PREPARATION INSTRUCTIONS

Soft tissue should be completely removed from the posterior elements of the spinal segments to be fused.
Cartilage should be completely removed from the facet joints (Figure 1).

PREPARE FUSION BED

Prepare the posterolateral fusion bed by decorticating the transverse process and lamina to the level of bleeding bone (Figure 2).
Select the appropriate size Magnifuse Bone Graft based on size/volume of defect to fill the bony void completely.
PREPARE
GRAFTING MATERIAL

Retain locally harvested autologous bone graft material from laminotomy and decortication.

Once bone has been removed from all soft tissue, mince with a rongeur (Figure 3).

LOCAL BONE PLACEMENT

Lay the locally harvested bone on top of the decorticated surface in the posterolateral portion of the spine. Pack well until transverse process to transverse process is covered (Figure 4).
Deliver Graft to the Sterile Field

Examine the packaging to ensure that any of the packaging material or contents is missing or damaged, the label is illegible or missing, or if the product expiration has passed.

Observing proper sterile technique open the outer packaging and place the inner packaging containing the desired Magnifuse Bone Graft into the sterile field.
PREPARATION INSTRUCTIONS

Hydrate Magnifuse Bone Graft in sterile saline for 1 to 2 minutes prior to implantation. If desired, soak and/or inject blood directly onto hydrated Magnifuse Bone Graft material.

Place the hydrated Magnifuse Bone Graft on top of the locally harvested bone on either side of the spine.

Ensure the Magnifuse Bone Graft product completely covers the transverse processes (excluding the mesh tabs) (Figure 5).

Recommend one Magnifuse Bone Graft for each side of the spine per level fused.

The Magnifuse Bone Graft is not intended to be a load bearing device but is intended to be used as a bone void filler as it will be remodeled/replaced by host bone during the healing process.
FEATURES AND BENEFITS

- Selectively harvested process optimizes natural growth factors.
- Self-contained delivery system.
- Patented fiber technology.
- Radiopaque.

IMPORTANT PRODUCT INFORMATION

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 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.

SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

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 (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.
The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

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

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.

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