NORAKER®

THE BIOGLASS® COMPANY

Summary of Safety and Clinical Performance (SSCP)

Patients version

GlassBone® Injectable Putty

1. Device identification and general information

- **Brand name: GlassBone® Injectable Putty.**

There are several other trade names (brands) under which the GlassBone Injectable Putty (GB-IP) device is marketed: these devices are identical, only the name changes.

These brands are: AktiBONE Injectable Putty (XAK-IP) and Bio Logic Glass Injectable Putty (XBG-IP).

- **Basic UDI-DI : 0376019113DT735MA**

This number is used to identify the GlassBone Injectable Putty device and its equivalent references on the European market.

- **Name and address of the manufacturer**

Name: NORAKER

Address: 60 Avenue Rockefeller 69008 LYON – France

Tel: +33 4 78 93 30 92

www.noraker.com

- **Year of obtention of the first CE marking**

The first affixing of the CE marking and the placing on the market date from 2017.

2. Device description

GlassBone Injectable Putty is a synthetic, bioactive, and absorbable device for filling bone defects in adults and children.

- Composition: 45S5 bioactive glass granules, polyethylene glycol and glycerol.

45S5 bioactive glass granules are only composed of elements naturally present in bone tissue (Calcium, Phosphate, Sodium, Silicon). Throughout the glass resorption, the release of these ions will allow the formation of a surface mineral layer which composition and structure are similar to that from the bone. This layer provides GlassBone Injectable Putty an osteoconduction property: the cells regard the granules as natural bone and can therefore attach to it to produce their own bone tissue. This phenomenon makes it possible to create a strong chemical link between granules and living tissues.

In *vitro* cell culture assays have also shown that the released ions have a stimulating effect on the proliferation, differentiation, and activity of the cells responsible for bone tissue formation.

The granules resorption rate varies depending on patient metabolism, bone site and implanted volume. Bone defects are consolidated in about 12 months.

This device is MR safe.

3. Use of the device

Your surgeon has made sure that you can safely receive this device and that it is appropriate for your surgery.

- Intended use: filling, fusion and/or reconstruction of bone defects or gaps in the skeletal system, in orthopedic surgery, spine, craniomaxillofacial (CMF) surgery and ENT.

- Indications and target population: Loss or lack of bone substance for bone defects of traumatic, pathological, or surgical origin when autologous solutions are not applicable or sufficient in orthopaedics, neurosurgery, cranio maxillo facial and otorhinolaryngology surgery in children and 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 (in adult only).

- Contraindications and limitations:

GlassBone Injectable Putty should not be used:

- 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 (Ca2 +, PO43-, Na + and Si (OH) 4).
- In patients with pre-existing conditions or disease that may interfere with the good healing of tissues (patients treated with bisphosphonates, for example).
- In patients who have undergone or will undergo chemotherapy or radiation therapy at or near the site of implantation.
- In 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 Injectable Putty is not recommended during the periods of pregnancy and lactation.

4. Risks and warnings

Contact your doctor or a healthcare professional if you think you have any side effects related to the device, its use or if you are concerned about the risks. This document is not intended to replace a consultation with a professional.

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 grafting (see part 6. Other therapeutic solutions). If you experience any of the complications listed above or any other side effects, contact your surgeon as soon as possible.

5. Summary of Clinical evaluation and Post-Market Clinical Follow-up (PMCF)

- **Clinical background on the device**

GlassBone Injectable Putty is CE marked and used since JUN 2017.

According to the map of the degree of novelty for a DM of the ANSM, its degree of novelty is of 1: lacking or minor novelty. In other words, GlassBone Injectable Putty is classified like a device whose novelty is non-existent or minor. The device is without modification or negligible compared to a similar DM already on the market.

- **Clinical evidence for CE marking**

The demonstration of the device safety and performance is based on clinical data issue from: literature, post market clinical follow up and data held by the manufacturer

- **Clinical context of the device**

To date, more than 30,000 units of GlassBone Injectable Putty have been sold. 3% of implanted patients were included in a clinical study to demonstrate the achievement of device safety and performance requirements.

773 patients aged 7 to 80 years were included in 8 studies, covering all indications of the device. The average post-operative follow-up of patients included in these studies is 12 months: these data are consistent with the literature (state of the art). The results of fusion, reconstruction or filling performance at 12 months are in accordance with the state of the art. These clinical data confirm the benefit/risk balance of the product used in accordance with the indications of use.

- **Safety**

Thanks to post-market surveillance, NORAKER can evaluate the benefit/risk ratio associated with the use of GlassBone Injectable Putty device based on:

- Clinical studies set up for the different indications of the device (see table below)
- Hospital records, allowing patient follow-up
- Received customer complaints
- Material vigilance (= process of collecting and analyzing information on incidents related to the use of medical devices. The objective of this process is to prevent the (re)occurring of incidents and risks of serious incidents involving a medical device, by taking appropriate preventive and/or corrective measures).

The available clinical data show the achievement of the claimed performances for each indication:

Indication	Performance achieved	Benefits	Risk
Fusion or reconstruction of deformities and degenerative diseases in spine	92% fusion minimum at 12 months	Improvement of patient quality of life. No bone harvest	No complications related to GlassBone Injectable Putty identified
Fusion or reconstruction of deformities and degenerative bone pathologies in orthopedic	100% filling at 12 months	Improvement of patient quality of life. No bone harvest	No complications related to GlassBone Injectable Putty identified
Filling and reconstruction of bone defects due to resection of tumors, cyst or infection and in case of prosthetic revision	100% filling 88% reconstruction minimum At 12 months	Improvement of patient quality of life. No bone harvest	No complications related to GlassBone Injectable Putty identified
Filling after surgical bone defect (donor sites after removal of autograft, trepanation, …)	100% filling at 12 months	Improvement of patient quality of life.	No complications related to GlassBone Injectable Putty identified
Filling after removal of cholesteatoma	100% filling at 12 months	Improvement of patient quality of life. No bone harvest	No complications related to GlassBone Injectable Putty identified
Filling and reconstruction due to maxilla and periodontium pathologies	More 90% reconstruction at 6 months 100% reconstruction at 10 months	Improvement of patient quality of life. No bone harvest	No complications related to GlassBone Injectable Putty identified

To date, any complication has been identified in the post-market surveillance implemented by NORAKER. Nevertheless, NORAKER considers that a risk of allergy could occur and follow it in a specific trend report.

The post market surveillance data (specifically PMCF clinical studies) permit to conclude that the benefits of GlassBone Injectable Putty outweigh the risk.

6. Other therapeutic solutions

Your surgeon has selected the right treatment for your surgery from possible alternatives. It made sure that you could safely receive this device.

Common options for performing a bone graft include:

- autograft: use of autologous bone (autograft) i.e., bone tissue from the patient himself. The donor and the recipient are thus the same individual. Today, this treatment remains the reference treatment. However, transplant harvesting requires the creation of a second surgical site for bone collection and may lead to complications at this donor site: pain, infection, fracture, loss of sensation, hematomas. These complications, the limited amount, and the variable quality of the available bone material as well

as the extension of surgery duration are the main limitations of autograft, leading health professionals to use bone substitutes.

- allogeneic transplantation: use of tissues of human origin, distributed by tissue banks. These transplants are subject to prior authorization.
- xenograft: the use of non-viable tissues or derivatives of animal origin. They are of various origins: coral, cuttlefish, mammals. Most bone substitutes of animal origin come from cattle.
- synthetic bone substitutes: use of synthetic materials, that do not contain any derivative or tissue of biological origin and are not derived from such sources. Their compositions are various (calcium phosphate, calcium sulfate, bioactive glasses...). These substitutes may be absorbable or non-absorbable.

Grafts are used when conservative treatments (first line approaches when pathologies are not severe) have failed and when surgery is required. In this case, they are mainly used in combination with others implants such as rods, screws, plates and prothesis. They can also be used alone or not at all. Their mains functions (prevent progression of disease, mechanical support etc.) are different as bone grafts functions. Thus, these alternative treatments cannot be compared with bone grafts. They are considered as complementary implants

Likewise, drug treatments, chemotherapy, radiotherapy, physiotherapy… are complementary and can't be considered as a total alternative solution.

Therapeutic alternatives to GlassBone Injectable Putty are autologous bone, allograft, xenograft, and other families of synthetic substitutes.