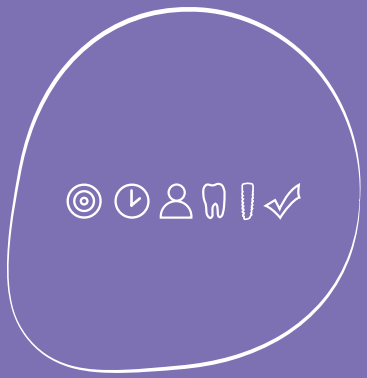
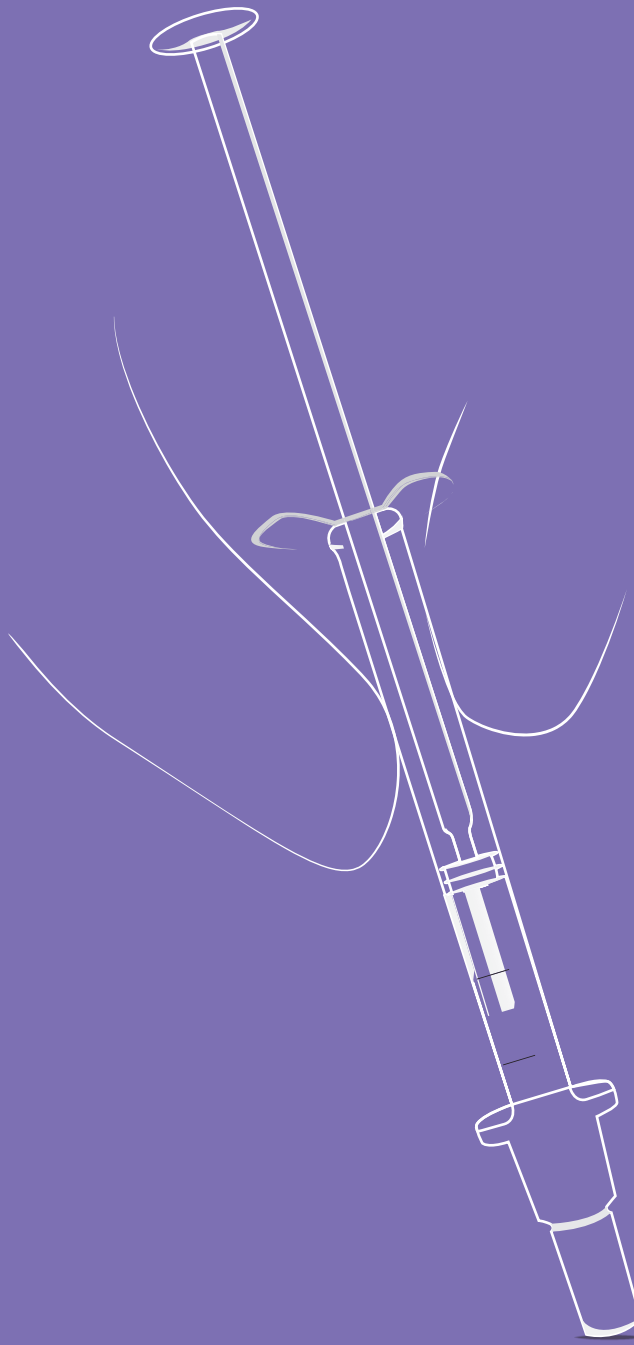
Product Information



MIS Warranty: MIS exercises great care and effort in maintaining the superior quality of its products. All MIS products are guaranteed to be free from defects in material and workmanship. However, should a customer find fault with any MIS product after using it according to the directions, the defective product will be replaced.



3.

Introduction.

The past decade's technological advancements have brought about a new era in our understanding of bone growth and repair. Augmentation procedures became a part of routine dental surgical care, using different methods and various granulated materials from different sources, such as autografts, allografts and alloplasts. BONDBONE® is a revolutionary synthetic bone grafting material, designed to facilitate easy handling and reduce the time required for dental augmentation procedures.

Overview.

BONDBONE® is a novel synthetic bone grafting material, considered to be a breakthrough in the field of dental bone augmentation. BONDBONE® is composed of biphasic calcium sulfate, well-established and widely documented for its biocompatibility, osteoconductivity and bioresorbability. Biphasic calcium sulfate is fast setting and its physical properties are not affected by the presence of blood and saliva.

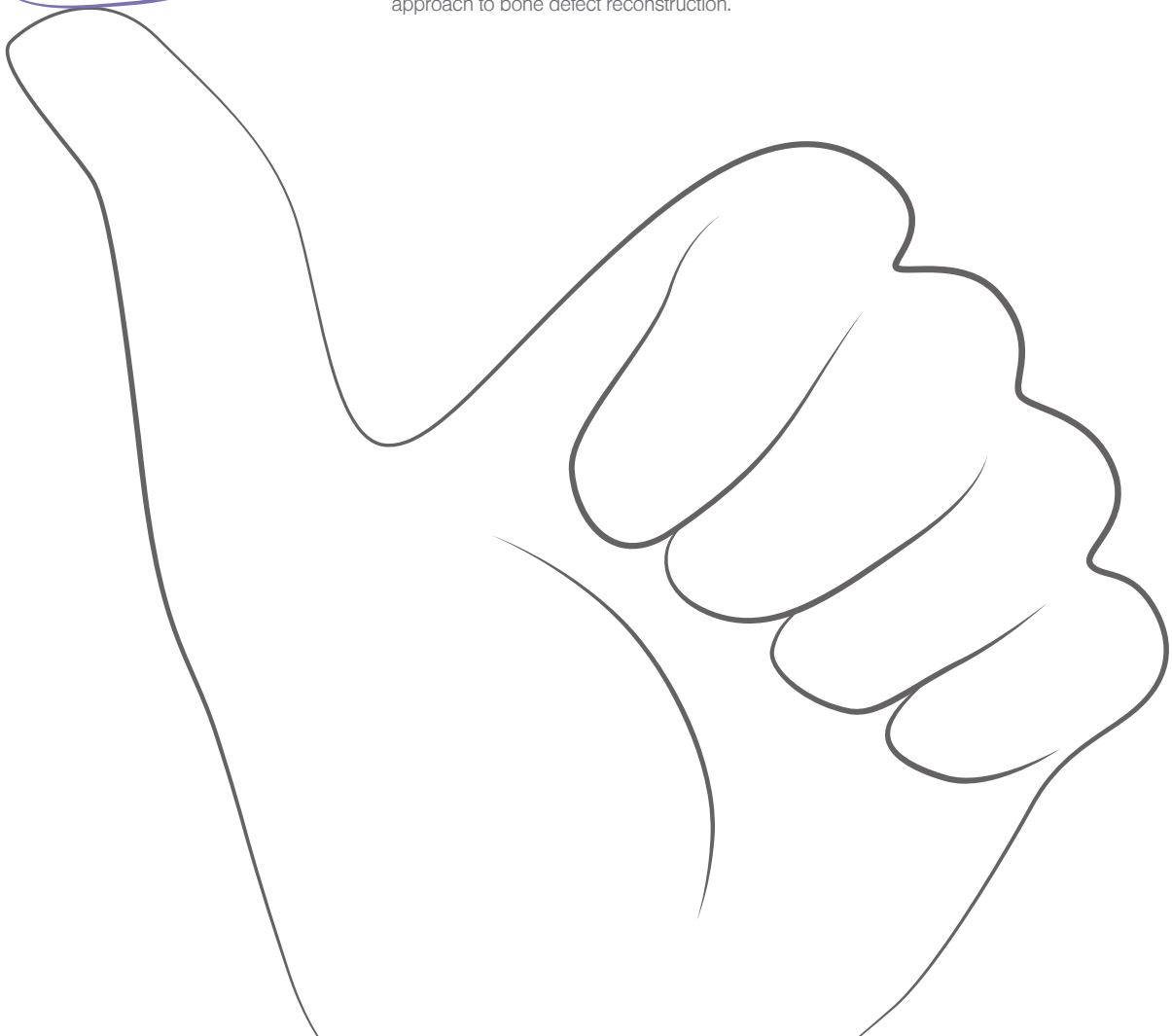
Fast setting; preventing particle migration

A Multi-Purpose Solution.

BONDBONE® can be mixed with other granular bone-filling products to prevent particle migration, creating an outstanding composite graft. By itself, BONDBONE® provides an excellent solution for socket preservation procedures. In specific cases, BONDBONE® can be used as a resorbable barrier over other bone grafting materials.

Advantages.

BONDBONE® is available in a powder form, supplied in 1cc and 0.5cc easy-to-use drivers and packed in 3-unit packages. With its unique driver and simple delivery method, BONDBONE® provides a new approach to bone defect reconstruction.



Excellent binder

BONDBONE® is an excellent binder for other granular augmentation materials. It facilitates easy handling and prevents particle migration, supporting predictable outcomes.

Versatile

BONDBONE® may be used either as a bonding material within a composite graft or by itself. It boosts other grafting materials for the augmentation of large defects and can be used alone for small defects and for socket preservation procedures. BONDBONE® can also be used as a barrier over other augmentation materials.

Easy handling

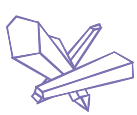
The initial pliable BONDBONE® paste sets within two to five minutes, allowing both significant reduction of procedure time and excellent handling.

Perfect stability

Setting is not affected by the presence of blood or saliva.

Pure & safe

BONDBONE® does not contain any components other than calcium sulfate.



Osteoconductive

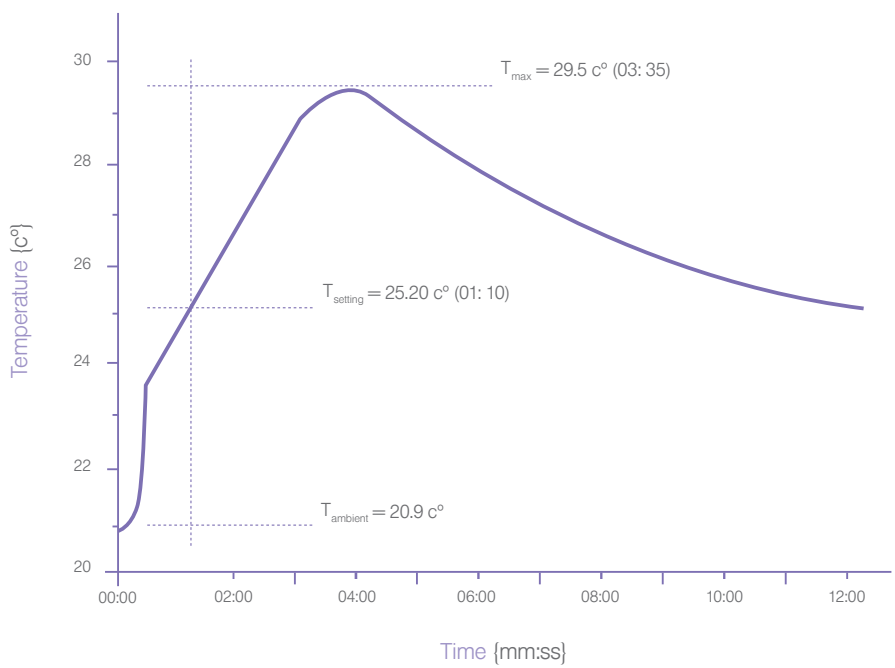
The uniquely advantageous structure of BONDBONE® incorporates micropores - allowing infiltration of growth factors, and macropores - facilitating cell proliferation and angiogenesis.

Completely resorbs

BONDBONE® completely resorbs, leaving behind newly regenerated natural bone.

Material Characteristics.

BONDBONE® is an ideal product in terms of clinical use, allowing a reasonable working time of three to five minutes. Its unique composition complies with the ambient human biological environment: The temperature level reached during setting will not exceed 30°C (85°F) and the neutral pH of the surrounding tissue is kept stable.



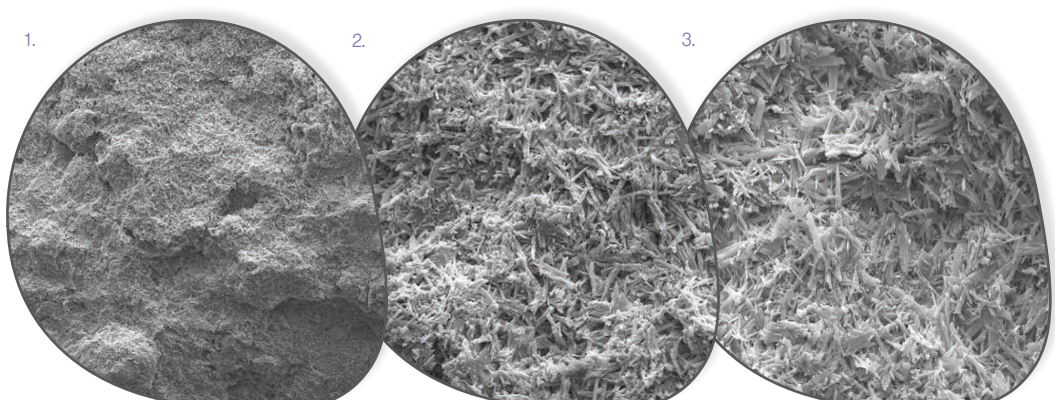
Source: RMS Foundation

Featuring both macropores and micropores, BONDBONE® structure is characterized by a porosity rate of 46%.

Macropores
Ranging from 300μm to 800μm, macropores allow angiogenesis and cell proliferation, inducing bone tissue regeneration.

Micropores
Ranging from 1μm to 50μm, micropores allow infiltration of growth factors.

The needle-like particles reinforce the mechanical characteristics of the material. The composition is characterized by a bioresorption rate, compatible to that of the new bone regeneration. Turnover time is four to ten weeks.

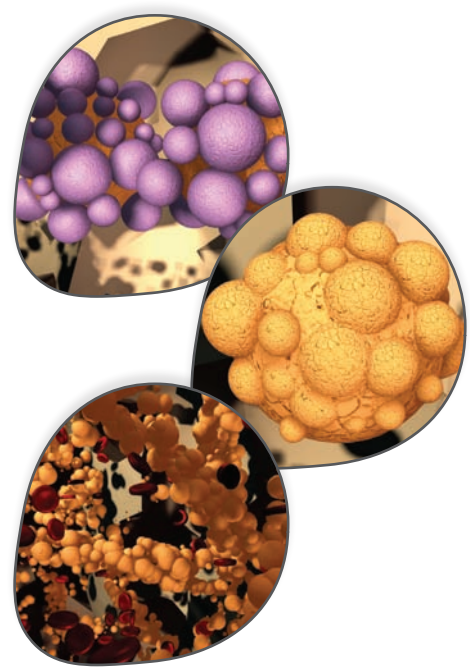


SEM images: RMS Foundation

Mechanism of Action.

Once BONDBONE® is mixed with saline, the granulated powder goes through an accelerated setting process. The setting process forms a rigid structure that is highly crystalline, even in the presence of blood, proteins, and saliva. The unique particle-size distribution controls the reaction rate, optimizing both setting time and the resulting microstructure. This microstructure determines mechanical characteristics and resorption rate, comparable to that of bone remodeling.

- Predictable setting time

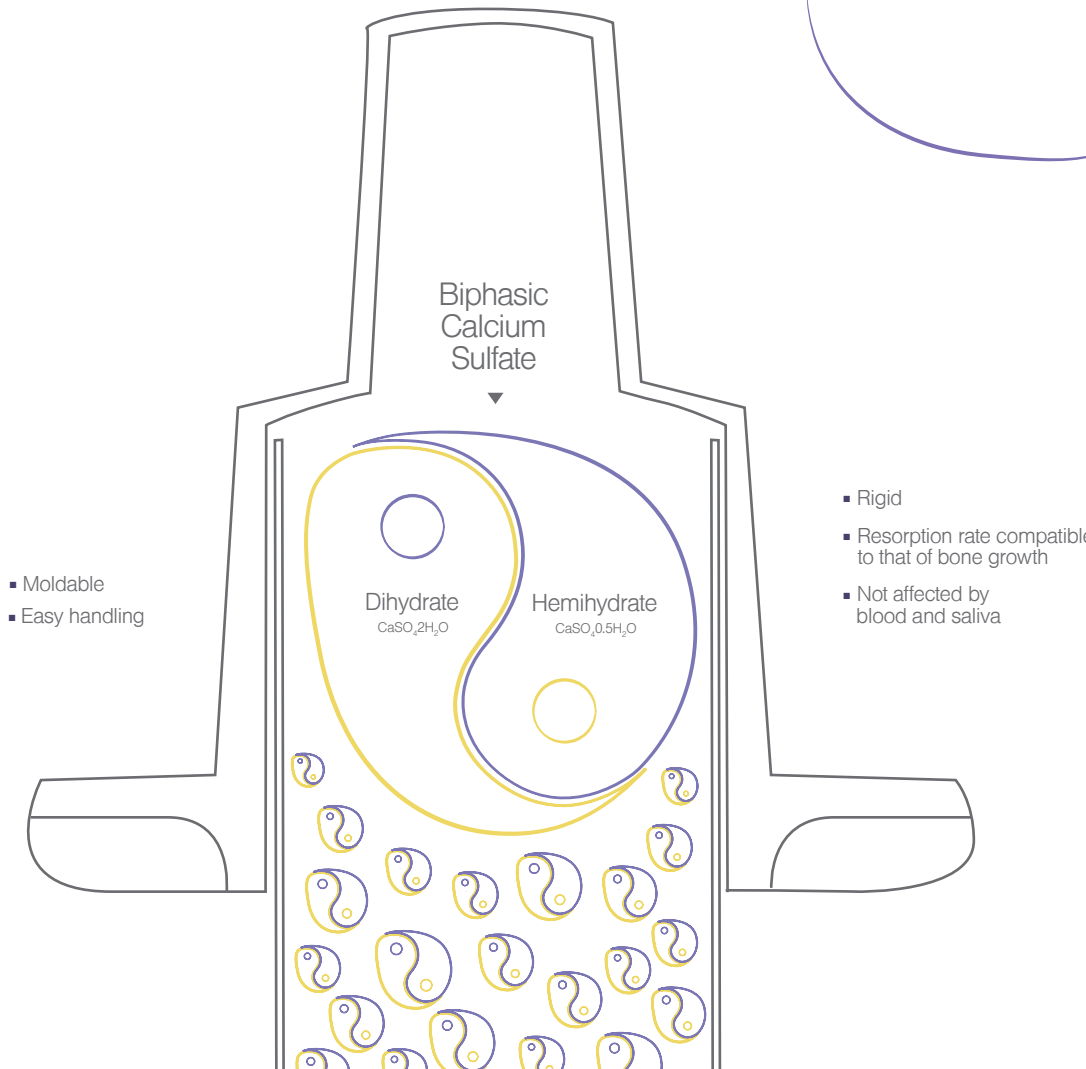


1. Seed crystals

2. Rapid growth and crystallization

3. A crystal net is rapidly built despite the harsh environment

The Concept of **Biphasic Calcium Sulfate.**



- Moldable
- Easy handling

- Rigid
- Resorption rate compatible to that of bone growth
- Not affected by blood and saliva

Clinical Cases.

Case 1 exemplifies BONDBONE® being used in a composite graft, combined with other granular graft material.

Case 2 shows BONDBONE® being used as a stand-alone product.

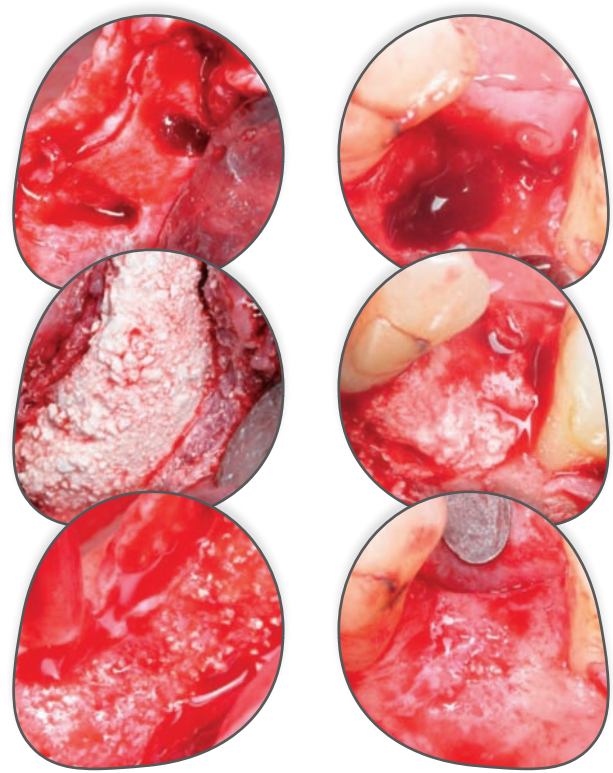
Case 1.

1. Large defect in a narrow ridge following implant failure

2. Placement of a composite graft made of BONDBONE® and a granular material

3. Healing after three months

Case 2.



1. Bone defect before treatment

2. BONDBONE® placement

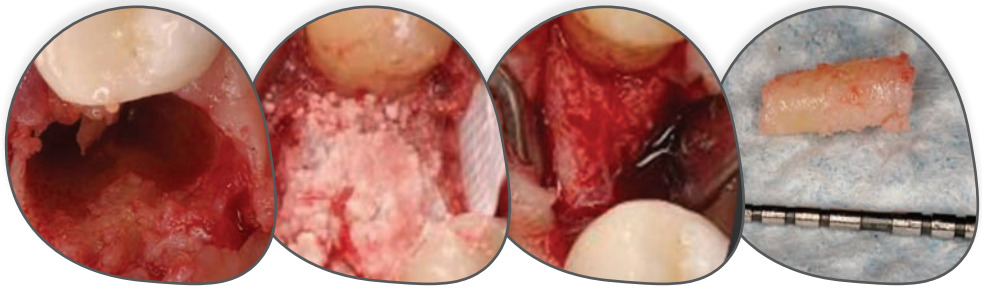
3. Healing after three months

Photos: Dr. Amos Yahav

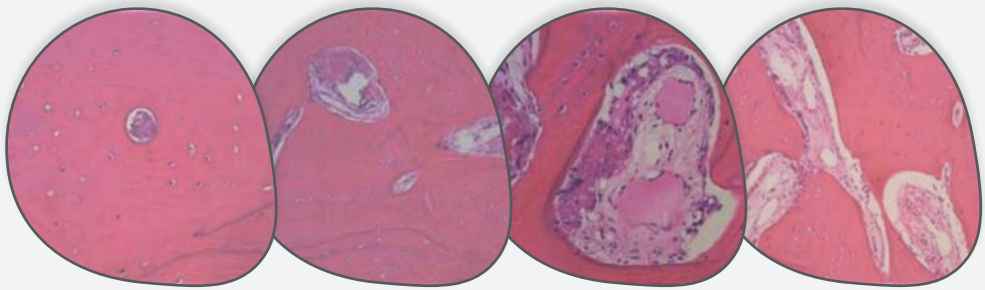
Histology.

Histological sections present a dense lamellar bone formed without remnants of BONDBONE®.

Socket preservation

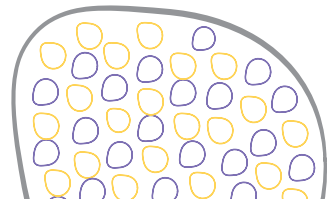


Regenerated bone after healing



Photos: Dr. Robert A. Horowitz

FAQs.



1.

What is BONDBONE®?

1

BONDBONE® is a novel synthetic bone graft material considered to be a breakthrough in the field of dental bone grafting. It is composed of biphasic calcium sulfate, which has documented biocompatible, osteoconductive, and bioresorbable properties. The biphasic calcium sulfate is fast setting and its physical properties are not affected by the presence of blood or saliva. Indications for use: BONDBONE® can be used in two different ways:

1. In conjunction with other granular augmentation materials.
2. Alone, in defects of less than 10mm in diameter and with support of at least 3 bony walls.

BONDBONE® does not interfere with the healing process and is totally resorbed and replaced by bone at a rate equivalent to that of bone formation.

What are the main advantages of BONDBONE®?

2

BONDBONE® has unique advantages when used with additional bone graft materials and as a stand-alone product.

▪ BONDBONE® has excellent handling properties: The initial pliable paste hardens in approximately three minutes ▪ Osteoconductive: Its unique porous structure allows infiltration of growth factors through micropores, as well as angiogenesis and cell proliferation through macropores. ▪ BONDBONE® significantly reduces procedure time. BONDBONE® has a predictable resorption time that results in an increased percentage of vital bone available during implant placement ▪ BONDBONE® will act as a binder when combined with the granules of other bone graft materials. This enables additional volume to be maintained ▪ Safety: BONDBONE® is purely synthetic. It does not contain any components other than calcium sulfate.

What is the resorption rate of BONDBONE®?

3

BONDBONE® has a resorption rate that is comparable to the rate of natural bone growth and will not interfere with the healing process.

Does it contain any additives other than calcium sulfate?

4

BONDBONE® offers high performance with absolutely no elements other than pure calcium sulfate; the well-known advantages of calcium sulfate are maximized for optimal healing. Because of the biphasic structure of BONDBONE®, the advantages of both hemihydrate and dihydrate calcium sulfate are realized, without the need for additives.

2.

What is the setting time of BONDBONE®?

5

The setting time of approximately three minutes allows for outstanding handling properties. In addition, it is the only bone graft material that can set in an aqueous environment and in the presence of blood and saliva. The reaction temperature is lower than 30°C (85°F) and it has a neutral pH, thus reducing the patient's discomfort during surgery.

Can BONDBONE® act as a binding material?

6

Yes, definitely. Mixing BONDBONE® with other granular graft materials (Autografts, Xenografts, Allografts and Alloplasts) creates a cementable composite graft mixture. The clinician may use the desired material to mix with BONDBONE®, but it is recommended to choose a long-term, space-maintaining material for larger defects that require longer healing time. When used as a binder, a 2:1 ratio of BONDBONE® to particulate graft material is recommended.

What will the x-ray show while working with BONDBONE®?

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During BONDBONE® application the x-ray shows a complete radiopaque image identical to the surrounding bone. A week later, a radiolucent image may be shown in the perimeter, and it will expand to the entire area within 3 weeks. This does not indicate the material is resorbed, but it is the osteoid prior to calcification. Within a few weeks, the area will be radiopaque again.

Is BONDBONE® stable post-setting?

8

Yes. The initial strength is obtained right after setting and is reduced over time as the bone rebuilds. This occurs at a rate that is comparable to that of bone regeneration.

How does the unique microstructure of BONDBONE® affect bone regeneration?

9

BONDBONE® has a unique porous structure that allows for the infiltration of growth factors through its micropores and cell proliferation through its macropores. This allows for angiogenesis to occur.

Is BONDBONE® fully resorbable?

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Yes, it is fully resorbed, leaving behind a normal bone morphology.

3.

Can BONDBONE® be mixed with antibiotics and growth factors?

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Yes. BONDBONE® is composed of pure calcium sulfate, which can be combined with antibiotics and growth factors.

Can BONDBONE® be mixed with blood?

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No. Despite the fact BONDBONE® sets in presence of blood and saliva, blood will not activate the material into setting. Because of this, it is always recommended to use sterile saline. Due to the porous structure of BONDBONE®, blood will penetrate all layers of the material effectively.

Do all synthetic bone products provide the same results?

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No, synthetic materials are divided into resorbable synthetics, such as calcium sulfate, and nonresorbable or partially resorbable materials. The clinician should choose the material according to the indication and the desired outcome.

Why is BONDBONE® different from other synthetic products?

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BONDBONE® is a novel biphasic calcium sulfate and is the only calcium sulfate that can set in the presence of blood and saliva. Moreover, due to its composition and form, it has the ability to serve as an excellent binder for composite grafts.

How can I use BONDBONE® ?

15

You can use BONDBONE® in two ways: By itself or as a composite graft. By itself, if the defect is not larger than 10 mm and has at least three walls of bony support, BONDBONE® can be used. BONDBONE® can also be used as a composite graft in more complex cases. The setting reaction begins when the powder is mixed with saline. The site should be slightly overfilled to compensate for the compression and setting process.

Why would I use BONDBONE® if I am happy with my current graft material?

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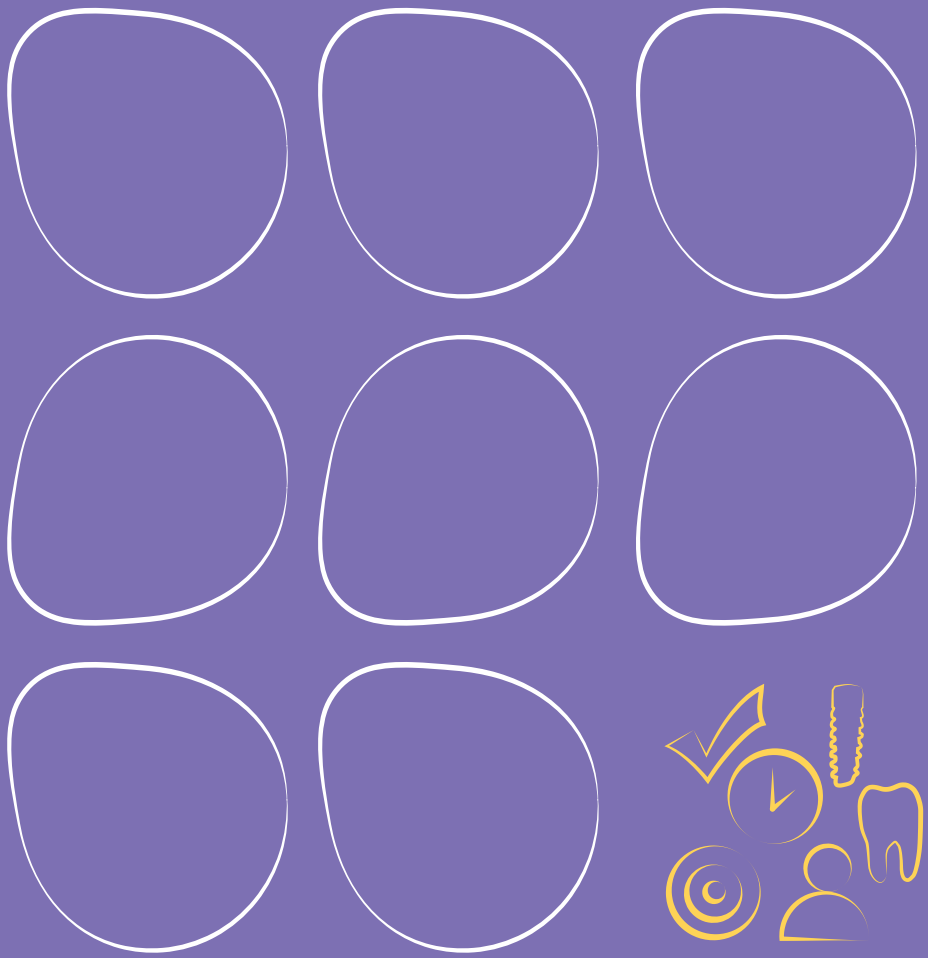
When combined with your current graft material, BONDBONE® is an excellent binder in a composite graft. Its easy setup process and ability to set in the presence of blood and saliva eliminates particle migration and reduces procedure time.

Packaging.

BONDBONE® is available in 1cc and 0.5cc sterile drivers and contains three units per package.



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