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 and the manufacturer of the device

The device is named GlassBone Injectable Putty.

(b) the model of the device

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

Reference	Designation	Volume*
GB-IP1.0	GlassBone Injectable Putty (GB-IP)	1 cc
GB-IP2.5		2.5 cc
GB-IP5.0		5 cc
GB-IP10		10 cc

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

2. Intended use

(a) the intended purpose of the device

GlassBone Injectable Putty is a synthetic, bioactive and resorbable bone substitute indicated for the filling, reconstruction and / or fusion of bone defects or gaps in spine, orthopedic, craniomaxillofacial (CMF) surgery, otolaryngology (ENT).

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

GlassBone Putty is indicated in adult population for loss or lack of bone substance for bone defects of traumatic, pathological or surgical origin.

3. Special operating instruction for the use of the device

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 external wounds open 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 $Si(OH)_4$), to 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 case of chronic metabolic conditions (unbalanced diabetes, hyperparathyroidism, osteomalacia, chronic inflammatory rheumatism, severe or fractural osteoporosis, calcium metabolism disorder...).
- During severe renal and hepatic infections.
- In conjunction with taking treatment known to affect the skeleton.
- In the irradiated bone (according to radiological criteria indicating osteonecrosis).
- To replace structures subject to high mechanical stresses.
- In neonatology service.
- In case of unsutured meningeal breach in cranio-spinal surgery

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. Intended performance and adverse effects

(a) the intended performance of the device; and

The intended performances are filling, reconstruction and / or fusion.

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

No side effects directly related to the device have been reported to date.
However, an unknown allergy to any of the constituents of the product, a delay in consolidation or a failure of fusion could occur as a result of the use of the device.

Possible complications following the procedure are general complications due to surgery or anaesthesia: post-surgery symptoms (pain, redness, inflammation, oedema, hematoma, seroma, swelling, ...), post-operative infection, delayed 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. 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.
The occurrences of risks and damages are 0% directly related to the device.

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

The combination of any drug substance or other medical devices with GlassBone Injectable Putty 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.(a)

(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

The device is composed of 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).

Polyethylene glycol and glycerol are used to link bioactive glass granules.

(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 Injectable Putty must be notified to NORAKER and to the Therapeutic Goods Administration.

Manufacturer: NORAKER
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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	24/09/2021	Creation