Inion BioRestore™ / Inion BioRestore™ Plus

Summary of Safety and Clinical Performance (SSCP)

For patients

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Inion BioRestore™ / Inion BioRestore™ Plus

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or laypersons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP 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

1.1. Device trade name(s)

Inion BioRestore™ / Inion BioRestore™ Plus
Additional trade names: Inion CPS BioRestore™, Inion OTPS BioRestore™, Inion GTR BioRestore™

1.2. General description of the system

The **Inion BioRestore™ / Inion BioRestore™ Plus** implants are made of bioabsorbable and bioactive glass. They are intended to fill bone defects and provide a matrix for new bone formation while the implant degrades. The new bone formation is achieved by the bone growth supporting and stimulating (i.e. osteoconductive and osteostimulative) properties of the porous bioactive material.

The devices do not remain in the body permanently, as most of the material remodels into bone and degrades in six months.

The implants are available in granular form and solid shapes of different sizes. They are not intended to carry load.

Inion BioRestore™ Plus implants have slightly higher density than **Inion BioRestore™** implants, which improves their handling and shaping properties during implant preparation. All solid-shaped implants may be cut or shaped to fit the anatomy of the surgical site.

1.3. Manufacturer; name and address

Inion Oy
Lääkärinkatu 2
FI-33520 Tampere
FINLAND

1.4. Basic UDI-DI

6438408INIONBIORESTORERQ

1.5. Year when the device was first CE-marked

- **2007** Initial CE marking for **Inion BioRestore™** implants.
- **2009** Addition of **Inion BioRestore™ Plus** implants.
- **2020** Addition of **Inion BioRestore™** Morsels in syringe and new package sizes.

2. Intended use of the device

2.1. Intended purpose

The **Inion BioRestore™ / Inion BioRestore™ Plus** is a bioactive, absorbable, synthetic bone graft substitute. The devices are intended for filling, restoration, and/or augmentation of bony voids or gaps by new bone formation, which is achieved by the osteoconductive and osteostimulative properties of the porous bioactive material.

The **Inion BioRestore™ / Inion BioRestore™ Plus** is used either separately or in conjunction with autogenous (patient's own) bone or allograft bone (bone of another person).

2.2. Indications and intended patient groups

Indications for use:

The **Inion BioRestore™** morsels are indicated to be gently pressed into bony voids or gaps of the skeletal system, to fill, restore, and/or augment

- mandibular or maxillofacial bone defects (i.e., jaw/face), and
- defects in the extremities, spine and pelvis.

The **Inion BioRestore™ / Inion BioRestore™ Plus** block-shaped implants are indicated to be gently pressed into bony voids or gaps of the skeletal system, to fill and/or restore

- defects in the extremities.

These osseous defects may be surgically created or resulting from traumatic injury to the bone.

Intended patient groups:

The target patient population for all **Inion BioRestore™ / Inion BioRestore™ Plus** devices consists of adult patients, who require bone grafting surgery and who are not contraindicated.

2.3. Contraindications

- Defects that are intrinsic to the stability of the bony structure.
- Active or potential infection.
- Patient conditions including:
  1. Use of medication known to affect the skeleton (e.g., chronic glucocorticoid usage >10 mg/day for the previous 3 months). Estrogen replacement therapy is allowed.
  2. Need for chronic anticoagulant therapy (e.g., heparin). Prophylactic use of Coumadin or aspirin postoperatively is allowed.
  3. A systemic metabolic disorder known to adversely affect bone healing and mineralization (e.g., poorly controlled insulin-dependent diabetes, renal osteodystrophy, Paget's disease), other than primary osteoporosis.
  4. Any existing condition or disease that will interfere with good soft tissue and bone healing.
  5. Defects requiring graft material to exceed the volume of 30 cm^3.
  6. Limited blood supply.
  7. When patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse).
  8. Patients with known allergy to the implant constituents or its degradation products.

3. Device description

3.1. Device description and material/substances in contact with patient tissues

The **Inion BioRestore™ / Inion BioRestore™ Plus** implants are made of bioabsorbable and bioactive glass.

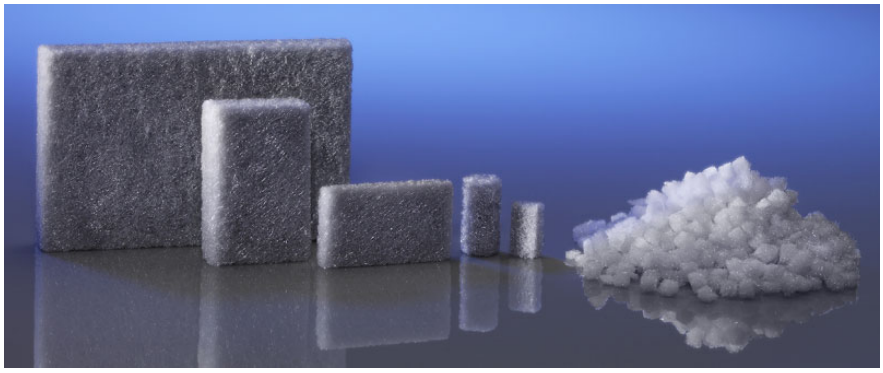
Maximum of 39 grams of the implanted material can be implanted in a patient. The amount of each material constituent in that case is: SiO_2 (Quartz sand) 19.7 g, K_2O

(Potassium oxide) 6.3 g, CaO (Calcium oxide) 5.3 g, Na_2O (Sodium oxide) 4.3 g, P_2O_5 (Phosphorous pentoxide) 1.2 g, MgO (Magnesium oxide) 1.2 g, B_2O_3 (Diboron Trioxide) 0.5 g, and TiO_2 (Titanium (IV) oxide) 0.1 g.

Evidence demonstrates the material safety of this bioabsorbable and bioactive glass composition. The mechanical strength and degradation characteristics of these implants are sufficient and appropriate for packing into bony voids or gaps of the skeletal system to fill, restore, and/or augment bony defects.

Exemplary images of the implants are presented in Figure 1 below.

Figure 1. Exemplary images of the implants.



3.2. Information about medicinal substances in the device, if any

None.

3.3. Description of how the device is achieving its intended mode of action

Bioactive glasses have a long history of safe medical use. They undergo a time-dependent, kinetic modification of the surface that occurs when implanted in living tissue. Specifically, the surface reaction results in the formation of a Calcium phosphate layer that is similar in composition and structure to the hydroxyapatite found in natural bone mineral. This layer provides scaffolding onto which the patient's new bone will grow allowing complete repair of the defect.

Based on preclinical testing and clinical data of **Inion BioRestore™ / Inion BioRestore™ Plus**, most of the material remodels into bone and degrades *in vivo* in six months.

3.4. Description of accessories, if any

None.

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use, or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1. How potential risks have been controlled or managed

Only professional surgeons use the **Inion BioRestore™ / Inion BioRestore™ Plus** devices. The surgeon should be familiar with bone grafting and internal/external fixation techniques, the devices, the method of application and the surgical procedure prior to performing the surgery.

The surgeon is informed of residual risks and undesirable side effects in the *Instructions for Use*, which is accompanying each product package and available on the Inion website.

4.2. Remaining risks and undesirable effects

Remaining risks and undesirable side effects with potential harm to the patient are similar to autogenous bone grafting procedures:

- Implantation of foreign materials can result in an inflammatory response or allergic reaction.
- Incorrect selection, placement or positioning of the implant can cause subsequent undesirable results (e.g. delayed bone formation, mechanical irritation), or breakage of implants.
- Implant can break or loosen as a result of early stress, activity or load bearing.
- Infections attributed to the surgical procedure, such as superficial wound infection, deep wound infection, and deep wound infection with osteomyelitis.
- Neurovascular injuries that can occur due to surgical trauma.
- Thin soft tissue coverage over the implant or use in areas where the graft cannot be adequately contained (to prevent motion and migration of the material) may increase the risk of complications.
- Other complications that may arise as a result of surgery may include: delayed bone formation, failure of restoration, loss of bone graft, graft protrusion and/or dislodgement, pain, swelling, and general complications that may arise from anesthesia and/or surgery.

Residual risks related to the insertion of the implants that may cause inconvenience for the user:

- Incorrect selection, placement or positioning of the implant can cause subsequent undesirable results (e.g. delayed bone formation, mechanical irritation), or breakage of implants.

Special patient populations

- There are no data from the use of the **Inion BioRestore™ / Inion BioRestore™ Plus** in pregnant women.

4.3. Warnings and precautions

All warnings in the *Instructions for Use* are directed to the surgical team and do not have relevance to the patient pre-or postoperatively. The warnings are listed in the electronic *Instructions for Use* placed on the website.

Precautions with relevance to the patient pre- or postoperatively are listed below. Some precautions are directed to the surgical team. All Precautions are listed in the electronic *Instructions for Use* placed on the website.

- The patient must not place mechanical load on the operated area for at least 5–6 months after the operation when implanted with **Inion BioRestore ™ / Inion BioRestore™ Plus.** Early weight-bearing, stress or activity can break or loosen the **Inion BioRestore™ / Inion BioRestore™ Plus** bone filler implants.
- Thin soft tissue coverage over the implant, or use in areas where the graft cannot be adequately contained (to prevent motion and migration of the material) may increase the risk of complications.

4.4. Summary of any field safety corrective action, if applicable

No field safety corrective actions (recalls) have been conducted for the **Inion BioRestore™ / Inion BioRestore™ Plus** since the original CE certification in 2007.

5. Summary of clinical evaluation and post-market clinical follow-up

5.1. Clinical background of the device

The first **Inion BioRestore™** products were CE-marked initially in 2007. Since then, the device has been sold in Europe, USA, and numerous other countries worldwide, with no significant changes in the product design. The long-term post-market data demonstrate

the clinical safety and performance of the device. After launching into market, approximately 36 200 surgical operations have been conducted with these implants during 2007–2022.

Bioactive glasses have a long history of safe medical use. No new or innovative materials, processes, assemblies or techniques are associated with the design, manufacture or surgical use of the **Inion BioRestore™ / Inion BioRestore™ Plus** bone graft substitute.

5.2. Clinical evidence for the CE-marking

The **Inion BioRestore™ / Inion BioRestore™ Plus** has been used in investigator-driven clinical studies, and scientific articles have been published in medical journals presenting the results of these studies. In addition, one clinical study and six post-market clinical follow-up studies have been performed for the **Inion BioRestore™ / Inion BioRestore™ Plus** after the initial CE certification.

The clinical data available for the **Inion BioRestore™ / Inion BioRestore™ Plus** demonstrates the products' performance and safety within their intended use. Consequently, performance and safety data is available for the relevant applications and patient populations. The nature, severity and frequency of adverse device effects are within the ranges published for similar products.

5.3. Product Safety and Performance

The use of the **Inion BioRestore™ / Inion BioRestore™ Plus** in the claimed indications is considered to be safe when the *Instructions for Use* are followed. In addition, performance and safety of the Inion BioRestore™ have been confirmed by clinical use and post-marketing experience. There have been no relevant safety issues.

The Table 1 on the next page presents a summary of the clinical data and reported clinical outcomes. The data is from clinical studies and publications with **Inion BioRestore™ / Inion BioRestore™ Plus**.

Table 1. Summary of the clinical data and reported clinical outcomes with Inion BioRestore™ / Inion BioRestore™ Plus.

Intended use and indications:	The **Inion BioRestore™ / Inion BioRestore™ Plus** is a bioactive, absorbable, synthetic bone graft substitute intended for filling, restoration, and/or augmentation of bony voids or gaps by new bone formation, which is achieved by the osteoconductive and osteostimulative properties of the porous bioactive material. The **Inion BioRestore™ / Inion BioRestore™ Plus** is used either separately or in conjunction with autogenous or allograft bone.
	The **Inion BioRestore™** (Inion CPS BioRestore ™, Inion GTR BioRestore ™, and Inion OTPS BioRestore ™) morsels are indicated to be gently pressed into bony voids or gaps of the skeletal system, to fill, restore, and/or augment mandibular or maxillofacial bone defects and defects in the extremities, spine and pelvis. The osseous defects may be surgically created or resulting from traumatic injury to the bone. The **Inion BioRestore ™ / Inion BioRestore ™ Plus** block-shaped implants are indicated to be gently pressed into bony voids or gaps of the skeletal system, to fill and/or restore defects in the extremities. The osseous defects may be surgically created or resulting from traumatic injury to the bone.
Performance reported:	100% bone healing at the end of follow-up. *(number of fusion cases per total cases *100%)*
Benefits:	Healing of patient's bone after grafting with bioabsorbable, bioactive implant. No bone harvest due to synthetic material. Sterile, antimicrobial, well-tolerated material.
Risks/Safety reported:	0% complications reported related to **Inion BioRestore™ / Inion BioRestore™ Plus** by the end of the follow-up. *(number of complication cases per total cases *100%)*
	0% delayed/ non-union cases reported related to **Inion BioRestore™ / Inion BioRestore™ Plus** by the end of the follow-up. *(number of delayed/ non-union cases per total cases *100%)*
	0% wound/incision healing issues reported related to **Inion BioRestore™ / Inion BioRestore™ Plus** by the end of the follow-up. *(number of unsuccessful wound/ incision healing cases per total cases *100%)*

The data collected from sales information and complaints supports the data presented in Table 1 above: the overall and individual complication rates since the launch of the product line are 0.00%.

The data shows evidence of a clearly positive benefit/risk profile, with results of complete bone healing without complications, as reported to Inion, identified from clinical studies, or from published literature.

There is no data from the clinical use of the **Inion BioRestore™ / Inion BioRestore™ Plus** in pregnant women. The post market data collected does not indicate any specific patient populations, or areas of indications, which would have specific complications or a different benefit/risk profile.

To ensure patient safety, Inion continuously and systematically collects and analyzes information in the post-market phase from **Inion BioRestore™ / Inion BioRestore™ Plus** devices, and from similar devices. Both proactive protocols and methods, as well as complaints and market-related experience are used as source data to assess potential new risks, benefits, and to observe trends in the collected data.

The product has been unchanged in the market for a long time and the long-term post-market data demonstrate the clinical safety and performance of the device. However, in order to gain additional clinical data for these product items, two post-market clinical follow-up studies on **Inion BioRestore™ / Inion BioRestore™ Plus** products are being conducted.

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

The materials used to replace bone defects have evolved throughout history. Suitable bone graft materials include for example biological, such as autografts and allografts; synthetic graft materials, such as ceramic-based grafts and bioactive glasses; and growth factor based grafts.

Autografts are considered the “gold standard” in bone grafting. The other common graft types are allografts, and synthetic bone graft substitutes.

Examples of biological and synthetic graft devices categorized based on the graft type are shown in Table 2 below.

Table 2. Examples of biological and synthetic graft devices categorized based on the graft type.

CATEGORY	DESCRIPTION
Autografts	Bony material from the patient.
Allograft-based	Bony materials and cartilage from other humans. Allograft bone used alone or in combination with other materials.
Xenograft-based	Bony materials from animals. Used alone or in combination with other materials (bovine bone, porcine bone, and corals).
Factor-based	Natural and recombinant growth factors used alone or in combination with other materials.
Ceramic-based	Includes calcium sulfate, calcium phosphate, and bioactive glass alone or in combination.
Polymer-based	Both degradable and non-degradable polymers used alone and in combination with other materials.
Composites	Combination of two or more different materials (e.g. polymer/ceramics) for the desired application.

7. Suggested training for users

Only professional surgeons use the **Inion BioRestore™ / Inion BioRestore™ Plus** devices. Users should be familiar with the devices, their special nature (biodegradable), the method of application and the surgical procedure prior to performing the surgery.