GUIDOR®

easy-graft

synthetic bone graft substitutes

guiding ORAL REHABILITATION

GUIDOR® *easy-graft*

Soft from the syringe.
Hard in the defect.

GUIDOR® *easy-graft*
The Handling Advantage

Simplifying bone regeneration techniques

In their forward thinking 2003 article, Hämmerle & Jung[1] stated: "Developments in bone augmentation procedures can be related either to simplification of the clinical handling or to influencing of biological processes. To simplify clinical handling, new materials should comprise a matrix with optimal cell ingrowth capacities and good mechanical properties, providing space for tissue regeneration. No membrane and no specific procedures for mechanical fixation should be necessary.

This would reduce the technique sensitivity and increase the predictability of bone augmentation. The use of synthetic materials would result in lower surgical risks and lower morbidity in augmentation procedures and would represent an important step forward in simplifying bone regeneration techniques."…

…with GUIDOR® easy-graft and its easy handling such considerations become reality.

GUIDOR® *easy-graft*
Mouldable from the Syringe, *in situ* Hardening

Principle

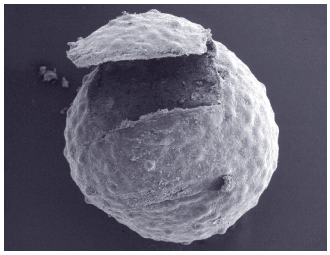


Fig 1
Each granule is pre-coated with a polylactic-co-glycolic acid (PLGA) polymer layer of 10 µm.

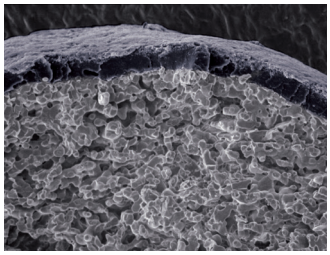


Fig 2

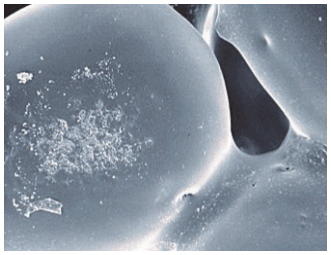


Fig 3
When the supplied BioLinker is added to the syringe contents it softens the polymer coating of the granules creating a sticky yet mouldable mass.

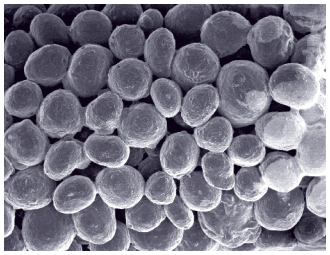


Fig 4

Handling

Fig 1
Add BioLinker in the syringe.

Fig 2
Pulling back the plug of the syringe slightly facilitates the wetting of the granules, as does moving back and forth the plunger and the plug 1-3 times.

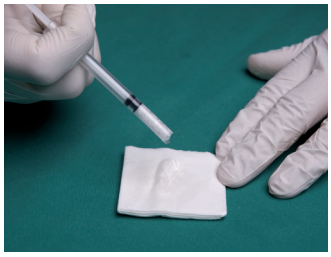


Fig 3
Discard excess of BioLinker.

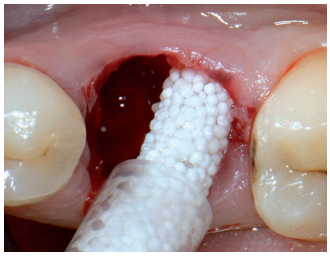


Fig 4
Direct application of the product into the defect.

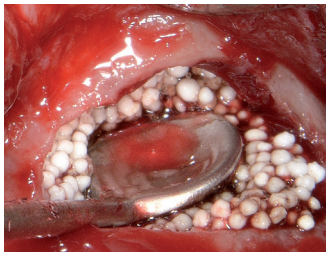


Fig 5
GUIDOR® *easy-graft* granules are pressure-resistant and should be condensed in the defect.

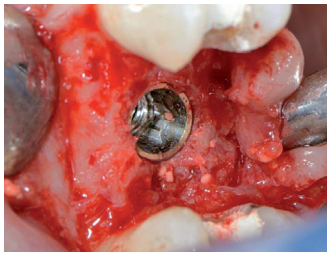
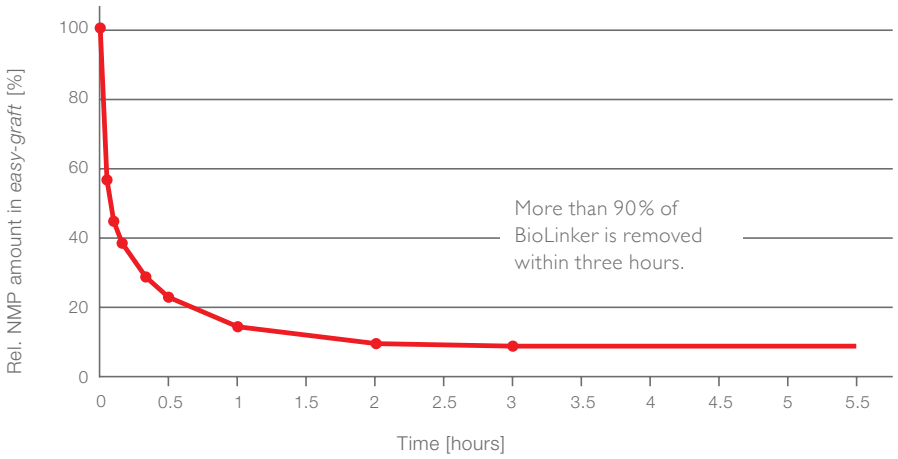
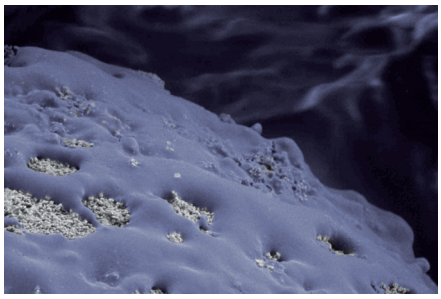


Fig 6
Depending upon time scale, granules embedded on the surface of new bone will be observed. Excess granules can sometimes be seen in the soft tissue and can easily be removed at re-entry if desired.

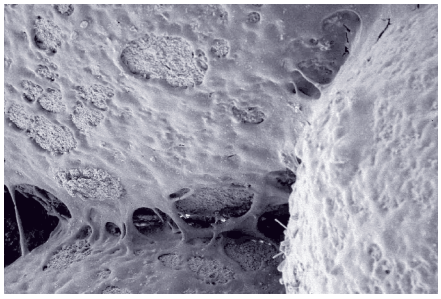
GUIDOR® *easy-graft*
Resorption Process for BioLinker and PLGA Polymer Coating



Stage 1
BioLinker is extracted within hours.
BioLinker is extracted by incoming blood, promoting rehardening of the material. More than 90% of BioLinker is removed from the bone graft substitute within three hours[1] and excreted through the urine within 1-3 days[2]. BioLinker contains N-Methyl-2-pyrrolidone (NMP), a solvent widely used in pharmaceutical and medical devices such as dental membranes, subcutaneous drug-release systems etc.



During resorption
Colored electron microscope image of GUIDOR® *easy-graft* CRYSTAL during resorption. The resorption of the PLGA coating (blue) exposes the biphasic calcium phosphate (white).



Resorption of the PLGA coating
Electron microscope image from an *in vitro* degradation experiment

Stage 2
The PLGA polymer coating is resorbed over a few weeks.
In parallel to the healing and regeneration process, the PLGA coating and adhesive connection between the granules gradually weakens (three to six weeks *in vitro*), exposing the microporous, osteoconductive scaffold.

Resorption of PLGA releases small amounts of lactic and glycolic acid. Lactic acid is degraded by metabolic processes. Glycolic acid can be degraded in the body or be excreted with the urine.

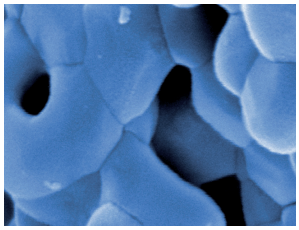
PLGA polymers are widely used in devices such as membranes, screws and plates for maxillofacial surgery, suture anchors, and cages for spinal surgery.

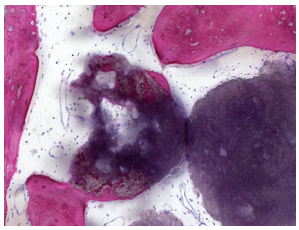
Choosing between GUIDOR® bone graft substitutes

GUIDOR® Synthetic Bone Graft Substitutes
Resorption and Porosity Profiles

GUIDOR® bone graft substitutes *easy-graft* are 100 % synthetic, with no elements of animal or human origin. They are biocompatible and osteoconductive. The total porosity of 70% consists of macropores providing space for vascularization and bone regeneration and micropores allowing optimal fluid circulation. Each product also features two distinctly different calcium phosphate forms, offering a choice of resorption profile matched to need: CLASSIC/CLASSIC⁺ and CRYSTAL/CRYSTAL⁺.

CLASSIC/CLASSIC⁺ - 100 % resorbable, more space for new bone

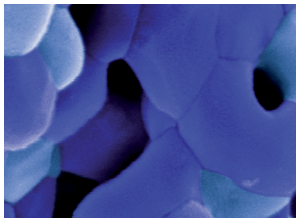


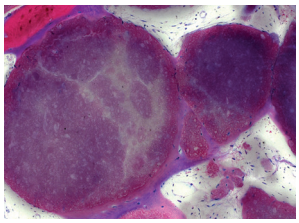


CLASSIC/CLASSIC⁺ consists of a phase-pure ß-TCP. Material resorption and bone regeneration proceed in parallel. CLASSIC/CLASSIC⁺ profile is fully resorbed within 5 to 15 months. In clinical practice, resorption of phase-pure ß-TCP is observed after shorter healing periods. No foreign material remains in the body.

The resorption process can be clearly seen by the irregular shape of the previously spherical *easy-graft* CLASSIC granule.
Human histology, 4 months after *easy-graft* CLASSIC application.
Courtesy Dr. Minas Leventis, Athens, Greece and Dr. Heiner Nagursky, University of Freiburg in Breisgau, Germany.

CRYSTAL/CRYSTAL⁺ - Partially resorbable, integration into bone

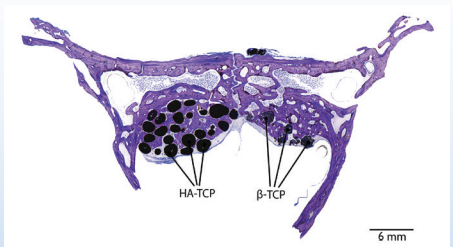




CRYSTAL/CRYSTAL⁺ consists of a biphasic calcium phosphate (BCP) compound formed in the ratio of 60% Hydroxyapatite and 40 % ß-TCP. The BCP serves as a stable scaffold for long-term volume preservation and HA gets embedded into new bone.

easy-graft CRYSTAL granules remain incorporated into newly formed bone.
Human histology, 8 months after *easy-graft* CRYSTAL application.
Courtesy Dr. Antonio Flichy, Valencia, Spain and Dr. Heiner Nagursky, University of Freiburg in Breisgau, Germany.

Comparison between CLASSIC and CRYSTAL



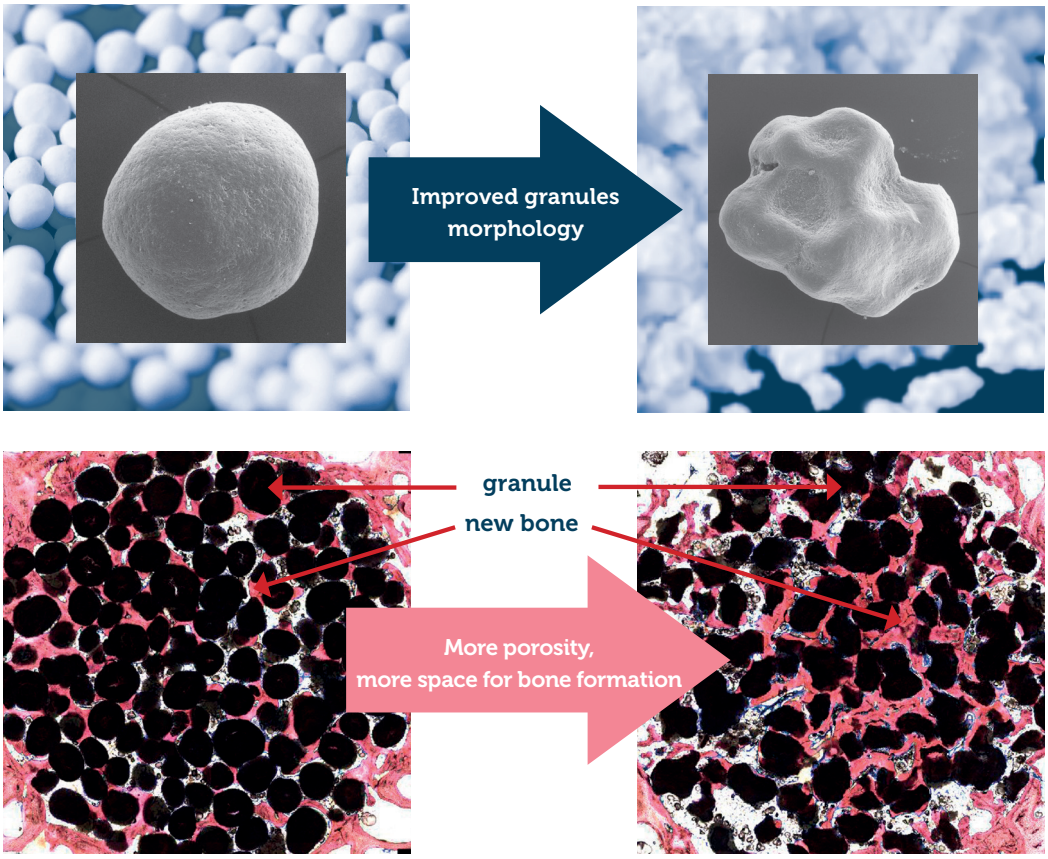
Animal histology, 3 months after *easy-graft* CLASSIC (ß-TCP, right) and *easy-graft* CRYSTAL (BCP, left) application.

An animal study from Valdivia and al[1] shows that both, *easy-graft* CLASSIC/ and *easy-graft* CRYSTAL are able to maintain volume and support the formation of new bone under physiological pressure. Percentage of new bone was higher using *easy-graft* CLASSIC providing more space for bone ingrowth while resorbing. On the other hand, the augmented volume was better preserved and the amount of lamellar bone was increased using *easy-graft* CRYSTAL.

Your choice of sphere shape

easy-graft CLASSIC/CRYSTAL granules

easy-graft CLASSIC⁺/CRYSTAL⁺ granules



Histologies NAMSA – sheep study

Our recommendation between CLASSIC/CLASSIC⁺ and CRYSTAL/CRYSTAL⁺

If timing of implant placement after augmentation is > 6 months, it is recommended to use *easy-graft* CRYSTAL/CRYSTAL⁺ to provide better volume preservation in the meantime.

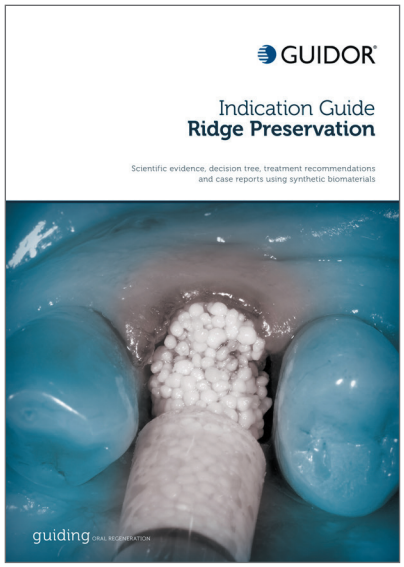
Indications and Guidance

easy-graft CLASSIC/CLASSIC+	*easy-graft* CRYSTAL/CRYSTAL+
***easy-graft* CLASSIC/CLASSIC+ and other ß-TCP materials are documented in:**	**easy-graft CRYSTAL/CRYSTAL+ and other BCP (60% hydroxyapatite / 40% ß-TCP) materials are documented in:**
• Sinus floor elevation [1]	• Sinus floor elevation [6]
• Periodontal defects [2]	• Periodontal defects [7]
• Defects after removal of bone cysts [3]	• Defects after removal of bone cysts [8]
• Augmentation of alveolar crest [4]	• Augmentation of alveolar crest [9]
• Extraction defects [5]	• Extraction defects [10]

Our Indication Guides

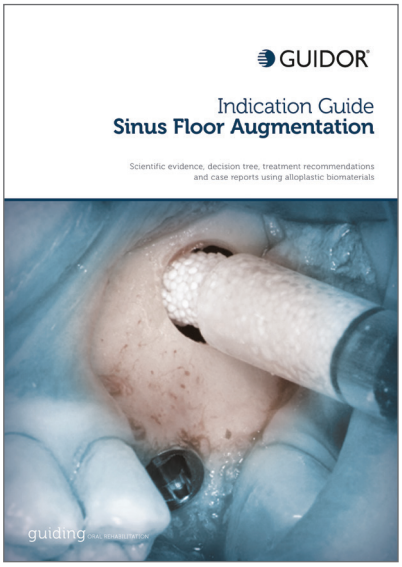
For more detailed recommendations on how to apply our products in a specific indication, please ask for our indication guides.

Ridge Preservation



Peri-implant Augmentation

Sinus Floor Augmentation



Before use, carefully read the instructions for use.
For more information, please contact our local affiliate to receive these indication guides and also check **www.guidor.com**

Product References

Product	**GUIDOR® *easy-graft* CLASSIC**		
Reference no.	CI1-012	CI1-072	CI1-002
Units	3 x 0.15 ml	3 x 0.25 ml	3 x 0.4 ml
Granule size	500 – 630 µm	500 – 1000 µm	500 – 1000 µm
Material	Phase-pure ß-tricalcium phosphate (> 99 %)		

Product	**GUIDOR® *easy-graft* CRYSTAL**		
Reference no.	CI5-012	CI5-072	CI5-002
Units	3 x 0.15 ml	3 x 0.25 ml	3 x 0.4 ml
Granule size	450 – 630 µm	450 – 1000 µm	450 – 1000 µm
Material	Biphasic calcium phosphate (60 % hydroxyapatite / 40 % ß-TCP)		

Product	**GUIDOR® *easy-graft* CLASSIC⁺**		
Reference no.	CI1-112	CI1-172	CI1-102
Units	3 x 0.15 ml	3 x 0.25 ml	3 x 0.4 ml
Granule size	500 – 630 µm	500 – 1000 µm	500 – 1000 µm
Material	Phase-pure ß-tricalcium phosphate (> 99 %)		

Product	**GUIDOR® *easy-graft* CRYSTAL⁺**		
Reference no.	CI5-112	CI5-172	CI5-102
Units	3 x 0.15 ml	3 x 0.25 ml	3 x 0.4 ml
Granule size	450 – 630 µm	450 – 1000 µm	450 – 1000 µm
Material	Biphasic calcium phosphate (60 % hydroxyapatite / 40 % ß-TCP)		

Clinical cases

Dr. Minas Leventis

Indication	Ridge preservation
Patient	Female, 23 years old
Position	Maxillary right second premolar (15)
Material used	GUIDOR® *easy-graft* CLASSIC

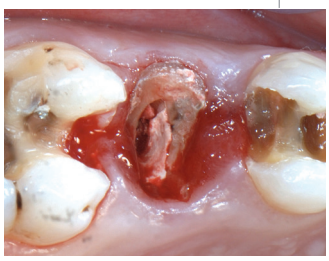


Fig. 1 Maxillary right second premolar (tooth 15) with caries.

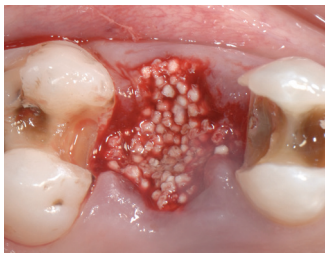


Fig. 2 Ridge preservation with *easy-graft* CLASSIC, after atraumatic extraction.

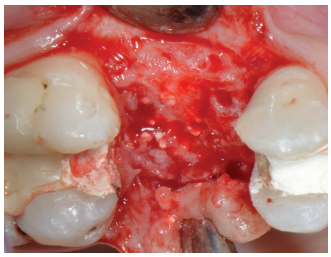


Fig. 3 Situation at re-entry 4 months post-op. *easy-graft* CLASSIC granules are well integrated in new bone.

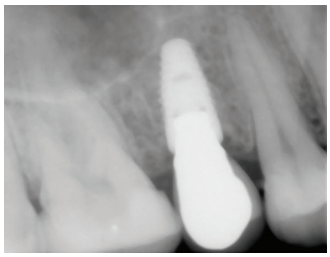


Fig. 4 Final radiograph 16 months post-op.

Dr. Minas Leventis

Indication	Peri-implant bone regeneration, immediate implantation
Patient	Female, 45 years old
Position	Maxillary right central incisor (11)
Material used	GUIDOR® *easy-graft* CRYSTAL

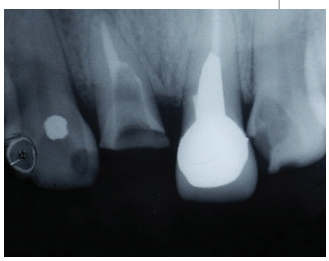


Fig. 1 X-ray of initial situation.

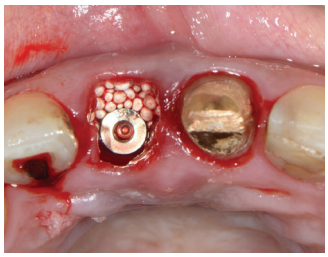


Fig. 2 Immediate implant placement and grafting.

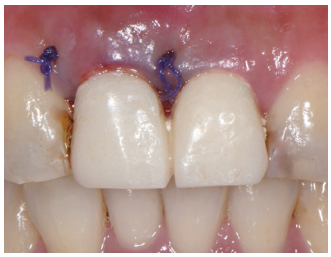


Fig. 3 Immediate provisional restoration.

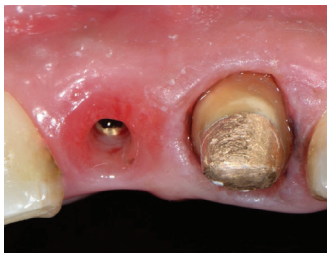


Fig. 4 5 months post-op, excellent preservation of the architecture of the ridge.

Dr. Antonio Flichy-Fernández

Indication	Lateral sinus floor augmentation
Patient	Case series of 20 sinus floor augmentations [1]
Position	Maxillary molar teeth
Material used	GUIDOR® *easy-graft* CRYSTAL, GUIDOR *calc-i-oss* CRYSTAL

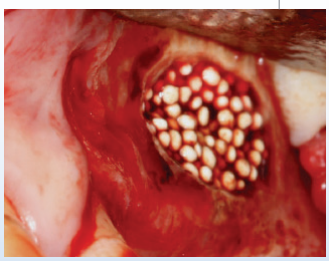


Fig. 1 Lateral sinus floor augmentation with *easy-graft* CRYSTAL.

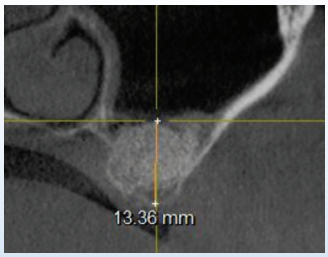


Fig. 2 Control CBCT at 6 months.

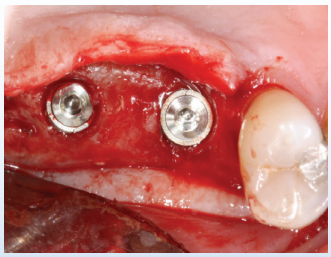


Fig. 3 Implantation at 6 months. (position 16, 17).

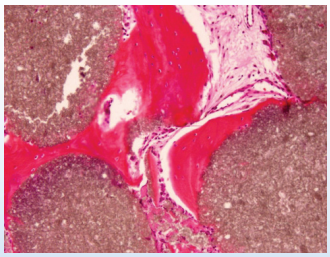


Fig. 4 Histology showing *easy-graft* CRYSTAL embedded in newly formed bone.

Frequently Asked Questions

MATERIAL PROPERTIES

What is the difference between GUIDOR® *easy-graft* CLASSIC *and* GUIDOR® *easy-graft* CRYSTAL?

GUIDOR® *easy-graft* CLASSIC contains phase-pure ß-tricalcium phosphate (ß-TCP) and is resorbed over a period of 5-15 months. GUIDOR® *easy-graft* CRYSTAL contains biphasic calcium phosphate (60% hydroxyapatite, 40% ß-TCP). It is partially resorbable. The BCP serves as a stable scaffold for long-term volume preservation and gets embedded into new bone.

GUIDOR® *easy-graft* CLASSIC and GUIDOR® *easy-graft* CRYSTAL - How do I decide which material is suitable in a specific case?

The topic of material selection is a matter of clinician and surgical planning preference. See timing/staging of dental implant.

GUIDOR® *easy-graft* CRYSTAL: Are there two types of granules (HA and ß-TCP) in GUIDOR® *easy-graft* CRYSTAL?

No. Every single granule consists of a compound of 60% hydroxyapatite and 40% ß-TCP.

APPLICATION

Mixing with BioLinker: How long should GUIDOR® *easy-graft* granules be in contact with the BioLinker in the syringe?

The granules must be completely wetted with BioLinker. A complete wetting can be achieved by moving back and forth the plunger and the plug 1 - 3 times. Typically this takes around 20 - 40 seconds.

Should defects be overfilled?

No, overfilling is not recommended.

How should GUIDOR® *easy-graft* material be condensed?

Experienced GUIDOR® *easy-graft* users use various aids such as flattened stoppers or the plunger of the GUIDOR® *easy-graft* applicator syringe. Over larger areas the material can be evenly condensed by pressing down a piece of gauze (moistened with physiological saline solution) with the finger for 10 - 30 seconds.

Can GUIDOR® *easy-graft* products be used in combination with dental membranes?

Yes, it is at the discretion of the practitioner.

When would the use of a membrane be recommended?

GUIDOR® *easy-graft* products are stable and do not require a membrane for containment in 3 or 4 walled defects. Flat (non-concave defects with limited walls) and defects of a critical size may require the additional support of a barrier membrane. Sites where a full thickness periosteal relieving flap is created may also benefit from a barrier membrane for exclusion of soft tissue ingress. The decision to use a membrane is part of therapy planning and is the responsibility of the practitioner.

Can GUIDOR® *easy-graft* products be mixed with autogenous bone or bone graft substitutes or with preparations such as BMP-2 and Enamel matrix proteins in the application syringe?

No, mixing GUIDOR® *easy-graft* products with autogenous bone chips or foreign materials will cause the material to harden prematurely in the syringe, or will prevent the material from hardening in the defect. This means that GUIDOR® *easy-graft* products will lose their unique handling advantage.

Does GUIDOR® *easy-graft* adhere to the bone surface?

No. GUIDOR® *easy-graft* products do not adhere to tissue and do not contain adhesives. The granules adhere to one another and form a mouldable mass because of the coating of the granules with PLGA ("sticky granules").

Can GUIDOR® *easy-graft* products be ground down after hardening?

Grinding down is not recommended. The effect of the rotary forces may cause the graft to loosen in the defect, which may endanger the bone regeneration. Excess material should be removed before hardening (e.g. with a curette).

INDICATIONS

Is it necessary to cover the material with soft tissue after socket grafting?

No, the material will also heal in place without a soft-tissue cover. The material surface should be well condensed during socket preservation. The application of retention may be useful depending on the shape of the extraction socket. A temporary restoration serves to protect the graft surface from the tongue and foodstuffs. For examples of applications see the Sunstar GUIDOR® guidebook for ridge preservation.

When can an implant be placed after using GUIDOR® *easy-graft* products to fill the extraction sockets?

GUIDOR® *easy-graft* products are osteoconductive bone graft substitutes. The time of implant placement can be selected in accordance with experience with comparable materials (e.g. ß-TCP granules, bone replacement materials of bovine origin). A definite answer to this common question cannot be given, because the regeneration of bone depends on the anatomical and physiological conditions at the extraction site, and the time of implant placement depends on the treatment philosophy.

Can an implant be placed immediately with subsequent filling of the defect with GUIDOR *easy-graft*?

Yes, peri-implant gaps and bone deficiencies around implants with primary stability can be filled with GUIDOR® *easy-graft* products (See page 10).

Can GUIDOR® *easy-graft* products be used for fixing implants without primary stability?

No. Implants must be anchored in local bone with primary stability. GUIDOR® *easy-graft* products are suitable for filling bone deficits around implants anchored in pristine bone.

Are GUIDOR® *easy-graft* materials radio opaque?

Yes, GUIDOR® *easy-graft* CLASSIC and GUIDOR® *easy-graft* CRYSTAL are both opaque to x-rays.

How long do GUIDOR® *easy-graft* products remain stable in the body?

The adherence of the granules is determined by the PLGA coating. It is resorbed over a period of 3 - 6 weeks. During this period, the strength of the material gradually decreases.

Does the volume of GUIDOR® *easy-graft* change during the healing process?

During the initial phase of degradation, *easy-graft* CLASSIC may swell by taking up body fluids, thus supporting a close contact to the surrounding bone tissue. When applied in larger defects, this might result in slight sensation of pressure by the patient.

Evidence Base

Publications supporting dental application of GUIDOR® synthetic biomaterials:

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