FISIOGRAFT SPONGE – POWDER – GEL

The use of PLA-PGA copolymers in dentistry:
Synthetic bioabsorbable polymers such as polylactic acid and polyglycolic acid used in various proportions, have been for many years, the most reliable components of numerous medical devices in the fields of dental, maxillofacial and orthopedic surgery, in the forms of, synthetic; bone plates pins and screws, surgical sutures and shaped blades for maxillofacial applications. Unlike products used in orthopedic and maxillofacial surgery which have a high mechanical resistance, in the field of dental surgery these polylactic/polyglycolic copolymers can have a low density because they must only function as a space maintainer and precisely for its low density, guarantees a total absorption time ranging from 4 to 8 months, depending upon 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.
The principal use of **FISIOGRAFT** is to function as an absorbable biocompatible space maintainer, allowing blood to permeate through it and stabilizing the blood coagulum which is progressively substituted by osteoprogenitor cells, up until the formation of new bone. The spongy structure of **FISIOGRAFT does not create an obstacle to the advancement of the osteons which are absorbed in a physiological manner, favoring their solidification into bone tissue**. From various histological tests, which were also reconfirmed by SEM (Scanning Electron Microscopy), neither short nor long term undesirable tissue reactions were observed. All the subsequent biocompatibility studies, first in animals then in man, document that **FISIOGRAFT is extremely** biocompatible.
FISIOGRAFT is available in three different forms, **SPONGE**, **POWDER** and **GEL**. The three different forms make **FISIOGRAFT** easier to use, both in relation to the type of surgical operation as well as in relation to the implant site because each type can be used singularly or combined with any of the other forms

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

CE 0426

FISIOGRAFT	SPONGE	POWDER	GEL
Presentation	Packed in single doses sterilized by gamma radiation		
Packaging	1-5 pieces	1-5 pieces	1-5 syringes
Unit weight	220 mg	500 mg	500 mg
Unit volume	aprox. 0, 86 ml	aprox. 2 ml	0,5 ml
Composition	*Polylactic/Polyglycolic copolymer; Dextran*	*Polylactic/Polyglycolic copolymer; Dextran*	*Copolymers and homopolymers of Lactic and Glycolic Acid; PEG*

Warning: Product must not be resterilized. *If the sticker on the inner package, which indicates that the product is sterile, is NOT red, DO NOT use the product. Should there be any irregularities 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. 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 he implanted the product.It is recommended to attach the label of the product to the patient's clinical chart. Any unused material remaining in the syringe or in the vial must be properly deposed of after the treatment in order to avoid the risk of cross contamination if used on other patients.*

Contraindications: In general the use of FISIOGRAFT does not present generic 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** 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 after the expiration date indicated on the package.
Conserve the original packaging. Even if is not necessary, it 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.

General methods of use

FISIOGRAFT is a product formulated and based on a Polylactic/Polyglycolic copolymer available in 3 original forms, it is easy and safe to use, destined for the filling of bone cavities, natural or pathologic, which necessitate the regenerate of new bone.

In the study published in "Implantologia Orale (2003; 4:77-80)", entitled *"Biomaterials utilized in bone regeneration: histological results"*, the quantity of mineralized bone, the amount of medullary spaces and the quantity of residual material were taken into consideration once regenerated bone was obtained, 6-8 months after the various space-maintainers had been grafted.
The data expressed in the chart below, indicates that all the biomaterials utilized did produce new bone formation, but **FISIOGRAFT** was shown to be the most absorbable material.
This study was also presented at the Congress of the American Academy of Osseointegration, that took place in March of 2004 San Francisco, the **poster was awarded 1° Prize.**

	Newly formed bone	**Medullary spaces**	**Residual material**
BIOCORAL	42%	40%	18%
BIO-OSS	39%	34%	27%
BIOGLASS	40%	43%	17%
DFDBA	29%	37%	34%
FISIOGRAFT	**43%**	**56%**	**1%**
HYDROXYAPATITE	41%	30%	31%
AUTOLOGOUS BONE	42%	40%	18%
PEP-GEN P-15	40%	37%	23%
CALCIUM SULFATE	48%	39%	13%

The histological results confirm that **FISIOGRAFT** has the characteristic of being the "**ideal space maintainer**".
Its centripetal and progressive erosion, up until when it is totally degraded, permits bone tissue to regenerate without any outside interference with the physiologic repair process.

In the field of dentistry the main areas for the application of **FISIOGRAFT** are surgical extractions, periodontal procedures and implantology. The methodology for the use of the three types of **FISIOGRAFT** which are commercially available can be performed using similar procedures which can easily be summarized as follows:

• 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 best possible 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 fill the site

A general rule is to completely fill the site up to the coronal borders of the cavity.

FISIOGRAFT is available in three different forms which can be used in various situations either singularly or combined together to optimize the filling.

The SPONGE type is generally cut into fragments using sterile scissors or a scalpel to approximate its dimensions with those of the receiving site. The criterion is to next take fragments of the Sponge and lightly pack them using a cylindrical compactor or a ball until the filling is complete.

From the moment the SPONGE type is saturated with liquid, for example blood, it loses its initial consistency and becomes much more malleable. It is important to compact the Sponge after it has been completely the complete hydrated. In cases when there is an abnormal scarcity of blood at the receiving site, it is helpful to wet the SPONGE with a few drops of sterile saline solution.

The POWDER type is applied to the receiving site with a spatula or with a periosteal elevator. The imbibition of the POWDER with blood renders it more cohesive. Due to the characteristic of its form, it is not possible to compact, the POWDER type is used in simple cavities without any crevices and relatively small in size.

The POWDER type can also be mixed with the GEL type which will produce a much denser mixture and also makes it easier to place into the receiving site.

The *GEL* type is supplied in a syringe from which the product can be extruded directly into the receiving site. As with the SPONGE type it is a good rule, above all in cases with deep and complex defects, to subdivide the filling process into several steps. After each additional layer the GEL type, being soaked with blood, results more dense and if necessary, the density can be increased even further by mixing it with the POWDER type: in this way the most optimal compactness for **FISIOGRAFT** can be obtained more effectively and simply.

• How to cover the filled site

Covering the application site of **FISIOGRAFT**, once it has been filled, depends strictly upon the type of procedure that was

performed and the choice of the doctor. The possibilities can be summarized as follows:

a) Uncovered site: the material is exposed to the oral environment and therefore only the sutures that are placed over it, keeps it in position. It is preferable NOT to pull the sutures tight, eventually leaving part of the **FISIOGRAFT** uncovered because the product cannot be attacked by bacteria, if the patient follows a correct and frequent oral hygiene with a 0,2% Chlorhexidine mouth rinse.

b) Site covered with a gingival flap: in this case the muco-gingival flaps are positioned directly over the grafted material until a closure by primary intention is obtained. This procedure may require the careful execution of periosteal release incisions.

c) Site covered with a membrane: in this case it is interposed between the **FISIOGRAFT** (SPONGE. POWDER and/or GEL) and the flap which must close by primary intention (see preceding paragraph), a membrane provides mechanical separation between the grafted area (which is undergoing the regeneration process) and the neighboring epithelial and connective tissues, according to the principals of guided tissue regeneration (GTR).
For this purpose one may use a non-absorbable membrane, which however must be removed in due time, or else an absorbable one which does not require a surgical reentry for its removal. This last type, absorbable, is overwhelmingly preferable because it doesn't require a second surgery for the removal of the membrane itself; this type is favored and made possible thanks to the efficiency of **FISIOGRAFT** which defends and maintains the space under the membrane, preventing a possible collapse of an absorbable type membrane.

• 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.

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The product was designed for use by the dental profession and must be used according to instructions for use only be qualified personnel.
Il producer does not assume any responsibility for damages derived from improper or inadequate use of the product. The person using the product is obligated to personally check the suitability of the product for the use he intends to use it for, above all if they are not indicated in the instructions for use.

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