INSTRUCTIONS FOR USE

GlassBone Injectable Putty
Bioactive Bone Substitute

Description and indications
GlassBone Injectable Putty is a synthetic, resorbable, biocompatible and bioactive substitute device (bioactive glass 45S5), intended for the filling, reconstruction and / or fusion of bone defects or gaps of the skeletal system, in orthopedic surgery, spine, cranio-maxillofacial surgery and ENT.
It 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 and otorhinolaryngology surgery 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 (donor sites after removal of autograft, trepanation,…)
- Filling after removal of cholesteatoma
- Filling and reconstruction due to maxilla and periodontium pathologies.

It must be applied by qualified surgeons (orthopedists, neurosurgeons, cranio-maxillofacial surgeons, stomatologists and ENT surgeons) trained in bone grafting and fixation techniques and who have read these instructions for use.
The radio-opacity of GlassBone Injectable Putty makes it possible to discern bone substitute granules following their implantation. As the granules resorb, the radio-opacity of the bone defect approaches that of the surrounding bone.
GlassBone Injectable Putty biomaterial is a non-hardening paste, ready to use.

Contraindications
GlassBone Injectable Putty should not be used:
- In case of chronic or acute infection not treated with appropriate therapy.
- In patients who have suffered severe trauma with open external wounds near the defect, which are likely to become infected.
- In patients with a known allergy to bioactive glass or its constituents (Ca^{2+}, PO_4^{3-}, Na^+ and Si $(OH)_4$), polyethylene glycol and / or glycerol.
- In patients with pre-existing conditions or disease that may interfere with proper tissue healing.
- In patients who have undergone or will undergo chemotherapy or radiation therapy at or near the site of implantation.
- In the irradiated bone (according to radiological criteria indicating osteonecrosis).
- To replace structures subjected 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 and pediatric population.
- 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 Injectable Putty is not recommended during the periods of pregnancy and lactation.

Composition
GlassBone Injectable Putty is an injectable paste composed of 45S5 bioactive glass granules (69%) mixed with a resorbable binder combining polyethylene glycol (12%) and glycerol (19%).

Mechanism of action / Performance / Benefits
During its implantation, GlassBone Injectable Putty is in contact with bone and biological fluids. Bioactive granules consist only of elements naturally present in bone tissue (Ca, P, Na, Si, O). After implantation, the binder is rapidly absorbed, allowing fluid circulation and cellular and vascular colonization of interstitial spaces between bioactive glass granules.
The resorption of bioactive glass will allow the formation on the surface of a layer of carbonate hydroxyapatite, which composition and structure are similar to the mineral phase of bone. This layer gives the granules their osteoconduction property and makes it possible to create a strong link between the granules and the living tissues.
The claimed clinical performance is the filling, reconstruction and / or fusion of bone defects allowing the regeneration of the bone.
The associated benefits are the absence/decrease of autologous bone sampling, a decrease in pain and an improvement in quality of life.

Instruction for use
- Check the expiry date. Do not use the product if it is exceeded.
- Do not use the device if the sterile packaging is damaged.
- Check each device before use, in order to detect any deterioration. If this is the case, do not use the implant.
- GlassBone Injectable Putty does not require mixing, humification or other preparation prior to use. Humidification could dissolve the binder prematurely.
- Remove any soft and/or pathological tissues from the implantation site.
- Open the outer pouch (sterile barrier) and take out the inner pouch on the sterile field.
- Once the surgical site is prepared, open the internal pouch and remove the applicator.
- Unscrew the wing cap. Depending on the size of the defect and at the convenience of the surgeon, the tip can be unscrewed as well.
- Position the applicator at the level of the bone defect and press the plunger to gently fill the defect. Avoid direct contact between the delivery device and the patient's tissues. Use a sterile instrument if necessary. The device can also be placed directly in an intervertebral cage in spinal surgery.
- Fully fill the defect with GlassBone injectable Putty.
- It is also possible to deposit the paste in a sterile cup and then perform the implantation with a sterile instrument.
- The closure of the surgical site depends on the surgery performed and on the surgical site (membrane, stitches ...).
- This device is MR safe.

Warnings and precautions for use

In relation to the surgical procedure
-The general principles of asepsis and patient medication should be respected when using GlassBone Injectable Putty. GlassBone Injectable Putty does not substitute antibiotic therapy treatment during infection.
- The combination of any drug substance with GlassBone Injectable Putty during implantation is the responsibility of the surgeon.
- Handle GlassBone Injectable Putty with a surgical instrument to avoid piercing surgical gloves.
- It is advisable to trim up the recipient site before implantation.
- Avoid placing paste outside the bone defect. Remove it if necessary.
- If positioned outside the implantation site, moving or migrating, bioactive glass can cause wear of the joints and interfere with movement.
- Do not exert excessive pressure on the defect. Excessive pressure could cause an embolism of fat or paste in the bloodstream or cause the paste to be extruded beyond the implantation site, damaging the surrounding tissues.
- GlassBone Injectable Putty does not have sufficient mechanical strength to withstand a load before the bone tissue is formed. When used in load-bearing areas such as mandible fractures, standard internal or external stabilization techniques should be used to achieve rigid stabilization in all planes.
- It is necessary to follow the usual post-operative procedures of treatment and rehabilitation associated with bone grafts.

In relation to the medical device
- GlassBone Injectable Putty is a device that resorbs over time to make way for a regenerated bone. The binder is reabsorbed in a few days. Regarding the granules, no clinical studies currently available demonstrate complete resorption.
- GlassBone Injectable Putty is a non-hardening, ready-to-use paste.
- GlassBone Injectable Putty is a sterile single-use device and must not be re-sterilized or reused under any circumstances. Reuse can cause contamination and impaired performance of the bone substitute.

Adverse effects
No side effects directly related to the device have been reported to date. However, an unknown allergy to one of the constituents of the product could occur. Delayed union or failed fusion may also occur depending on the patient's metabolism.
Possible complications are general complications due to surgery or anesthesia: post-surgical symptoms (pain, redness, inflammation, edema, hematomas, seroma, swelling ...), postoperative infection, delay in consolidation, loss of fracture reduction, fusion failure, fracture, loss of bone graft, protuberance of the graft. These complications are the same as those that can occur with autologous bone grafts.
Any serious incident that may occur in connection with GlassBone Injectable Putty must be notified to NORAKER and the competent authority of the Member State in which the patient or surgeon is established.

Patient information
- The patient must be informed by the surgeon of the potential risks and adverse effects related to implantation and give his/her agreement to the proposed intervention.
- The surgeon must inform the patient receiving this device that the success of the implantation also depends on its behavior and good compliance with the post-operative hygiene instructions.
- The patient must report to his surgeon any event that may compromise the proper integration of the implant and undergo postoperative controls.
- 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
Sterile device packed in sealed double-pouches and sterilized by gamma radiation (sterile barrier ensured by external pouch). Sterility is guaranteed until the expiry date if the sterile barrier has not been opened or damaged. Re-sterilization is prohibited.

Storage and disposal
Devices must be stored in their original unopened packaging, in a dry, clean place, protected from sunlight and at a recommended temperature between 15°C and 25°C.
The disposal of the device (packaging, syringe, remaining paste) must 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.

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

NORAKER®
THE BIOGLASS® COMPANY

	Do not use if package opened or damaged	
	Consult instruction for use	
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
	Manufacturing date	
MD	Medical device	
2024/11	Last update	
REF	Reference	
LOT	Batch number	
UDI	Unique Device Identifier	
	Use-by date	
	Caution	
	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	
STERILIZE	Do not resterilize	
	Single sterile barrier system with protective packaging inside	