FISIOGRAFT nanoH.A.-reinforced

FISIOGRAFT nanoH.A.-reinforced is a device composed of a granulate inserted into a syringe, permitting it to be applied directly into the bone defect. The granules are made of a composite material composed of nanohydroxyapatite-dextran using a mixture of Polylactic/Polyglycolic copolymer and polyethyleneglycol as a carrier. All the materials listed have been used for many years in space maintainers destined for guided regeneration of bone tissue.
These devices are used for the regeneration of periodontal bone defects, implants, post-extraction sites and for bone lesions remaining after dental and maxillofacial surgery.
The peculiarity of **FISIOGRAFT nanoH.A.-reinforced** is that it is made of a substance; that permits blood originating from cortical bone which is a progenitor for new bone tissue, to permeate it at the application site, that is easily applied into a bone defect where it is necessary to develop new bone: the formulation in granules permits blood to penetrate everywhere.
The components of **FISIOGRAFT nanoH.A.-reinforced**

- A part of it is absorbed and leave space for new bone: the Polylactic/Polyglycolic copolymer are metabolized by hydrolysis and is degraded in time, the dextran and polyethyleneglycol are removed from the site by organic fluids
- A part of it is not absorbed, these become nuclei for ossification for the deposit of hydroxyapatite produced by the osteoblasts: in fact, the nanometric hydroxyapatite for its dimensional and chemical/physical characteristics, remain at the site and constitute an aggregation point for the hydroxyapatite produced by the osteoblasts, until they are totally incorporated in the new bone.

Invasive surgical type Medical Device in contact with submucosal and intraosseous tissues utilized in dental and maxillofacial surgery.
Bone filling material based on nanohydroxyapatite and a copolymer of PLA/PGA. CE 0426

Presentation	Single use packaging sterilized by gamma radiation
Form	2 syringes
Unit weight	1000 mg
Unit Volume	1 ml
Composition	*Copolymers and homopolymers of lactic and glycolic acid; Dextran; Nanohydroxyapatite; PEG*

Warning: Product must not be re-sterilized. If the sticker on the inner package, which indicates that the product is sterile is NOT red, DO NOT use the product. If any irregularities are noticed with the packaging, isolate the non-conforming product and dispose of it as "special waste". If the Safety Thermal Test on the box is dark gray in color, DO NOT USE the product.
Any material that is not used and remains in the syringe must be disposed of after the treatment in order to avoid the risk of cross contamination due to use with other patients.
As cited in the European Directive 93/42 and subsequent amendments the dentist is responsible for guaranteeing the traceability of the product, to be more precise, he must be able to trace back to the patient into which the product was implanted. It is recommended to attach the label of the product to the patient's clinical chart.

Contraindications: In general the use of FISIOGRAFT nanoH.A.-reinforced does not present any specific contraindications, except for individual intolerances in patients which have presented specific sensitivity towards the components. In general, all the contraindications typical for oral and maxillofacial surgery remain valid. The use of **FISIOGRAFT nanoH.A.-reinforced** is therefore contraindicated in cases when there is an acute or chronic infection at the surgical site, if the patient is being treated with immunosuppressive drugs or in immunodepressed patients. The product is not intended for use in babies, pregnant women and/or women who are breastfeeding.

Collateral effects: it can cause, in particularly predisposed subjects, edema at the implant site.

Note for conservation: - DO NOT USE FISIOGRAFT nanoH.A.-reinforced after the expiration date indicated on the package. Conserve the original packaging. Even if it is not necessary, is preferable to conserve the product in the refrigerator; in this case prior to use, the temperature of the product should be brought to room temperature. DO NOT FREEZE.

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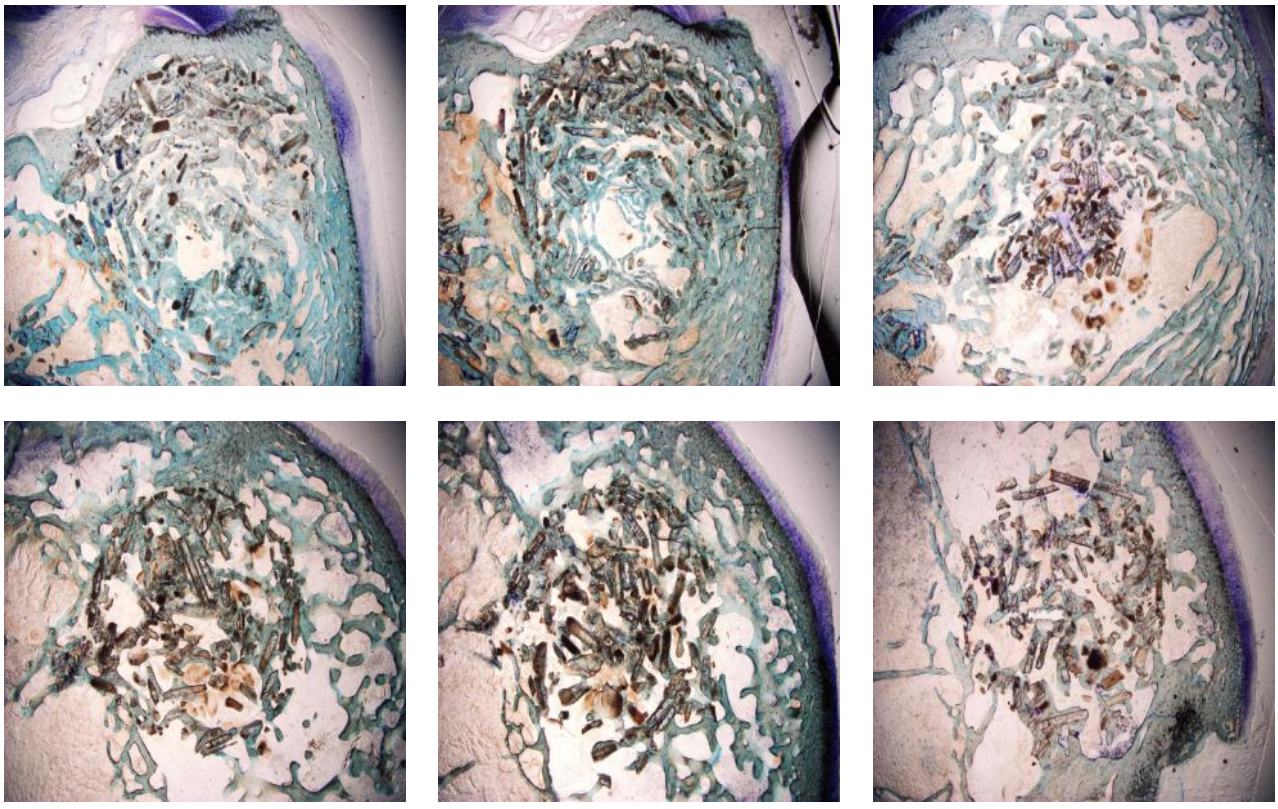
 Instructions for use drafted on: 31/07/2015

FISIOGRAFT nanoH.A.-reinforced (nanohydroxyapatite in granules conveyed in gel) takes advantage of the characteristics of other Ghimas products which have already been certified and utilized for many years.
Hydroxyapatite, thanks to its chemical affinity and cristallografic properties with the inorganic components that make up bone, is capable of establishing chemical bonds and to guarantee a more rapid integration of implants with bone and the surrounding tissues. Many studies have evidenced the role performed by hydroxyapatite in favoring the osteointegration process of the implant, with or without other polymeric space maintainers.

Some research shows that hydroxyapatite, unlike tricalcium phosphate, is not absorbed. Other authors have found that the hydroxyapatite is absorbed.
The nanohydroxyapatite present in **FISIOGRAFT nanoH.A.-reinforced,** synthesized according to a unique technique developed by Ghimas with a granulometry between 70 and 100 nanometers, it presents structural, dimensional and biofunctional characteristics, which replicate that of the natural hydroxyapatite present in the dentine, cementum and bone.

This non-absorbable biomimetic nanohydroxyapatite binds with the components of the bone tissue, facilitating the deposition of the hydroxyapatite formed by the osteogenetic cells. From the biocompatibility studies, the nano-hydroxyapatite utilized as a space maintainer are less flogogenic than normal hydroxyapatite and induce a major production of bone alkaline phosphatase and osteocalcine, both of which are indicators of increased production of bone.
In addition, histomorphological studies document, the peculiar property of promoting cellular differentiation to form new bone and to orient it more rapidly towards a trabecular structure.



Critical size defects in trabecular bone of the distal femur of a rabbit (diameter 6 mm - profundity 10 mm) 12 weeks after positioning the nano-hydroxyapatite.

Bioabsorbable synthetic polymers such as Polylactic acid and Polyglycolic acid, available in various concentrations, have for many years, proven to be the most reliable components of numerous medical devices in the fields of dental, maxillofacial and orthopedic surgery in the forms of bone plates, synthetic pins and screws, sutures, and shaped blades for maxillofacial applications. Unlike products used in orthopedic and maxillofacial surgery, which require a high degree of mechanical resistance, in the field of dental surgery these polylactic/polyglycolic copolymers can have a low density since they must only function as a space maintainer. It is precisely for their low density which guarantees a total absorption time ranging from 4 to 8 months, which is in relation to the quantity of the material implanted, the reactivity of the patient and the level of blood circulation at the implant site. The final by-products resulting from the metabolism of these polymers are carbon dioxide and water.

Dextran is utilized as a binder to generate the granules of nano-hydroxyapatite. These are dispersed in a gel composed of a mixture of polyethyleneglycol, which has been used for many years as a coformulant in other space maintainers.
The granules of nano-hydroxyapatite and dextran have been smoothened in order to eliminate any sharp corners which result after crushing, then they are sifted to obtain a dimension between 250 e 1000 micron.
The study of the behavior of the granulate in terms of stability in an aqueous medium has shown that the dextran and copolymer Polylactic-polyglycolic/glycol coating prevents the release of the nano-hydroxyapatite for at least six weeks. The polymeric components which encapsulate and protect the inorganic granules, prevent it from flaking.
In this way, blood which originates from surrounding bone tissue can organize itself into a stabile coagulum inside of the filler, allowing for a harmonic growth of new bone with regards to the needs of the site.

• How to prepare the application site

The receiving bone site must first be perfectly clean, without any contaminant materials such as tartar, granulation tissues and portions of very thin bone which, if not properly vascularized, can become necrotic: therefore it is very important to use curettes, rotary instruments at low RPM's and possibly even bone forceps of an appropriate size to clean the receiving site in the bestpossible way. At the end of the treatment, the bone cavity must be clean and the walls sufficiently thick without any roughness; any exposed roots must be completely decontaminated and polished: for this an etching solution such as supersaturated solution of citric acid can be used on the root. If there appears to be little bleeding at the site, after it has been cleaned, use a round bur to curettage the walls which will increase the presence of medullar blood rich with osteoblastic cells.

How to apply:

Surgical procedure for the therapy of intrabony defects

1. Local anesthesia
2. intrasulcular incision with releasing incisions in order to expose the defect
3. Reflect a full thickness flap
4. Fill the defect with **FISIOGRAFT nanoH.A.-reinforced, compact the granules without using excessive force**
5. Reposition the flap using interrupted stitches that will be removed after 10 days.

Surgical procedure for raising the floor of the maxillary sinus

1. Local anesthesia
2. Implementation of a mucoperiosteal flap by means of a palatal paracrestal incision with 2 two releasing incisions, reflection of the full thickness flap
3. Perform an osteotomy on the lateral wall of the Higmoro antrum, inscribing a window with an elliptical shape
4. With the window open, reflect the membrane
5. Create sufficient space and fill with **Fisiograft nanoH.A.-reinforced**, compact the granules without using excessive force (generally 2-3 syringes of product are necessary)
6. When the filling is completed, cover the open window an absorbable membrane
7. Sutire the flap
8. At 10 days post-op remove the sutures

• How to perform a correct postoperative recovery

After surgery the patient must be warned about the possible appearance of various degrees of swelling and tenderness, generally in proportion to the severity and extensiveness of the surgery. Generally the treatments are limited to the use of a Chlorhexidine based mouth rinse, initially at 0,2% for the first week, followed by 0,12% three times per day substituting daily brushing, which is prohibited for the first 7/10 days at the surgical site. Only if necessary should analgesics and anti-inflammatory medications be administered, while antibiotics should not be prescribed as a routine therapy, except in cases when a membrane is used or when the surgeon feels it is necessary. Between the seventh and tenth day the sutures may be removed afterwards the patient can resume using a soft toothbrush. A follow-up of the progress of the regeneration can be made at a later date but is at the discretion of the surgeon. However is recommended that a radiograph 6-8 months postoperative be taken, this is considered sufficient time for a complete regeneration to take place and an addition follow-up of the patient is also recommended at 12 and 18 months.