BencoDental™

Gibson Healthcare® Alloplast

Synthetic Bone Graft System

Instructions for Use

Device Description

Gibson Healthcare® Alloplast synthetic bone grafting system contains:

- Syringe containing beta-tricalcium phosphate (β-TCP) granules coated with poly (lactide-co-glycolide) (PLGA)
- Ampule containing BioLinker™ Activator (N-methyl-2-pyrrolidone and water)

Gibson Healthcare® Alloplast is a bioresorbable, synthetic, porous bone graft substitute. It consists of two components: granules (supplied in syringe) and BioLinker activator (supplied in ampule). After mixing the components together, Gibson Healthcare® Alloplast forms a moldable mass that can be applied directly from the syringe into the bone defect. Gibson Healthcare® Alloplast hardens in contact with body fluids, allowing a working time of approximately one minute after application into the bone defect. Depending on blood inflow, hardening may take longer. Gibson Healthcare® Alloplast is provided in the particle sizes of 500 – 630 µm for smaller defects and 500 – 1000 µm for larger defects. Gibson Healthcare® Alloplast is a biocompatible and osteoconductive material that allows for complete resorption by the body. Gibson Healthcare® Alloplast can be used in combination with dental membranes. Gibson Healthcare® Alloplast contains no animal or human derived substances. β-TCP and PLGA are derived from synthetic raw materials.

Indications

Gibson Healthcare® Alloplast is indicated for the treatment of intraoral / maxillofacial osseous defects. Dental and maxillofacial indications may include:

- Extraction defects (alveolar ridge preservation)
- Periodontal defects
- Peri-implant defects
- Augmentation of deficient alveolar crest (e.g. Guided Bone Regeneration, GBR)
- Sinus floor augmentation
- Defects after surgical extractions
- Defects after removal of bone cysts
- Defects after root resection or apicoectomy
- Defects after removal of autologous bone

Contraindications

- Gibson Healthcare® Alloplast should not be used in pregnant or nursing women.
- Bone grafting should not be considered for patients where general oral surgery is contraindicated.
- Gibson Healthcare® Alloplast use should be avoided in cases where there is uncontrolled disease or therapies which are detrimental to the healing of bone, such as:
  - acute or chronic infection (osteomyelitis) in or around the surgical site
  - Severe metabolic diseases, such as uncontrolled or poorly controlled diabetes mellitus, hyperparathyroidism, or osteomalacia
  - Osteoporosis
  - High dose therapy with corticosteroids
  - Severe renal dysfunction, severe liver disease

Precautions

- Gibson Healthcare® Alloplast should only be used by dentists and physicians qualified in the required techniques. Common standards and guidelines apply for the surgical procedure and the course of treatment.
- No allergic reaction against Gibson Healthcare® Alloplast is known. However, if an allergy against Gibson Healthcare® Alloplast or any of its components is suspected, the product should not be applied in the affected patient.
- Safety of Gibson Healthcare® Alloplast has not been established in pregnant and nursing women, in immune-deficient patients (e.g. diabetes, chemotherapy, radiotherapy, HIV-infections), in patients with reduced tissue regeneration capacity, and in pediatric patients.
- BioLinker activator contains N-methyl-2-pyrrolidone. N-methyl-2-pyrrolidone is an irritant to eyes, respiratory system and skin. Wear gloves and protective goggles when working with BioLinker activator. Change gloves and wash hands thoroughly after contact with BioLinker activator. In case of eye contact, immediately flush eyes with copious amounts of water for at least 10 minutes and consult a physician.
- The BioLinker activator ampule may be under pressure. Open the ampule carefully using the precautions described above.
- Gibson Healthcare® Alloplast should be opened just before use. Aseptic handling techniques are essential during application of Gibson Healthcare® Alloplast.
- Before filling bone defects, the site should be debrided thoroughly to remove any residual soft or granulation tissue and the site should be free of infection.
- Do not overfill the defect to allow tension-free suturing of the soft tissue.
- When using Gibson Healthcare® Alloplast alone (without a membrane), primary closure of the flap should be achieved to assure success.
- Do not leave the defect open for the following indications: periodontal defects, filling of peri-implant defects, augmentation of alveolar crest (e.g. Guided Bone Regeneration, GBR), sinus floor augmentation, defects after surgical removal of retained teeth, defects after removal of bone cysts, defects after root end resection, defects after removal of autologous bone.
- All bone grafting procedures can experience variable results depending on the graft material, the applied technique, and defect size and configuration. Various factors may influence the outcome and should be considered: age of the patient and quality of patient bone, location and size of the defect, adequate filling of the bone void or gap, intimate contact of viable bone and bone graft substitute, wound closure and stabilization of the graft site to prevent migration of the graft material.
- Smoking may diminish the capacity for bone healing. Inform patients that they should abstain from smoking during the healing period.

Surgical procedure notes

Surgical procedure notes are intended as guidelines for the use of Gibson Healthcare® Alloplast as a part of established surgical techniques. They are not intended to replace or change established techniques. Gibson Healthcare® Alloplast should only be used by dentists qualified in the required technique (see “Precautions”).

Extraction defects / defects after surgical extractions: After tooth removal, the socket should be debrided of all necrotic and periodontal tissue. The walls of the socket should be freshened (e.g. with a round bur) without jeopardizing the integrity and viability of the socket walls or the interradicular bone (if present). Bleeding originating from the host bone should be observed to indicate viability.

Periodontal defects: Thorough debridement of the osseous defect walls, root planning and scaling of the root surfaces (when applicable) are required. Primary closure over the site should be achieved as completely as possible by using suturing material and flap designs suitable for periodontal indications.

Filling of peri-implant defects: The osseous defect walls should be thoroughly debrided. The dental implant surface should be free of contaminations. The dental implant should be stably anchored in host bone. Gibson Healthcare® Alloplast is not intended for load-bearing applications (see “Warnings”) and cannot be used to fixate dental implants that demonstrate mobility at the time of insertion or post loading.

Augmentation of alveolar crest: Techniques that are suitable for the site and extent of ridge augmentation (e.g. Guided Bone Regeneration procedures, ridge split techniques, sandwich osteotomy, minimally invasive subperiostal grafting) should be used for augmentation of the alveolar crest. Practical training in the required technique is highly recommended (see “Precautions”). Mechanical stability of the augmented site during the healing period should be considered. Additional fixation/graft containment devices may be necessary to prevent graft deformation, graft displacement or insufficient bone formation. The use of a dental membrane depends on the surgical technique and is recommended if the defect is large or if limited bony retention is present.

Sinus floor augmentation: Techniques that are suitable for the anatomical situation should be employed (e.g. transcrestal or lateral approach to the maxillary sinus, immediate or delayed placement of dental implants). The sinus lining should be detached and intact prior to grafting. Grafting should take place in the void between the elevated sinus lining and the residual bone.

Defects after removal of bone cysts / defects after root resection or apicoectomy: After creation of an adequate surgical access to the lesion, the cyst tissue / inflammatory soft tissue should be thoroughly removed. If necessary, root resection and retrograde filling should be performed. The bony wall of the defect is freshened (e.g. with a round bur). Bleeding should be observed originating from the host bone to indicate viability.

Defects after removal of autologous bone: Harvesting of autologous bone for autologous bone grafting should follow accepted surgical procedures. Gibson Healthcare® Alloplast should be placed and shaped to reconstruct the anatomical contours.

Possible Adverse Effects

Possible adverse reactions associated with bone graft substitute grafting procedures include: edema, bleeding after surgery, temporary or permanent paresthesia or anesthesia due to close proximity to a nerve bundle in the surgical site, post-operative infection of the soft tissue and/or bone (osteomyelitis), soft tissue ulceration, insufficient bone formation, fracture or inflammation of the newly formed bone, premature resorption, poor wound healing and loss of soft tissue, graft material loss and localized pain.

Possible adverse reactions associated with the use of the device include: eye, respiratory and skin irritation.

Interaction with Other Substances

None known.

Instructions for Use

A. Site Preparation

I. Radiographic evaluation of the defect site is essential to assess the extent of the defect and for surgical planning. The required amount of Gibson Healthcare® Alloplast alloplastic bone grafting system should be estimated prior to the surgical intervention based on radiological and clinical examination. **The amount of Gibson Healthcare® Alloplast used per patient during one appointment or surgical application should be restricted to a total of 1.8 ml.** As part of surgical planning, calculate the amount of Gibson Healthcare® Alloplast required for each appointment using Table 1, which contains the volume (ml) in each syringe by product

Table 1: Gibson Healthcare® Alloplast product characteristics

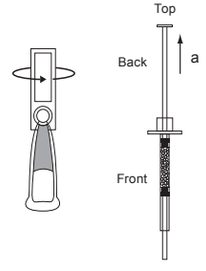
Product	Granule Size	Volume (ml) in Syringe
Gibson Healthcare® Alloplast Small	500-630 µm	0.15
Gibson Healthcare® Alloplast Medium	500-1000 µm	0.25
Gibson Healthcare® Alloplast Large	500-1000 µm	0.40

For further information please refer to “Warnings”.

II. Routine surgical procedures should be used to expose the surgical site. Once exposed, eliminate all granulation or necrotic tissue at the defect site. Bleeding should be observed originating from the host bone to indicate viability. Intra-marrow penetration (e.g. by perforation of cortical bone) is useful to ensure bleeding from the host bone, which aids bone regeneration.

B. Gibson Healthcare® Alloplast bone grafting system Preparation

As a complete system, no other bone graft material (e.g. autogeneous bone chips, xenografts, etc.) should be added to the syringe of granules.



I. Prepare BioLinker™ Activator and granules immediately prior to graft application.

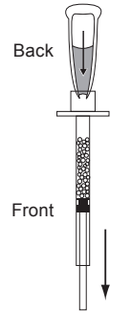
Caution: Wear gloves and protective goggles. ampule may be under pressure.

Carefully open the ampule containing BioLinker activator by twisting off the lid.

Hold the syringe in an upright position with the plunger (a) at the top. Open the syringe containing the granules by pulling out the plunger at the back of the syringe and placing it onto a sterile field.

Caution: The plunger will be needed again, avoid contact with contaminated surfaces.

Continue to hold the syringe in an upright position to avoid loss of granules.



II. Wet Granules with BioLinkeractivator

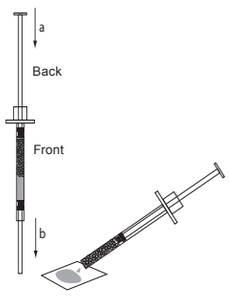
Add the BioLinker activator to the granules through the funnel-shaped opening at the back of the syringe.

Pull down on the plug, located at the front of the syringe, just enough to thoroughly wet the granules with BioLinker activator.

Replace the plunger back into the top of the syringe. Move the plunger and the plug back and forth slowly

1 – 3 times until the granules are completely wet and the excess BioLinker activator is located at the front of the syringe.

Caution: Blood, blood products and other liquids should not be added to the wet granules prior to placement in the defect to ensure the material does not prematurely harden.

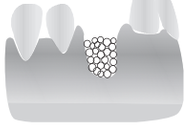


III. Expel Excess BioLinkeractivator

Remove the plug (b) from the front of the syringe. Expel the excess BioLinker activator from the front of the syringe into a sterile dish or a sterile swab by pushing the granules toward the syringe opening with the plunger (a).

Caution: Do not compress wet granules during this step to prevent interference with a smooth ejection of the material from the syringe.

C. Gibson Healthcare® Alloplast bone grafting system Placement and Containment



I. Apply Wet Granules to Defect

To facilitate the formation of new bone to the maximum extent, Gibson Healthcare® Alloplast should only be implanted in close contact to well vascularized surrounding bony tissue.

Refreshment of bleeding just prior to graft application may be necessary.

Depress the plunger of the syringe to introduce the granules directly into the prepared defect.

II. Placement & Containment in Defect

Shape and compress to conform to defect contours using sterile dental instruments.

Do not overfill the defect.

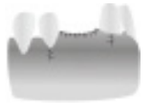
Gibson Healthcare® Alloplast hardens in contact with body fluids, such as blood, in approximately 1 minute and forms a solid but porous implant.

The handling properties of Gibson Healthcare® Alloplast facilitate placement and containment of the material in the bone defect.

Resorbable or non-resorbable dental membranes may be used with Gibson Healthcare® Alloplast to facilitate containment and to provide a barrier against soft tissue ingrowth.

Caution: High N-methyl-2-pyrrolidone (NMP) exposure may cause malaise, headache, stomach pain and nausea for up to four days. The amount of Gibson Healthcare® Alloplast used per patient during one surgical application should be restricted to a total of 1.8 ml (see also "Warnings")

D. Site Closure



The surgical site should be closed as per standard practice (e.g. by suturing the mucoperiostal flap or by approximating the wound edges using sutures).

E. Post-Treatment Patient Care

I. Patient care following treatment is patient and indication specific and should follow the same regimen as similar cases utilizing autogenous/or any standard surgical bone grafting procedures. Post-surgical care should include, but is not limited to: appropriate wound management, appropriate medication (e.g. antibiotics, analgesics), an appropriate oral hygiene regimen (including antibacterial rinses), and follow-up visits. The patient should be cautioned against chewing on or brushing the surgical area for at least 1 to 2 weeks or as long as the clinician deems necessary.

II. A healing time of 6 months is recommended to allow bone formation and maturation prior to placement of endosseous implants. However, appropriate healing time has to be determined by the clinician based on the patient's individual situation.

Warnings

Caution: BioLinker activator contains N-Methyl-2-pyrrolidone. Findings from animal experiments suggest that N-Methyl-2-pyrrolidone may cause harm to the unborn child. Gibson Healthcare® Alloplast should therefore not be used during pregnancy.

High N-methyl-2-pyrrolidone (NMP, contained in the BioLinker activator) exposure may cause malaise, headache, stomach pain and nausea for up to four days. Animal and human testing shows that NMP exposure resulting from the application of 1.8 ml of Gibson Healthcare® Alloplast during a single surgical application is safe. Therefore, the amount of Gibson Healthcare® Alloplast used per patient should be restricted to a total volume of 1.8 ml, which corresponds either (i) to 12 applications Gibson Healthcare® Alloplast Small, or (ii) to 7 applications Gibson Healthcare® Alloplast Medium, or (iii) to 4 applications Gibson Healthcare® Alloplast Large, or (iv) to any combination of application sizes with a total volume not to exceed 1.8 ml, considering the per-unit volumes given in Table 1.

Do not place Gibson Healthcare® Alloplast in direct contact with nerve tissue.

Gibson Healthcare® Alloplast should be used in areas where it can be adequately contained to prevent motion and migration of the graft material.

Gibson Healthcare® Alloplast is not intended for immediate load-bearing.

Do not overfill the defect.

Do not compromise blood supply to the defect area.

Gibson Healthcare® Alloplast is gamma-sterilized and intended for single use only. Do not resterilize or reuse Gibson Healthcare® Alloplast.

Gibson Healthcare® Alloplast is radiopaque and may possibly mask underlying pathological conditions.

Do not use Gibson Healthcare® Alloplast if package is opened or damaged, or if the expiration date has been exceeded.

Properties

Gibson Healthcare® Alloplast forms a porous scaffold in the defect that will be completely resorbed within 5 to 15 months. After placement of Gibson Healthcare® Alloplast in the defect, the pore volume allows the uptake of blood. During an initial phase, Gibson Healthcare® Alloplast may swell and increase in volume by taking up body fluids, thus supporting a close contact to the surrounding bone tissue. Swelling of the material in bone defects might result in slight sensation of pressure felt by the patient. Newly forming bone tissue will grow into the pore volume and, in the course of material degradation, into the space previously occupied by Gibson Healthcare® Alloplast.

Gibson Healthcare® Alloplast consists of β-TCP, PLGA and BioLinker activator. Resorption proceeds via three steps: 1) The BioLinker activator is metabolized and excreted within days mainly through the urine. 2) The absorbable polymer (PLGA) is cleaved by hydrolysis. The degradation products are excreted. 3) The resorption of β-TCP takes place mostly parallel to bone regeneration. Gibson Healthcare® Alloplast is solely a bone graft substitute. The application of the material does not guarantee a treatment success. The success of the therapy depends on many factors such as surgical technique, habits, age and the bone regeneration potential of the patient.

Storage Instructions

Gibson Healthcare® Alloplast should be stored under dry conditions and in its original packaging. Storage temperature should not be below 41° Fahrenheit (5 °C) or above 77° Fahrenheit (25 °C). Keep away from sunlight.

Manufactured by
Degradable Solutions AG
Wagistrasse 23
8952 Schlieren
Switzerland

Distributed by

BencoDental™
800.GO.BENCO • BENCO.COM
295 CenterPoint Blvd, Pittston, PA 18640

Rx Only	USA law restricts this device to sale by or on the order of physician
STERILE R	Sterilized using irradiation
	Use-by-date
	Do not re-use
	Temperature Limits
	Do not use if package is damaged
	Keep away from Sunlight
REF	Catalogue Number
	Consult instructions for use
QTY	Quantity
LOT	Batch code
	Manufacturer

MS1229 Rev. 0 01/2024