



# ***easy-graft*** and ***calc-i-oss***

Alloplastic bone graft substitutes



# 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<sup>(1)</sup> 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.

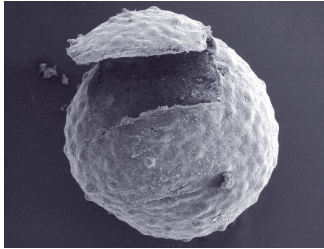
This would reduce the technique sensitivity and increase the predictability of bone augmentation. The use of synthetic (alloplastic) materials would result in lower surgical risks and lower morbidity in augmentation procedures and would represent an important step forward in simplifying bone regeneration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

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

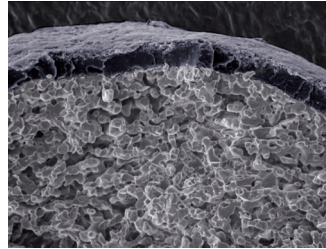
# GUIDOR *easy-graft*

## Mouldable from the Syringe, *in situ* Hardening

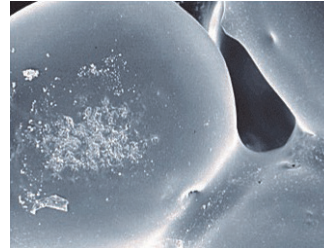
### Principle



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

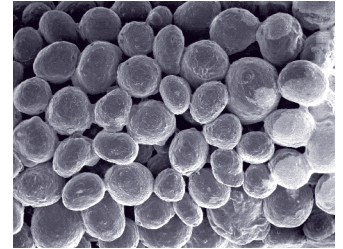


**Fig 2**



**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



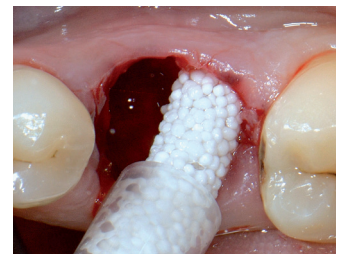
**Fig 1**  
Add BioLinker in the syringe.



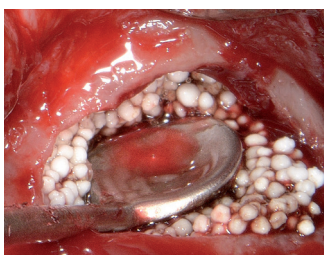
**Fig 2**  
Pulling back the plug of the syringe slightly facilitates the wetting of the granules, as does moving back and forth the plunger and the plug 1-3 times.



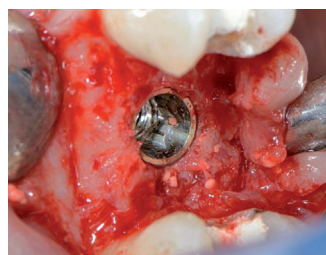
**Fig 3**  
Discard excess of BioLinker.



**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.

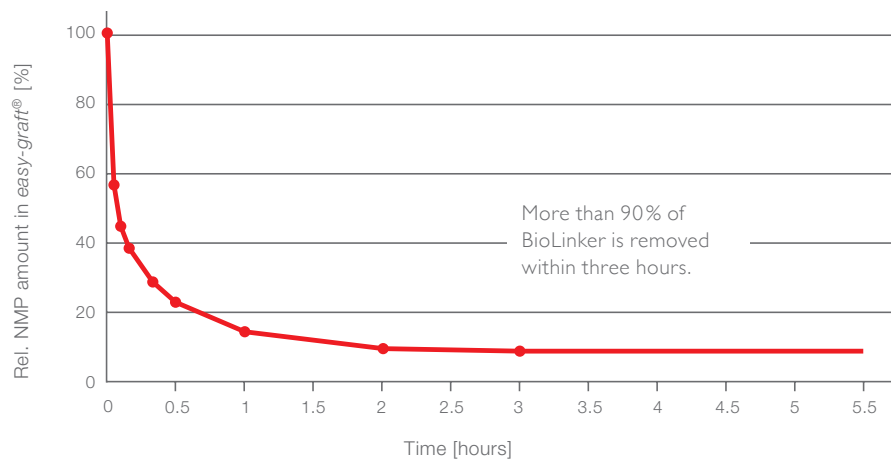


**Fig 6**  
Depending upon time scale, granules embedded on the surface of new bone will be observed. Excess granules can sometimes be seen in the soft tissue and can easily be removed at re-entry if desired.



# GUIDOR *easy-graft*

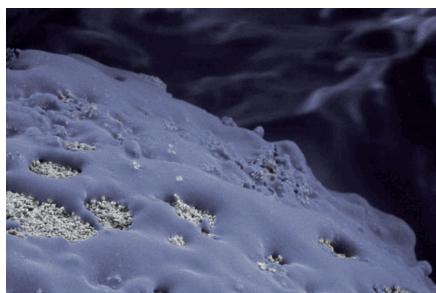
## Resorption Process for BioLinker and PLGA Polymer Coating



### Stage 1

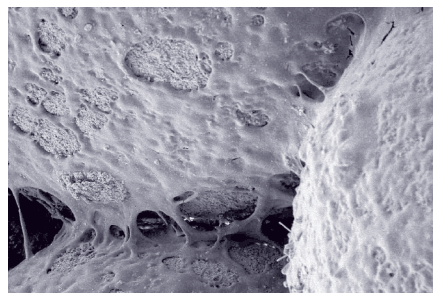
#### BioLinker is extracted within hours.

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<sup>(1)</sup> and excreted through the urine within 1-3 days<sup>(2)</sup>. 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.

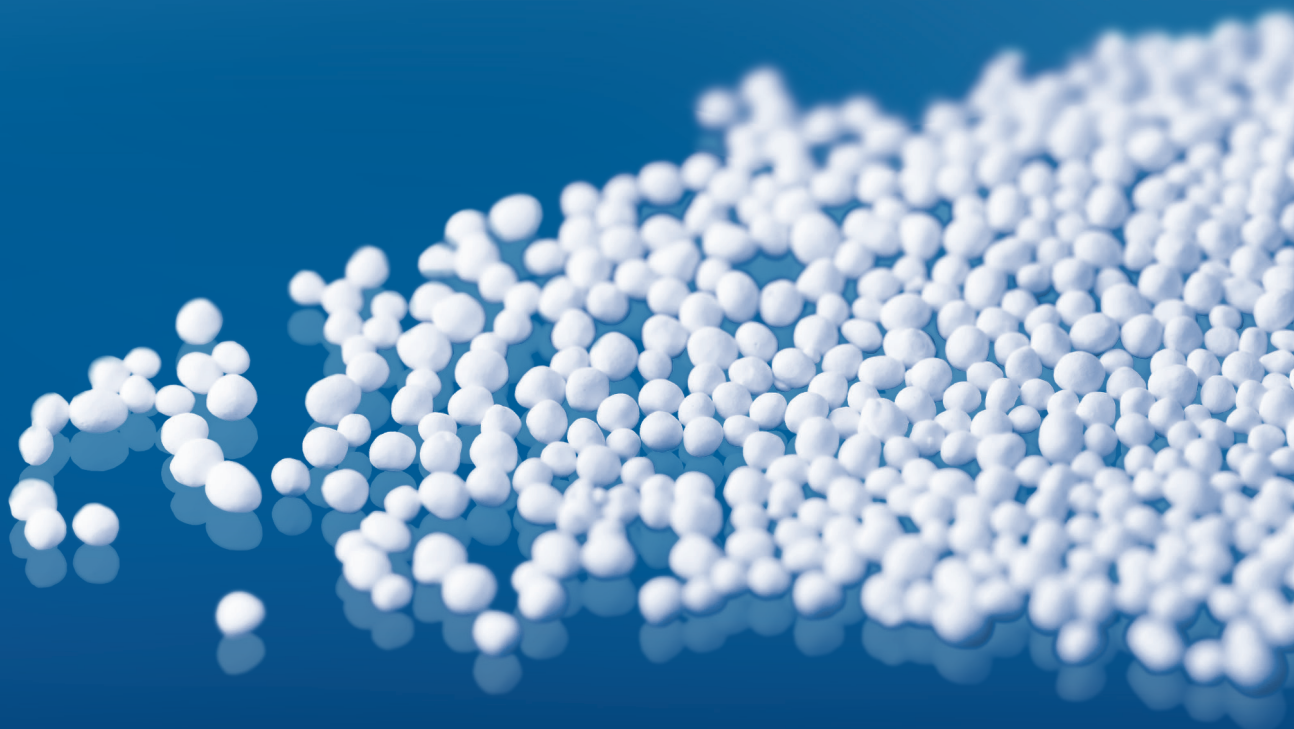
In parallel to the healing and regeneration process, the PLGA coating and adhesive connection between the granules gradually weakens (three to six weeks *in vitro*), exposing the microporous, osteoconductive scaffold.

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.

# GUIDOR *calc-i-oss*

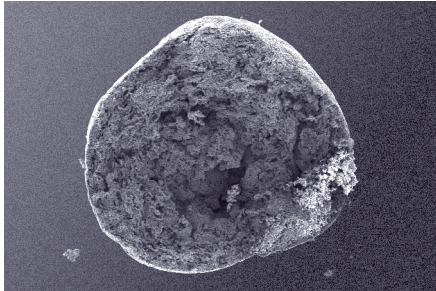
Traditional Granules.  
**Versatility.**





## GUIDOR *calc-i-oss* Traditional Granules

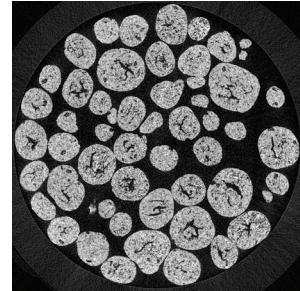
### Highly Porous, Osteoconductive Granules



GUIDOR *calc-i-oss* granule

#### Concept

After several years of refinement, GUIDOR *calc-i-oss* answers the original demand for an alloplast bone graft granule with similarities to natural bone.



### Versatility



#### Versatile Application

Unlike gritty particulates, GUIDOR *calc-i-oss* is presented as stable spherical granules.

The spheres are easy to handle and allow for a variety of application options such as:

- Mixing with blood
- Mixing with blood preparation (e.g. PRP or CGF),
- Mixing with autogenous bone or other bone graft materials

### Sterile Double Packaging



GUIDOR *calc-i-oss* is provided in sterile double packaging to achieve the highest surgical standards.

# Choosing between GUIDOR bone graft substitutes



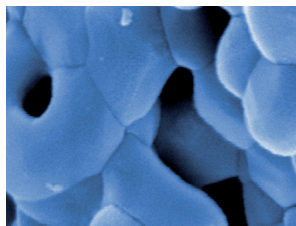


# GUIDOR Alloplastic Bone Graft Substitutes

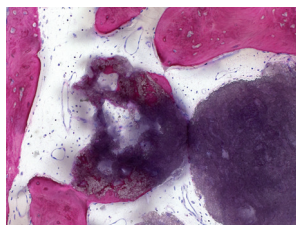
## Resorption and Porosity Profiles

GUIDOR bone graft substitutes *easy-graft* and *calc-i-oss* are 100 % alloplastic, 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 and CRYSTAL.

### CLASSIC - 100 % resorbable, more space for new bone

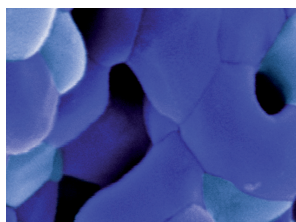


CLASSIC consists of a phase-pure  $\beta$ -TCP. Material resorption and bone regeneration proceed in parallel. CLASSIC profile is fully resorbed within 5 to 15 months. In clinical practice, resorption of phase-pure  $\beta$ -TCP is observed after shorter healing periods. No foreign material remains in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

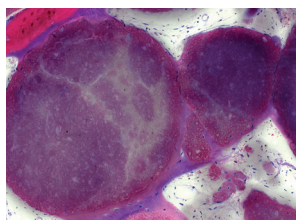


The resorption process can be clearly seen by the irregular shape of the previously spherical *easy-graft* CLASSIC granule. Human histology, 4 months after *easy-graft* CLASSIC application. Courtesy Dr. Minas Leventis, Athens, Greece and Dr. Heiner Nagursky, University of Freiburg in Breisgau, Germany.

### CRYSTAL - Partially resorbable, integration into bone



CRYSTAL consists of a biphasic calcium phosphate (BCP) compound formed in the ratio of 60% Hydroxyapatite and 40 %  $\beta$ -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 ( $\beta$ -TCP, right) and *easy-graft* CRYSTAL (BCP, left) application.

An animal study from Valdivia and al<sup>1</sup> 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.

# Indications and Guidance

<b>easy-graft CLASSIC and calc-i-oss CLASSIC</b>	<b>easy-graft CRYSTAL and calc-i-oss CRYSTAL</b>
<b>easy-graft CLASSIC and other <math>\beta</math>-TCP materials are documented in:</b>	<b>easy-graft CRYSTAL and other BCP (60% hydroxyapatite / 40% <math>\beta</math>-TCP) materials are documented in:</b>
<ul style="list-style-type: none"> <li>• Sinus floor elevation <sup>(1)</sup></li> <li>• Periodontal defects <sup>(2)</sup></li> <li>• Defects after removal of bone cysts <sup>(3)</sup></li> <li>• Augmentation of alveolar crest <sup>(4)</sup></li> <li>• Extraction defects <sup>(5)</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Sinus floor elevation <sup>(6)</sup></li> <li>• Periodontal defects <sup>(7)</sup></li> <li>• Defects after removal of bone cysts <sup>(8)</sup></li> <li>• Augmentation of alveolar crest <sup>(9)</sup></li> <li>• Extraction defects <sup>(10)</sup></li> </ul>

## Your choice of handling

In all these indications, you can either take advantage of the handling benefit of GUIDOR *easy-graft*, our mouldable in situ hardening bone graft system that can be directly applied from the syringe or also use our traditional particles GUIDOR *calc-i-oss* in combination with our GUIDOR *matrix barrier*.

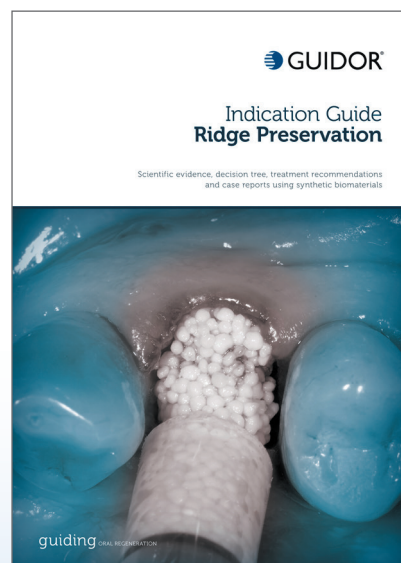
## Our recommendation between CLASSIC and CRYSTAL

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

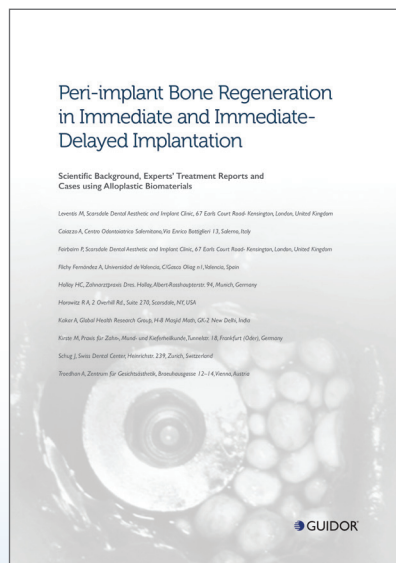
## Our Indication Guides

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

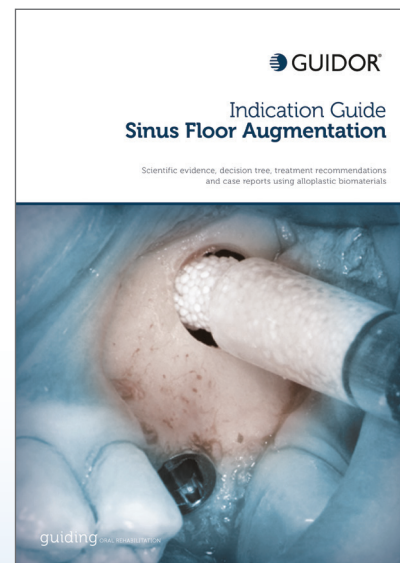
### Ridge Preservation



### 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](http://www.guidor.com)



## Product References

Product	<b>GUIDOR <i>easy-graft</i> CLASSIC</b>		
Reference no.	C11-012	C11-072	C11-002
Units	3 × 0.15 ml	3 × 0.25 ml	3 × 0.4 ml
Granule size	500–630 µm	500–1000 µm	500–1000 µm
Material	Phase-pure β-tricalcium phosphate (>99%)		

Product	<b>GUIDOR <i>easy-graft</i> CRYSTAL</b>		
Reference no.	C15-012	C15-072	C15-002
Units	3 × 0.15 ml	3 × 0.25 ml	3 × 0.4 ml
Granule size	450–630 µm	450–1000 µm	450–1000 µm
Material	Biphasic calcium phosphate (60% hydroxyapatite / 40% β-TCP)		

Product	<b>GUIDOR <i>calc-i-oss</i> CLASSIC</b>		
Reference no.	A02-103B	A02-103C	A02-103D
Units	3 × 0.5 ml	3 × 1.0 ml	3 × 2.0 ml
Granule size	315–500 µm	500–1000 µm	1000–1600 µm
Material	Phase-pure β-tricalcium phosphate (>99%)		

Product	<b>GUIDOR <i>calc-i-oss</i> CRYSTAL</b>	
Reference no.	A09-211	A09-231
Units	3 × 1.0 ml	3 × 2.5 ml
Granule size	450–1000 µm	450–1000 µm
Material	Biphasic calcium phosphate (60% hydroxyapatite / 40% β-TCP)	

## Clinical cases

### Dr. Minas Leventis

Indication	Ridge preservation
Patient	Female, 23 years old
Position	Maxillary right second premolar (I5)
Material used	GUIDOR <i>easy-graft</i> CLASSIC



**Fig. 1** Maxillary right second premolar (tooth I5) with caries.



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



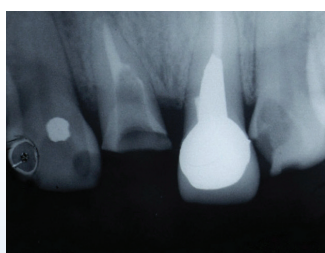
**Fig. 3** Situation at re-entry 4 months post-op. *easy-graft* CLASSIC granules are well integrated in new bone.



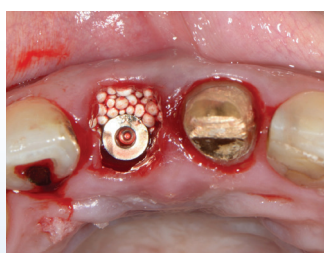
**Fig. 4** Final radiograph 16 months post-op.

### Dr. Minas Leventis

Indication	Peri-implant bone regeneration, immediate implantation
Patient	Female, 45 years old
Position	Maxillary right central incisor (I1)
Material used	GUIDOR <i>easy-graft</i> CRYSTAL



**Fig. 1** X-ray of initial situation.



**Fig. 2** Immediate implant placement and grafting.



**Fig. 3** Immediate provisional restoration.

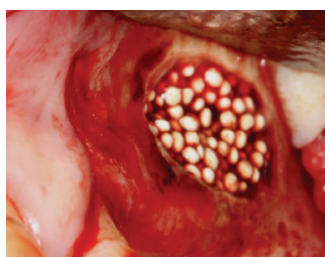


**Fig. 4** 5 months post-op, excellent preservation of the architecture of the ridge.

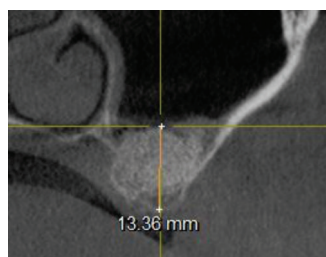


## Dr. Antonio Flichy-Fernández

Indication	Lateral sinus floor augmentation
Patient	Case series of 20 sinus floor augmentations <sup>1</sup>
Position	Maxillary molar teeth
Material used	GUIDOR <i>easy-graft</i> CRYSTAL, GUIDOR <i>calc-i-oss</i> CRYSTAL



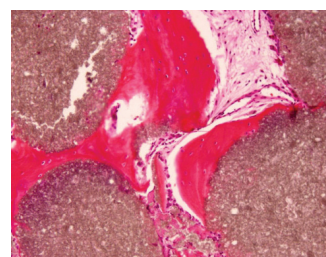
**Fig. 1** Lateral sinus floor augmentation with *easy-graft* CRYSTAL.



**Fig. 2** Control CBCT at 6 months.



**Fig. 3** Implantation at 6 months. (position I6, I7).



**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  $\beta$ -tricalcium phosphate ( $\beta$ -TCP) and is resorbed over a period of 5-15 months. GUIDOR *easy-graft* CRYSTAL contains biphasic calcium phosphate (60% hydroxyapatite, 40%  $\beta$ -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 $\beta$ -TCP) in GUIDOR *easy-graft* CRYSTAL?

No. Every single granule consists of a compound of 60% hydroxyapatite and 40%  $\beta$ -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. GUIDOR *calc-i-oss* products are ideal to mix with patient's blood or blood preparation (e.g platelet-rich plasma), sterile saline or autogenous bone.

### **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.  $\beta$ -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 alloplastic biomaterials:

### *in vivo* / preclinical studies

Bizenjima T, Takeuchi T, Seshima F and Saito A: Effect of poly (lactide-co-glycolide) (PLGA)-coated beta-tricalcium phosphate on the healing of rat calvarial bone defects: a comparative study with pure-phase beta-tricalcium phosphate. *Clinical Oral Implants Research* (2016).

Favero V, Lang N P, Canullo L, Urbizo Velez J, Bengazi F and Botticelli D: Sinus floor elevation outcomes following perforation of the Schneiderian membrane. An experimental study in sheep. *Clinical Oral Implants Research* (2015).

Schmidlin P R, Nicholls F, Kruse A, Zwahlen R A and Weber F E: Evaluation of moldable, in situ hardening calcium phosphate bone graft substitutes. *Clinical Oral Implants Research* (2013).

Yip I, Ma L, Mattheos N, Dard M and Lang N P: Defect healing with various bone substitutes. *Clinical Oral Implants Research* (2014).

Zigdon H, Lewinson D, Bick T and Machtei E E: Vertical Bone Augmentation Using Different Osteoconductive Scaffolds Combined with Barrier Domes in the Rat Calvarium. *Clinical Implant Dentistry and Related Research* (2012).

### Clinical studies

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El Sayed E, Khalil A and Saleh M: Clinical and radiographical evaluation of immediate implant versus delayed implant after socket preservation of upper anterior teeth. *Alexandria Dental Journal* (2015) 40: 79-85.

Jurisc M, Manojlovic-Stojanoski M, Andric M, Kokovic V, Danilovic V, Jurisc T and Brkovic B B: Histological and morphometric aspects of Ridge preservation with a moldable, in situ hardening bone graft substitute. *Arch. Biol. Sci.* (2013) 65(2): 429-437.

Kakar A, Chaudhary V, Kakar R C, Lahori M and Kakar K: Indirect Sinus Elevation And Implant Placement Using A Modified Crestal Approach - A Case Report. *The Journal of Academy of Oral Implantology* (2011) 3(Jan-Apr): 37-40.

Leventis M D, Fairbairn P, Kakar A, Leventis A D, Margaritis V, Lückerrath W, Horowitz R A and Nagursky H: Minimally invasive alveolar ridge preservation utilizing an in situ hardening  $\beta$ -tricalcium phosphate bone substitute. A multicenter case series. *International Journal of Dentistry* (2016) 2016.

Neumeier S and Neumeier-Wühr S: The use of polylactide-coated beta-TCP Closure of oroantral communications. *Implants* (2010) 4(4): 32-36.

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Troedhan A, Schlichting I, Kurrek A and Wainwright M: Primary implant stability in augmented sinuslift-sites after completed bone regeneration: a randomized controlled clinical study comparing four subantrally inserted biomaterials. *Scientific reports* (2014) 4.

Troedhan A, Wainwright M, Kurrek A and Schlichting I: Biomechanical Stability of Dental Implants in Augmented Maxillary Sites: Results of a Randomized Clinical Study with Four Different Biomaterials and PRF and a Biological View on Guided Bone Regeneration. *BioMed Research International* (2015) 2015.

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# Distributors

## Austria

Medos Austria  
Tel.: +43 1 71 514 74  
E-Mail: [info@medosaustria.at](mailto:info@medosaustria.at)  
[www.medos.at](http://www.medos.at)



## Bulgaria

MiPlant EOOD  
Nat. tel.: +359 0700 1 55 44  
E-Mail: [miplant@miplant.bg](mailto:miplant@miplant.bg)  
[www.miplant.bg](http://www.miplant.bg)

## Chile

San Juan SA  
Tel.: +56 2 224 333 90  
E-Mail: [ventas@dentalstore.cl](mailto:ventas@dentalstore.cl)  
[www.dentalstore.cl](http://www.dentalstore.cl)

## Croatia

Cirkon-Dental  
Tel.: +385 915 464 696  
E-Mail: [cirkondental.mario@gmail.com](mailto:cirkondental.mario@gmail.com)



## Czech Republic

BIOMED PRAHA, spol. s r.o.  
Tel.: +420 731 464 759  
E-Mail: [info@biomed-praha.cz](mailto:info@biomed-praha.cz)  
[www.biomed-praha.cz](http://www.biomed-praha.cz)

## France

Biotech Dental France  
Tel.: +33 04 90 44 60 60  
[www.biotech-dental.com](http://www.biotech-dental.com)

## Germany

BEGO Implant Systems  
Tel.: 0421 2028-246  
Email: [info@bego-implantology.com](mailto:info@bego-implantology.com)  
[www.bego.com](http://www.bego.com)



Pluradent  
Tel.: +49 69 82 98 3100  
[www.pluradent.de](http://www.pluradent.de)



MF Dental  
Tel.: +49 9605 924 520  
E-Mail: [info@mf-dental.de](mailto:info@mf-dental.de)  
[www.mf-dental.de](http://www.mf-dental.de)



Implantis  
Tel.: +49 341 27139 241  
E-Mail: [service@implantis.eu](mailto:service@implantis.eu)  
[www.implantis.eu](http://www.implantis.eu)



## Great Britain

Panadent Ltd.  
Tel.: +44 168 988 17 88  
E-Mail: [info@panadent.co.uk](mailto:info@panadent.co.uk)  
[www.panadent.co.uk](http://www.panadent.co.uk)

## Greece

Dentopolis  
Tel.: +30 2 114 079 041  
E-Mail: [info@dentopolis.gr](mailto:info@dentopolis.gr)  
[www.dentopolis.gr](http://www.dentopolis.gr)



## Hungary

Realtrade Kft  
Tel.: +36 1 261 6630  
E-Mail: [info@realtrade.hu](mailto:info@realtrade.hu)  
[www.realtrade.hu](http://www.realtrade.hu)

## Israel

Raviv Dental  
Tel.: +972 50 665 19 91  
E-Mail: [info@ravivuniversal.com](mailto:info@ravivuniversal.com)  
[www.ravivuniversal.com](http://www.ravivuniversal.com)



## Italy

Biotech Dental Italia  
Tel.: +39 089 9712629  
[www.biotech-dental.com/it/](http://www.biotech-dental.com/it/)

## Jordan

Al Rawdah Medical Supplies LLC  
Tel.: +962 7 904 848 12  
E-Mail: [alrawdah.medical@gmail.com](mailto:alrawdah.medical@gmail.com)  
Facebook: Alrawdah Medical Supplies



## Kuwait

Al-Muneer General Trading & Contracting  
Tel.: +965 257 476 42  
E-Mail: [nmatta@medicomfort-me.com](mailto:nmatta@medicomfort-me.com)  
[www.medicomfort-me.com](http://www.medicomfort-me.com)



## Latvia

Malli Dental  
Tel.: +371 672 941 20  
E-Mail: [info@malli.lv](mailto:info@malli.lv)  
[www.malli.lv](http://www.malli.lv)

## Lebanon

FPM s.a.r.l. Surgical & Dental products  
Tel.: +961 1 495 111  
E-Mail: [m.harb@fpm-me.com](mailto:m.harb@fpm-me.com)  
[www.fpm-me.com](http://www.fpm-me.com)



## Poland

Implacore Sp. z o.o.  
Tel.: +48 61 663 07 85  
E-Mail: [biuro@implacore.pl](mailto:biuro@implacore.pl)  
[www.implacore.pl](http://www.implacore.pl)



## Portugal

B.I.P. Innovative Dental Systems LDA  
Tel.: +351 91 525 30 50  
[www.biotech-dental.com/pt-pt/](http://www.biotech-dental.com/pt-pt/)

## Russia

Rocada Dent Ltd.  
Tel.: +7 843 570 68 80  
E-Mail: [a.gabdrakhimova@rocadamed.ru](mailto:a.gabdrakhimova@rocadamed.ru) and /or  
[l.libragimova@rocadamed.ru](mailto:l.libragimova@rocadamed.ru)  
[www.rocadamed.ru](http://www.rocadamed.ru)



## Saudi-Arabia

Asnan for Medical Devices  
Tel.: +966 11 445 85 48  
E-Mail: [m.sayed@asnan.net.sa](mailto:m.sayed@asnan.net.sa)  
[www.asnan.net.sa](http://www.asnan.net.sa)



## Serbia

Mikodental d.o.o.  
Tel.: +381 15 300 261  
E-Mail: [mikodentaloffice@gmail.com](mailto:mikodentaloffice@gmail.com)  
[www.mikodental.rs](http://www.mikodental.rs)



## Slovakia

EuDent, s.r.o.  
Tel.: +421 434 286 219  
E-Mail: [office@eudent.sk](mailto:office@eudent.sk)  
[www.eudent.sk](http://www.eudent.sk)



## South Africa

Sourcemed  
Tel.: +27 21 461 29 85  
E-Mail: [gk@sourcemed.co.za](mailto:gk@sourcemed.co.za)  
[www.sourcemed.co.za](http://www.sourcemed.co.za)

## Spain

Biotech Dental Spain  
Tel.: +34 911 930 210  
[www.biotech-dental.com/es/](http://www.biotech-dental.com/es/)



## Switzerland

heico Dent GmbH  
Tel.: +41 71 793 90 00  
E-Mail: [info@heicodent.ch](mailto:info@heicodent.ch)  
[www.heicodent.ch](http://www.heicodent.ch)

## Syria

Ouzoun Trading Center  
Tel.: +963 933 449 899  
E-Mail: [info@ouzoun.com](mailto:info@ouzoun.com)  
[www.ouzoun.com](http://www.ouzoun.com)



## UAE

Sapling Drug Store  
Tel.: +971 508 516 101  
E-Mail: [abduhalim@saplingdx.com](mailto:abduhalim@saplingdx.com)  
[www.saplingdx.com](http://www.saplingdx.com)

## Ukraine

Stamil LLC  
Tel.: +380 44 22 707 55  
+380 44 33 773 53  
E-Mail: [info@stamil.ua](mailto:info@stamil.ua)  
[www.stamil.ua](http://www.stamil.ua)



Manufacturer:

Degradable Solutions AG  
Wagistrasse 23,  
8952 Schlieren/Zurich  
Switzerland

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