Exclusively Distributed By:
Zimmer Dental Inc.
1900 Aston Ave.
Carlsbad, CA 92008 / USA
Phone: +1 760.929.4300
+1 800.854.7019
www.zimmerdental.com

Instructions for Use

IngeniOs™ HA 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 HA Synthetic Bone Particles are a spongious bone substitute for filling bone defects. The structure is a porous scaffold characterised by an interconnecting, open-cell macroporosity resembling cancellous bone. The particles are biocompatible and made of 100% hydroxyapatite ceramic with a phase purity of ≥ 95% and are available as polygonal broken granules in various sizes. The total porosity is approximately 80%. *IngeniOs* HA Synthetic Bone Particles are radiopaque and therefore detectable in post operative x-rays. *IngeniOs* HA Synthetic Bone Particles are supplied sterile by means of gamma irradiation and are intended for single use.

When in contact with vital bone, *IngeniOs* HA Synthetic Bone Particles are osseointegrated by the body over the course of several months. Bone resorption and formation processes due to osteoclasts and osteoblasts can occur during physiological remodelling. *IngeniOs* HA Synthetic Bone Particles have intraosseous and extraosseous tissue compatibility, are without local or systemic toxicity and do not pose a risk of infection or allergy.

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

0-802501	*IngeniOs* HA Synthetic Bone Particles	0.25cc, 0.25-1mm (250-1000µm)
0-800501	*IngeniOs* HA Synthetic Bone Particles	0.5cc, 0.25-1mm (250-1000µm)
0-801001	*IngeniOs* HA Synthetic Bone Particles	1.0cc, 0.25-1mm (250-1000µm)
0-802001	*IngeniOs* HA Synthetic Bone Particles	2.0cc, 0.25-1mm (250-1000µm)
0-900501	*IngeniOs* HA Synthetic Bone Particles	0.5cc, 1-2mm (1000-2000µm)
0-901001	*IngeniOs* HA Synthetic Bone Particles	1.0cc, 1-2mm (1000-2000µm)
0-902001	*IngeniOs* HA Synthetic Bone Particles	2.0cc, 1-2mm (1000-2000µm)

INDICATIONS

- Oral-maxillofacial surgery, dentistry, implantology, periodontology
  - Defects after removal of bone cysts
  - Augmentation of the atrophied alveolar ridge
  - Sinus floor elevation (subantral augmentation)
  - Filling of alveolar defects following tooth extraction for alveolar ridge preservation
  - Filling of extraction defects to create an implant bed
  - Filling of two or multi-walled infrabony pockets, and bi and trifurcation defects
  - Support function for a membrane in guided tissue regeneration (GTR)
  - Defects after surgical removal of retained teeth or corrective osteotomies
  - Other multi-walled bone defects of the alveolar ridge

RESTRICTIONS ON USE

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

IngeniOs HA Synthetic Bone Particles use should be restricted for patients with the following circumstances or biologic conditions:

- Acute and chronic infections at the operation site (soft tissue infections; inflammatory bacterial bone diseases; osteomyelitis). During antibiotic therapy, the surgeon/practitioner should decide whether to use I*ngeniOs* HA Synthetic Bone Particles based on a benefit-risk analysis.
- Severe metabolic diseases, such as uncontrolled diabetes mellitus
- Disorders of calcium metabolism
- Drugs that interfere with calcium metabolism, such as steroid hormones
- Immunosuppressive therapy
- Endocrinological bone diseases
- Radiotherapy
- Nicotine abuse

The use of *IngeniOs* HA 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* HA Synthetic Bone Particles.

WARNINGS

Do not re-sterilize *IngeniOs* HA Synthetic Bone Particles. Do not use *IngeniOs* HA 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 HA Synthetic Bone Particles should not be used in infected or contaminated wounds/bone defects.
IngeniOs HA Synthetic Bone Particles are not intended to be used for hemostasis.
IngeniOs HA Synthetic Bone Particles have not been evaluated in pregnant women or children.
IngeniOs HA Synthetic Bone Particles cannot be re-sterilized. Any opened but unused *IngeniOs* HA 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* HA 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 HA 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 localization, nature and scope of the defect.

- The implant bed should be prepared by carefully removing bone fragments, necrotic tissue and connective tissue. Direct contact between *IngeniOs* HA Synthetic Bone Particles and bleeding vital bone is necessary and thorough freshening of the bone before introduction is essential.
- Before being introduced into the defect, *IngeniOs* HA Synthetic Bone Particles should be mixed with autologous blood from the defect region.
- *IngeniOs* HA Synthetic Bone Particles can also be used together with autologous cancellous bone.
- The bone defect must be filled completely. Overfilling must be avoided to achieve tension-free closure.
- For endosseous dental implants a period of 4-6 months and for sinus floor elevation a period of 6-12 months should elapse between defect filling with *IngeniOs* HA Synthetic Bone Particles and insertion of the dental implant.

NOTE

The multiporous structure of the particles must not be destroyed (e.g. by excessive compaction), since it provides the basis for penetration of the material and cell supply.

IngeniOs HA Synthetic Bone Particles should not be introduced in a dry state into the defect, because angiogenic ingrowth can no longer be assured. *IngeniOs* HA Synthetic Bone Particles should therefore be mixed with the patient's blood or with physiological saline solution before placement.

Tension-free and saliva-proof wound closure is always required when using *IngeniOs* HA Synthetic Bone Particles in oral and maxillofacial surgery and dentistry. The use of a membrane is advised especially for larger defect surfaces.

STERILITY

IngeniOs HA Synthetic Bone Particles have been gamma radiation sterilized and are for single use only. *IngeniOs* HA 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 preprinted label for the patient's file has been included for convenience.

STORAGE

IngeniOs HA Synthetic Bone Particles should be stored in the outer packaging, at room temperature and in a dry place.
IngeniOs HA 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

Manufactured By

curasan
Lindigstrasse 4
63801 Kleinostheim
Germany

Tel.: +49 (0) 6027 / 40900-0
Fax: +49 (0) 6027 / 40900-29
Email: info@curasan.com
www.curasan.com

CE 0483

Visit us at www.zimmerdental.com

Ordering Information

zimmer | dental

Distributed By:

USA **Zimmer Dental Inc.**
1900 Aston Avenue
Carlsbad, CA 92008
USA
Tel: (800) 854-7019, (760) 929-4300
Fax: 760-431-7811

EU **Zimmer Dental GmbH**
Wentzinger Strasse 23
D-79106 Freiburg
Germany
Tel: +49-(0)761-15647-0
Fax:+49-(0)761-15647-490

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

Date of revision of the text
28.08.2020

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