ENR 75-082_A.1

GlassBone®

Bioactive Bone Substitute

GRANULES

Caution Instruction for Use

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Manufacturer

REF References	(mm) Granule size	VOL (cc/cm3) Volume
GB1.3/5	1-3mm	5cc
GB1.3/10	1-3mm	10cc
GB1.3/16	1-3mm	16cc
GB05.1/5	0.5-1mm	5cc
GB1.3/1-U	1-3mm	1cc
GB05.1/1-U	0.5-1mm	1cc
GB05.1/05-U	0.5-1mm	0.5cc

	Consult instructions for use
	Do not use if package is damaged and consult instruction for use
CE 0459 2008	Device EC-marked by the GMED notified body. Placed on the market in 2008
2024/01	Last update
LOT	Batch number
	Use-by date
	Keep dry
	Keep away from sunlight
15°C 25°C	Temperature limit 15-25°C (storage)
	Do not reuse
STERILE R	Sterile, Gamma irradiation
STERILIZE	Do not resterilize
	Manufacturing date
MD	Medical Device
	Single sterile barrier system with protective packaging inside
UDI	Unique Device Identifier

EN – INSTRUCTION FOR USE

Bioactive bone substitute

Description and Indications

GlassBone Granules is a synthetic and biocompatible bone substitute device (bioactive glass 45S5), intended for the filling, reconstruction and/or fusion of bone defects or gaps in the skeletal system.

GlassBone Granules is indicated in case of loss or lack of bone substance for bone defects of traumatic, pathological or surgical origin when autologous solutions are not applicable or sufficient in orthopedics, neurosurgery, cranio maxillo facial (CMF) and otorhinolaryngology (ENT) surgeries in adult population :

- Fusion or reconstruction of deformities and degenerative diseases in spine,
- Fusion or reconstruction of deformities and degenerative bone pathologies in orthopedic,
- Filling and reconstruction of bone defects due to resection of tumors, cyst or infection and in case of prosthetic revision,
- Filling after surgical bone defect[1] (donor sites after removal of autograft, …),
- Filling after removal of cholesteatoma,
- Filling and reconstruction due to maxilla and periodontium pathologies.

It must be used by qualified surgeons (orthopedists, neurosurgeons, maxillofacial surgeons, stomatologists and otorhinolaryngologists) trained in bone grafting and fixation techniques who have read these instructions for use.

GlassBone Granules can be used according to the following indication guide[2]:

Destination	Granules size		Expected Lifetime
	0.5-1 mm	1-3 mm	
Spine		X	12 months
Orthopedic		X	12 months
CMF	X		9 months
ENT	X		10 months

Contraindications

GlassBone Granules should not be used:

- In Paediatric Patients
- In case of chronic or acute infection not treated with appropriate therapy
- In patients who have suffered serious trauma with external wounds open near the defect, which could become infected.
- In patients with known allergy to bioactive glass or its constituents (Ca^{2+}, PO_4^{3-}, Na^+ and Si $(OH)_4$).
- In patients with pre-existing conditions or disease that may interfere with the good healing of tissues
- In the irradiated bone (according to radiological criteria indicating osteonecrosis)
- To replace structures subject to high mechanical stresses
- During severe renal and hepatic infections.
- In conjunction with a treatment known to affect the skeleton.
- In case of unsutured meningeal breach in cranio-spinal surgery.
- In neonatology service

To date, we do not have any studies conducted in pregnant women or data related to use during breastfeeding. As a safety measure, the implantation of GlassBone Granules is not recommended during the periods of pregnancy and lactation. In addition, a warning is required for patients treated in special clinical situations (tumor, ongoing chemotherapy and radiation therapy, immunodeficiency ...)

Composition of GlassBone Granules

GlassBone Granules (45S5) consist only of elements found naturally in bone tissue: 45 wt% silicon dioxide (SiO_2), 24.5 wt% calcium oxide (CaO), 24.5 wt% sodium oxide (Na_2O) and 6 wt% phosphorus pentoxide (P_2O_5).

Mechanism of action / Performance / Benefits

During its implantation, GlassBone Granules is in contact with bone and biological fluids. The release of ions during resorption will allow the surface formation of a layer of carbonated hydroxyapatite, whose composition and structure are similar to the mineral phase of bone. This layer gives GlassBone Granules its osteoconduction property and creates a strong link between the granules and living tissue.

The claimed clinical performance is the filling, reconstruction and/or fusion of bone defects allowing the regeneration of the bone.

The main associated benefits are the reduction of graft site morbidity and/or the absence/decrease of autologous bone sampling in other site with a decrease in pain in Spine, Orthopaedic and CMF destinations and a limitation of recurrent/residual disease in ENT destination.

Additional benefits with quality-of-life improvement are also identified in each destination:

- Spine: Reduction of pain and spine deformity reduction
- Ortho: Reduced rate of fracture, Reduced rate of tumour recurrence, Reduced rate bone infection recurrence
- CMF: Reduction of pain
- ENT: Functional hearing improvement

All these benefits (main and additional) influence the quality-of-life improvement of patients.

Instructions for use

- Check the expiry date. Do not use the product if it is exceeded.
- Do not use if the sterile packaging (external blister) is damaged, opened prematurely or exposed to environmental conditions other than those specified.
- Check each device before use to detect any deterioration. If deterioration is present, do not use the implant.
- Eliminate all soft and/or pathological tissue from the implantation site.
- Open the outer blister (sterile barrier) and remove the inner blister on the sterile field.
- Once the surgical site has been prepared, open the inner blister.
- If necessary, mix the substitute in a sterile cup with another constituent (saline serum, autologous bone from the implantation site and/or from another operating site bone, bone marrow and/or patient blood, depending on the clinical context, surgical specialty and surgeon practice. From a therapeutic point of view, there is no difference between the use of these mixtures compared to GlassBone Granules used alone whatever the situation: the choice depends on the surgeon's practice, the patient's disease, and the available constituents.
- Do not mix into the inner blister containing the granules as hemocompatibility nor compatibility of the blister with other constituents has not been tested.
- Using a sterile instrument, fill in the defect. Do not compress the material in the site or blot the blood/moisture in the positioned graft.
- After placement of GlassBone Granules, ensure the primary closure of the soft tissues at the graft site. Resorbable or non-resorbable membranes can also be used for the closure.
- This device is MR safe.

Warnings and precautions for use

Regarding the surgical procedure

- The general principles of asepsis and patient medication must be observed when using GlassBone Granules.
- GlassBone Granules does not substitute antibiotic therapy treatment during infection.
- Interaction of GlassBone Granules with drug has not been tested. The combination of any drug substance with GlassBone Granules during implantation is the responsibility of the surgeon.
- Manipulate GlassBone Granules with a surgical instrument to avoid piercing surgical gloves.
- It is advisable to revive the recipient site before implantation.
- Completely fill the defect with GlassBone Granules. It is possible to perform the application of GlassBone Granules if the defect has sufficient bone wall.
- Avoid placing granules outside of the bone defect. Remove them if necessary.
- Avoid direct contact of GlassBone Granules with the skin.
- If it moves/migrates, the bioactive glass can cause wear of the joints and interfere with movement. Prevention of movement and granule migration is essential for proper bone formation. Do not apply excessive pressure to the defect. Excessive pressure may cause embolization of fat in the bloodstream.
- GlassBone Granules maintains its volume that is to say it does not shrink or expand.
- GlassBone Granules does not have sufficient mechanical strength to withstand load bearing before hard tissue is formed. When used in load bearing areas such as mandible fractures, standard internal or external stabilization techniques should be followed to achieve rigid stabilization in all planes.
- It is necessary to follow the usual post-operative treatment and rehabilitation procedures associated with bone grafts.
- The closure of the operative site depends on the surgery performed and the surgical site (membrane, sutures, etc.). An adequate closure of the graft site is mandatory (e.g., with cortical bone window, collagen membrane, mucosal-periosteum flap, fascia or muscle flap).

Regarding the medical device

- GlassBone Granules is a device that resorbs over time to make way for regenerated bone. There is currently no clinical study available that demonstrates complete resorption of the granules.
- This device does not harden like cement.
- GlassBone Granules is a sterile single-use device and must never be re-sterilized or reused. Reuse may cause contamination and impairment of bone substitute performance.

Adverse effects

No side effect directly linked to the device has been reported to date. However, an unknown allergy to one of the constituents of the product may be possible. Possible complications are the general complications due to surgery or anesthesia: Post-surgical symptoms (pain, redness, inflammation, oedema, hematomas, seroma, swelling, bleeding, ...), postoperative infection, recurrence/residual disease, otorrhea, pulmonary embolism, vein thrombosis, wound leakage, nerve palsy or paresthesia, mechanical failure, delay in consolidation, loss of fracture reduction, fusion failure, fracture, loss of bone graft, protrusion of the graft.

These complications are the same as those that can occur with autologous bone grafting. Possible adverse event is not more severe than those expected of similar products if the instructions are followed correctly by a qualified surgeon familiar with bone grafting techniques.

Any serious incident which may occur in connection with GlassBone Granules must be notified to NORAKER and to the competent authority of the Member State in which the patient or the surgeon is established.

Patient information

- The patient must be informed by their surgeon of the potential risks and adverse effects of implantation and agree to the proposed procedure.
- The surgeon should inform the patient who is the recipient of this device that the success of implantation depends on their behavior and good compliance with post-operative hygiene instructions.
- The patient must report any incident to their surgeon that could compromise the proper integration of the implant and undergo postoperative checks.
- After surgery, an implant card with its fascicle is filled out by the medical staff and given to the patient. He will have to keep it for life. Also, it is advisable to scan it when returning home.
- The SSCP (Summary of Safety and Clinical Performance) of the device is available on the manufacturer's website (www.noraker.com) (or on EUDAMED as soon as available).

Sterilization and packaging

GlassBone Granules is a single-use device, sterilized with gamma irradiation (sterile barrier ensured by external blister). Sterility is guaranteed until the expiration date if the sterile barrier has not been opened or damaged.

Storage & Disposal

The devices must be stored in their original unopened packaging in a clean, dry place, away from direct sunlight and at a recommended temperature between 15°C and 25°C.

Disposal of the device should be carried out in accordance with local regulations and practices, at the risk of exposing users and patients to pathogens and contaminating the waste circuit.

Basic UDI-DI: 0376019113DT731M2

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1 For surgical bone defect, GB-G is used for filling any bone cavity without direct indication and without having a direct therapeutic themselves

2 Based on clinical data