In Spine – any bone grafting material is either **autograft**, **autograft extender**, **alternative** or an **autograft replacement**[1,2]

Why do you need different grafting material? Because the quality of autograft matters

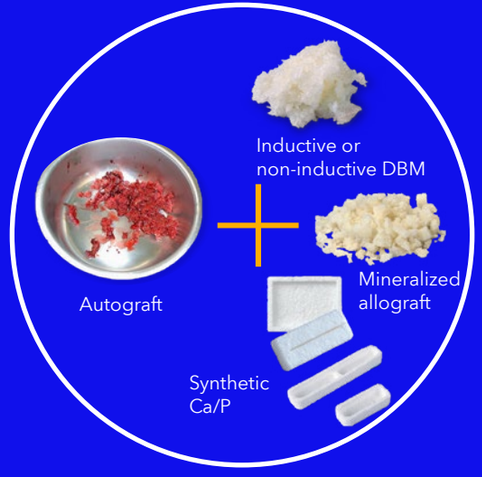
Is there enough high quality autograft available?

Yes — **No**

Autograft

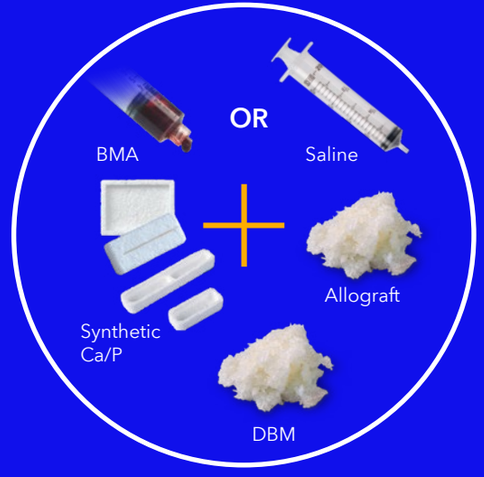
Bone graft from patient harvesting procedure prior to surgical procedure.

Extender



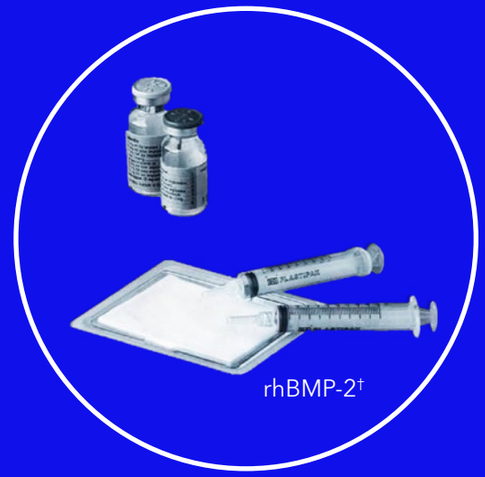
Bone graft used with autograft.

Enhancer



Bone graft used with BMA or Saline.

Autograft Replacement



Bone graft that encourages bone growth at the sites where it is implanted without having to harvest autograft[3]

†approved for use in certain lumbar spine procedures.

1. Boden (2002) Spine 27(16 Suppl 1) S26-31.
2. Burkus (2002) J Spine Disord Tech 15(5) 337-349
3. Burkus (2004) Orthopedics 27(7) 723-728

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Infuse™ Bone Graft Important Product Information

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

- 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 child-bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments.

- Women of child-bearing 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.

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

Infuse™ Bone Graft/Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology

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 System 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 Anteralign™ Spinal System LS 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 Anteralign™ Spinal System TL interbody device 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, the Pivox™ Oblique Lateral Spinal System, the Anteralign™ Spinal System TL, and Anteralign™ Spinal System LS 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.

08/2024 - UC202304414 EN - [WF#7468499]