



INFUSE® Bone Graft

Autograft Alternative



Sinus Augmentation Procedure (“Sinus Lift”) with INFUSE® Bone Graft

A window is created in the lateral bony wall of the sinus, and the window is removed.



The sinus membrane is elevated to provide space for INFUSE® Bone Graft in the desired location.



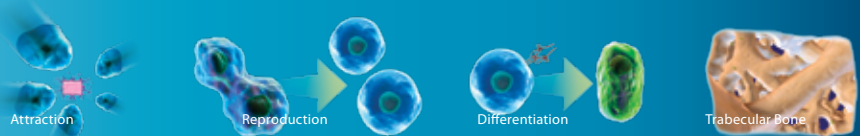
After the INFUSE® Bone Graft is prepared for implantation, it is cut into pieces allowing for easy and precise placement and is then evenly distributed in the lower third of the sinus where bone growth is desired.



Soft tissue is returned to its natural position covering the window in the lateral wall of the sinus and fixed into place with dental sutures.



INFUSE® Bone Graft induces new bone formation for dental implant placement.



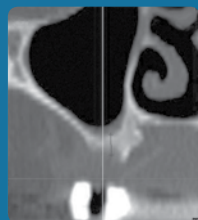
Dental implants can be placed after adequate bone has been induced (typically six months post-op).



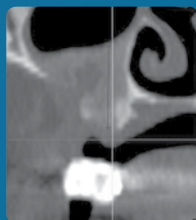
INFUSE® Bone Graft consistently and predictably forms bone in sinus augmentation.

- » Two consecutive randomized, controlled, multicenter trials
- » Six centers participated in the first 48-patient trial
- » 21 centers participated in the second 160-patient trial, two-year postfunctional loading
- » 99 patients received INFUSE® Bone Graft, two-year postfunctional loading follow-up

Level 1 Clinical Evidence

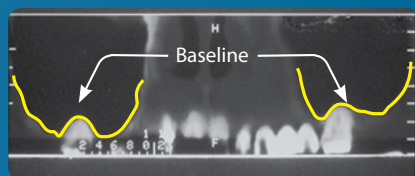


Pre-op
(3.9 mm Baseline)

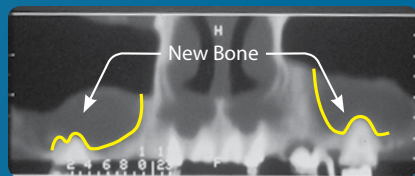


6 Months Post-op
(16.0 mm Total Height)

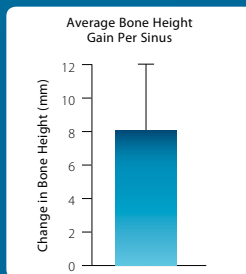
Ninety-eight out of 99 patients in the sinus lift randomized controlled trials (RCTs) who received INFUSE® Bone Graft grew new, viable bone. The patient who did not grow bone had a chronic infection and failed a subsequent autografting procedure.



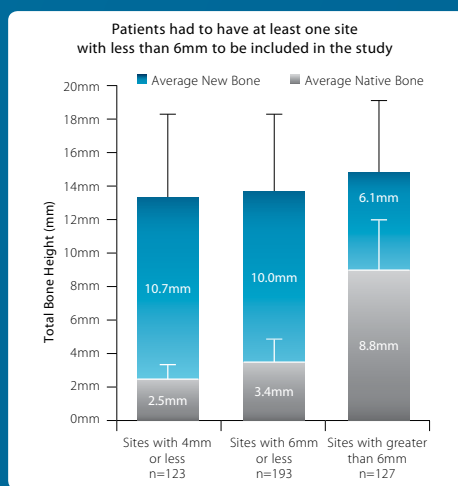
Pre-op



16 Weeks
Post-INFUSE® Bone Graft Placement



An average of 8.2 mm of mature, viable bone was induced with the use of INFUSE® Bone Graft, resulting in an average of 13.8 mm of total bone for implant placement.



Patients received multiple implants per sinus, some of which were placed into sites with greater than 6mm of native bone due to anatomical configuration.

This product has not been tested in pregnant women to determine if it could harm a developing fetus. This product has also not been studied in nursing mothers. Women of childbearing age should not become pregnant for one year following treatment with the product. Women of childbearing age should be warned of potential risks to a fetus and should discuss other possible dental treatments with their doctor.

Rx Only

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.



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