

HAVE YOU
CONSIDERED
**INFUSE[®] BONE
GRAFT**
IN YOUR
DENTAL
PROCEDURES?



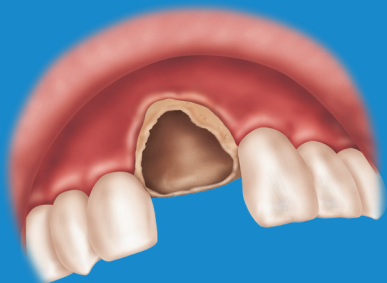
Do you have enough bone
for dental implant placement?

Do you know what your
bone graft options are?

Medtronic

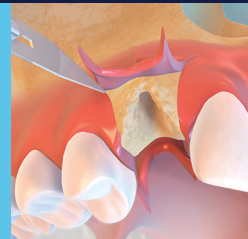
WHAT IS BONE GRAFTING?

LOCALIZED ALVEOLAR RIDGE AUGMENTATION WITH INFUSE BONE GRAFT



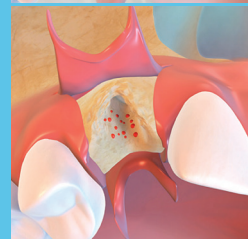
1

Incisions are made around the site to expose the socket. The socket is cleaned out.



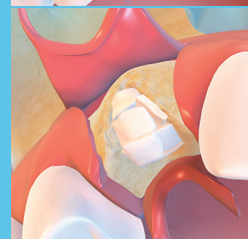
2

The remaining bone is scraped to cause bleeding in the socket.



3

After Infuse Bone Graft is prepared, it is cut into pieces. Infuse Bone Graft is loosely packed into the socket where bone growth is desired.



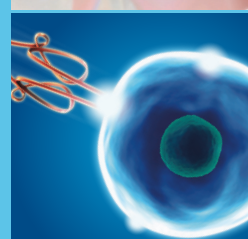
4

Soft tissue is closed over the defect using dental sutures.



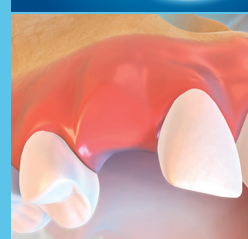
5

Infuse Bone Graft induces new bone formation for dental implant placement.

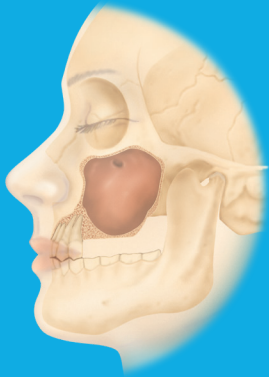


6

Dental implants can be placed after adequate bone has formed (typically 6 months post-op).

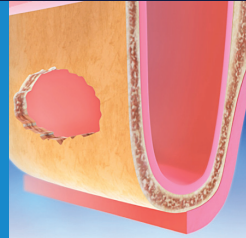


SINUS AUGMENTATION PROCEDURE ("SINUS LIFT") WITH INFUSE BONE GRAFT



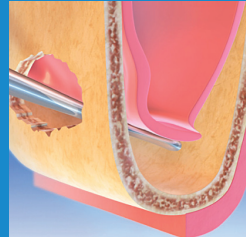
1

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



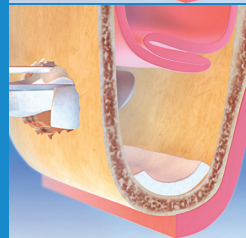
2

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



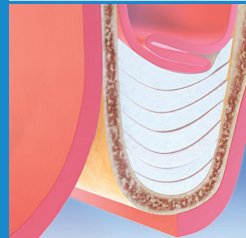
3

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.



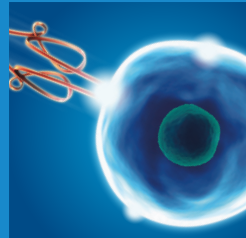
4

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.



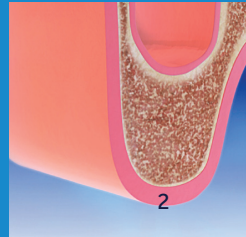
5

Infuse Bone Graft induces new bone formation for dental implant placement.



6

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



WHAT ARE THE DIFFERENT TYPES OF BONE GRAFTS?

Xenograft

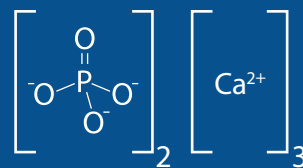
Bone taken from an animal source and transplanted into your body



1

Alloplast

Synthetically made material to be used in your body as a bone graft alternative



2

WHAT ARE THE **BENEFITS AND DRAWBACKS** OF EACH GRAFT TYPE?

Xenograft

Benefits:

- Commonly used in surgery
- Not human derived
- Readily available
- Well documented success
- May heal small defects by itself
- Portions of the graft may turn into your own bone

Drawbacks:

- Low risk for disease transmission
- Does not stimulate your body's cells to form bone
- Portions of the graft may remain in your body for years to come
- Limited in its ability to heal large defects by itself

Alloplast

Benefits:

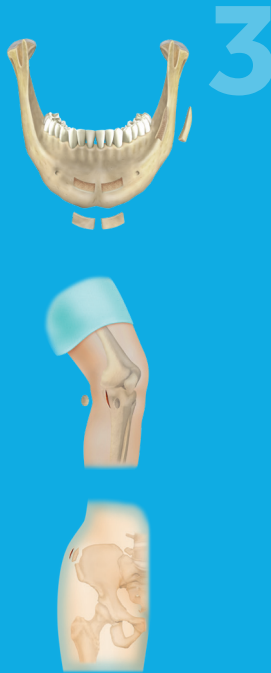
- Commonly used in surgery
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Drawbacks:

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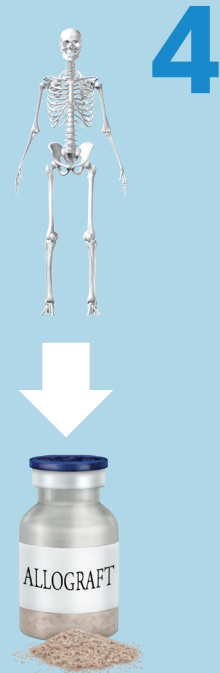
Autograft

Bone taken surgically from one part of your body and transplanted to another part



Allograft

Bone taken from a human cadaver and transplanted into your body



Autograft

Benefits:

- No potential for immune reaction or disease transmission
- Commonly used in surgery
- Well documented success
- May heal large or small defects by itself
- Transplanting your own bone forming cells to help heal the defect

Drawbacks:

- Risk of pain and/or infection at harvest site which may last for a long time
- Additional surgery and anesthesia are required
- May not be an option for some patients

Allograft

Benefits:

- Commonly used in surgery
- Well documented success
- May heal small defects by itself
- Portions of the graft may turn into your own bone

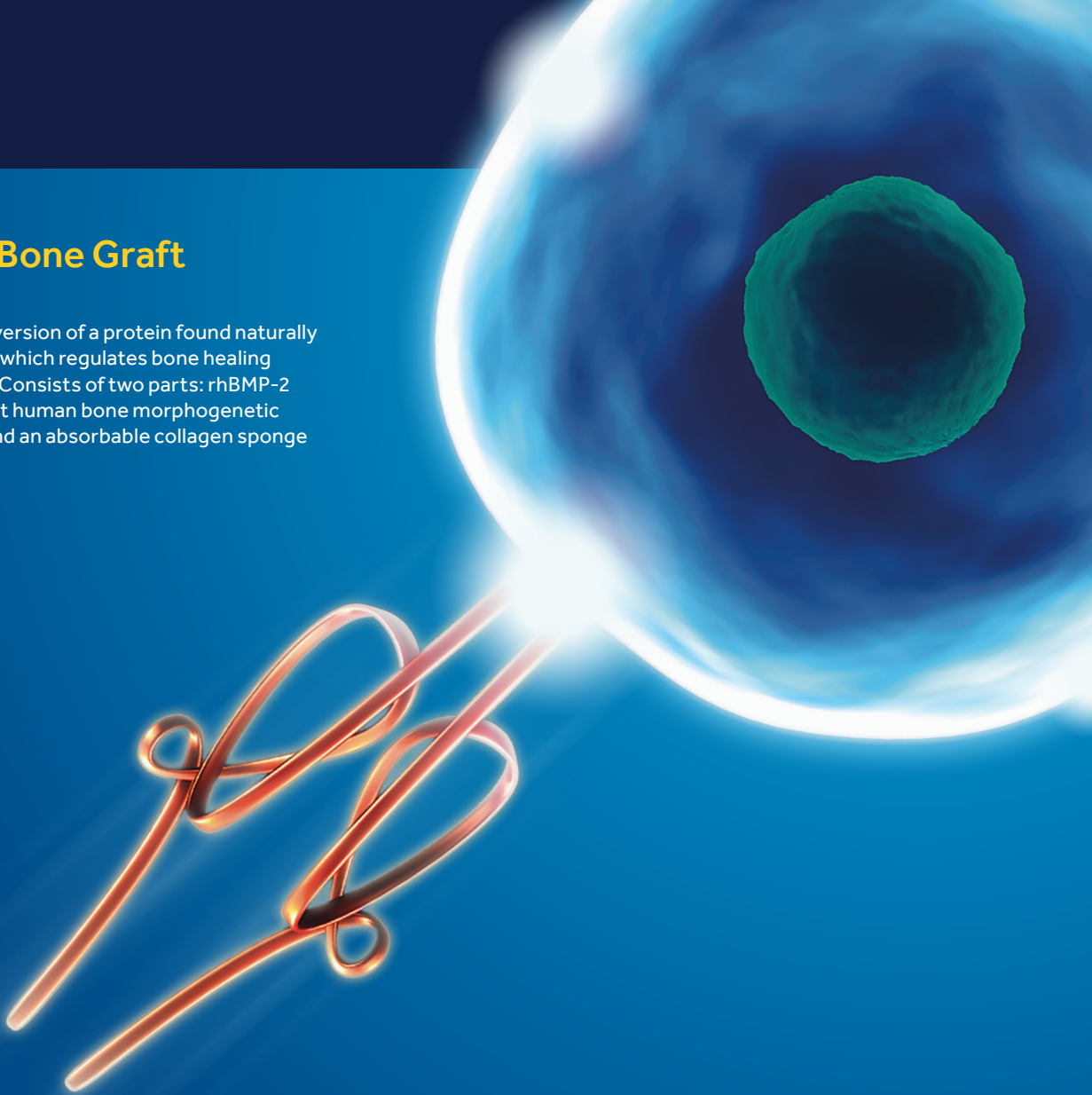
Drawbacks:

- Low risk for disease transmission
- Does not stimulate your body's cells to form bone
- Portions of the graft may remain in your body for years to come
- Limited in its ability to heal large defects by itself

5

Infuse Bone Graft

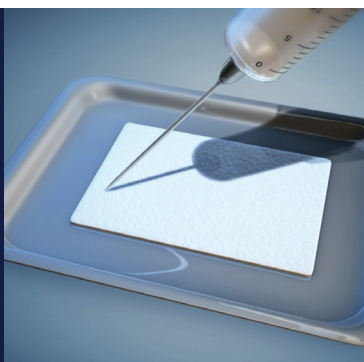
A synthetic version of a protein found naturally in your body which regulates bone healing and growth. Consists of two parts: rhBMP-2 (recombinant human bone morphogenetic protein-2) and an absorbable collagen sponge



WHAT IS INFUSE BONE GRAFT?

Consists of 2 parts:

- A protein which tells your body to make your own bone
- A collagen sponge used to deliver the protein to the defect site



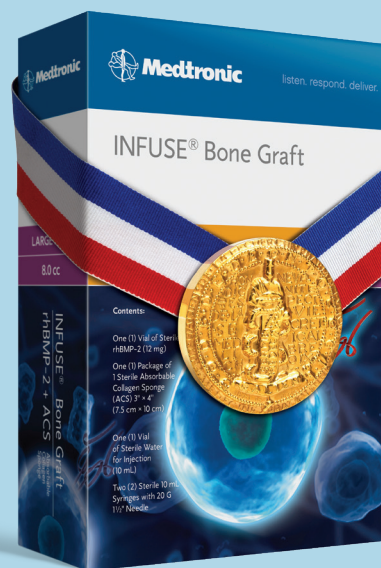
Winner of the 2008 Prix Galien USA Award** for Best Biotechnology Agent

- Voting committee includes Nobel laureates.

**To learn more about the Prix Galien USA Award visit prix-galien-usa.com/

Has been approved for use in different areas of the body including:

- Certain spine procedures*
- Tibia procedures*
- Certain dental procedures*



* For complete indications and more information, please see brief summary in the back of this brochure for important safety information.

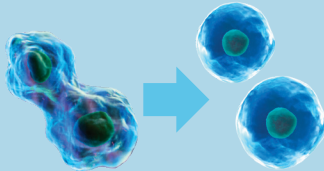
HOW DOES INFUSE BONE GRAFT WORK?*

1. Infuse Bone Graft is surgically placed where you need bone to grow.
2. A protein signal is sent out to the body to recruit cells to that area.
3. Those cells are changed into bone building cells.
4. Bone building cells begin making your own bone in that area.

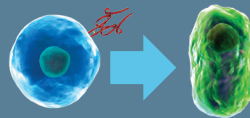
Infuse Bone Graft tells your body to make its own bone!!!



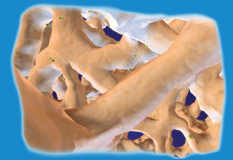
Attraction



Reproduction



Differentiation



Bone

WHAT ARE THE BENEFITS OF INFUSE BONE GRAFT?

- You don't need a second surgery to harvest bone from another place in your body.
- Bone grows where Infuse Bone Graft is placed. ¹
- Proven, predictable bone growth results.
- Infuse Bone Graft directs your body to grow your own bone! There is no residual graft material after bone is formed.
- Proven clinically safe and effective for bone formation! ²

References: 1,2: Summary of Safety and Effectiveness (SSE) PDF called SSE Infuse Dental P050053.

*Commonly accepted mechanism of action.1

WHAT ARE THE DRAWBACKS OF INFUSE BONE GRAFT?

- You may experience short term mild to severe facial swelling (edema) after the surgery.
- It has not been studied for use in patients under 18 years of age.
- It cannot be used in patients with an active infection at the defect site.
- It should not be used in pregnant women, women who plan to become pregnant in the next 12 months, or women who are nursing.
- It should not be used in people with immune deficiencies due to other treatments, such as radiation therapy, chemotherapy, or steroid therapy.

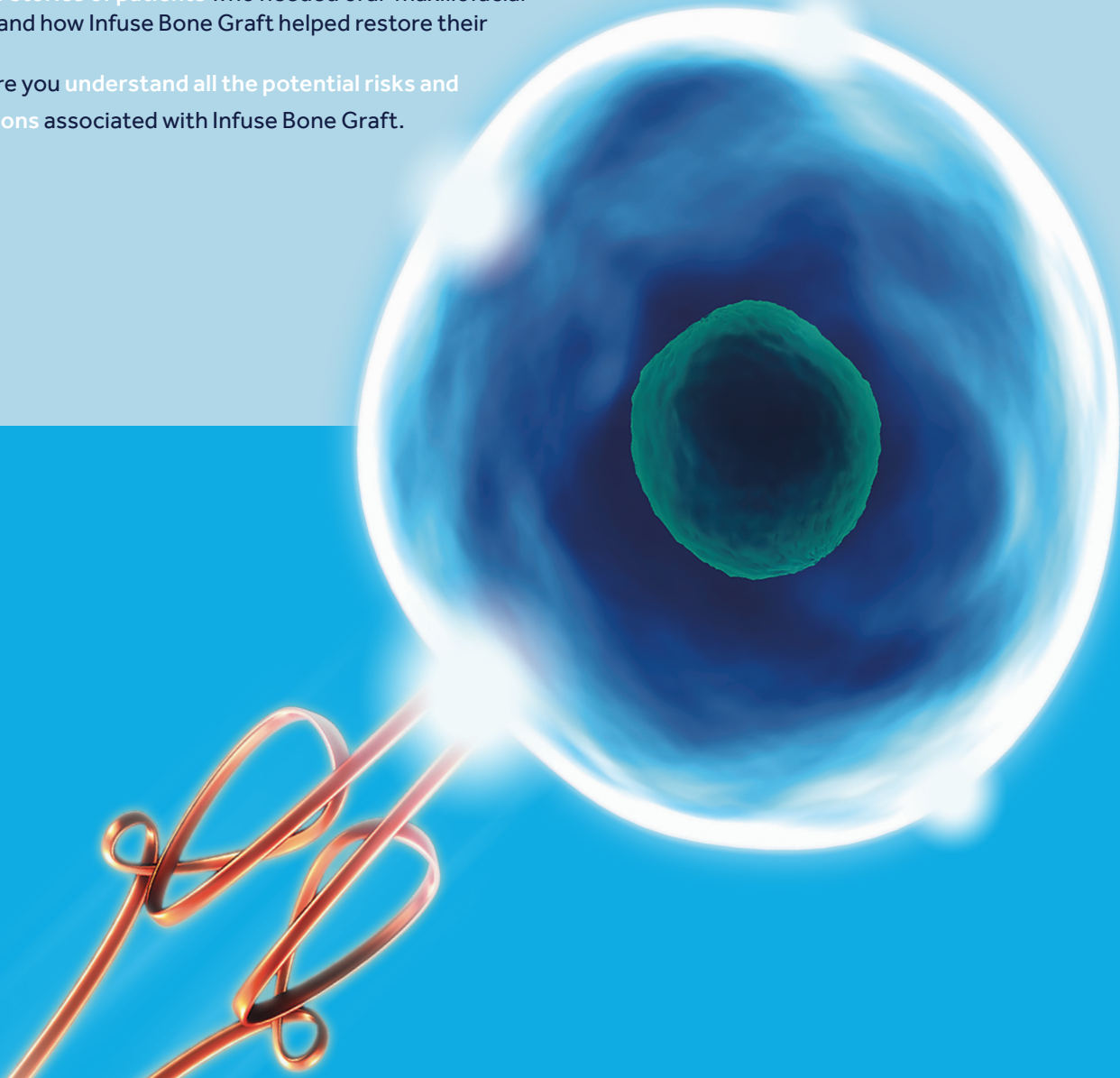
QUESTIONS TO ASK YOUR DOCTOR

- Why do I need a bone graft?
- Please describe the procedure to me.
- What are my bone graft choices?
- How long will my treatment take?
- What, if any, medications will be prescribed?
- What is the best treatment course for me?
- Am I a candidate for Infuse Bone Graft?

PRIOR TO PROCEDURE

FIND OUT MORE

- Learn all about Infuse Bone Graft and how it is used in dental surgeries.
- Find out what to expect during a sinus augmentation or ridge augmentation procedure and whether you're a candidate.
- Listen to stories of patients who needed oral-maxillofacial surgery and how Infuse Bone Graft helped restore their smiles.
- Make sure you understand all the potential risks and precautions associated with Infuse Bone Graft.



BRIEF SUMMARY

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 1 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.

Warnings and Precautions for INFUSE® Bone Graft

This device has not been tested in pregnant women to determine if there is any effect on a developing fetus.

This device has also not been studied in nursing mothers.

When tested in female rabbits that received the rhBMP-2, a component of the device, developed an immune response and later became pregnant, the following was seen:

- The antibodies developed by the mother were able to reach the developing rabbit fetus. The effect of these antibodies on the developing rabbit fetus is not currently known.
- Some bone formation abnormalities were observed in a small number of the rabbit fetuses tested. It is not known if these changes would disappear as the rabbit fetus continued to develop or at some time after birth.

This device should not be used immediately prior to or during pregnancy. Women of child-bearing potential should be advised not to get pregnant for one year following treatment with the device. Women of child bearing potential should be warned of potential risk to a fetus and should discuss other possible orthopedic treatments with their surgeon.

BMP-2 plays a critical role during fetal development in humans and other animals. It is not known whether a pregnant woman, previously exposed to BMP-2 by implantation with the device, might develop a second immune response to BMP-2 from the developing fetus with adverse effects for the woman or baby. In a rabbit pregnancy study to investigate this issue, no increase in anti-BMP-2 antibodies was observed.

Medtronic

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