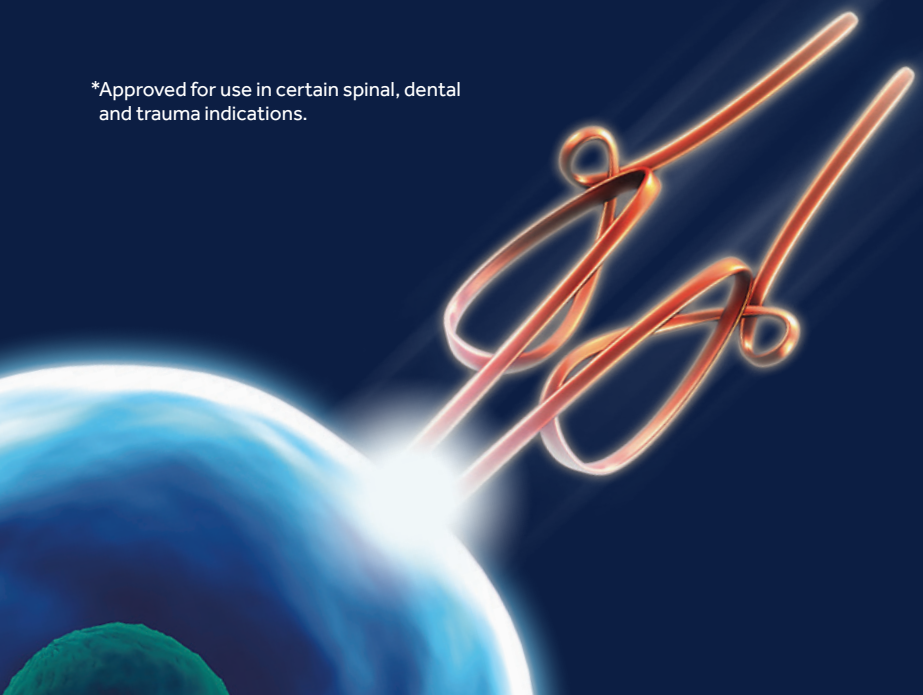
# Infuse®
## Bone Graft

# TRUSTED.
# PROVEN.
# PREDICTABLE.

Infuse Bone Graft is the Premium Product for Autograft Replacement due to its high osteoinductivity.*

- Eliminates the Need for a Second Incision to Harvest Iliac Crest Bone
  - A Benefit to You and Your Patients
- Proven Osteoinductivity Ensures Predictable Bone Formation
  - Gives You Confidence in this Safe and Effective Technology
- Now Available with Expanded Indications
  - Allowing More Patients Access to this Proven Technology

*Approved for use in certain spinal, dental and trauma indications.



Infuse® Bone Graft with PEEK Clydesdale® Spinal System

**OLIF25™ Procedures**
with certain sizes** of the PEEK Clydesdale® Spinal System at a single-level from L2–L5

Infuse® Bone Graft with PEEK Perimeter® Interbody Fusion Device

**OLIF51™ Procedures**
with certain sizes** of the PEEK Perimeter® Interbody Fusion Device at a single-level from L5–S1

**ALIF Procedures**
with certain sizes** of the PEEK Perimeter® Interbody Fusion Device at a single-level from L2–S1

**Refer to the Infuse® Bone Graft/Medtronic Interbody Fusion Device package insert for additional information.

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MICHELSON TECHNOLOGY AT WORK

# Contact your local Medtronic Sales Representative for more information or visit bmp2.com to learn more.

**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

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 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, and the CLYDESDALE® 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. 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.

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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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