Made for DSI LTD.
59 haAvoda str.
Ashdod, 7706300 Israel
+972-8931-7235
www.dsisrael.com

Highly purified mineral bone matrix with the slow resorption rate

DSI Zenoss Chips

INSTRUCTIONS FOR USE

PURPOSE

DSI Zenoss Chips is a biocompatible bone mineral matrix and is manufactured from bovine bone according to a controlled and validated multistage purification process, while all organic components are removed. A highly osteoconductive but slowly resorbed biomaterial. Zenoss Chips promote grafts that maintain structural integrity and sustain increasing vital bone formation over time. The long-term presence of Zenoss chips stabilizes the graft, leading to the retention of both volume and the desired form of augmented sites. Furthermore, bone mineral density is also increased. As a result of this, grafted sites provide an ideal environment for long-term implant survival.
The inorganic bone matrix of DSI Zenoss Chips has macro- and microscopic structures similar to human bone. The formation and in growth of new bone at the implantation site is favoured due to its trabecular architecture and interconnecting macro and micropores. It maintains volume, reliably blocks the osteoclastic potential of periosteum and maxillary sinus mucosa (osteoclasts of hematogenous origin), prevents the ingrowth of soft tissue in the application area.

INDICATIONS

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

DIRECTIONS FOR USE

- The general principles of sterile handling and patient medication must be followed.
- The filling of periodontal defects with Zenoss graft requires successful treatment of the periodontal lesion (root planing, debridement) prior to the implantation. The defect should be covered with a membrane (e.g., DSI Zenoss Bio) for optimal tissue regeneration.
- After exposure of the bony defect with mucoperiosteal flap, all granulation tissue must be carefully removed.
- The material should be placed in direct contact with well-vascularized, bleeding bone surfaces.
  The cortical bone should be mechanically perforated to facilitate the ingrowth of new blood vessels and bone-forming cells.
- We suggest mixing DSI Zenoss chips with the patient's blood or with physiological saline solution before the implantation. The chips are placed into the defect, using sterile instruments (spatula or spoon). The use of excessive force will result in the crushing of particles and loss of trabecular architecture.
- In situ modeling may be performed with a sterile spatula or other suitable instrument.
- Overfilling of the defects should be avoided.
- It is advisable to cover the graft with a membrane barrier (e.g., DSI Zenoss Bio).

- When closing the wound, the soft tissue flap should completely cover the implanted graft and should be fixed by sutures.
- If primary wound closure cannot be achieved, further mobilization of the flap (incision through the periosteum) should be performed.
- A surgical dressing may be placed over the wound for one to two weeks.
- Sites grafted with Zenoss Chips should be allowed to heal approximately 6 months prior to implant placement.
- A basic requirement for successful periodontal treatment includes control of any bacterial infection as well as thorough oral hygiene. It is advised that preceding the surgical intervention, there be a hygiene phase, which would include proper instruction for the patient. A postoperative maintenance phase can ensure long-term therapeutic success.

PRECAUTIONS

Zenoss graft should only be used by trained dentists or oral surgeons. In order to facilitate the formation of new bone, the graft should only be implanted in direct contact with a well-vascularized bony tissue (selective osteoplasty of adjacent cortical bone may be necessary) and, if essential, micro-fracturation of the adjoining bone might be performed.

From experience, mechanical loading (compression loading) areas augmented with Zenoss Chips is possible after 6 months at the earliest. Importantly the appropriate timing of implant insertion depends on the local bone volume at the time of implant insertion. In larger defects, a mixture of autogenous bone or bone marrow may improve the formation of new bone. Zenoss graft should be secured to prevent motion and migration, use in areas where the graft can be adequately contained. Do not leave the defect open.

Zenoss Bone Grafts should be used with special caution in patients with:

- Acute or chronic infection (osteomyelithis) at the surgical site.
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia).
- Osteoporosis.
- Severe renal dysfunction.
- Severe liver disease.
- High dose therapy with corticosteroids.
- Vascular impairment at the implant site.
- Autoimmune disease.
- Radiotherapy.
- Heavy smokers.
- Effect on pregnant or lactating women is not known.

STERILITY

Blister package sterilized by gamma radiation.

STORAGE

Do not use after the expiry date mentioned on the outer package.
Store in a dry and dark place in tightly closed containers at temperature (+5°C…+25°C).
Avoid contact with moisture! After opening, keep only in original container.

PACKAGING:

DSI Zenoss	Type	Size	REF
Chips	1000-5000 µm	1.0 cc	**ZGC40100**
Chips	1000-5000 µm	2.0 cc	**ZGC40200**


STERILE R

ATTENTION! The sterility of the product cannot be guaranteed if the package bears evidence of damage, has been opened previously or wet.

Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material. The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.