



IngeniOs® Synthetic Bone Particles Bone Augmentation Material

Product Information



ZIMMER BIOMET
Your progress. Our promise.

IngeniOs Synthetic Bone Particles Bone Augmentation Material



Why Bone Augmentation Is Needed?

Bone augmentation is most often used to prepare a site for dental implants that are needed to replace a missing tooth or teeth. Bone in an area where teeth have been lost naturally shrinks or resorbs over time, both in height and width. As a result, new bone must be grafted to create a secure site for placing implants and to achieve aesthetic results. Bone grafting can also be used to save teeth that have experienced bone loss.¹

What Does Bone Augmentation Entail?

The surgical site is numbed locally. In the region requiring bone reconstruction, a small opening is created. A bone replacement material such as IngeniOs Synthetic Bone Particles is placed into the opened receptor site. The bone replacement material is then stabilized with a protective covering (a so-called membrane) and closed for the duration of the healing phase.¹

What Are IngeniOs Synthetic Bone Particles?

IngeniOs Synthetic Bone Particles are bone grafting products of non-biologic origin used in a variety of indications to rebuild oral bone, including jaw augmentation, filling defects, tooth extraction sites as well as sinus floor elevation. IngeniOs Synthetic Particles are made primarily of calcium and phosphate, elements found naturally in the human body. The particles are designed to provide a structure for the ingrowth of natural bone to replace what has been lost due to a variety of reasons.

What Types Of Bone Grafts Exist?

Bone can be taken from another part of the patient's body and transplanted to the site needing regeneration. Because this method of bone grafting may result in post-surgical pain and discomfort at the donor site, bone grafts are commercially available to avoid this surgical step. Commercially-available bone grafts originate from human donors or animal bone, or they can be manufactured from non-biologic sources, like IngeniOs Synthetic Bone Particles.



What Happens To IngeniOs Synthetic Bone Particles In The Body?

Some types of IngeniOs Synthetic Bone Particles, IngeniOs HA for instance, remain in the body for very long durations to serve as an ongoing scaffold to support regenerated bone. Other IngeniOs Synthetic Bone Particles, like IngeniOs β -TCP Bioactive is absorbed naturally by the body and replaced by the body's own bone after a period of time.²

How Do I Know It Is Safe?

IngeniOs Synthetic Bone Particles are sterile, biocompatible and non-biologic. They are manufactured using strict specifications for consistency and quality. Zimmer Biomet Dental is committed to offering products with the highest possible quality and safety standards. For this reason, an Independent Notified Body reviews and approves the manufacturer per standard processes. IngeniOs Synthetic Bone Particles are medical devices that comply with European Regulations for CE Certification.²

Are There Any Side Effects Caused By IngeniOs Synthetic Bone Particles?

While no specific side effects are known, patients may experience incompatibility reactions to implanted materials. No interactions between IngeniOs Synthetic Bone Particles and medicinal products or other medical devices are known.²

What Has To Be Considered?

IngeniOs Synthetic Bone Particles have not been evaluated in pregnant women or children. In addition, use of IngeniOs Synthetic Bone Particles should be restricted for patients with the following circumstances or biologic conditions:

- Acute and chronic infections in the surgical area (soft-tissue infections; inflamed, bacterial bone diseases; osteomyelitis). In patients on antibiotic therapy, it is at the doctor's discretion whether to use IngeniOs Synthetic Bone Particles based on a benefit/risk analysis.
- Severe metabolic disorders, such as severe diabetes mellitus that is uncontrollable or difficult to manage
- Steroid treatment
- Drugs that interfere with calcium metabolism
- Immunosuppressant therapy
- Endocrine bone diseases
- Radiation therapy
- Nicotine abuse

The use of IngeniOs Synthetic Bone Particles to fill bone defects may be the best solution despite the presence of some of the circumstances listed above.²

References

1. Elgali, I., et al., Guided bone regeneration: materials and biological mechanisms revisited. Eur J Oral Sci, 2017. 125(5): p. 315-337.
2. IngeniOs Synthetic Bone Particles Instructions for use (IFU).

Please note that while this brochure is designed to address some of the frequently asked questions about IngeniOs Synthetic Bone Particles individual factors may limit product use in certain indications. Please read instructions for use for more information.



Contact us at 1-800-342-5454 or visit
zimmerbiometdental.com

Zimmer Biomet Dental
Global Headquarters
4555 Riverside Drive
Palm Beach Gardens, FL 33410
Tel: +1-561-776-6700
Fax: +1-561-776-1272

Unless otherwise indicated, as referenced herein, all trademarks are the property of Zimmer Biomet; and all products are manufactured by one or more of the dental subsidiaries of Zimmer Biomet Holdings, Inc. and marketed and distributed by Zimmer Biomet Dental and its authorized marketing partners. IngeniOs products are manufactured by Curasan AG. For additional product information, please refer to the individual product labeling or instructions for use. Product clearance and availability may be limited to certain countries/regions. This material is intended for clinicians only and does not comprise medical advice or recommendations. This material may not be copied or reprinted without the express written consent of Zimmer Biomet Dental.
ZB0717 REV A 05/20 ©2020 Zimmer Biomet. All rights reserved.

