven in prospective clinical studies.[4,5,6]

The MIS syringe allows for the delivery of graft material directly into deep bony voids, for example the interbody space. The MIS cannulas and plungers that are packaged with the graft material allow for delivery through retractor systems such as Metrx™ System and Quadrant™ System. The cannula lengths provided are 10cm and 22cm which should accommodate voids and different depths.

OSTEOINDUCTIVITY BY PRODUCT[1†]



Animal testing is not necessarily indicative of human clinical outcome.

1 Histological scoring table based on images from Edwards, JT et al. Clin Orthop Relat Res. 1998;357:219-228

† Data on File from Medtronic internal testing (11/2016):
Grafton™ DBM products, Magnifuse™ Bone Graft, Xpanse™ Bone Insert, Mastergraft™ Matrix ongoing final product testing (2006-2014); Accell Connexus®, three manufacturing lots tested on 2005; Accell Evo3®c, three manufacturing lots tested on 2010/2014; Intergro® Putty, one manufacturing lot tested on 2004; Accell TBM®, two manufacturing lots tested on 2010; DBX® Strip, three manufacturing lots tested on 2010; DBX® Mix, two manufacturing lots tested on 2010; DynaGraft® II, one manufacturing lot tested on 2003; Allomatrix® DBM, five manufacturing lots tested on 1999/2005; OrthoBlast® II DBM Putty, two manufacturing lots tested on 2003/2005; Accell DBM 100, two manufacturing lots tested on 2003/2005; OsteoSet®2 DBM, two manufacturing lots tested on 2008; Osteocel® Plus, four manufacturing lots tested on 2011-16; Osteocel® Pro, three manufacturing lots tested on 2016; Puros® one manufacturing lot tested on 2010; Optium® one manufacturing lot tested in 2017.

TECHNOLOGY APPLICATION

Use

Grafton DBF Inject can be used in orthopaedic or reconstructive bone grafting procedures. It can also be used in combination with autologous bone or other forms of allograft bone, or alone as a bone graft.

Alternative Options for Spinal Treatment

NONSURGICAL TREATMENT. Nonsurgical, conservative treatments, including spinal injections and physical therapy, are commonly used and are generally recommended or required before spinal fusion.

SURGICAL DECOMPRESSION WITHOUT FUSION. Decompression of neural structures in the absence of fusion has demonstrated quality outcomes for certain indications, often related to which there is no existing or iatrogenic deformity or instability of the spine.

SURGICAL FUSION WITHOUT INSTRUMENTATION. Fusion of vertebrae was originally attempted without the use of stabilizing implants. Uninstrumented lumbar spinal fusion procedures are rare due to risk of pseudarthrosis, or failure to fuse.

TECHNOLOGY PREPARATION

Education

Medtronic offers hospital staff several training opportunities on the use of our products and tissue, including training on, where applicable, technologies, pathologies and processes.

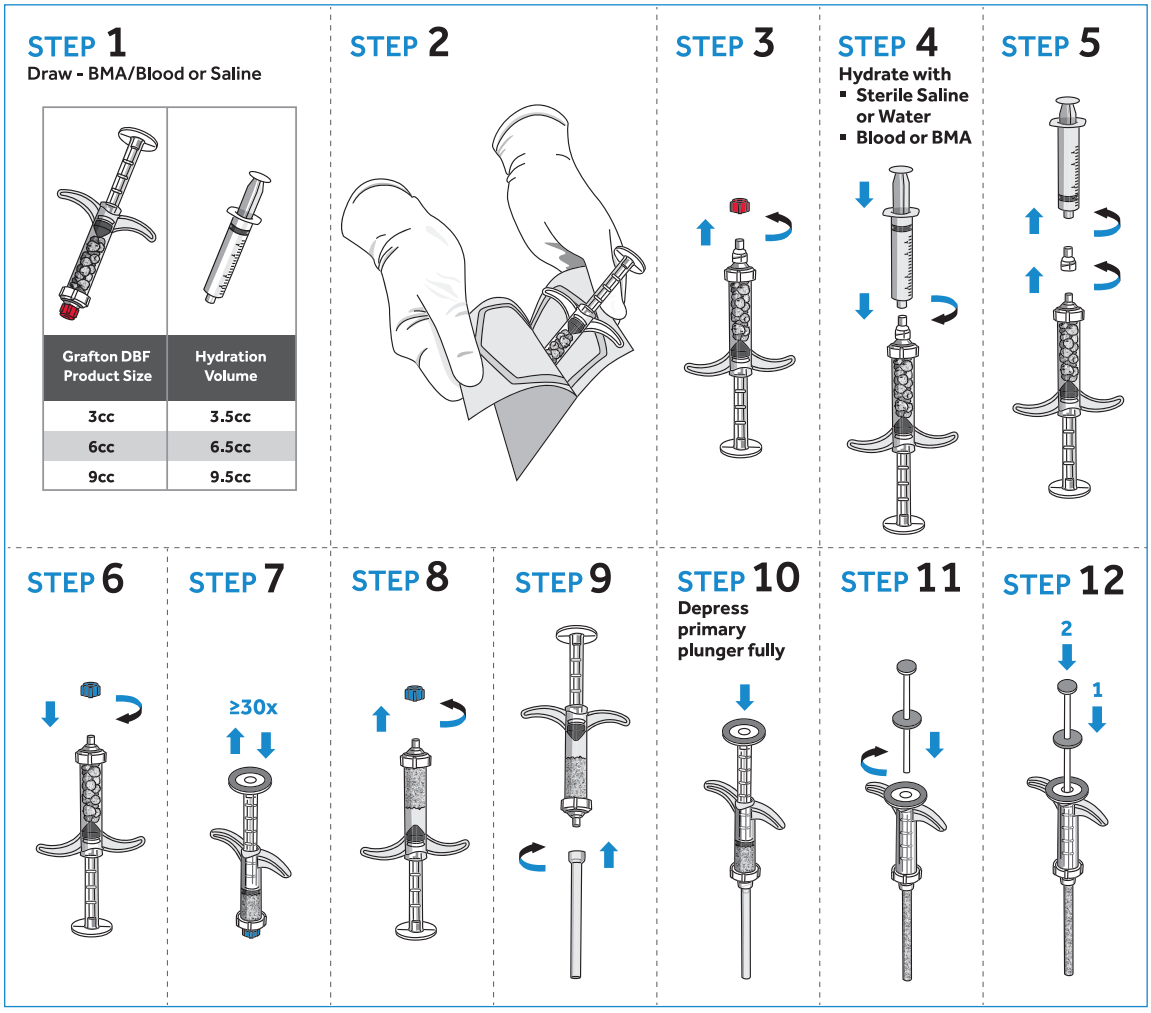
Surgeon education and training events featuring Grafton DBF Inject are offered throughout the year at various locations.

Surgeons and hospital staff will also be provided with other technology materials for review.

Please contact your local Medtronic sales representative for more information.

Opening and Preparation

All components are provided sterile. The graft material is provided in dual barrier foil pouch, while the accessories are provided in a single barrier. The below graphic demonstrates the steps required to prepare Grafton DBF Inject for use. The IFU should be consulted for full opening procedures.



Sterilization

The contents of an individual Grafton DBF Inject are intended for single patient use. All the syringe components have been sterilized prior to the addition of the graft material. Grafton DBF inject is labeled as "Aseptically Processed, Passes USP Sterility Tests" or "Sterile" which means it was aseptically processed and tested for sterility according to procedures in the current U.S Pharmacopeia.

Treatment with Low-Dose Gamma Irradiation

For tissues that are not sterilized with gamma irradiation, Medtronic may use low dose gamma irradiation as an adjunct to aseptic processing to reduce bioburden.

Grafts labels containing "Treated with Gamma Irradiation" indicate that low dose (1.0- 1.8 megrads) gamma irradiation was used as a means of reducing the tissue bioburden on the donated allograft prior to processing.

A product label statement will indicate any tissue treated with low dose gamma irradiation (1.3-1.8 megarads) used to treat the particular tissue graft, in addition to any low level gamma irradiation that may have been used on the donated allograft material.

Transportation, Storage & Handling

Grafton DBF Inject is supplied Sterile-A and is labeled for long-term storage between 15°C and 30°C, comparable to room temperature.

Transport time is a very small part of the total storage time of Grafton DBF inject, but this is where the greatest temperature fluctuations are possible. A study has been performed to evaluate the effect of extreme shipping temperatures on osteoinductive properties of Grafton DBM products. In this study, products subjected to temperature fluctuations ranging between -20°C and 60°C over a 20-day period exhibited no difference in osteoinductivity compared to control samples maintained at room temperature.[†]

Visually inspect all sterile-barrier packaging before use. If the sterile barrier is damaged or the integrity has been compromised, do not use the product. Contact your Medtronic representative for return information. Visually inspect the product before use. If the product is damaged, do not use the product. Contact your Medtronic representative for return information.

CODING AND PAYMENT

Inpatient

ICD-10-PCS

Hospitals use ICD-10-PCS to report inpatient services. Demineralized bone allograft is reported as nonautologous tissue substitute. For Spinal fusion applications, demineralized bone allograft is included in the 6th character device value of the fusion procedure code and not separately reported.

Use the code most appropriate for the surgical procedure being performed.

Medicare Severity Diagnosis-Related Groups (MS-DRG)

The use of this product does not drive DRG assignment. Individual patient diagnosis(es) and the reporting of any surgical procedures performed will determine the appropriate MS-DRG. Potential MS-DRG assignment varies due to the product's various indications.

For spinal applications, cases are commonly assigned to the MS-DRGs for spinal fusion, MS-DRGs 453-460 and MS-DRGs 471-473. Additional MS-DRGs include but are not limited to: MS-DRGs 901-909; MS-DRGs 957-959; and MS-DRGs 981-983.

Outpatient

CPT Code

When Using Grafton DBF Inject in a spinal application, report code 20930 (allograft, morselized, or placement of osteopromotive material, for spine surgery only).

CPT	Description	APC
+20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only. (List separately in addition to code for primary procedure).	Packaged

For non-spine related applications, the insertion of allograft is included in the primary procedure code and is not separately reported. Use the code most appropriate for the surgical procedure being performed.

HCPCS code

There is not a Healthcare Common Procedure Coding System (HCPCS) Level II code assigned to this item.

Payer Advocacy

Refer to payer policies and guidelines for specific coverage criteria.

Additional Payment for implants may be allowed if negotiated as part of the contract with the commercial payer.

Coding and Reimbursement Assistance

SPINELINE®
Spine Coding and Reimbursement Support

Provides coding, billing and reimbursement assistance for spinal procedures performed using Medtronic products.

Phone: 877-690-5353

Email: (Physician) **SpinalCodingMD@medtronic.com**
(Hospital) **SpinalCodingHospital@medtronic.com**

Internet: **medtronic.com/SpineLine**

The materials and information cited here are for informational purposes only and are provided to assist in obtaining coverage and reimbursement for healthcare services. However, there can be no guarantee or assurances that it will not become outdated, without the notice of Medtronic, Inc., or that government or other payers may not differ with the guidance contained herein. The responsibility for coding correctly lies with the health care provider ultimately, and we urge you to consult with your coding advisors and payers to resolve any billing questions that you may have. All products should be used according to their labeling.

THERAPY ACCESS SOLUTIONS

Provides assistance with a prior authorization or denials for patients whose medical needs are consistent with FDA approved/cleared indications or are otherwise in accordance with payer policies. Contact Medtronic's Therapy Access Solutions at 866-446-3873 or at **RS.MemSpineTherapyAccess@medtronic.com** for assistance.

SUMMARY OF INDICATIONS, WARNINGS & PRECAUTIONS

Grafton DBF Inject can be used in orthopaedic or reconstructive bone grafting procedures. The product can also be used in bone grafting procedures in combination with autologous bone or other forms of allograft bone, or alone as a bone graft.

Contraindications

The presence of infection at the transplantation site is a contraindication for the use of this allograft.

Caution

This allograft may contain trace amounts of antibiotics (gentamicin), antiseptic (povidone-iodine) and alcohol solutions. Caution should be exercised if the patient is allergic to these antibiotics or chemicals.

Precautions

Despite the viral inactivation and extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of a communicable disease through the use of this tissue graft is still possible. Bacterial infection at the graft site may also occur. Adverse outcomes potentially attributable to Grafton DBF Inject must be reported promptly to Medtronic.

If injecting Grafton DBF inject into the defect site, precaution should be taken not to:

Over-pressurize the delivery device, as this may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissues.

Over-pressurize the defect site, as this may lead to fat embolization or embolization of the device material into the bloodstream.

Syringe/Accessory Kit

Intended Use

The Graft Preparation and Delivery Device is intended for the delivery of hydrated allograft, autograft or synthetic bone graft materials to an orthopaedic surgical site. In addition, it is designed to facilitate the premixing of bone graft materials with fluids such as I.V. fluids, blood, plasma concentrate, platelet rich plasma, bone marrow or other specified blood components as deemed necessary by the clinical use requirements.

Warnings/Precautions

There are no specific warnings, precautions, or adverse effects associated with the use of this device.

Additional Information

Is this product implantable? Yes

How was the product cleared? Since Grafton DBF inject has been minimally manipulated and does not contain a carrier, it is regulated as a 361 HCT/P (human cells, tissues, and cellular and tissue based products).

Is your facility licensed and registered to distribute human tissue?
Yes, copies of licenses and registrations are available upon request. You can access them online on **medtronic.com** in the Allograft Tissue Resource Center.

Does the product require additional instruments? No

Does the product need to be checked by Biomed? No

Does the product contain mercury? No

Does the product contain latex? No

Is this product MRI safe? Yes

Does the product contain carbon-based tissue?
Yes – Human

Is the tissue tracked? Yes
The product is tracked in accordance with federal (USA) regulations under 21 CFR 1271 established requirements for tracking human tissue products. (Please see package insert for complete details).

PRODUCT ORDERING INFORMATION

Part Number	Description	Graft Volume
T50303	Grafton DBF Inject	3cc
T50306	Grafton DBF Inject	6cc
T50309	Grafton DBF Inject	9cc

† Data on file. Animal testing is not necessarily indicative of human clinical outcome.
‡ Based on internal sales data.

1. Edwards, JT et al. Osteoinduction of Human Demineralized Bone: Characterization in a Rat Model. *Clin Orthop Relat Res*. 1998;357:219-228
2. 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
3. Traianedes K, Russell JL, Edwards JT, Stubbs HA, Shanahan IR, Knaack D. Donor Age and Gender Effects on Osteoinductivity of Demineralized Bone Matrix. *Appl Biomater* 70B:21-29, 2004.
4. Anand N, Baron EM, Thaiyananthan G, Khalsa K, Goldstein TB. Minimally invasive multilevel percutaneous correction and fusion for adult lumbar degenerative scoliosis: a technique and feasibility study. *J Spinal Disord Tech* 2008;21:459-67.
5. 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.
6. Kang J, An H, Hilibrand A, Yoon ST, Kavanagh E, Boden S. Grafton™ and local bone have comparable outcomes to iliac crest bone in instrumented single-level lumbar fusions. *Spine* 2012;37:1083-91.

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

The materials and information cited here are for informational purposes only and are provided to assist in obtaining coverage and reimbursement for health care services. However, there can be no guarantee or assurances that it will not become outdated, without the notice of Medtronic, Inc., or that government or other payers may not differ with the guidance contained here. The responsibility for coding correctly lies with the healthcare provider ultimately, and we urge you to consult with your coding advisors and payers to resolve any billing questions that you may have. All products should be used according to their labeling.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.