INSTRUCTIONS FOR USE

GlassBone Injectable Putty
Bioactive Bone Substitute

Description
GlassBone Injectable Putty is a synthetic, bioactive and resorbable device for the filling of bone defects in adults and children. It is an injectable paste composed of 45S5 bioactive glass granules mixed with a resorbable binder combining polyethylene glycol and glycerol. After implantation, the binder is rapidly absorbed, enabling cellular and vascular colonisation of the granules.

The bioactive granules (particle size 0.09 to 0.71 mm) consist only of elements naturally present in bone tissue (Ca, P, Na, Si, O). The release of these ions during resorption of the bioactive glass 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 Injectable Putty its osteoconduction property and creates a strong chemical link between the granules and living tissue. In vitro tests in cell cultures have also demonstrated that the released ions have a stimulating effect on the proliferation, differentiation and activity of cells responsible for the formation of bone tissue.

The radiopacity of GlassBone Injectable Putty makes it possible to observe the bone substitute granules following their implantation. As the granules are resorbed, the radiopacity of the bone defect approaches that of the surrounding bone.

The GlassBone Injectable Putty biomaterial is a non-hardening, readyto- use paste.

Indications
GlassBone Injectable Putty is indicated for the filling of bone defects in dental surgery, orthopaedic surgery, spinal surgery and maxillofacial surgery.

Contraindications
GlassBone Injectable Putty should not be used:

- In case of acute or chronic infection of the surgical site
- In patients with severe trauma with open wounds susceptible to infection near the defect.
- In patients with known allergies to bioactive glass or its components (Ca^{2+}, PO_4^{3-}, Na^+ and $Si(OH)_4$), to polyethylene glycol and/or glycerol.
- In patients with pre-existing conditions or diseases that may interfere with good tissue healing.
- In patients who have undergone or will undergo chemotherapy or radiotherapy at or near the implant site.
- Chronic metabolic disorders (uncontrolled diabetes, hyperparathyroidism, osteomalacia, chronic inflammatory rheumatism, severe or fracturing osteoporosis, etc.).
- Severe renal and hepatic infections and dysfunctions.
- Receiving treatment known to affect bones.
- In paediatric population

Instructions for use
GlassBone Injectable Putty does not require mixing, moistening or other preparation before use. Moistening may cause the binder to dissolve prematurely. This device does not harden like cement.

1. Eliminate all soft and/or pathological tissue from the implantation site.
2. Open the outer bag (sterile barrier) and remove the inner bag on the sterile field.
3. Once the surgical site has been prepared, open the inner bag and remove the applicator.
4. Unscrew the wing cap. Depending on the size of the defect and preference of the surgeon, the tip can also be unscrewed.
5. Position the applicator at the bone defect and press the plunger to gently fill the defect. Use a sterile instrument for assistance if necessary.
   It is also possible to place the paste in a sterile dish and then implant it with a sterile instrument.

Warnings on the surgical procedure
- It is recommended to trim up the recipient site before implantation.
- Fill the defect completely with GlassBone Injectable Putty.
- Avoid placing the paste outside of the bone defect. Remove it if necessary.
- Prevention of movement and granule migration is essential for proper bone formation.
- If it moves/migrates, the bioactive glass contained in the paste can cause wear of the joints and interfere with movement.
- Do not apply excessive pressure to the defect. Excessive pressure may cause embolisation of fat or paste in the bloodstream.
- The combination of any drug substance with GlassBone Injectable Putty during implantation is the responsibility of the surgeon.
- The general principles of asepsis and patient medication must be observed when using GlassBone Injectable Putty.
- GlassBone Injectable Putty does not have sufficient mechanical strength to withstand load-bearing before the hard tissue is formed. When used in bearing areas such as fractures of the mandible, standard internal or external stabilization techniques must be followed to achieve rigid stabilization in all planes.

Precautions for use
- GlassBone Injectable Putty should be used by qualified surgeons (dental surgeons, orthopaedists, neurosurgeons, maxillofacial surgeons, stomatologists) trained in the techniques of bone grafting and fixation and having reviewed the present instructions for use.
- Do not use the device if the sterile packaging is damaged or if the implant is damaged.
- Do not use after the expiration date.
- To avoid piercing surgical gloves, handle GlassBone Injectable Putty with a surgical instrument.
- GlassBone Injectable Putty is a sterile disposable device and should not be re-sterilised or re-used. Reuse may cause contamination and impairment of bone substitute performance.
- No studies have been conducted in pregnant women and there are no data on use during breastfeeding. As a security measure, implantation of GlassBone Injectable Putty is not recommended during pregnancy and lactation.
- GlassBone Injectable Putty has not been evaluated for safety and compatibility in the MRI environment.
- GlassBone Injectable Putty can't be implanted in children.

Information for patients
- The patient should be informed by the surgeon of potential risks and adverse effects during implantation and agree on the proposed procedure.
- The surgeon should inform the patient who is the recipient of this device that the success of the implantation depends on his/her behaviour.
- The patient should report to his/her surgeon any event that could compromise the proper integration of the implant and undergo postoperative checks.

Adverse effects
Possible complications are the same as those, which can occur in an autologous bone graft procedure: post-surgical symptoms (pain, redness, inflammation, oedema, hematomas, etc.), post-operative infection, unknown allergy to one of the components of the product, etc.

Postoperative precautions
It is necessary to follow the usual post-operative treatment and rehabilitation procedures associated with bone grafts.

Sterilisation and packaging
Sterile device packaged in sealed double bags and sterilized by gamma radiation. Sterility is guaranteed until the expiration date if the sterile barrier has not been opened or damaged.

Storage and 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 should be carried out in accordance with local regulations and practices.
Re-sterilisation is prohibited.

REF	Volume (cc)
GB-IP1.0	1cc
GB-IP2.5	2.5cc
GB-IP5.0	5cc
GB-IP10	10cc

	Do not use if package opened or damaged	
CE 0459 2017	Device CE-marked by the GMED notified body. Placed on the market in 2017.	
	Manufacturer	NORAKER 60 Avenue Rockefeller, 69008 LYON FRANCE Tel.: +33 (0)4 78 93 30 92 Fax: +33 (0)4 72 35 94 37
2023/05	Last update	
REF	Reference	
LOT	Batch number	
	Use-by date	
	Instructions for Use	
	Keep in dry place	
	Store away from sunlight	
15°C 25°C	Temperature limit 15-25°C	
	Do not reuse	
STERILE R	Sterile, Gamma irradiation	
	Do not resterilize	

NORAKER®
THE BIOGLASS® COMPANY