Cerasorb® M DENTAL

Resorbable, pure-phase beta-tricalcium phosphate matrix with interconnecting porosity for bone regeneration for use in dental and maxillofacial surgery

DESCRIPTION:
Cerasorb M DENTAL is a sterile, synthetic, multi-porous biocompatible ceramic matrix in granular form for filling bone defects. The material with micro-, meso- and macro pores in a range of 0.1-500 µm supports rapid ossification with local bone, thus accelerating the resorption process. With its phase purity of ≥ 99%, the ceramic material complies with US standard specification ASTM F 1088-04. The validated manufacturing process guarantees batch conformity and reproducibility. The calcium content is 38.3 % (± 1 %) and the phosphate content is 61.2 % (± 1 %).
Cerasorb M DENTAL is available in different sizes (150–500 µm, 500-1000 µm, 1000–2000 µm) as polygonal granules that are suited for specific applications in inflexible defect beds.
Techniques for surgical placement of Cerasorb M DENTAL are equivalent to similar operations using particulate bone grafts.

PROPERTIES/ACTIONS:
The Cerasorb M DENTAL ceramic matrix creates a network of large, smoothly interconnected pores (porosity of approx. 65 vol. %). A ceramic material of this porosity ensures optimal resorption to encourage rapid bone regeneration.
In contact with vital bone, the material is resorbed and simultaneously replaced by new bone. As a synthetic, bioactive ceramic material, Cerasorb M DENTAL has excellent intra- and extra-osseous tissue compatibility and is neither locally nor systemically toxic. Potential risks of allergenic reactions or infections that may result from materials of biological origin do not exist.
Cerasorb M DENTAL is gamma sterilized, comes in double sterile packaging and is for single use only.
Cerasorb M DENTAL is radiopaque from its mineralogical density, so its status can be monitored regularly.

INDICATIONS AND USAGE:
Cerasorb M DENTAL is recommended for:
- 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).
The placing of dental implants after bone augmentation with Cerasorb M DENTAL is possible. Prior to placing the implant, verification needs to be provided that sufficient new bone was formed to provide a stable implant bed. This verification should be performed using appropriate medical measures, such as radiography.

The size of the defect to be filled determines the choice of the granular size of Cerasorb M DENTAL to be used.

**INSTRUCTIONS FOR USE:**

- Cerasorb M DENTAL must only be employed by or under the supervision of medical professionals with experience in the required surgical techniques and the use of biomaterials. The exact operating procedure depends on the location, type and size of the defect.

- To prepare the graft bed, bone fragments and necrotic tissue must be carefully removed before applying Cerasorb M DENTAL. Direct contact with perfused vital bone is important for its function as a bone regeneration material and, therefore, a thorough freshening of the bone surface before applying the granules is obligatory.

The selection of granule size depends on the size of the defect to be filled and on the time that is planned for restoration because Cerasorb M DENTAL is resorbed quickly due to its high porosity. For bone regeneration to succeed with Cerasorb M DENTAL through the promotion of angiogenesis and wound healing, the granules should be mixed with the patient's fresh blood from the defect region before application. If desired, combine the Cerasorb M DENTAL/autologous blood mixture with PRP.

- Due to the polygonal structure of Cerasorb M DENTAL, greater mechanical stability will be achieved in a subangular defect bed. It is important that the defect should be filled with granules of suitable size. The categorization of a defect area as micro, medium or large should be determined by the medical professional who will be using Cerasorb M DENTAL.

- It is recommended to use the grain size category of 150-500 μm for the filling or treatment of micro-defects of the maxillofacial bone or the periodontal area.

- The use of grain size 500-1000 μm is recommended for medium to large bone defects to assist with elevation.

- In certain cases, it is possible to mix grain size 150-500 μm with grain size 500-1000 μm for large defects to cover the whole volume.

- The grain size of 1000-2000 μm should only be used in a surgical area of the maxillofacial region other than the periodontal region.

- For large defects, Cerasorb M DENTAL can be mixed with autogenous spongiosa of comparable size.

- The bone defect must be completely filled. Strong compacting or destruction of granule structure (e.g. by crushing) must be avoided. The porous structure of the ceramic makes it possible for the bone cells and blood vessels to grow into the granule matrix, which is completely resorbed and simultaneously substituted by the patient's local bone.

- Overfilling must be avoided to allow for a tension-free closure.

- The mucoperiosteal flaps can be sutured to achieve primary closure and to minimize particle loss. In some cases the surgeon may want to place a surgical
dressing or membrane over the wound. In cases of larger defect surfaces the user must decide on the use of a membrane.

- For endosseous dental implants a time interval of 4-6 months should pass between defect filling with Cerasorb M DENTAL and placing of the implant. In the case of a sinus lift, it may be necessary to wait somewhat longer (even 9-12 months) depending on the patient and the radiological findings.

**CONTRAINDICATIONS:**
Bone grafting should not be considered for patients where general oral surgery is contraindicated (e.g. infection at the site of grafting).

The use of Cerasorb M DENTAL should be avoided in cases of all diseases or therapies which adversely affect the healing of the defect, e.g.
- Acute and chronic infections in the operating area (e.g. soft tissue infections; inflamed, bacterial bone diseases; osteomyelitis)
- Severe metabolic diseases, such as non- or poorly controlled diabetes mellitus
- Disorders of calcium metabolism or treatment by pharmaceuticals interfering with calcium metabolism
- Treatment with steroids, antineoplastic drugs, immunosuppressives, high dose glucocorticoids
- Endocrinological bone diseases
- Severe renal dysfunction, severe liver disease
- Vascular impairment

Despite the presence of some of the listed circumstances, the use of Cerasorb M DENTAL may be the best solution for rectifying bone defects. The patient must be duly informed of the possible effects of these complicating circumstances on the anticipated success of using Cerasorb M DENTAL.

**PRECAUTIONS:**
Cerasorb M DENTAL should be mixed with the patient’s fresh blood. It should not be applied dry to the defect and should not be soaked in aqueous solutions (e.g., physiological NaCl or antibiotics).

If desired, combine the Cerasorb M DENTAL/autologous blood mixture with PRP. In large defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.

The use of a membrane is recommended in cases where the defect is large or limited bony retention is present. A primary closure of defects, preferably tension free, is highly recommended.

Caution: granule sizes greater than 800 µm should not be used for periodontal applications.

**ADVERSE REACTIONS:**
No adverse reactions have been reported.

INTERACTIONS:
No interactions between Cerasorb M DENTAL and pharmaceuticals or other medical devices have so far been reported.

HANDLING/STABILITY:
Cerasorb M DENTAL must be stored dry in its outer carton at room temperature.

Cerasorb M DENTAL is supplied as a radiation sterilized product in double sterile packages (glass vials in blisters). The medical device must not be used if the blister is visibly damaged. Check that the blister is intact by applying gentle, even pressure. Cerasorb M DENTAL must not be resterilized.

Cerasorb M DENTAL must not be used after the expiration date on the container.

HOW SUPPLIED:

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<th>Granule sizes</th>
<th>Package sizes</th>
<th>5 x 0.5 cc</th>
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<th>5 x 2.0 cc</th>
<th>1 x 5.0 cc</th>
<th>1 x 10.0 cc</th>
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<tr>
<td>150–500 µm</td>
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<td>500–1000 µm</td>
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<td>1000–2000 µm</td>
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+= pack sizes available

CAUTION: Federal law restricts this device to sale by or on the order of a licensed dentist or physician.

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<tr>
<th>Symbols</th>
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