NORAKER®

THE BIOGLASS® COMPANY

Summary of Safety and Clinical Performance (SSCP)

Patients version

Granules Dental Range

This document is a summary of safety and clinical performance for a given medical device. The information presented below is intended for patients or lay persons.

The summary of safety and clinical performance is not intended to give general advice on the treatment of a medical condition.

Please contact your doctor or pharmacist in case you have questions about your medical condition or about the use of the device in your situation.

This summary of safety and clinical performance is not intended to replace an implant card or the Instructions For Use to provide information on the safe use of the device.

1. Device identification and general information

1. Brand name: GlassBone® Granules Dental

There are several other trade names (brands) under which the GlassBone Granules Dental (GBD-G) device is marketed: these devices are identical, only the name changes.

These brands are: Activioss Granules (ACT-G), AktiBone Granules Dental (XAKD-G), BiologicGlass Granules Dental (XBGD-G).

2. Basic UDI-DI: 03760191I3DT739MJ

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

3. 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

4. Year of obtention of the first CE marking

The first affixing of the CE marking and placing on the market dates from 2008 (GlassBone Granules, that includes dental indications).

2. Device description

GlassBone Granules Dental is a synthetic and biocompatible bone substitute device (bioactive glass 45S5), intended for the filling or reconstruction of bone defects or bone preservation in dental and maxillofacial systems surgery.

- Composition: 45S5 bioactive glass granules

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 Granules Dental 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 link between granules and living tissues.

The granules resorption rate varies depending on patient metabolism, bone site and implanted volume. Bone defects are consolidated in about 6 months.

The lifetime of the device (duration during which it ensures its performances) is 6 months.

This device is MR safe and sterile.

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 or reconstruction of bone defects or bone preservation in dental and maxillofacial system surgery

- Indications and target population:

Loss or lack of bone substance for bone defects of surgical, traumatic or pathological origin when autologous solutions are not applicable or sufficient in dental surgery adult population:

- Sinus elevation and filling before implantation
- Periodontal defects filling and reconstruction
- Extraction sites, (alveolar ridge preservation, implant preparation, reconstruction or augmentation)
- Cyst cavities filling

- Contraindications and limitations:

GlassBone Granules Dental should not be used:

- In case of chronic or acute infection not treated with appropriate therapy.
- In patients who have suffered severe trauma with external wounds open near the defect, which could become infected.
- In patients with a 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) and in special clinical situations (tumor, ongoing chemotherapy and radiation therapy, immunodeficiency ...).
- During severe renal and hepatic infections.
- In conjunction with a treatment known to affect the skeleton.

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 Dental 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 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, they are not more severe than those expected of similar products: post-surgical symptoms (pain, discomfort, abscess, redness, inflammation, oedema, hematomas, seroma, swelling, bleeding, ...), postoperative infection, recurrence/residual disease, wound dehiscence, wound leakage, delay in consolidation, loss of bone graft, membrane exposure (if applicable), protuberance of the graft, tooth sensitivity, gingival recession, subsidence of the flap, abscess formation, resorption or ankylosis of the treated root, etc. Adverse events are less than 5% during the first 6 months (4.6% were found in the literature).

These complications are the same as those that can occur with autologous bone grafting (see part 6. Other therapeutic solutions). 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.

If you experience any of the complications listed above or any other side effects, contact your surgeon as soon as possible. Any serious incident which may occur in connection with Glassbone Granules Dental must be notified to NORAKER and to the competent authority of the Member State in which the patient or the surgeon is established.

Follow-up recommendations:

- Patients recipients of this device must be informed by their surgeon of the potential risks and adverse effects of bone substitution and agrees to the proposed procedure.
- Patients' recipients of this device should be informed by the surgeon that the success of bone substitution depends on their behavior and good compliance with post-operative hygiene instructions.
- A post-operative follow-up consultation is required to assess healing and ensure everything is going as planned. The follow up is explained by the surgeon with at least one visit during the first 6 months.
- Patients' recipients of this device must report any incident to their surgeon that could compromise the proper integration of the bone substitute 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.

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

1. Clinical background on the device

GlassBone Granules Dental is CE marked and used since 2008.

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 Granules Dental 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.

2. 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.

3. Clinical context of the device

To date, more than 67,941 units of Glassbone Granules have been sold[1] (with 28 248 units specific for Activioss). 1,4% of implanted patients were included in a clinical study to demonstrate the achievement of device safety and performance requirements in dental surgery.

376 patients were included in 7 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 reconstruction or filling performance at 6 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.

4. Safety

Thanks to post-market surveillance, NORAKER can evaluate the benefit/risk ratio associated with the use of Glassbone Granules Dental 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 analysing 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

[1] 63,896 units sold from the launch on the market until 25/07/2023

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
Sinus elevation and filling	9.0 ± 3.4 mm [min 2 - max 17.5] is the mean gain in sinus floor height. 99% implants success (osteointegration of implant) at 6 months.	No bone harvest. 99% Implants success at 6 months	No complications related to Glassbone Granules Dental identified
Periodontal pocket	Periodontal pockets treated with Activloss Granules reached a non-pathological in 100% of patients at 12 months	No bone harvest	No complications related to Glassbone Granules Dental identified
Extraction and implant placement	100% implant success (osteointegration of implant) at 6 months	No bone harvest. 100% Implants success at 6 months	No complications related to Glassbone Granules Dental identified
Cystic lesions	100% filling	No residual disease identified	No complications related to Glassbone Granules Dental 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 Granules Dental 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 Granules Dental are autologous bone, allograft, xenograft and other families of synthetic substitutes.