Magnifuse™ II DBM is assembled at the time of use by the clinician. The clinician is able to combine the provided demineralized allograft with the recovered local autograft and then pack into a unique self-contained resorbable mesh using the disposable funnel and plunger. The surgeon can then place a fully contained construct in bone voids.

- Utilizes proprietary demineralized fiber technology
- PGA mesh bag provides a self-contained delivery mechanism
- PGA mesh bag helps prevent graft migration
- Disposable instruments facilitate the assembly process
- Radiopaque for assessment of graft location
- Conforms to patient anatomy

Magnifuse™ II DBM is a human based allograft product. It contains human allograft bone that has been processed removing the mineral component leaving only the organic portion of bone. Bone void fillers (BVF) containing demineralized bone matrixes (DBM) have been shown to have osteoinductive potential when tested in an athymic rat assay.1,2 Magnifuse™ II DBM is unique in that it is assembled with autograft tissue in a 1:1 matrix using a disposable plastic funnel and plunger and placed inside the resorbable mesh bags provided. Magnifuse™ II DBM does not use a carrier, providing a large volume of allograft per cc. The mesh bag is comprised of Polyglycolic Acid (PGA), commonly used in absorbable sutures.


2. Animal studies are not always indicative of human clinical outcomes
Magnifuse™ II DBM is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., the posterolateral spine and pelvis) 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™ II DBM is resorbed/remodeled and replaced by host bone during the healing process.

**Graft Preparation instructions**

1. Open the outer packaging and transfer the inner packaging to the sterile field.
2. Using a syringe, inject sterile water, sterile saline, or blood into the pouch containing allograft material. Knead the allograft packaging to ensure complete hydration. Use the 5cc for the medium size and 10cc or the large size.
3. Open the allograft package and transfer the contents to a sterile bowl. Mix with morselized autograft to obtain a 1:1 ratio with the homogeneous allograft/autograft mixture.
   
   Note: Autograft size should be less than 2mm in diameter to help prevent clogging when inserting into funnel/mesh.
4. Remove the funnel and mesh from the inner packaging.
5. Place the PGA mesh pouch on the funnel barrel until it is completely engaged.
6. Transfer half of the allograft/autograft mixture to the funnel and advance it into the barrel.
7. Insert the plunger and compress the allograft/autograft mixture within the barrel.
   a. Verify the desired length of the bone graft.
8. Depress the plunger into the barrel and express the graft mass into the PGA mesh pouch. Disengage the mesh pouch from the barrel of the funnel.
9. Once the pouch is disengaged from the barrel, tighten the closure tie to prevent the graft material from loosening.
10. Cut the remaining mesh pouch with sterile surgical scissors.
11. Repeat steps 5 through 10 for a second graft.

Please see surgical technique for an illustrated version of these instructions.

**Recommended Posterolateral Spine usage**

The Product should be placed between two well decorticated transverse process. Ensure the prepared graft site is in direct contact with the graft material. The Magnifuse™ II DBM can be packed and shaped to contour to the surgical site. The product can be secured to the graft site, if necessary, via sutures, staples, or wires.

**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, where applicable, technologies, pathologies, and processes. Surgeon education and training events featuring Magnifuse™ II 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.

Below is a list of a few of those educational items.

- Magnifuse™ II Surgical Technique using as a bone void filler PMD012924-1.0 LITMAGNBR14
- Magnifuse™ DBM: Evaluation of bone formation potential in a sheep femoral defect white paper PMID006124 LITMGNSSWP11
- Degradation and Removal of the graft delivery bag component of Magnifuse™ Bone Graft PMID009000 LITMAGWP13
Sterilization

Magnifuse™ II DBM products have been aseptically processed and tested for sterility according to the procedures in the current U.S. Pharmacopeia USP standard, as indicated by the package label.

Pretreatment with low-dose gamma irradiation

Medtronic may use low dose gamma irradiation as an adjunct to aseptic processing to reduce bioburden prior to the demineralization process. Magnifuse™ II DBM package labels containing “pretreated with Gamma Irradiation” indicate that low dose (1.0 – 1.8 megarads) 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.

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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>459</td>
<td>Spinal fusion except cervical w mcc</td>
</tr>
<tr>
<td>460</td>
<td>Spinal fusion except cervical w/o mcc</td>
</tr>
<tr>
<td>471</td>
<td>Cervical spinal fusion w mcc</td>
</tr>
<tr>
<td>472</td>
<td>Cervical spinal fusion w cc</td>
</tr>
<tr>
<td>473</td>
<td>Cervical spinal fusion w/o cc/mcc</td>
</tr>
</tbody>
</table>

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®

Spine Coding and Reimbursement Support

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

Phone:  877-690-5353

Email:   (Physicians) spinalcodingmd@medtronic.com
         (Hospital) spinalcodinghospital@medtronic.com

Internet:  www.medtronicsofamordanek.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 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™ II DBM is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis) 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™ II DBM may be used in a manner comparable to autogenous bone or allograft bone. Magnifuse™ II DBM 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™ II DBM is resorbed/remodeled and replaced by host bone during the healing process.

Contraindications
The following are contraindications for the use of Magnifuse™ II 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™ II 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.

Indications
The CD Horizon™ Spinal System with or without Sextant™ instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD Horizon Spinal System may also be used for the same indications as an adjunct to fusion. With the exception of degenerative disc disease, the CD Horizon Legacy™ 3.5mm rods and the CD Horizon Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD Horizon Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion.

These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. The CD Horizon Spire™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor. In order to achieve additional levels of fixation, the CD Horizon Spinal System rods may be connected to the Vertex™ Reconstruction System with the Vertex rod connector. Refer to the Vertex Reconstruction System Package Insert for a list of the Vertex indications of use.
**Additional Information**

**Is the product implantable?**
- Yes

**How was the product cleared?**
- Cleared via 510(k) path – K122513 (Copies available upon request or from the FDA web site http://www.accessdata.fda.gov/cdrh_docs/pdf13/K122513.pdf)

**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 – Human

**Is this product MRI safe?**
- Yes

**What temperature should the product be stored?**
- Store this product at 15° – 30°C (59° – 86°F). Do not Freeze

**Is the tissue tracked?**
- Yes

The product is tracked in accordance with Federal (USA) regulations under 21 CFR1271 established requirements for tracking human tissue products.

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

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**Product Ordering Information**

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<thead>
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<th>Part Number</th>
<th>Description</th>
<th>Notes</th>
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<td>7509505</td>
<td>Magnifuse™ II Regular</td>
<td>2.5cm × 5cm</td>
</tr>
<tr>
<td>7509510</td>
<td>Magnifuse™ II Large</td>
<td>2.5cm × 10cm</td>
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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.