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Instructions for Use

IngeniOs™ β-TCP Bioactive Synthetic Bone Particles

Before using this product, the surgeon/practitioner should carefully study the indications, contraindications, recommendations, warnings and instructions and fully comply with them. The manufacturer, the importer and the distributor of these products are not liable for complications, other negative effects or damages that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on. The surgeon/practitioner is responsible for any such complications or other consequences.

DESCRIPTION

IngeniOs β-TCP Bioactive Synthetic Bone Particles are a matrix of resorbable, silicated beta-tricalcium phosphate for the filling, bridging and reconstruction of bone defects. The structure is a porous biocompatible synthetic scaffold of ceramic material and is characterized by an open-cell porosity of approximately 75%. *IngeniOs* β-TCP Bioactive Synthetic Bone Particles are radiopaque and therefore detectable in post-operative x-rays. The product is available in various grain sizes and is supplied sterile by means of gamma irradiation and is intended for single use.

When in contact with vital bone, *IngeniOs* β-TCP Bioactive Synthetic Bone Particles are resorbed by the body over a period of months and are simultaneously replaced by local, endogenous bone. As a synthetic, bioactive ceramic material, the product has intraosseous and extraosseous tissue compatibility without local or systemic toxicity.

IngeniOs β-TCP Bioactive Synthetic Bone Particles are packaged in the following configurations. Please note that not all configurations are available in every country or region:

0-602501	*IngeniOs* β-TCP Bioactive Synthetic Bone Particles	0.25cc, 0.25-1mm (250-1000µm)
0-600501	*IngeniOs* β-TCP Bioactive Synthetic Bone Particles	0.5cc, 0.25-1mm (250-1000µm)
0-601001	*IngeniOs* β-TCP Bioactive Synthetic Bone Particles	1.0cc, 0.25-1mm (250-1000µm)
0-602001	*IngeniOs* β-TCP Bioactive Synthetic Bone Particles	2.0cc, 0.25-1mm (250-1000µm)
0-700501	*IngeniOs* β-TCP Bioactive Synthetic Bone Particles	0.5cc, 1-2mm (1000-2000µm)
0-701001	*IngeniOs* β-TCP Bioactive Synthetic Bone Particles	1.0cc, 1-2mm (1000-2000µm)
0-702001	*IngeniOs* β-TCP Bioactive Synthetic Bone Particles	2.0cc, 1-2mm (1000-2000µm)

INDICATIONS

Oral and maxillofacial surgery and dentistry

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filing of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of the maxillary sinus floor

RESTRICTIONS ON USE

IngeniOs β-TCP Bioactive Synthetic Bone Particles use should be restricted for patients with the following circumstances or biologic conditions:

- Acute and chronic infections in the surgical area (soft-tissue infections; inflammatory bacterial bone diseases; osteomyelitis). In patients on antibiotic therapy, it is at the surgeon's/practitioner's discretion whether to use *IngeniOs* β-TCP Bioactive Synthetic Bone Particles based on a benefit/risk analysis.
- Severe metabolic disorders, such as severe diabetes mellitus that is uncontrollable or difficult to manage

Date of revision of the text
28.08.2020
Print date <e.g. xx/2021>
Ver. 2 – 08.2020

- Disorders of calcium metabolism
- Steroid treatment
- Drugs that interfere with calcium metabolism
- Immunosuppressant therapy
- Endocrine bone diseases
- Radiation therapy
- Nicotine abuse

The use of *IngeniOs* β-TCP Bioactive Synthetic Bone Particles to fill bone defects may prove to be the best solution despite the presence of some of the circumstances listed above. The patient should be informed appropriately about the possible effects of the complicating circumstances on the expected success of the use of *IngeniOs* β-TCP Bioactive Synthetic Bone Particles.

WARNINGS
Do not re-sterilize *IngeniOs* β-TCP Bioactive Synthetic Bone Particles.
Do not use *IngeniOs* β-TCP Bioactive Synthetic Bone Particles if the packaging providing the sterile barrier, including the cap, vial, or outer tray has been damaged or compromised in any manner (i.e. cracked, opened or punctured).

Other relative restrictions on use include steroid and anticoagulant treatment which may affect the surgical site, surrounding tissue, or patient's healing function. Careful patient selection including consultation with the attending physician is strongly recommended prior to treatment.

PRECAUTIONS
IngeniOs β-TCP Bioactive Synthetic Bone Particles should not be used in infected or contaminated wounds/bone defects.
IngeniOs β-TCP Bioactive Synthetic Bone Particles are not intended to be used for hemostasis.
IngeniOs β-TCP Bioactive Synthetic Bone Particles have not been evaluated in pregnant women or children.
IngeniOs β-TCP Bioactive Synthetic Bone Particles cannot be re-sterilized. Any opened but unused *IngeniOs* β-TCP Bioactive Synthetic Bone Particles must be discarded.

Particles placed in the maxilla should not perforate the sinus floor membrane. Poor bone quality, poor patient oral hygiene, heavy tobacco use, uncontrolled systemic diseases (diabetes, etc.), reduced immunity, alcoholism, drug addiction, and psychological instability may contribute to lack of integration and/or subsequent device failure.

Changes in Performance
It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the expected performance of the product (e.g., infection or exudates around the surgical site, pain, or any other unusual symptoms that the patient has not been told to expect).

Hygiene & Maintenance
Potential candidates should establish an adequate oral hygiene regimen prior to procedure. Following particle placement, the clinician should instruct the patient on proper surgical site care. The patient should also be instructed to maintain routinely scheduled prophylaxis and evaluation appointments.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.

ADVERSE EFFECTS
No interactions between *IngeniOs* β-TCP Bioactive Synthetic Bone Particles and medicinal products or other medical devices are known.

The following complications may occur relative to particle placement: pain, discomfort, dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, lack of integration, loss of bone, and migration of the particles. Other adverse effects may also occur as a result of iatrogenic factors and host responses.

METHOD OF APPLICATION and TECHNIQUE INFORMATION
- *IngeniOs* β-TCP Bioactive Synthetic Bone Particles may only be used by, or under the supervision of, specialised personnel experienced in the required techniques and in the use of biomaterials. The choice

of application form and the exact surgical procedure depend on the site, nature and extent of the defect.

- When preparing the implant site, residual bone, connective and necrotic tissue must be carefully removed. *IngeniOs* β-TCP Bioactive Synthetic Bone Particles require direct contact with bleeding vital bone and thorough debridement of the bone is mandatory prior to insertion.
- Prior to insertion into the defect, *IngeniOs* β-TCP Bioactive Synthetic Bone Particles should be mixed with autologous blood from the defect region. Platelet-rich plasma (PRP) or platelet-mediator concentrate (PMC) can be added to the *IngeniOs* β-TCP Bioactive Synthetic Bone Particles and autologous blood combination of the same patient.
- *IngeniOs* β-TCP Bioactive Synthetic Bone Particles can also be used together with autologous spongiosa or bone marrow aspirate.
- The bone defect must be filled completely. Overfilling must be avoided to achieve tension-free closure.
- With endosseous dental implants, a period of 4-6 months should elapse between filling a defect with *IngeniOs* β-TCP Bioactive Synthetic Bone Particles and dental implant placement, or 6-12 months in the case of a sinus floor elevation procedure.

NOTE:
The open-cell structure of the particles must not be destroyed (e.g. by excessive compaction), as it forms the basis for cell migration and absorption.

IngeniOs β-TCP Bioactive Synthetic Bone Particles should not be introduced in a dry state into the defect, because angiogenic ingrowth can no longer be assured. *IngeniOs* β-TCP Bioactive Synthetic Bone Particles should therefore be mixed or impregnated with autologous blood before insertion.

Tension-free and saliva-proof wound closure is always required when using *IngeniOs* β-TCP Bioactive Synthetic Bone Particles product in oral and maxillofacial surgery and dentistry. Therefore, the use of a membrane is advised, especially for larger defect surfaces.

STERILITY
IngeniOs β-TCP Bioactive Synthetic Bone Particles have been gamma radiation sterilized and are for single use only. *IngeniOs* β-TCP Bioactive Synthetic Bone Particles are packaged sterile. The sterile package should only be opened and the product removed immediately before use. If the sterile package is damaged, do not use the product.

SINGLE USE
This product is delivered sterile and is intended for single use only. Any remaining opened product must be discarded. Do not re-sterilize the product. Possible risks associated with reuse of a single use device include, but are not limited to, loss of sterility, loss of functionality and/or transmission of infectious agents if the device has come in contact with blood, bone, tissue or other body fluids.

SHELF LIFE
The product's expiration date is indicated by the hourglass symbol on the product label, followed by the year and month of expiration.

PRODUCT PACKAGING
All products have been prepared and packaged within an environmentally controlled room, and sterilized for convenience and immediate use. The particles and the glass vial packaging are sterile within the barrier of the plastic outer tray. The label on the glass vial packaging for each device contains a lot number that should be recorded in the patient's file to ensure complete traceability of the product. A pre-printed label for the patient's file has been included for convenience.

STORAGE
IngeniOs β-TCP Bioactive Synthetic Bone Particles should be stored in the outer packaging, at room temperature and in a dry place.
IngeniOs β-TCP Bioactive Synthetic Bone Particles should not be used after the expiry date.

Date of revision of the text
28.08.2020
Print date <e.g. xx/2021>
Ver. 2 – 08.2020

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Symbols	Use of Symbols
STERILE R	Sterilization by radiation
2 STERILIZE	Do not resterilize
2	For single use only
LOT	Lot/Batch number
	Use by
	Comply with Instructions for Use

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	Do not use if package is damaged
	Manufacturer
	Catalog number
	Prescription Only
	European Conformity
	QR-Code (Barcode)
GS1	QR-Code (Barcode) with Device Identification