Kazemi
ORAL SURGERY &
DENTAL IMPLANTS

Infuse- rhBMP2 material
Important Safety Information

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 consumers 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 consumers with any active malignancy or consumers undergoing treatment for a malignancy, in pregnant women, or consumers 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 childbearing 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 childbearing potential should be advised to not become pregnant for one year following treatment with this device.

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

Use in Oral-maxillofacial surgery

INFUSE® Bone Graft contains a manufactured bone graft material that is approved by the U.S. Food and Drug Administration (FDA) for use in certain maxillofacial bone grafting procedures, such as sinus augmentation and localized alveolar ridge augmentation. It provides an alternative to bone-harvest surgery, a secondary procedure which can be painful for some patients and lengthens the healing process. INFUSE® Bone Graft provides proven, predictable bone formation and is supported by extensive research and clinical results.
Forming new bone with rhBMP-2

The active ingredient in INFUSE® Bone Graft is recombinant human bone morphogenetic protein-2 (rhBMP-2). rhBMP-2 is a manufactured version of a natural protein found in small quantities in the body. The purpose of the protein is to stimulate bone formation. Certain BMPs have been studied for decades because of their inherent ability to heal bone. Of these,

rhBMP-2 has been studied more than any other BMP and is FDA-approved for use in certain oral surgeries.

One of the primary advantages of INFUSE® Bone Graft is that it is an alternative to autograft—the use of autogenous bone (from the hip, rib, leg, jaw or chin) for implantation into a void or defect elsewhere in the body, such as the bones of the jaw.

During oral surgery with INFUSE® Bone Graft, the rhBMP-2 protein is mixed with sterile water. The solution is then soaked onto an absorbable collagen sponge (ACS), which is made from a material found in bone and tendons. The ACS releases the protein over time in the location where it is placed, providing a scaffold on which new bone can grow. As the graft site heals, the ACS is resorbed and replaced by bone.

In instances of jaw bone resorption, rhBMP-2 may be placed in the section or sections of the jaw bone that need to be built back up in preparation for dental implants.

Contraindications for INFUSE® Bone Graft surgery

INFUSE® Bone Graft should not be used:

- In patients with a known hypersensitivity to rhBMP-2, bovine Type I collagen or to any other components of the formulation
- In the vicinity of a resected or extant tumor
- In patients with any active malignancy or in patients undergoing treatment for a malignancy
- In patients with an active infection at the operative site
- In pregnant women

Additional Safety Information for INFUSE® Bone Graft

Due to the chemotactic properties of INFUSE® Bone Graft and the angiogenesis associated with new bone formation, facial edema may occur in some (but not all) patients.

INFUSE® Bone Graft has not been studied in investigational device exemption (IDE) trials with patients who:

- Are skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure)
- Currently are or may become pregnant

Studies & Evidence

Clinical study information provides detailed data on the effectiveness of INFUSE® Bone Graft for oral-maxillofacial surgery. With its decade of clinical use, rhBMP-2 has become one of the most extensively researched biologic agents commercially available today.

INFUSE® Bone Graft has over 10 years of approved market utilization and remains a safe and efficacious alternative to harvesting an individual's own bone. INFUSE® Bone Graft has gone through the most stringent pathway for approval as a Class III Device with the U.S. Food and Drug Administration.

INFUSE® Bone Graft has a well-defined safety profile—without the possible pain and bone graft complications associated with bone harvest procedures.

Clinical studies

Five multi-center studies including 312 patients, examined the effective concentration, safety and efficacy of rhBMP-2/ACS in sinus augmentation and localized alveolar ridge augmentation. Patients enrolled in the sinus augmentation trials were compared to autogenous bone graft harvested from the iliac crest, the tibial plateau, or other sources. Core trephines were taken in each of these trials to examine bone formation facilitated by rhBMP-2. This trial data is the only that provides human histology from rhBMP-2-generated bone. Not only is this bone adequate to support the placement of endosseous dental implants, it exhibits long-term survival under functional loading.

Case studies

Case studies provide additional evidence demonstrating both the clinical utility and bone formation that is capable with implantation of INFUSE® Bone Graft. It is capable of generating adequate bone height and width to allow for the placement of dental implants.

Pre-clinical data

Pre-clinical studies demonstrated that INFUSE® produced mature, viable bone, indistinguishable from native bone. These studies also provided information on osseointegration of placed endosseous dental implants, and their long-term survival following functional loading.

Summary of safety and effectiveness data

Check out www.bmp2.com for complete information about the Indications of Use, Contraindications, Warnings and Precautions, Device Description, Adverse Events, Summary of Preclinical Testing and Summary of Clinical Testing.

Ridge Augmentation

A localized alveolar ridge augmentation after tooth extraction, or "ridge augmentation," involves placing INFUSE® Bone Graft directly into the empty socket where a tooth's roots used to be, to help create the natural shape of the gums and jaw that may have been lost following tooth extraction. Patients usually need a ridge augmentation procedure after losing one or more teeth, to prepare for future dental restoration.
Rebuilding bone in the localized alveolar ridge

The localized alveolar ridge of the jaw is the bone that surrounds the roots of the teeth. When a tooth is removed, it leaves behind an empty socket in the localized alveolar ridge bone. Typically, the socket will heal on its own, filling in with bone and tissue. Sometimes the walls of the socket are thin and break during tooth removal, or they were missing before the procedure. When the bony wall on the side facing the cheek is missing, it's called a "buccal

wall defect." These types of sockets typically do not heal to their previous height and width, and bone loss continues because there's no tooth to retain the bone.

If a patient wants to replace a lost tooth with a dental implant or lost tissue has caused an aesthetic problem, then the localized alveolar ridge must be rebuilt. INFUSE® Bone Graft can help promote bone growth. After a tooth extraction, it can help preserve the height and width of the localized alveolar ridge.
During ridge augmentation surgery

A ridge augmentation procedure is performed by placing graft material into the tooth socket. This may be done immediately after the tooth has been removed. The gum tissue is then placed back over the socket and sutured. Once the socket area has healed, the localized alveolar ridge can be prepared for a dental implant.

Dental implants are designed to serve as the foundation for artificial teeth (crowns) that look, feel, and function like natural teeth. Dental implants typically are very small, screw-type posts placed into the jawbone where teeth are missing. The bone bonds with the post, manufacturing a strong foundation for artificial teeth. Dental implants help preserve facial structure and also help prevent the bone deterioration that usually occurs when teeth are missing.

A ridge preservation procedure typically is performed in the dental office under local anesthesia. Some patients also may request sedative medication as well.
After ridge augmentation surgery

Treatment results are specific to each individual patient, so they may vary from person to person. The entire process, from tooth extraction to final dental implant placement, may take up to a year.

Your surgeon will have a specific recovery plan for you to follow after your procedure. To maximize your potential for a successful outcome, you must carefully follow your recovery plan.
Potential risks and complications

As with any surgery, surgical treatment to promote bone growth in the jaw is not without risk. A variety of complications related to surgery or the use of INFUSE® Bone Graft may occur. Some of these may be severe and affect your results. Additional surgery also may be required to correct these complications.

Some possible complications include:

- Allergic reaction to the implant materials
- Bleeding, which may require a blood transfusion
- Bone formation that is not normal, in excess or in an unintended location
- Damage to nearby tissues or nerves
- Death
- Fetal development complications
- Infection

Pain or discomfort
Respiratory (breathing) problems
Scar formation or other problems with the surgical incision
(Short-term) mild to severe swelling
Side effects from anesthesia or the surgical approach
Skin swelling or irritation

Sinus Augmentation

A sinus augmentation, or "sinus lift," is a surgical bone grafting procedure that is performed in the maxillary (upper jaw) sinus cavity (above the area that anchors your teeth) to prepare the patient for dental restoration. Some patients have such small amounts of existing bone in these areas that dental restoration simply cannot occur without sufficient formation of new bone. Your surgeon may feel that autogenous bone or INFUSE® Bone Graft is needed to form the necessary bone in this area for reliable and functional dental restoration. In this case, INFUSE® Bone Graft or autogenous bone harvested from another site in your body may be placed into your upper jaw to promote bone growth in the floor of the sinus cavity to anchor the dental implants to allow for dental restoration.

A sinus augmentation may be an appropriate oral surgery if you want to replace teeth with dental implants because you are:

Missing more than one tooth in the back of the upper jaw
Missing a large amount of bone in the back of the upper jaw
Missing teeth due a congenital (present at birth) defect or condition
Missing most of the teeth in the upper jaw and need firm anchorage for multiple implants

A bone graft procedure can help achieve the bone height required by dental implants.
During sinus augmentation surgery

There are many ways for a surgeon to perform a sinus augmentation. In one of the most common ways, the oral-maxillofacial surgeon makes an incision in the gum and gently pulls the gum tissue back. The surgeon then cuts into the gum area to expose the sinus membrane. The membrane is then lifted from the bony sinus floor to manufacture a space for bone graft material. The bone graft material is then placed in the space to help the body grow bone and form a thicker sinus floor.

Once the bone graft site has healed, the jaw bone below the sinus may be prepared for a dental implant or other dental restoration.

A sinus augmentation is generally performed in the dental office under local anesthesia. Some patients also may request oral or intravenous sedative medication as well.
After sinus augmentation surgery

Treatment results are specific to each individual patient, so they may vary from person to person. The entire process, from tooth extraction to final dental implant placement, may take up to a year.

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Some possible complications include:

- Allergic reaction
- Death
- Development of respiratory problems
- Ectopic and/or exuberant bone formation (abnormal bone formation)
- Edema (swelling)
- Erythematous tissue(redness of skin caused by dilation)
- Fetal development complications
- Hematoma (clotted blood)
- Incisional complications
- Infection
- Inflammation
- Itching
- Pain
- Scar formation
- Tissue or nerve damage

If you think you may be experiencing some of these issues after your surgery, contact your doctor immediately.

Patient Name: _____

Patient signature: _____

Date: _____

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