Medtronic

HOSPITAL OVERVIEW
AND TECHNICAL ASSESSMENT

Magnifuse™

Demineralized Bone Graft

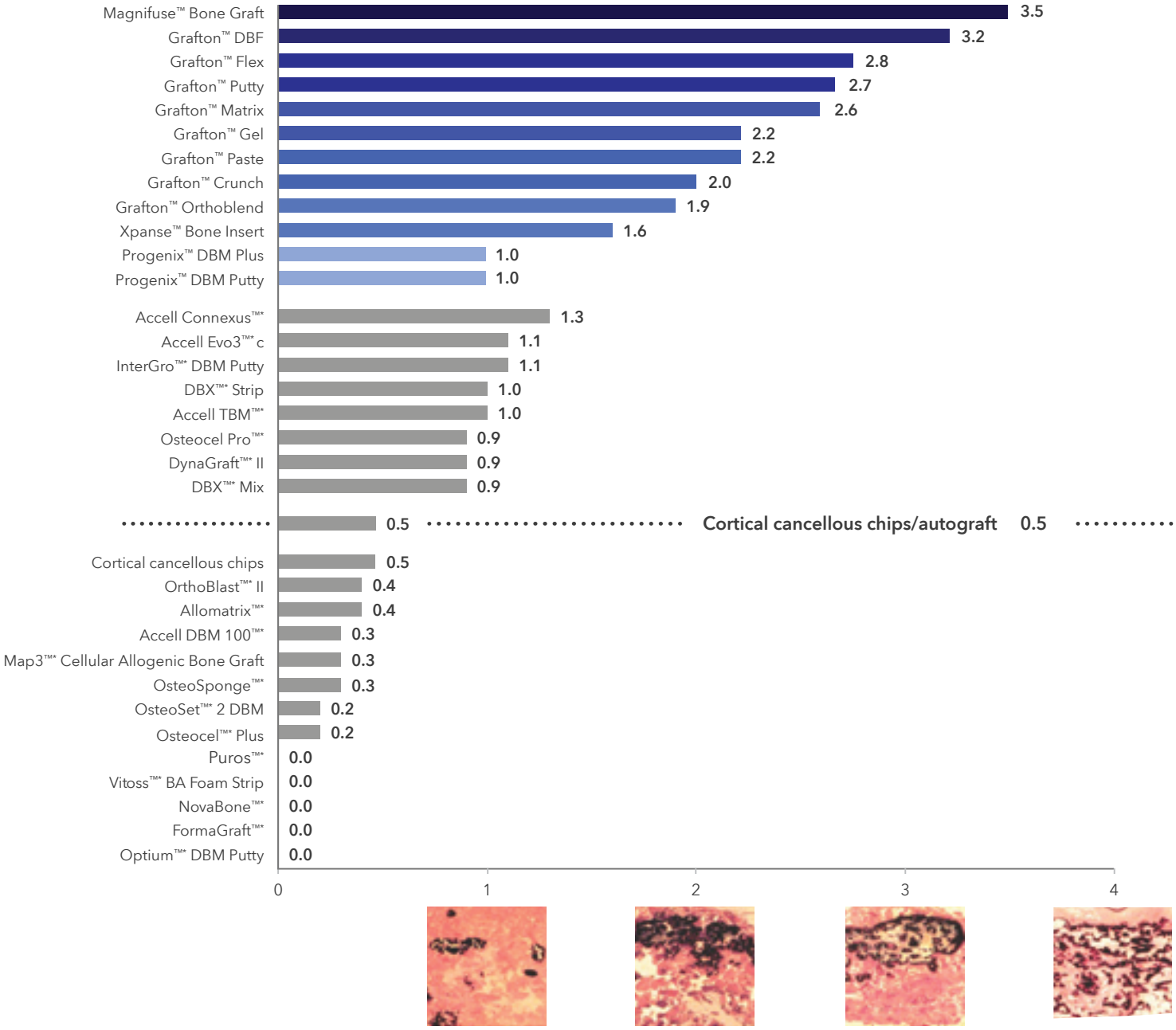
Magnifuse™ DBM is a unique self-contained demineralized bone matrix. Combining demineralized bone fibers with surface demineralized cortical chips, Magnifuse™ DBM allows the surgeon to easily place the allograft material in bone voids.

- Utilizes proprietary demineralized fiber technology
- PGA mesh bag provides a self-contained delivery mechanism
- PGA mesh bag helps prevent graft migration
- Radiopaque for assessment of graft location
- Conforms to patient anatomy
- Highest osteoinductivity[1,2]
- 100% allograft, no carrier
- 88.9% fusion rate in posterolateral spinal fusions[2]

1. Among leading brands of demineralized bone matrix based on internal pre-clinical models tested to date. Animal testing is not necessarily indicative of human clinical outcomes.
2. Data on file at Medtronic.

Osteoinductivity by product[3]

Osteoinduction is the capacity of extracellular signals (in the DBM) to attract, proliferate, and differentiate mesenchymal stem cells (MSCs) or immature bone cells into osteoblasts and form healthy bone tissue. The most direct and accurate way of measuring osteoinductivity is to evaluate the bone forming ability of a graft in a rat's muscle pouch.[4] Since the rat's muscle pouch is devoid of any bone, only osteoinductive materials can induce bone formation. Animal studies should not be interpreted to predict clinical performance.



3. Data on file at Medtronic from internal testing, 05/2020. Animal testing is not necessarily indicative of human clinical outcomes.

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

Grafton™ DBM products, Magnifuse™ bone graft, Xpanse™ bone insert (2006-2019); 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 lot tested in 2017.

Technology overview

Magnifuse™ DBM is a human allograft based product. It is allograft bone that is processed by removing the mineral, leaving only the organic portion of bone. Bone void fillers containing demineralized bone matrix (DBM) have been shown to have osteoconductive potential when tested in an athymic rat assay.[4,*] Magnifuse™ DBM is unique in that it has both demineralized fibers and surface demineralized cortical chips, all contained in a resorbable mesh bag. While many other DBMs use a carrier, Magnifuse™ DBM does not use a carrier, providing a large volume of allograft per cc.

Magnifuse™ DBM comes in several sizes, allowing it to be used in a variety of grafting procedures.

The PGA mesh bag is comprised of polyglycolic acid, commonly used in absorbable sutures.

Technology application

Magnifuse™ DBM is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., spine, pelvis, and extremities) not intrinsic to the stability of the bony structure. Adequate fixation should be used to stabilize the implant site during bone formation and healing in bony voids or gaps of the skeletal system.

Preparation for use

To achieve optimal handling characteristics, Magnifuse™ DBM should be hydrated prior to use. Hydrate the Magnifuse™ DBM for one to two minutes in a small amount of fluid such as bone marrow aspirate, blood, sterile water, or sterile saline.

Recommended spine use

The product should be placed in contact with well decorticated bony surfaces of the spine (i.e., transverse processes, lamina, or facets). The use of local bone is recommended. Ensure the local bone/allograft on the graft site is in direct apposition with the Magnifuse™ DBM. Magnifuse™ DBM can be packed and shaped to contour to the surgical site. The product can be secured to the graft site, if desired, via sutures, staples, or wires.

Magnifuse™ DBM can be used in, but is not limited to, spinal fusion procedures.

Alternative treatment options

- **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 pathologies in which there is no existing or iatrogenic deformity or instability of the spine.
- **Spinal 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 pseudoarthrosis, or failure to fuse.

Technology preparation

Education

Medtronic offers hospital staff a number of training opportunities on safe use of our products, including training on technologies, pathologies, and processes, where applicable. Surgeon education and training events featuring Magnifuse™ DBM are offered throughout the year at various locations. Please contact your local Medtronic sales representative for more information. Surgeons and hospital staff are also provided with other technology materials for review.

Sterilization

Magnifuse™ DBM is packaged in a ready-to-use form, in single patient use containers. Magnifuse™ DBM products have been aseptically processed and tested for sterility according to the procedures in the current U.S. Pharmacopeia, as indicated by the package label.

Treatment with Low-Dose Gamma Irradiation – Medtronic may use low-dose gamma irradiation as an adjunct to aseptic processing to reduce bioburden. Magnifuse™ DBM package labels containing "Treated with Gamma Irradiation" indicate that low dose (1.0 – 1.8megarads) gamma irradiation was used as a means of reducing the bioburden on the donor tissue.

Do not subject this allograft to additional disinfection or sterilization procedures.

Please see the package insert for the most current sterilization information.

4. Edwards JT, Diegmann MH, Scarborough NL. Osteoinduction of human demineralized bone: characterization in a rat model. Clin Orthop Relat Res. (357): 219-28, 1998.

* Animal studies are not always indicative of human clinical outcomes.

Coding and payment

Inpatient

ICD-10-PCS

The insertion of demineralized bone allograft is included in the 6th character device value of a spinal fusion procedure code and not reported separately. Procedures outside of spinal fusion may require the use of an ICD-10-PCS code for the application of allograft bone.

Medicare Severity-Diagnosis Related Groups (MS-DRG)

Individual patient diagnosis(es) and the reporting of any surgical procedures performed will determine the appropriate MS-DRG. Spinal fusion procedures typically group to the following MS-DRGs. The use of this product may not affect MS-DRG assignment.

28	Spinal procedures w mcc
29	Spinal procedures w cc or spinal neurostimulators
30	Spinal procedures w/o cc/mcc
453	Combined anterior/posterior spinal fusion w mcc
454	Combined anterior/posterior spinal fusion w cc
455	Combined anterior/posterior spinal fusion w/o cc/mcc
456	Spinal fus exc cerv w spinal curv/malig/infec or extensive fusion w mcc
457	Spinal fus exc cerv w spinal curv/malig/infec or extensive fusion w cc
458	Spinal fus exc cerv w spinal curv/malig/infec or extensive fusion w/o cc/mcc
459	Spinal fusion except cervical w mcc
460	Spinal fusion except cervical w/o mcc
471	Cervical spinal fusion w mcc
472	Cervical spinal fusion w cc
473	Cervical spinal fusion w/o cc/mcc

Under the MS-DRG system, cases may be assigned to a number of other MS-DRGs, based on individual patient diagnosis and presence or absence of additional surgical procedures performed.

* MCC – Major Complication and/or Comorbidity.
CC – Complication and/or Comorbidity.

Outpatient

CPT™* Code

When using this product in a spinal application, report code +20930 (allograft, morselized, or placement of osteopromotive material, for spine surgery only).

For non-spine related applications, the insertion of allograft may be included in the primary procedure code and 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™ Reimbursement Support Center

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

E-mail: RS.CSTreimbursementsupport@medtronic.com

Web: 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 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 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.

Summary of indications, contraindications, and warnings

Indications

Magnifuse™ DBM is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., spine, pelvis, and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone.

Magnifuse™ DBM may be used in a manner comparable to autogenous bone or allograft bone. Magnifuse™ DBM may be mixed with fluid such as bone marrow aspirate, blood, sterile water, or sterile saline in order to adjust the consistency and handling characteristics of the bone graft material.

Magnifuse™ DBM is resorbed/remodeled and replaced by host bone during the healing process.

Contraindications

The following are contraindications for the use of Magnifuse™ DBM

- The presence of infection at the transplantation site
- Treatment of spinal insufficiency fractures

Caution

This product may contain trace amounts of antibiotics (gentamicin), surfactant, and other solutions used in processing the bone tissue as well as the PGA mesh. Caution should be exercised if the patient is allergic to these antibiotics or chemicals.

Precautions

Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing have been used in the qualification of all tissue donors. Despite the viral inactivation and extensive tissue donor selection and qualifications process used in providing this tissue graft, transmission of an infectious disease through the use of this tissue graft is still possible. Bacterial infection at the graft site may also occur. Any adverse outcomes potentially attributable to Magnifuse™ DBM must be reported promptly to Medtronic.

Adequate fixation should be used to stabilize the implant site during bone formation and healing in bony voids or gaps of the skeletal system.

Additional information

Is the product implantable?

- Yes

How was the product cleared?

- Cleared via 510(k) path – K082615

Is your facility licensed and registered to distribute human tissue products?

- Yes

(Copies of licenses and registrations available upon request)

Does the product require additional instruments?

- No

Note: this product should always be used in conjunction with supplemental fixation. Those systems will have their own instrumentation.

Does the product need to be checked by Biomed?

- No

Does the product contain Mercury?

- No

Does the product contain Latex?

- No

Does the product contain Carbon-based tissue?

- Yes

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.

Contact customer service or your sales representative for the most up-to-date version of the package insert or visit http://emanuals.medtronic.com

Product ordering information

Part Number	Description	Diameter × Length	Qty
7509007	Magnifuse™ Bone Graft	7.5mm × 25mm	1
7509010	Magnifuse™ Bone Graft	10mm × 25mm	1
7509014	Magnifuse™ Bone Graft	14mm × 25mm	1
7509215	Magnifuse™ Bone Graft	1cm × 5cm	2
7509211	Magnifuse™ Bone Graft	1cm × 10cm	2
7509212	Magnifuse™ Bone Graft	1cm × 20cm	2
7509145	Magnifuse™ Bone Graft	1.75cm × 5cm	2
7509141	Magnifuse™ Bone Graft	1.75cm × 10cm	2

Magnifuse™ Bone Graft important product information

Indications

Magnifuse™ bone graft is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., spine, pelvis, and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. Magnifuse™ bone graft may be used in a manner comparable to autogenous bone or allograft bone. Magnifuse™ bone graft may be mixed with blood, sterile water or sterile saline in order to adjust the consistency and handling characteristics of the bone graft material.

Magnifuse™ bone graft is resorbed/remodeled and replaced by host bone during the healing process.

Contraindications

The following are contraindications for the use of Magnifuse™ bone graft

- The presence of infection at the ransplantation site.
- Treatment of spinal insufficiency fractures.

Caution

This product may contain trace amounts of antibiotics (gentamicin), surfactant, and other solutions used in processing

the bone tissue as well as the PGA mesh.

Caution should be exercised if the patient is allergic to these antibiotics or chemicals.

Precautions

Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing have been used in the qualification of all tissue donors. Despite the viral inactivation and extensive tissue donor selection and qualifications process used in providing this tissue graft, transmission of an infectious disease through the use of this tissue graft is still possible. Bacterial infection at the graft site may also occur. Any adverse outcomes potentially attributable to Magnifuse™ bone graft must be reported promptly to Medtronic (i.e., spine, pelvis, and extremities).

Adequate fixation should be used to stabilize the implant site during bone formation and healing in bony voids or gaps of the skeletal system.

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Customer Service:
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medtronic.com

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.

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

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