PATIENT INFORMATION LEAFLET

Patient information materials assist patients to:
- understand the medical device being implanted, both prior to and following surgery;
- have informed consent conversations with their health professional; and
- report any adverse events associated with their implanted medical device.

1. Device identification

(a) the name of the device

The device is named GlassBone Granules.

(b) the model of the device

They are different references depending on the volume of the product.

Reference	Designation	Granules size*	Volume**
GB1.3/5	GlassBone Granules (GB-G)	1-3mm	5 cc
GB1.3/10		1-3mm	10 cc
GB1.3/16		1-3mm	16 cc
GB05.1/5		0.5-1mm	5 cc
GB1.3/1-U		1-3mm	1 cc
GB05.1/1-U		0.5-1mm	1 cc
GB05.1/05-U		0.5-1mm	0.5 cc

*The granules size is express in millimeter, mm

**The volume is express in cc, 1cc=1cm^3

2. Intended use

(a) the intended purpose of the device

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, in orthopedics, neurosurgery, cranio maxillo facial (CMF) and otorhinolaryngology (ENT) surgeries in adult population.

(b) the kind of patient on whom the device is intended to be used

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.

3. Special operating instruction for the use of the device

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 ...)

4. Intended performance and adverse effects

(a) the intended performance of the device;

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

(b) any undesirable side effects that could be caused by use of the device

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.

5. Residual risks

The residual risks of the device itself, i.e., the risks remaining after the implementation of the risk management measures, concern the allergic risks.

To date, no adverse effects directly related to the device are reported or detected.

6. Warning and precautions about interaction of the device with other equipment

The combination of any drug substance with GlassBone Granules during implantation is the responsibility of the surgeon.

7. Patient precautions

(a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and

Regular or preventive examination, monitoring or maintenance of the device are the responsibility of the surgeon.

(b) symptoms that could indicate that the device is malfunctioning; and

See part 4.(b)

(c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and

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.

(d) the expected device lifetime; and

The lifetime of the device is 12 months. When implanted, the resorption time is different depending on patient metabolism.

(e) anything that could shorten or lengthen the device lifetime; and

Not applicable

(f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and

Not applicable

(g) other circumstances in which the patient should contact a health professional in relation to the operation of the device

Not applicable

8. Component

(a) the materials and substances included in the device; and

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).

(b) any manufacturing residuals that could pose a risk to the patient

None

9. Incident

Any serious incident which may arise in connection with GlassBone Granules must be notified to NORAKER and to the Therapeutic Goods Administration.

Manufacturer:

NORAKER
Address: 60 avenue Rockefeller, 69008 LYON, France
Tel: +33 4 78 93 30 92
Fax: +33 4 72 35 94 37
Email: vigilance@noraker.com

Competent Authority:

Therapeutic Goods Administration
Address: PO Box 100, Woden ACT 2606, Australia
Email: info@tga.gov.au
Website: https://www.tga.gov.au/ or https://www.tga.gov.au/reporting-problems

Version	Date	Changes
A	27/03/2024	Creation