NORAKER®

THE BIOGLASS® COMPANY

Summary of Safety and Clinical Performance (SSCP)

Surgeons version

Granules Dental Range

This summary of safety and clinical performance is intended to provide public access to the main aspects of the safety and clinical performance of the device.

The summary of safety and clinical performance is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

Version B.1 (EN) of this summary of safety and clinical performance has been validated by a notified body.

The following information is intended for users/healthcare professionals.

I. Device identification and general information

1. Brand name

GlassBone® Granules Dental

It is available in different volumes: 0.5cc, 1cc and 2cc and different granule sizes: 0.5-1 mm and 1-3 mm.

There are several other trade names (brands) under which the GlassBone Granules Dental (GBD) 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).

The volumes and granule sizes available are the same as GlassBone Granules Dental.

GlassBone Granules Dental (GBD-G)	Activioss Granules (ACT-G)	AktiBONE Granules Dental (XAKD-G)	BiologicGlass Granules Dental (XBGD-G)	Granule size	Volume
GBD-GM0.5	ACT-GM0.5	XAKD-GM0.5	XBGD-GM0.5	0.5-1 mm	0.5 cc
GBD-GM1	ACT-GM1	XAKD-GM1	XBGD-GM1		1 cc
GBD-GM2	ACT-GM2	XAKD-GM2	XBGD-GM2		2 cc
GBD-GL1	ACT-GL1	XAKD-GL1	XBGD-GL1	1-3 mm	1 cc

When "GlassBone Granules Dental" is cited in the document, this includes the brands mentioned above.

2. Name and address of the manufacturer

Name: NORAKER
Address: 60 avenue Rockefeller – 69008 LYON - France
Phone: +33 4 78 93 30 92
SAS CAPITAL 300 000 €
N° RCS Lyon 483 190 518
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3. Unique manufacturer registration number

FR-MF-000000325

4. Unique Device Identifier (UDI-DI)

Basic UDI-DI for GlassBone Granules Dental range of products is: 0376019113DT739MJ (control key: MJ).

5. Nomenclature

GMDN: 16966 - Prosthesis, internal, bone, synthetic

EMDN: Q010302 - DENTISTRY GRAFT DEVICES

Regulation 2017/2185 codes are: MDN 1103, MDT 2003, MDT 2006, MDT 2008, MDT 2011, MDS 1005 irradiation and MDS 1008

6. Device class

This product is a medical device in accordance with Article 2 of Regulation 2017/745, class III according to the applicable classification rule 8 of Annex VIII to Regulation 2017/745.

7. Year of affixing 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).

8. Agent, name and unique registration number

Not applicable

9. Notified Body, name and unique identifier number

Name: GMED

Unique Identifier Number: 0459

II. Destination of the device

1. Intended use of the device

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.

2. 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- Filling after removal of cholesteatoma
- Filling and reconstruction due to maxilla and periodontium pathologies (in adult only).

3. Contraindications and limits

Glassbone Granules Dental must 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 for patients treated 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.

III. Device description

1. 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). The release of these ions during the resorption of bioactive glass will allow the formation on the surface of a layer of carbonate hydroxyapatite whose composition and structure are similar to the mineral phase of the bone. This layer provides GlassBone Granules Dental an osteoconduction property and creates a strong link between granules and living tissues.

This medical device does not contain any medicinal substance or tissues of human origin.

The radio-opacity of GlassBone Granules Dental makes it possible to discern bone substitute granules following their implantation. As the granule's resorption, the radio-opacity of the bone defect approaches that of the surrounding bone.

It is a single-use device.

Bone defects are consolidated in about 6 months and the bioactive glass granules are gradually resorbed. It should be considered that after 6 months; the device no longer fulfils its function even if the device is not totally degraded.

The current expiration date is 5 years after gamma sterilization.

The device is MR safe and sterile.

- Operating principles and mode of action

Implantation of Glassbone Granules Dental is done after elimination of all soft and/or pathological tissue from the implantation site. Once the surgical site has been prepared, the blister is open as explained in instruction for use. Glassbone Granules Dental can be mix with another constituent in sterile cup (patient blood, saline serum, implantation site autologous bone and/or antibiotic). To perform the application of Glassbone Granules Dental, the defect must have sufficient bone wall. The defect is completely fill using a sterile instrument without material compression (not apply excessive pressure to the defect) in the site nor blotting the blood/moisture in the positioned graft. Glassbone Granules Dental maintains its volume it does not shrink or expand. It is recommended to avoid placing granules outside of the bone defect. It is necessary to remove them if it happens. Finally, it is recommended to avoid direct contact of Glassbone Granules Dental with the skin.

After placement of Glassbone Granules Dental, ensure the primary closure of the soft tissues at the graft site. Resorbable or non-resorbable membranes can also be used for the closure. The closure of the operative site depends on the surgery performed and the surgical site (membrane, sutures, etc.). An adequate closure of the graft site is mandatory (e.g., with collagen or synthetic membrane (resorbable or non-resorbable), mucosal-periosteum flap,..)..

After implantation the interstitial spaces between the granules allow fluid circulation and cellular and vascular colonization. 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, preventing graft rejection. This layer gives the granules their osteoconduction property and makes it possible to create a link between the granules and the living tissues. Following the carbonate hydroxyapatite layer reactions, bone growth continues, and bioactive glass continues to degrade and serves as a scaffold for bone regeneration.

2. Reference to previous model(s) and description of changes

GlassBone Granules Dental Gamma irradiation is a further development of ActivIoss Granules Ethylene oxide (EtO). Only the sterilization mode is different.

3. Description of accessories intended for use with the device

No accessories are used with our device.

4. Description of other devices intended for use in combination with the device

No accessories or compatible devices are sold with GlassBone Granules Dental.

However, when implanted GlassBone Granules Dental can be mix with another constituent in sterile cup: patient blood, saline serum, implantation site autologous bone and/or antibiotic . This is described in the part "device operation principle and action mode" and in the instruction for use. No impact on performance and safety of the device is highlight with the use of additional constituent or not.

IV. Risks and warnings

1. Residual risks and adverse effects

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.

Possible complications or adverse event are not more severe than those expected of similar products if the instructions are followed correctly by a qualified surgeon familiar with bone grafting techniques: 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).

Device-related complications	Frequency of occurrence	Source
Allergy to the constituents of the dispositive	Only one customer (polyallergic) complaint to date out of a total of 67 941 GlassBone Granules units (0.001%) or equivalent references, with **28 248 units of Activloss**)	PMS and available clinical data
Surgical adverse event	Not more than those expected of similar products	

The profit/risk ratio is positive since the benefit is greater than the risk with an acceptable residual risk.

2. Warnings and Precautions

GlassBone Granules Dental should be used by qualified surgeons (dentist, implantologist, stomatologists) trained in bone grafting and fixation techniques who have read these instructions for use.

Regarding the surgical procedure

- The general principles of asepsis and patient medication must be observed when using GlassBone Granules Dental.
- The combination of any drug substance with GlassBone Granules Dental during implantation is the responsibility of the surgeon.
- Manipulate GlassBone Granules Dental with a surgical instrument to avoid piercing surgical gloves.
- It is advisable to revive the recipient site before implantation.
- Completely fill the defect with GlassBone Granules Dental. It is possible to perform the application of GlassBone Granules Dental if the defect has sufficient bone wall.
- Avoid placing granules outside of the bone defect. Remove them if necessary.
- Avoid direct contact of GlassBone Granules Dental with the skin.
- If it moves/migrates, the bioactive glass can cause wear of the joints and interfere with movement. Prevention of movement and granule migration is essential for proper bone formation.
- Do not apply excessive pressure to the defect. Excessive pressure may cause embolization of fat in the bloodstream.
- GlassBone Granules Dental maintains its volume that is to say it does not shrink or expand.
- GlassBone Granules Dental does not have sufficient mechanical strength to withstand load bearing before hard tissue is formed. When used in load bearing areas such as mandible fractures, standard internal or external stabilization techniques should be followed to achieve rigid stabilization in all planes.
- GlassBone Granules Dental should not be used in applications with immediate load bearing. Placing a dental implant under load can be done 5 to 6 months after filling. Immediate loading is the responsibility of the surgeon.
- It is necessary to follow the usual post-operative treatment and rehabilitation procedures associated with bone grafts.
- The closure of the operative site depends on the surgery performed and the surgical site (membrane, sutures, etc.). An adequate closure of the graft site is mandatory (e.g., collagen or synthetic membrane (resorbable or non-resorbable), mucosal-periosteum flap).
- The use of a membrane is recommended in cases where the defect is significant or if there is limited bone retention. Primary closure of defects, preferably without tension, is strongly recommended.

Regarding the medical device

- GlassBone Granules Dental is a device that resorbs over time to make way for regenerated bone. There is currently no clinical study available that demonstrates complete resorption of the granules.
- This device does not harden like cement.
- GlassBone Granules Dental is a sterile disposable device and must never be re-sterilized or reused. Reuse may cause contamination and impairment of bone substitute performance.

Patient information

The patient must be informed by their surgeon of the potential risks and adverse effects of bone substitution and agrees to the proposed procedure.

The surgeon should inform the patient who is the recipient of this device 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 patient's follow up is explained by the surgeon with at least one visit during the first 6 months.

The patient 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.

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).

3. Other aspect of security, if applicable

GlassBone Granules Dental has not been been subject to any safety event.

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

1. Summary of clinical data on equivalent devices: Glassbone Granules Dental (EtO)

Not Applicable

Following the implementation of a post-market clinical follow-up study, 3 studies have been completed with Glassbone Granules Dental (EtO sterilized):

- Sinus floor augmentation - SIGRAD

The aim of the retrospective study is to assess Glassbone Granules Dental (ACT-G) synthetic bone substitute in real life and aims to provide sufficient evidence of the device's clinical performance and safety. 189 patients (125 women (66%) and 64 men (34%)) who had undergone sinus floor augmentation to obtain adequate bone volume for dental implant placement with Glassbone Granules Dental bioactive glass between 2016 and 2020 for sinus floor elevation. At 5±1 months after implant placement, 96.3% of implants were retained and the mean gain in sinus floor height is 8.7 ± 3.4 mm [min 2 - max 17.5]. The 0.5-1mm subgroup of 170 patients (118 females (69.4%) and 52 males (30.6%)) have an implant success rate of 99% at 5±1 months and the

mean gain in sinus floor height is 9.0 ± 3.4 mm [min 2 - max 17.5]. No complications related to the use of Glassbone Granules Dental were noted. Safety was confirmed because no adverse event occurred with Activioss. The reconstruction's performance was confirmed with a good implant's survival.

- Sub-osseous periodontal filling - POGRAD

The aim of the retrospective study is to provide sufficient evidence of the Glassbone Granules Dental' clinical performance and safety. 88 patients who had undergone sub-osseous periodontal filling with Glassbone Granules Dental with Glassbone Granules Dental, bioactive glass, between 2016 and 2021 for periodontitis with minimum one-year post-operative follow-up. The population represented 55 women (62.5%) and 33 men (37.5%). Periodontal pockets treated with Glassbone Granules Dental reached a non-pathological depth (i.e. ≤ 4mm) in 98.9% of patients. The 0.5-1mm subgroup of 73 patients (44 females (60.3%) and 29 males (39.7%)) with periodontal pockets reached a non-pathological depth (i.e. ≤ 4mm) in 100% of patients at 12 months. Any complication was found in a population of 88 patients. Safety was confirmed because no adverse event occurred. Performance was confirmed with a good subosseous periodontal filling.

- Extraction and implant placement – COLGRAD

The aim of the retrospective study is to provide sufficient evidence of the Glassbone Granules Dental' clinical performance and safety. 36 patients who had undergone dental surgery with Glassbone Granules Dental Large, bioactive glass, between 2016 and 2021 for dental filling with implantation with minimum 6 months post-operative follow-up. Surgical techniques include sinus floor elevation and guided bone regeneration. The population represented 15 women (41.7%) and 21 men (58.3%). 100% of patients have implant success at 6 months post-op. Any complication related with Glassbone Granules Dental Large was found in a population of 36 patients. Safety was confirmed because no adverse event occurred. Performance was confirmed with implant success in 100% of patients.

2. Summary of clinical data relating to investigations of the device prior to CE marking, if applicable

Not Applicable

3. Summary of clinical data from other sources, if applicable

- **In literature**

Currently, the device Glassbone Granules Dental (EtO sterilized) is found in 4 publications:

- Venet L. Comblements sinusien par abord latéral et verre bioactif : revue de la littérature, expérience clinique et qualité osseuse, Thèse, 2013.

In these prospective cases study, 10 patients that had been implanted with Glassbone Granules Dental (0.5-1mm) for sinus augmentation were selected. A total of 23 implants were placed in these patients. The sinus augmentations were performed using the lateral access procedure. All patients presented good clinical outcomes. All implants were functional after a 6-months loading period. No adverse effect was observed and all patients were satisfied by the treatment. In the analyzed struts, there were a residual crest bone and

remodeled bone containing residual bioactive glass granules. After 6 months there were 33.83% (17.85 – 58.43%) ± 9.73 of bone formation compared with 42.12 % (17.58 – 58.59%) for healthy bone tissue. At the same time point there were about 20% residual bioactive glass particles. Histological analysis showed that the remaining bioactive glass particles were in the process of being resorbed. The first observations about the general appearance of the tissue found within the bone samples demonstrate a well vascularized and fibroblast-rich marrow. The presence of numerous osteoblasts and osteoid tissue lying thick on the edge of calcified tissues was indicative of an intense remodeling.

- **Bahammam, MA**. Effectiveness of bovine-derived xenograft versus bioactive glass with periodontally accelerated osteogenic orthodontics in adults: a randomized, controlled clinical trial. https://www.ncbi.nlm.nih.gov/pubmed/27903250 2016, 30;16(1):126.

In this prospective, single-masked clinical trial, 33 orthodontic patients (20 women, 13 men; mean age 21.2), were randomly allocated to one of three groups. Group 1 underwent a modified corticotomy technique on the labial side only, whereas group 2 was treated with the same technique combined with periodontally accelerated osteogenic orthodontics (PAOO) using a bovine-derived xenograft and group 3 was treated in the same way but combining PAOO with bioactive glass (0.5-1mm). At the end of the study period, there was a significantly greater increase in bonedensity in the two groups that had been treated with bone grafting when compared with the group that had been treated with a modified CAOT alone. Moreover, patients who were treated with the bovine derived xenograft showed a greater (albeit not statistically significant) increase in bone density than those who were treated with bioactive glass.

- **Carrotte, D.** Carrotte D, Burt-Pichat B, Rizzo S, Boivin G. Sinus bone augmentation using bioactive glass with repositioning of the bone flap. 2020.JPIO; 39:1-15.

In this retrospective cases study, 52 patients that had been implanted with Glassbone Granules Dental (0.5-1mm) for sinus augmentation were selected. A total of 110 implants were placed in these patients. The sinus augmentations were performed using the lateral access procedure. All patients presented good clinical outcomes. All implants were functional after a 12-months loading period. The histology analysis of the 2 explants showed that the augmented area have a normal bone structure with mineralized-bone trabeculae, bone marrow and some osteointegrated biomaterial fragments. The biomaterial is largely resorbed (Residual graft is 15% at 6.5 months and 7% at 22 months) with no sign of foreign body reaction. Bone appears to be more mature in the vicinity of the residual area with less residual granules and bone remodeling. The bone quality assessed by microhardness is similar between the residual and augmented area and equivalent at 6 and 22 months.

- **El Hawary 2021**. El-Hawary HE, Shawky M. Assessment of the sticky bone preparation of bioactive bone glass in grafting critical-sized surgical bony defects. Egyptian Dental Journal. 2021 Jul; 67: 1899-1908.

In this randomized clinical controlled trial, 24 were divided into two equal groups for cystic bony lesions. Cystic lesions exceeding 2 x 2 cm were enucleated, and the defect was obliterated with bioactive bone glass particles in group 1 and bioactive glass sticky bone in group 2 (bioactive glass granules + platelet rich fibrin).

In group 1, the percentage of decrease in the bone density during the first three months is higher in group 1 than group 2 that was then increased by nearly the same percentage at the six months interval, although statistically there is no significant difference between the two groups throughout the study period. The defects were completely filled in the 2 groups without loss of substitute. The healing went uneventful through all the cases. The surgically reconstructed defects did not show postoperative infection nor wound dehiscence or graft rejection throughout the healing phase. After resolving the postsurgical phase's signs, none of the patients exhibited any complaint during the whole study interval. The defect was reconstructed.

4. Overall Summary of Clinical Performance and Safety

The clinical claimed clinical performance is the filling and reconstruction of dental bone defects allowing the regeneration of the bone. The claimed performance is consistent with the results we currently have:

Reference	Population	GlassBone Granules Dental	Indication	Performance (%)	Follow-up (months)
Venet, 2013	Adult	Sterilized EtO Granular size: 0.5-1 mm	Sinus bone augmentation	33.83% bone formation	6
Bahamman, 2017	Adult	Sterilized EtO Granular size: 0.5-1 mm	Periodontal osseous defects	Probing depths were < 3 mm	9
Carrotte, 2020	Adult	Sterilized EtO Granular size: 0.5-1 mm	Sinus bone augmentation	93% fusion	12
El Hawary, 2021	Adult	Sterilized EtO Granular size: 0.5-1 mm	Cystic lesions	100% filling and consolidation	6
SIGRAD	Adult	Sterilized EtO Granular size: 0.5-1 mm	Sinus bone augmentation	9 mm gain in sinus floor height 99% Implant success	Minimum 6
POGRAD	Adult	Sterilized EtO Granular size: 0.5-1 mm; 1 – 3 mm	Periodontal pocket	100% with ≤ 4mm probing depths	12
COLGRAD	Adult	Sterilized EtO Granular size: 1 – 3 mm	Extraction and implant placement	100% Implant success	6

Current clinical results indicate that the benefits far outweigh the risks since the only risk associated with the identified device would be allergy.

	Benefits	Risk
Manufacturer's claim	- No bone harvesting graft site - Maintain/Survival implant - Limited recurrent / residual disease - Quality of life improvement: Optimize the esthetical and functional outcome (e.g, comfort, speech, chewing), visit decrease, easy to use for surgeons	- Surgical risk: possible complications but not more severe than those expected of similar products. - Device risk: No allergy
Available performance data	- No morbidity associated with harvesting graft site (no pain) - Sinus: Implant maintenance is confirmed (>90%) - Extraction/Implantation: Implant maintenance is confirmed (>90%) - No residual disease - Quality of life improvement	No complications related to Glassbone Granules Dental substitute. Surgical complications are not more severe than those expected of similar product and alternatives. No allergy.

5. Ongoing or planned post marketing clinical follow-up

The table below lists all ongoing and planned studies or registers concerning this medical device.

Destination	Indication	Statue	Grade	Objective
Upcoming clinical investigations				
Dental	Periodontal defect	Forthcoming 0/83	B	- Evaluation of tolerance through complication rate analysis - and performance through reconstruction analysis
Dental	Alveolar defect	TBD	B	- Evaluation of performance through filling analysis - Evaluation of tolerance
Dental	Cystic lesions	TBD	B or C	- Evaluation of performance through filling and reconstruction analysis - Evaluation of tolerance

For each study, a follow-up of complications is planned throughout the duration of the study. Events should be reported to NORAKER at any time. In addition, post-market surveillance data and other clinical data that will be collected will be incorporated as part of the annual updates of the clinical assessment.

VI. Other therapeutic solutions

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.

The gold standard remains the autologous bone but involves a sampling site on the patient and therefore a second surgical site that can cause additional complications: pain, infection, fracture, loss of sensation or hematomas. These complications, the lengthening of the operating time, the limited quantity and the variable quality of the available material are the main limitations of autologous transplantation, leading professionals to resort to bone substitutes. The most common options for replacing autograft are: allogeneics, xenografts and synthetic bone substitutes.

Allografts are tissues of human origin and are distributed by tissue banks and are subject to authorization. Xenografts are made from non-viable tissues of animal origin, stripped of their bone marrow, or derivatives made non-viable. They are of various origins: coral, cuttlefish, mammals. Most bone substitutes of animal origin come from cattle. The risk of pathogen transmission is not excluded.

As regards synthetic substitutes, they do not contain any derivative or tissue of biological origin and are not derived from such derivatives. Their composition varies (calcium phosphate, calcium sulfate, bioactive glass...) and can be absorbable or non-absorbable

Glassbone Granules Dental, like other synthetic bone substitutes, makes it possible to overcome the constraints of the sampling site (morbidity of the donor site) and to achieve the expected performance of the gold standard.

This summary table shows the advantages (+) and disadvantages (-) of other available solutions.

	Manipulation	Bioactivity	Transmission of possible pathogens	Availability	Osteoconduction	Osteoinducteur	Bioresorbable
Autograft	-	-	+	-	+	+	-
Allograft	+	-	-	-	+	-	-
Xenograft	+	-	-	+	+	-	-
Synthetic substitute	+	+	+	+	+	-	+ / -
BMP	+	-	-	+	+	+	+
Bioactive glass	+	+	+	+	+	-	+

VII. Suggested profile and training for users

Users are experienced surgeons (dentists, implantologist and stomatologist) with bone graft techniques. There is no specific training on the use of the device.

VIII. Reference to harmonized standards and common specifications applied

At the moment of writing this document, no common specification is published on our product, and only a few standards are harmonized according to Regulation 2017/745.

The list of harmonized standards applied is as follows for this device:

Number	Year	Title of standard
EN ISO 11137-1 + A2 (2018)	2015	Sterilization of health care products - Radiation - Part 1: requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 13485 + A11 (2021)	2016	Medical devices, Quality management systems, Requirements for regulatory purposes
EN ISO 14971 + A11 (2021)	2019	Medical devices - Applications of risk management to medical devices
EN ISO 11737-1 + A1 (2021)	2018	Sterilization of medical devices - Microbiological methods Part 1: Determination of the population of microorganisms on products
EN ISO 10993-9	2020	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
EN ISO 11737-2	2020	Sterilization of medical devices - Microbiological methods - Part 2 : tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation
EN ISO 15223-1	2021	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization

IX. Bibliography

Bahammam, M. A. (2016, Nov 30). Effectiveness of bovine-derived xenograft versus bioactive glass with periodontally accelerated osteogenic orthodontics in adults: a randomized, controlled clinical trial. BMC Oral Health, 16(1), 126.

Carrotte, D, B Burt-Pichat, S Rizzo, and G Boivin. " Sinusal bone augmentation using bioactive glass and bone flap repositioning. JPIO, 2020. 39: 1-15

El-Hawary, H., & Shawky, M. (2021). Assessment Of The Sticky Bone Preparation Of BioActive bone Glass in Grafting Critical-Sized Surgical Bony Defects. Egyptian Dental Journal, 67(3), 1899-1908.