

## Instructions for use

### Product description

**algisorb™** is a resorbable inorganic bone forming material of plant origin derived from red algae. **algisorb™** is a porous biological hydroxyapatite which is similar in composition to the mineral component of human bone. **algisorb™** is biocompatible, osteoconductive and pH neutral. The rate of biomaterial degradation and replacement by autologous bone are dependent on bone quality. The manufacturing of **algisorb™** is accomplished by validated GMP conditions. There is no risk of transmission of bacteria, viruses or prions. No immune reactions are known.

### Patient Preparation

Prior to use of **algisorb™**, a thorough clinical and radiographic evaluation should be conducted of the patient to rule out any bone disease and evaluate the quantity and quality of the soft tissue.

### Indications and usage

The intended use for **algisorb™** is:

- Augmentation of bony defects of the alveolar ridge
- Sinus elevation grafting
- Treatment of intrabony periodontal defects
- Extraction socket grafting

### Contraindications

Contraindications customary to elective oral surgery should be observed. **algisorb™** should not be used in patients with:

- Acute and chronic infections at the surgical site
- Vascular disorders
- Infections or metabolic disorders that may affect bone or wound healing e.g. uncontrolled diabetes
- Systemic disorders such as clotting disorders
- Osteoporosis
- Anticoagulant therapy
- Immunosuppressive therapy
- Insufficient soft tissue covering

Any other instance where the practitioner feels general or oral surgery is contraindicated.

Precaution in case of poor bone quality or heavy smoking.

**algisorb™** should not be placed in the vicinity of nerves.

**algisorb™** is not indicated for augmentation in load bearing and unstable indications.

Using **algisorb™** in connection with simultaneous or delayed implant placement, all contraindications for implant dentistry should be observed.

### Surgical guidelines

Note – The specified clinical instructions represent a general recommendation and should be critically considered by the clinician for each individual case.

**algisorb™** should be hydrated / saturated with fresh patient's blood. Blood can be obtained from either the surgical site or a venous draw. Saturation with blood will provide serum proteins and growth factors to the graft. This can be enhanced by slightly crushing the larger **algisorb™** particles into smaller pieces exposing the highly porous inner structure.

The defect area should be thoroughly cleaned of all granulation tissue.

A good vascularisation of the surrounding bone as well as the largest possible direct contact area between the **algisorb™** particles and the local bone are essential for bone regeneration. Poor blood circulation of the compact bone can be stimulated mechanically with small round bur perforations. Admixing of autogenous bone chips improves the healing process and enhances new bone formation.

The saturated **algisorb™** granulate can then be packed in small amounts into the cleaned, bleeding site with a sterile instrument (e.g. curette, spatula). Ensure a good contact to the host bone. Overfilling the defect should be avoided to minimize tissue tension and particle migration. For optimal tissue regeneration the defect has to be completely covered by a membrane. Tension free closure of the site should be accomplished assuring stability of the graft.

### Implantology

The rate of new bone formation is primarily dependent on the contact to and quality of the host bone.

With the one-stage procedure the prosthetic restoration can be accomplished about 6 months after grafting and implant placement depending on defect size and region.

With the two stage procedure and sufficient residual bone height (at least 5 mm) implant(s) can be inserted into the augmented area after about 6 months depending on defect size and region. The prosthetic restoration can be accomplished 6 months later.

With the two stage procedure and insufficient residual bone height (less than 5 mm) implant(s) can be inserted after 6-9 months depending on defect size and region.

The prosthetic restoration can be accomplished 6 months later.

### Periodontology

An important requirement for successful periodontal treatment is the control of bacterial infections and an adequate oral hygiene. It is recommended to instruct and prepare patients properly before surgery. Along with plaque control is required a precise treatment of the periodontal lesion (root planning, debridement) prior to **algisorb™** augmentation of periodontal defects. To reach optimal tissue regeneration the defect should be covered with a membrane.

### Postoperative care

It is important to instruct the patient regarding the need for regular oral hygiene. For the first 7-10 days postoperative, oral hygiene can be supplemented by a suitable anti mouth rinse. Mechanical load on the graft side should be avoided in the postoperative phase.

### Side effects and complications

No side effects due to the material have been reported.

Possible side effects of surgery can include temporary swelling, edema and hematoma.

Possible complications include inadequate bone regeneration, dislocation or exposure of **algisorb™** particles, postoperative bleeding, infection, dehiscence, and / or fistulation, nerve or vascular injuries, nerve damage due to surgical trauma and pain that is not attributable to the bone augmentation material.

Complications can be minimized by careful patient selection, atraumatic surgical technique and intended use of **algisorb™**.

### Safety Notice

All instructions for use should be read and understood prior to use. The user is responsible for the correct application of the materials as well as for the appropriate surgery.

The following instructions alone are not adequate enough to allow inexperienced users to provide professional treatment. It is strongly recommended that an experienced user provides training in handling and use of this product and in surgical augmentation techniques. **algisorb™** may only be used by dentists and oral and maxillofacial surgeons that are familiar with the anatomy of bone and soft tissue and experienced in diagnosis, pre-operative planning as well as appropriate surgical techniques.

**algisorb™** may only be used for indications specified in this document, and according to the general rules for surgical and oral surgical treatment. **algisorb™** may only be used if in perfect condition.

The user is also responsible to avoid or minimize general risks of surgery.

Surgery has to be conducted under aseptic conditions.

The manufacturer is not responsible for complications due to false indication, false combination of material and surgical technique as well as limitations of the treatment. Any liability for damage caused by this is excluded.

### Package and Storage

**algisorb™** is gamma sterilized and is intended for single patient use only. **algisorb™** must not be re-sterilized and all unused product should be disposed. **algisorb™** is delivered in single vials in a sealed Tyvek pouch. Both the vial and the contents are sterile. Do not use **algisorb™** if the vial has been tampered, if expiration date has been exceeded or if opened under non sterile conditions prior to usage. Store in the original package at room temperature, protected against light.

### Supply

Granulate: Particle Range: 0.3 -1.0 mm  
Contents: 0.5 ml, 1.0 ml, 2.0 ml

### Labeling Symbols



Do not re-use



Sterilized using irradiation



Caution, consult accompanying documents

Federal (USA) law restricts this device to sale by or on the order of a licensed physician or dentist.

### Manufactured by:

AlgOss Biotechnologies GmbH  
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### Manufactured for:



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