Medtronic

Spine bone graft categories

Passive | Active | Highly Active

Allograft

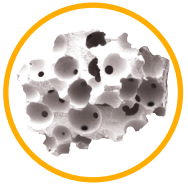
Composition
Cadaveric bone usually mineralized.

Mechanism of action
Osteoconductive

FDA Regulatory Pathway
HCT/Ps that are regulated as "361 products"

Data typically required
361 HCT/Ps require no FDA premarket review for safety and/or efficacy

Cortical and cancellous bone chips



Synthetics

Composition
Synthetically or naturally derived mineral or ceramic with or without carrier.

Mechanism of action
Osteoconductive

FDA Regulatory Pathway
510k
PMA

Data typically required
510ks require benchtop testing or preclinical data, usually in a rabbit or sheep

Mastergraft™ Family

Fibergraft™* BG Putty

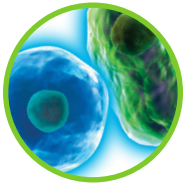
Signify™* Bioactive Bone Void Filler

AttraX™* Putty

Vitoss™* Synthetic Bone Graft

PMAs require pivotal human clinical trial to show safety and efficacy

iFactor™* Peptide Enhanced Bone Graft*



CBM

Composition
Cadaveric bone tissue with living cells.

Mechanism of action
Osteoconductive
Osteoinductive
Osteogenic

FDA Regulatory Pathway
HCT/Ps that are regulated as "361 products"

Data typically required
361 HCT/Ps require no FDA premarket review for safety and/or efficacy

ViviGen™* and ViviGen Formable™* Cellular Bone Matrix

Osteocel™* Plus and OsteoCel™* Pro Allograft Cellular Bone Graft

Trinity Elite™* Allograft

DBM

Composition
Demineralized cadaveric bone with or without carrier.

Mechanism of action
Osteoconductive
Osteoinductive

FDA Regulatory Pathway
HCT/Ps that are regulated as "361 products" and 510k

Data typically required
361 HCT/Ps require no FDA premarket review for safety and/or efficacy

Grafton™ DBF

OsteoAmp™* Allogeneic Morphogentic Proteins

OsteoStrand™* Fibers Morphogentic Proteins

Vesuvius™* DBM

510ks require benchtop testing or preclinical data, usually in a rabbit or sheep

Magnifuse™ Family

Grafton™ Family

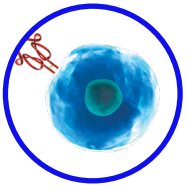
DBX™* DBM

Propel™* DBM

AlloSync™* Demineralized Bone Grafts

Accell™* Total Bone Matrix

BIO™* DBM



BMP

Composition
Recombinant human bone morphogenetic protein with carrier.

Mechanism of action
Osteoconductive
Highly osteoinductive

FDA Regulatory Pathway
PMA

Data typically required
PMAs require pivotal human clinical trial to show safety and efficacy

Infuse™ Bone Graft**

*Approved for use in certain single-level cervical procedures from C3-C4 to C6-C7 inside an allograft bone ring and with supplemental anterior plate fixation.

**Approved for use in certain l single-level lumbar spine procedures from L2-S1 with certain Medtronic interbody devices.

Animal data is not necessary indicative of clinical outcomes.

This guide is intended to help with proper categorization of bone grafting options.

Activity refers to the osteoinductivity of a product and requires signaling proteins.[1,2] Active and highly active products create and drive bone forming cells. Passive products (i.e., scaffolds only) do not have activity and therefore are not able to create nor drive bone forming cells. Some products are Passive (scaffolds only), Active (having limited to substantial inductivity) or Highly Active (very inductive).

The questions below can be applied to any bone graft and will help categorize each product.

What is the technology's composition?

- Synthetic (mineral or ceramic)
- Cadaveric bone and tissue (allograft, CBM, DBM)
- Growth factor (rhBMP)

What is the technology's mechanism of action (MOA)?

- **MOA** – the process by which a bone graft achieves new bone formation.
- **Osteogenic** – living cells, such as osteoblasts, that form new bone.
- **Osteoconduction** – passive scaffold to maintain space and allow for bone formation.
- **Osteoinduction** – signal that promotes active recruitment and stimulation of stem cells which differentiate into osteoblasts and form bone. Osteoinductivity can range from mild to high.

What type of performance data is required for FDA approval/clearance?

- Preclinical: rat, rabbit, dog, sheep, or non-human primate
- Clinical: human data

What is the regulatory pathway?

- **Section 361 HCT/P**
  Tissue therapies (human cellular and tissue products, or HCT/Ps) are not regulated as medical devices. There is no regulatory submission or clearance required for commercial distribution. Tissue manufacturers must register with the FDA and comply with AATB guidelines and FDA Good Tissue Practice regulations.
- **510K***
  FDA submission to demonstrate substantial equivalence to an existing product with preclinical (animal) and bench testing only. They must undergo significant preclinical (animal) testing, preparation of a regulatory filing, and review and clearance by the FDA before they can be legally marketed.
- **PMA***
  In addition to formulation and extensive preclinical (animal) studies, these products must also be evaluated in clinical (human) studies to demonstrate the safety and effectiveness in humans for the approved indications before being legally marketed.

* Please see package insert for the complete list of indications, warnings, precautions, adverse events, clinical results and other important medical information at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

Important Information | i-Factor™* Peptide Enhanced Bone Graft

Indications for Use:

The i-Factor™* peptide enhanced bone graft is indicated for use in skeletally mature patients for reconstruction of a degenerated cervical disc at one level from C3-C4 to C6-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or neurological deficit), with or out without neck pain, or myelopathy due to single-level abnormality localized to the disc space, and corresponding to at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays); herniated nucleus pulposus, spondylosis (defined nu the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels, after failure of at least 6 weeks of conservative treatment. i-Factor™* peptide enhanced bone graft **must** be used inside an allograft bone ring and with supplemental anterior plate fixation.

Contraindications:

The i-Factor™* peptide enhanced bone graft should not be used in situations where there is:

- An absence of load bearing structural support at the graft site
- Sensitivity to any components of i-Factor™* peptide enhanced bone graft
- Acute or chronic infections, systemic or at the operative site
- Metabolic or systemic disorders that affect bone or wound healing
- Compromised renal or hepatic function

Warnings:

- i-Factor™* peptide enhanced bone graft is designed for single patient use only. Attempting to reuse the putty will adversely affect product sterility and physical handling characteristics. DO NOT attempt to re-sterilize or re-use. Discard unused contents.
- Women of child-bearing potential should avoid becoming pregnant for one year after being treated with i-Factor™* peptide enhanced bone graft. The influence of i-Factor™* peptide enhanced bone graft on pregnant women and on fetal development is unknown.
- The effect of i-Factor™* peptide enhanced bone graft on nursing women has not been evaluated. It is not known if i-Factor™* peptide enhanced bone graft is excreted in human milk.
- The safety and effectiveness of i-Factor™* peptide enhanced bone graft when mixed with any additional components, e.g., autograft, allograft, other bone grafting materials, blood, saline or bone marrow aspirate, has not been established.
- The safety and effectiveness of i-Factor™* peptide enhanced bone graft used with implants other than allograft bone rings and anterior cervical plates, or applied in anatomic sites other than the cervical spine have not been established.
- The safety and effectiveness of i-Factor™* peptide enhanced bone graft has not been established in patients with pathology at more than one level and/or pathology not localized to the disc space.
- The safety and effectiveness of i-Factor™* peptide enhanced bone graft in patients who are not skeletally mature has not been established.
- The safety and effectiveness of i-Factor™* peptide enhanced bone graft in patients with hepatic or renal impairment has not been established.
- The safety and effectiveness of i-Factor™* peptide enhanced bone graft in patients with metabolic bone disease has not been established.

As with any surgical procedure, care should be exercised in treating individuals with pre-existing conditions that may affect the success of the surgical procedure.

- Bleeding disorders of any etiology: The safety and effectiveness of i-Factor™* peptide enhanced bone graft has not been established in patients with bleeding disorders of any etiology.
- Long-term steroidal therapy: The safety and effectiveness of i-Factor™* peptide enhanced bone graft has not been established in patients who have had long term steroidal therapy.
- Immunosuppressive therapy or high dosage radiation therapy: The safety and effectiveness of i-Factor™* peptide enhanced bone graft has not been established in patients who have had immunosuppressive therapy or high dosage radiation therapy.

Potential Adverse Events:

As with any surgery, surgical treatment of cervical degenerative disc disease is not without risk. A variety of complications related to the surgery or the use of i-Factor™* peptide enhanced bone graft may occur. The following is a list of potential adverse events that could be associated with the use of i-Factor™* peptide enhanced bone graft, some of which were identified in the i-Factor™* peptide enhanced bone graft clinical trial results. These adverse events include: (1) those associated with any surgical procedure; (2) those associated with anterior cervical discectomy and fusion (ACDF) surgery; and (3) those that may occur specifically with the use of i-Factor™* peptide enhanced bone graft. These risks may occur singly or in combination and may be severe and/or negatively impact patient outcomes. In addition to the risks listed below, there is also the risk that the procedure may not be effective and may not relieve or may cause worsening of symptoms. Additional surgery may be required to correct some of the potential adverse effects.

1. Risks associated with any surgical procedure:

- Anesthesia complications including an allergic reaction or anaphylaxis
- Infection (wound, local, and/or systemic) or abscess
- Wound complications including hematoma, site drainage, infection dehiscence and/or necrosis
- Mild to severe swelling, edema
- Soft tissue damage or fluid collections, including hematoma or seroma
- Pain/discomfort at the surgical incision and/or skin or muscle sensitivity over the incision, which may result in skin breakdown, pain, and/or irritation
- Heart or vascular complications including

Important Information | i-Factor™ Peptide Enhanced Bone Graft *continued*

bleeding, hemorrhage or vascular damage resulting in catastrophic or potentially fatal bleeding, ischemia, myocardial infarction, abnormal blood pressure, venous thromboembolism including deep vein thrombosis and pulmonary embolism, thrombophlebitis, or stroke
- Pulmonary complications including atelectasis or pneumonia
- Impairment of the gastrointestinal system including ileus or bowel obstruction
- Impairment of the genitourinary system including incontinence, bladder dysfunction, or reproductive system complications
- Neurological complications including nerve damage, paralysis, seizures, changes to mental status, or reflex sympathetic dystrophy
- Complications of pregnancy including miscarriage or congenital defects
- Inability to resume activities of daily living
- Death

2. Risks specifically associated with anterior cervical discectomy and fusion (ACDF) surgery, some of which were observed with use of i-Factor™* peptide enhanced bone graft:
   - Failure of fusion, with requirement for secondary surgical intervention
   - Early or late loosening, breakage or migration of internal fixation and/or graft material
   - Vertebral body fracture
   - Failure of symptom relief
   - Nonunion, malunion or delayed union
   - Worsening of neurologic status, arachnoiditis
   - Adjacent level degeneration
   - External chylorrhea or chylothorax
   - Recurrent laryngeal nerve injury with hoarseness
   - Superior laryngeal nerve injury and dysphagia
   - Tracheal, esophageal, or pharyngeal perforation
   - Dural injury with cerebrospinal fluid leakage, fistula, headache
   - Scar formation or other problems with the surgical incision
   - Vascular injury resulting in stroke, hemorrhage and possible death
3. Potential adverse events that may occur specifically with the use of i-Factor™* peptide enhanced bone graft include:
   - Extrusion or migration of the i-Factor™* peptide enhanced bone graft, as is possible with any bone graft, resulting in pain, neural impingement, physical impairment, or loss of function; any of which may require revision surgery
   - Allergic reaction to components of i-Factor™* peptide enhanced bone graft
   - Abnormal bone formation in an unintended location
   - Excessive or incomplete bone formation

For more detailed information on the specific adverse effects that occurred during the clinical trial, please refer to the Safety Results Section (Summary of IDE Clinical Study).

How Supplied:

The i-Factor™* peptide enhanced bone graft is provided in a pre-filled syringe. The syringe is comprised of the syringe barrel, plunger rod, plunger tip, and syringe cap. The pre-filled syringe of i-Factor™* peptide enhanced bone graft is packaged in an outer sterile barrier chevron-style peel pouch and inner vapor barrier foil pouch. The syringe barrel and plunger tip are lubricated with a thin layer of Dow Corning 360 Medical Fluid - 1000 CST (polydimethylsiloxane).

Storage:

The product should be stored in its original packaging at ambient room temperature.

Dosage and Administration:

i-Factor™* peptide enhanced bone graft is supplied to the clinician as a sterile device in a single-use, pre- filled syringe containing the graft material. No mixing or other preparation is required. The clinician simply removes the syringe from the sterile barrier package, removes the syringe cap, and dispenses the material.

Directions for Use:

The clinician should remove the syringe cap and dispense i-Factor™* peptide enhanced bone graft by depressing the syringe plunger. i-Factor™* peptide enhanced bone graft may be dispensed directly into the allograft ring or into a separate sterile receptacle where it can be transferred using traditional surgical instrumentation or by hand. The central cavity of the allograft ring should be filled with i-Factor™* peptide enhanced bone graft. With the exception of filling the allograft cavity with i-Factor™* peptide enhanced bone graft, a standard instrumented ACDF technique should be followed.

i-Factor™* peptide enhanced bone graft should only be placed in an allograft ring where it can be contained adequately.

NOTE: When opening the foil pouch containing the i-Factor™* peptide enhanced bone graft syringe, a very small amount of water may be retained within the pouch. This is a normal part of the steam sterilization process and does not affect the integrity or sterility of the product.

Manufactured by:

Cerapedics, Inc.

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40002-07-3

Important Information | Infuse™ Bone Graft

Warnings

- In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Reduced ossification of the frontal and parietal bones of the skull was noted infrequently (<3%) in fetuses of rabbit dams immunized to rhBMP-2; however, there was no effect noted in limb bud development. There are no adequate and well controlled studies in human pregnant women. Women of childbearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments.
- Women of childbearing potential should be advised that antibody formation to rhBMP-2 or its influence on fetal development has not been completely assessed. In the clinical trial supporting the safety and effectiveness of the Infuse™ bone graft/LT-Cage™ lumbar tapered fusion device, 2/277 (0.7%) patients treated with Infuse™ bone graft component and 1/127 (0.8%) patients treated with autograft bone developed antibodies to rhBMP-2. The effect of maternal antibodies to rhBMP-2, as might be present for several months following device implantation, on the unborn fetus is unknown. Additionally, it is unknown whether fetal expression of BMP-2 could re-expose mothers who were previously antibody positive. Theoretically, re-exposure may elicit a more powerful immune response to BMP-2 with possible adverse consequences for the fetus. However, pregnancy did not lead to an increase in antibodies in the rabbit study. Studies in genetically altered mice indicate that BMP-2 is critical to fetal development and that a lack of BMP-2 activity may cause neonatal death or birth defects. It is not known if anti-BMP-2 antibodies may affect fetal development or the extent to which these antibodies may reduce BMP-2 activity.
- Infuse™ bone graft should not be used immediately prior to or during pregnancy. Women of childbearing potential should be advised not to become pregnant for one year following treatment with the Infuse™ bone graft/Medtronic interbody fusion device.
- The safety and effectiveness of the Infuse™ bone graft/Medtronic interbody fusion device in nursing mothers has not been established. It is not known if BMP-2 is excreted in human milk.

The Perimeter™, Clydesdale™, Divergence-L™, and Pivox™ devices must be used with any supplemental fixation system cleared for use in the lumbar spine.

Important Information | Infuse™ Bone Graft *continued*

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR:

Infuse™ Bone Graft/LT-Cage™ Lumbar Tapered Fusion Device

Infuse™ Bone Graft/Inter Fix™ Threaded Fusion Device

Infuse™ Bone Graft/Inter Fix™ RP Threaded Fusion Device

Infuse™ Bone Graft/Perimeter™ Interbody Fusion Device

Infuse™ Bone Graft/Clydesdale™ Spinal System

Infuse™ Bone Graft/Divergence-L™ Anterior/Oblique Lumbar Fusion System

Infuse™ Bone Graft/Pivox™ Oblique Lateral Spinal System

The Infuse™ bone graft/Medtronic interbody fusion device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1, who may also have up to Grade I spondylolisthesis or Grade 1 retrolisthesis at the involved level.

The following interbody devices and surgical approaches may be used with Infuse™ Bone Graft:

- The LT-Cage™ lumbar tapered fusion device, implanted via an anterior open or an anterior laparoscopic approach at a single level.
- The Inter Fix™ or Inter Fix™ RP threaded fusion device, implanted via an anterior open approach at a single level.
- The Perimeter™ interbody fusion device implanted via a retroperitoneal anterior lumbar interbody fusion (ALIF) at a single level from L2-S1 or an oblique lateral interbody fusion (OLIF) approach at a single level from L5-S1.
- The Clydesdale™ spinal system, implanted via an OLIF approach at a single level from L2-L5.
- The Divergence-L™ anterior/oblique lumbar fusion stem interbody device implanted via an ALIF approach at a single level from L2-S1 or an OLIF approach at a single level from L5-S1.
- The Pivox™ oblique lateral spinal system implanted via an OLIF approach at a single-level from L2-L5.

The Infuse™ bone graft/Medtronic interbody fusion device consists of two components containing three parts – a spinal fusion cage, a recombinant human bone morphogenetic protein, and a carrier/scaffold for the bone morphogenetic protein and resulting bone. **These components must be used as a system for the prescribed indication described above. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in this document. The Infuse™ bone graft component must not be used without the Medtronic Interbody Fusion Device component.**

NOTE: The Inter Fix™ threaded fusion device and the Inter Fix™ RP threaded fusion device may be used together to treat a spinal level. The LT-Cage™ lumbar tapered fusion device, the Perimeter™ interbody fusion device, the Clydesdale™ spinal system, the Divergence-L™ anterior/oblique lumbar fusion system, and the Pivox™ oblique lateral spinal system implants are not to be used in conjunction with either the Inter Fix™ or Inter Fix™ RP implants to treat a spinal level.

The Infuse™ bone graft/Medtronic interbody fusion device is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen, or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor, in patients with any active malignancy, or patients undergoing treatment for a malignancy; in patients who are skeletally immature; in pregnant women; or in patients with an active infection at the operative site or with an allergy to titanium, titanium alloy, or polyetheretherketone (PEEK).

There are no adequate and well-controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child- bearing potential should be advised to not become pregnant for one year following treatment with this device.

Please see the Infuse™ bone graft package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, definition of DDD, and other important medical information. The package insert also matches the sizes of those sized devices that are indicated for use with the appropriate Infuse™ bone graft kit. An electronic version of the package insert may be found at www.medtronic.com/manuals.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.

Important Information | Grafton™ DBF

Indications
Grafton™ DBF 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 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
Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing were used in the qualification of tissue donors. Despite the viral inactivation and extensive tissue donor selection and qualification processes used in providing this tissue graft (see DONOR SCREENING AND TESTING), transmission of a communicable disease is still possible. Bacterial infection at the graft site may also occur. Adverse outcomes potentially attributable to Grafton™ DBF must be reported promptly to Medtronic. If injecting Grafton™ DBF 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.

For a complete list of indications, safety, and warnings for Grafton™ DBF, please visit https://manuals.medtronic.com/content/dam/emanuals/spinal/M708348B464EGraftonDBFDemineralizedBoneMatrixDBMFibersRevD.pdf

For more information visit Medtronic.com or call (800) 933-2635.

Important Information | Grafton™ Family

Indications

Grafton™ DBM and Grafton PLUS™ DBM are intended for use as a bone graft extender, bone graft substitute, and bone void filler 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. Grafton™ DBM (excluding the orthoblend form) and Grafton Plus™ DBM are also intended to be packed into bony voids or gaps to fill and/or augment dental intraosseous, oral, and cranio-/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone, including periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. Grafton™ DBM and Grafton Plus™ DBM may be used alone in a manner comparable to autogenous bone chips or allograft bone particulate (demineralized freeze dried bone), or they may be mixed with either allograft or autograft bone or bone marrow as a bone graft extender. Grafton™ DBM and Grafton PLUS™ DBM are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Grafton™ DBM and Grafton PLUS™ DBM are absorbed/remodeled and replaced by host bone during the healing process.

Note: The user should consider the fact that Grafton™ DBM crunch contains demineralized bone chips approximately 3 mm (±1 mm) in determining the appropriateness of this allograft for use in small defects.

Contraindications

The following are contraindications for the use of Grafton™ DBM and Grafton PLUS™ DBM:

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

Caution

This allograft may contain trace amounts of antibiotics (gentamicin), surfactant, and other processing solutions. Caution should be exercised if the patient is allergic to these antibiotics or chemicals.

Grafton PLUS™ DBM paste contains starch. Therefore, caution should be exercised in using Grafton PLUS™ DBM paste in a patient with a starch allergy and/or amylase deficiency.

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 qualification processes 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 Grafton™ DBM or Grafton Plus™ 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 (i.e., spine, pelvis, and extremities).

If injecting Grafton™ DBM or Grafton Plus™ DBM 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.

When used as a bone graft extender in bony voids or gaps of the skeletal system (i.e., spine, pelvis, and extremities), Grafton Plus™ DBM paste is intended for use only with autograft, not other allograft. Recommended ratios of Grafton Plus™ DBM paste to autograft as a bone graft extender are 1:1 or 2:1.

For a complete list of indications, safety, and warnings, please visit https://manuals.medtronic.com/content/dam/emanuals/spinal/M708348B324E_Grafton_eManual_revF.pdf

For more information visit Medtronic.com or call (800) 933-2635.

Important Information | Magnifuse™ Family

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 stability of bony structure. Voids or gaps may be surgically created defects or defects created by traumatic injury to bone. Magnifuse™ bone graft may be used in a manner comparable to autogenous bone or allograft bone. Magnifuse™ bone graft may be mixed with fluid such as bone marrow aspirate, blood, sterile water, or sterile saline to adjust consistency and handling

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

Contraindications

- 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 processing solutions used in processing bone tissue as well as mesh. Caution should be exercised if the patient is allergic to antibiotics or chemicals.

Precautions

Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing were used in the qualification of tissue donors. Despite viral inactivation and extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of infectious disease through use of tissue graft is still possible. Bacterial infection at the graft site may also occur. Adverse outcomes potentially attributable to Magnifuse™ bone graft 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.

For a complete list of indications, safety, and warnings, please visit https://manuals.medtronic.com/content/dam/emanuals/spinal/M708348B245E_Magnifuse_Rev%20D.pdf

For more information visit Medtronic.com or call (800) 933-2635.

1. Klar RM. The Induction of Bone Formation: The Translation Enigma. Front Bioeng Biotechnol. 2018 Jun 7;6:74.

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

medtronic.com/adminSource

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