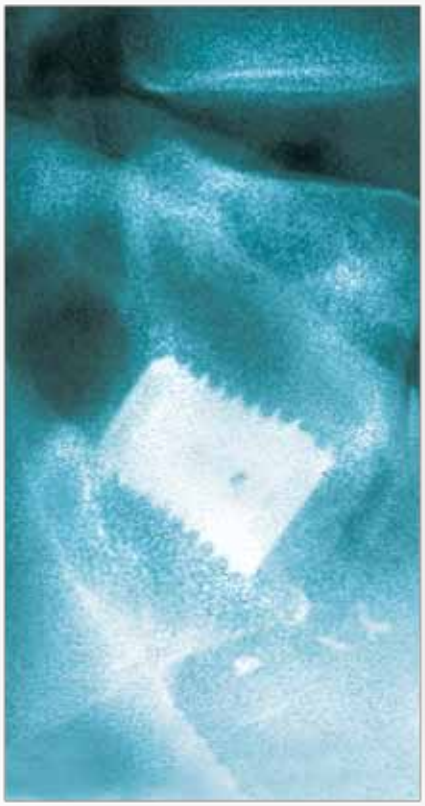
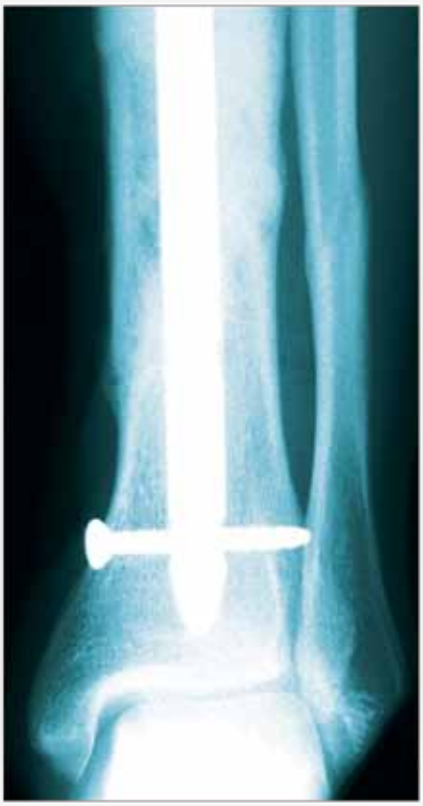
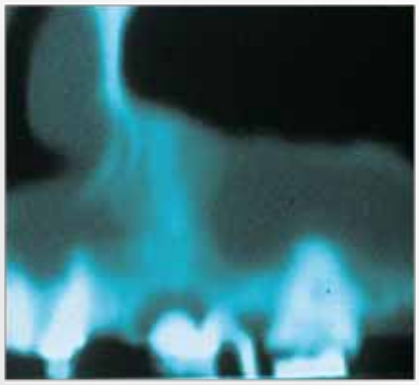
SPINE*

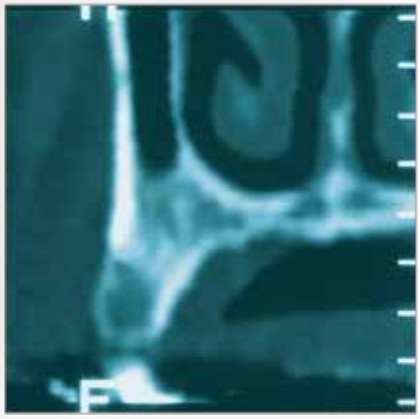


TRAUMA



DENTAL





MICHELSON TECHNOLOGY AT WORK

Surgical Applications and Clinical Outcomes

Spine Application – Approved 2002

Procedure:

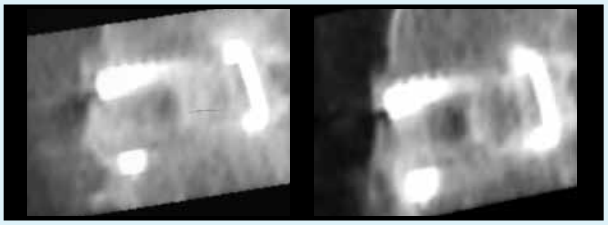
Anterior lumbar interbody fusion with LT-CAGE®, INTERFIX™ or INTERFIX™ RP Fusion Devices

Post-Operative Outcomes[1]

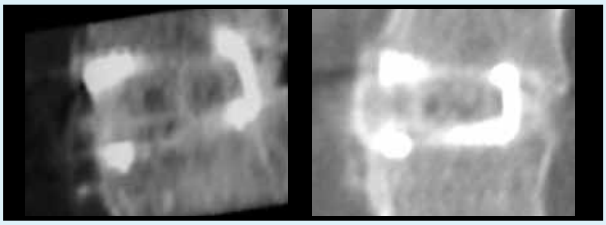
- 94.5% fusion at 24 months (p< 0.022)
- Eliminated graft donor site pain (>30% @ 2yrs)
- Improved clinical outcomes (low back pain and disability) (p<0.005)
- Median return to work reduced by 54 days (p<0.02)2

6-year Follow-up Complete[2]

- 98% fusion success
- Low rates of second surgery
- Improvements in clinical outcomes maintained



6 months 24 months



48 months 72 months

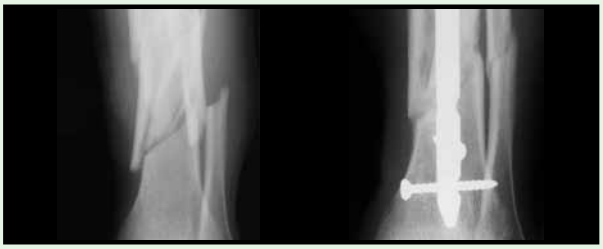
Trauma Application – Approved 2004

Procedure:

Acute open tibia fracture with intramedullary nail (IM) □xation within 14 days of injury

Post-Operative Outcomes[3]

- Reduced rate of infection by 44% in Type III fractures
- Reduction in nonunions by 29%



Preoperative 20 weeks

Dental Application – Approved 2007

Procedure

Maxillary Sinus Augmentation

Post-Operative Outcomes[4]

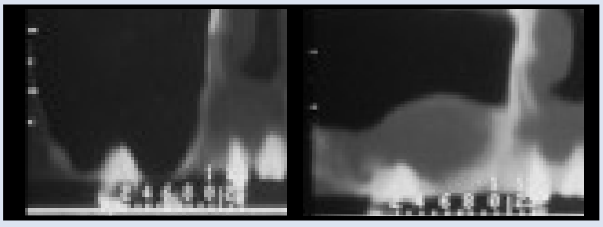
- An average of 8.2mm of new bone (height) formed
- Bone core samples taken at the time of dental implant placement showed mature (90-95% lamellar), viable bone with a rich vascular marrow space.
- Implant success rate equivalent to autogenous bone graft (p=0.99)
- 99% of patients grew new, viable, bone.

Procedure

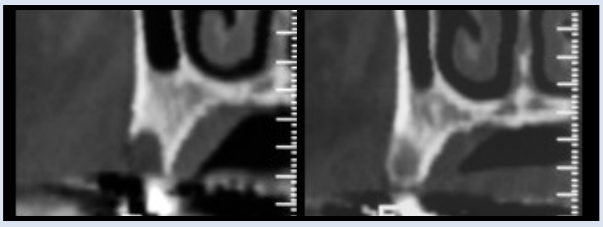
Localized Alveolar Ridge Augmentation

Post-Operative Outcomes[5]

- Bone formed in all patients grafted with INFUSE® Bone Graft
- Clinically signi□cant results vs the control in:
  - maintaining height (mean height change -0.02mm), and
  - restoring width (mean width change at socket crest 3.27mm).[4]



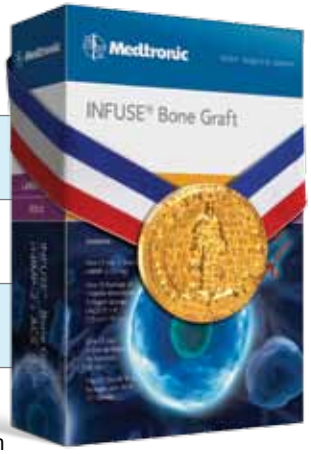
Preoperative 16 weeks



Preoperative 16 weeks

Research History and Clinical Studies of rhBMP-2/ACS

rhBMP-2/ACS Research History (Preclinical and Clinical)	20 years
Years of INFUSE® Bone Graft Clinical Use Since Approval*	7 years
Patients Treated with INFUSE® Bone Graft Since Approval	> 600,000 Patients‡
3 FDA PMA Approvals for INFUSE® Bone Graft	**Spine:** Anterior Lumbar Interbody Fusion with LT-CAGE® Device **Trauma:** Acute Open Tibia Fracture with IM Nail **Dental:** Maxillary Sinus Augmentation or Alveolar Ridge Augmentation
Prospective Clinical Studies with rhBMP-2/ACS	22 studies
Total Patients Enrolled in Prospective Clinical Studies with rhBMP-2/ACS†	> 2100 Patients
Patients with 6-year follow-up from the INFUSE® Bone Graft/LT-CAGE® Device Clinical Trial[2]	146 Patients



Winner of the 2008 Prix Galien USA award for Best Biotechnology Agent

*With LT-CAGE® Device
† Includes rhBMP-2 at all concentrations and control patients
‡ As of October 2008

Kit Configurations

Description	Item Number	Graft Volume	mg rhBMP-2	Approval
INFUSE® Bone Graft – XX Small	7510050	0.7cc	1.05mg	Spine§ Dental§
INFUSE® Bone Graft – X Small	7510100	1.4cc	2.10mg	Spine§ Dental§
INFUSE® Bone Graft – Small	7510200	2.8cc	4.2mg	Spine§ Dental§
INFUSE® Bone Graft – Medium	7510400	5.6cc	8.4mg	Spine§ Dental§
INFUSE® Bone Graft – Large	7510600	8.0cc	12.0mg	Spine§ Dental§
INFUSE® Bone Graft – Large II	7510800	8.0cc	12.0mg	Spine§ Trauma§ Dental§

§ See brief summary for indication

For more information about INFUSE® Bone Graft call (800) 876-3133 or (901) 396-3133 or visit www.infusebonegraft.com

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, WARNINGS, AND PRECAUTION FOR INFUSE® BONE GRAFT FOR CERTAIN ORAL MAXILLOFACIAL AND DENTAL REGENERATIVE USES

INFUSE® Bone Graft is indicated as an alternative to autogenous bone graft for sinus augmentations, and for localized alveolar ridge augmentations for defects associated with extraction sockets.

The INFUSE® Bone Graft consists of two components – recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) placed on an absorbable collagen sponge (ACS). **These components must be used as a system for the prescribed indication. 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 the package insert.**

INFUSE® Bone Graft 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 pregnant women, or patients with an active infection at the operative site.

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 dental 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.

INFUSE® Bone Graft has not been studied in patients who are skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure).

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

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR: INFUSE® BONE GRAFT

INFUSE® Bone Graft is indicated for treating acute, open tibial shaft fractures that have been stabilized with IM nail fixation after appropriate wound management. INFUSE® Bone Graft must be applied within 14 days after the initial fracture. Prospective patients should be skeletally mature. INFUSE® Bone Graft consists of two components – recombinant human Bone Morphogenetic Protein-2 solution and a carrier/scaffold for the bone morphogenetic protein solution and resulting bone. **These components must be used as a system. 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.**

INFUSE® Bone Graft 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 an active malignancy or patients undergoing treatment for a malignancy. INFUSE® Bone Graft should also not be used in patients who are skeletally immature, in patients with an inadequate neurovascular status, in patients with compartment syndrome of the affected limb, in pregnant women, or in patients with an active infection at the operative site.

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 package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.

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

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

The INFUSE® Bone Graft/Medtronic Titanium Threaded 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 INFUSE® Bone Graft/ LT-CAGE® Lumbar Tapered Fusion Device is to be implanted via an anterior open or an anterior laparoscopic approach. INFUSE® Bone Graft with either the INTER FIX™ or INTER FIX™ RP Threaded Fusion Device is to be implanted via an anterior open approach.

The INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device consists of two components containing three parts– a metallic 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 Titanium Threaded 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. LT-CAGE® Lumbar Tapered Fusion Device 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 Titanium Threaded 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 or titanium alloy.

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 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.

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

www.sofamordanek.com

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1 Burkus et al. *J Spinal Disorders,* 2002

2 Data on file

3 *Journal of Bone and Joint Surgery,* June 2006; 88-A:1258–1265. 131 patients with Grade III fractures

4 Boyne, at al. Bone Induction With rhBMP-2. *J Oral Maxillofacial Surgery,* 2005.

5 Fiorellini, Howell, Cochran, et al.; Effect of rhBMP-2 on Osseous Defect Healing; *J Periodontology,* April 2005.