easy-graft

synthetic bone graft substitutes

Predictable regeneration.
Simple handling.

Synthetic bone grafting
with defined regeneration profiles

GUIDOR® *easy-graft* is a synthetic bone graft substitute designed to support predictable bone regeneration without the use of animal or human-derived components. The material is biocompatible and osteoconductive, offering a total porosity of approximately 70%. It consists of macropores providing space for vascularization and bone regeneration and micropores for optimized fluid circulation. GUIDOR *easy-graft* is available in two distinct calcium phosphate compositions, allowing clinicians to select the most appropriate resorption profile for each clinical indication.

Fully Resorbable: CLASSIC+

- *easy-graft* CLASSIC+ consists of a phase-pure ß-TCP
- the 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 synthetic bone graft product remains in the body

Partially Resorbable: CRYSTAL+

- *easy-graft* 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
- HA gets embedded into new bone

GUIDOR *easy-graft* supports bone regeneration and bone formation. The application of the material does not guarantee a treatment success. The success of the therapy depends on many factors such as surgical technique and habits, age and the regeneration potential of the patient.

Predictable graft placement with clear indications and a simple, step-by-step workflow

GUIDOR *easy-graft* CLASSIC+ and CRYSTAL+ are intended for the filling of mostly unloaded and preferably multi-walled dental or maxillofacial bone defects. The implantation site should be free of infections and soft or granulation tissue. Indications may include:

- Defects after removal of bone cysts
- Periodontal defects
- Peri-implant defects
- Augmentation of the alveolar crest (e.g. Guided Bone Regeneration – GBR)
- Defects after root-end resection
- Extraction sockets
- Defects after surgical removal of retained teeth
- Sinus floor elevation procedures
- Defects after removal of autologous bone

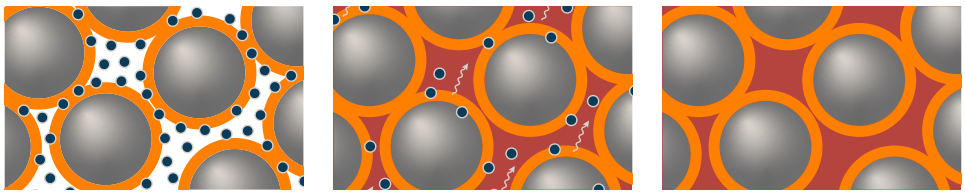
Step-by-step application

1. Add the supplied BioLinker to the syringe containing the granules.
2. Gently pull back the plug to wet the granules, then move the plunger back and forth 1-3 times for uniform activation.
3. Discard any excess BioLinker
4. Apply the material directly into the defect.

Please note
The product should be packed / gently condensed into the defect site. Excess granules may occasionally migrate into the soft tissue. These granules can be easily removed at re-entry, if desired.

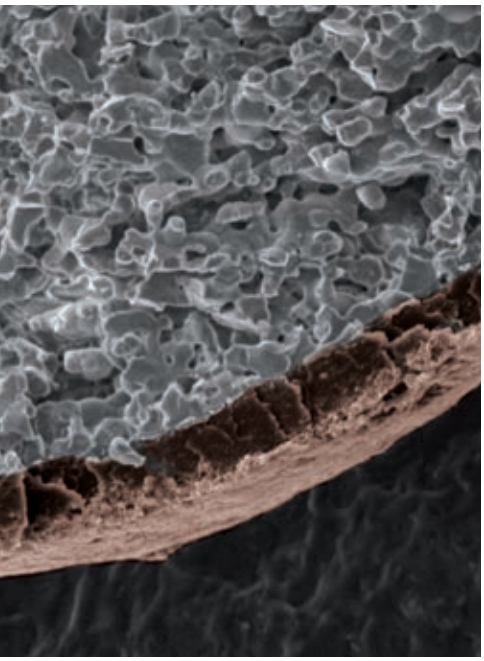
Controlled in-situ hardening
through a simple material interaction

Upon mixing, the BioLinker temporarily softens the polymer coating, creating a cohesive and moldable graft material. Once in contact with body fluids, the BioLinker is flushed out, allowing the material to harden in situ. Within approximately one minute, a stable, porous scaffold of interconnected granules is formed.



Three integrated components
working together for stable graft regeneration

Three complementary components are precisely coordinated to ensure secure graft placement and predictable handling. While the graft hardens in situ, the system gradually transitions to support natural bone regeneration. This controlled interaction is designed to maintain stability during the early healing phase.



1

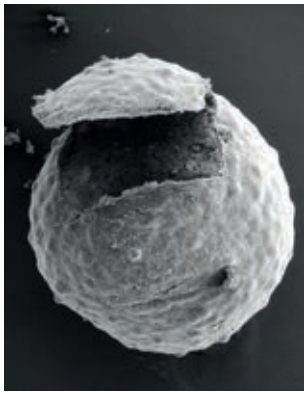
Calcium Phosphate Granules
Osteoconductive scaffold supporting bone regeneration.

2

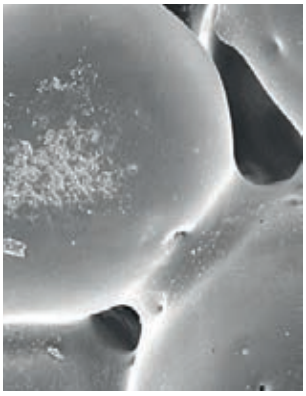
PLGA Polymer Coating
Each granule is coated with a 10 µm layer of polylactic-co-glycolic acid (PLGA). PLGA polymers are widely used in devices such as membranes, screws and plates for maxillofacial surgery, suture anchors, and cages for spinal surgery and are considered Biocompatible.

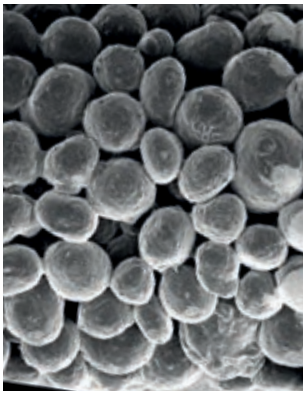
3

BioLinker-N-Methyl-2-pyrrolidone (NMP)
A solvent widely used in pharmaceutical and medical devices such as dental membranes, subcutaneous drug-release systems etc.



Each granule is pre-coated with PLGA.

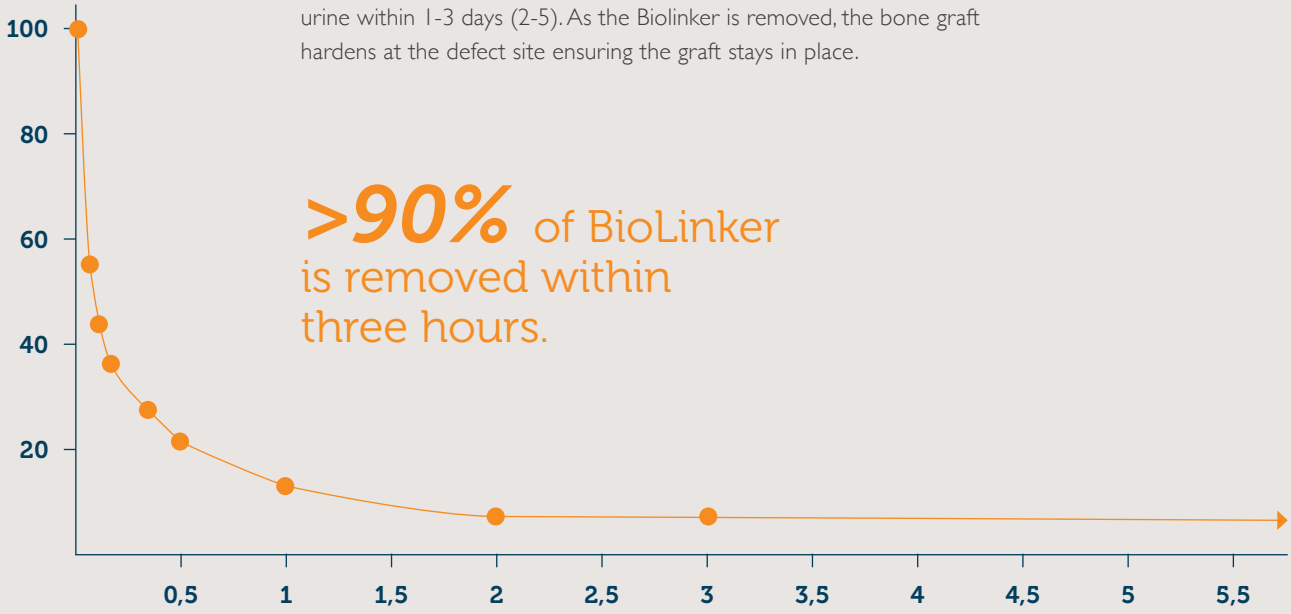




When the supplied BioLinker is added to the syringe contents it softens the polymer coating of the granules creating a sticky yet mouldable mass.

Removal of BioLinker

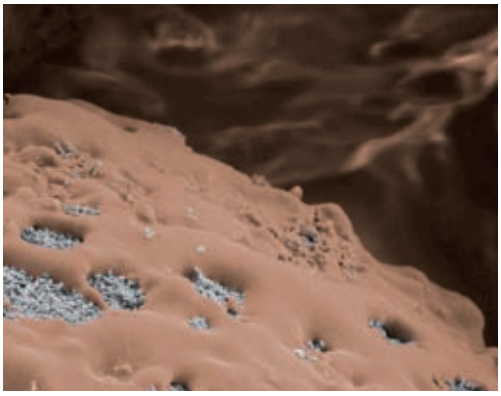
More than 90% of the Biolinker is eliminated from the bone graft substitute within three hours of grafting(1) and excreted through urine within 1-3 days (2-5). As the Biolinker is removed, the bone graft hardens at the defect site ensuring the graft stays in place.



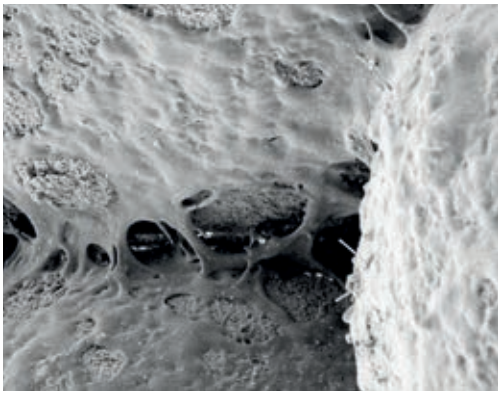
>90% of BioLinker is removed within three hours.

Breakdown and removal of PLGA

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.



During resorption
Colored electron microscope image of GUIDOR easy-graft CRYSTAL showing resorption of the PLGA coating (orange) and exposure of biphasic calcium phosphate (white).



PLGA resorption
Electron microscope image from an in vitro degradation study.

GUIDOR *easy-graft*
Solutions at a glance

	↗ CLASSIC+	↗ CRYSTAL+
Composition	Phase-pure ß-tricalcium phosphate (> 99 %)	Biphasic calcium phosphate (60 % hydroxyapatite / 40 % ß-TCP)
Granule Size	500 – 630 µm (0.15 ml) 500 – 1000 µm (0.25 and 0.4 ml)	450 – 630 µm (0.15 ml) 450 – 1000 µm (0.25 and 0.4 ml)
Indications for Use	• Defects after removal of bone cysts • Periodontal defects • Peri-implant defects • Augmentation of alveolar crest (e.g. Guided Bone Regeneration, GBR) • Defects after root end resection • Extraction defects	
Product Codes - Single Pack		
0.15 ml **0.25 ml** **0.4 ml**	C11-115 C11-175 C11-105	C15-115 C15-175 C15-105
Product Codes - Pack of three		
0.15 ml **0.25 ml** **0.4 ml**	C11-112 C11-172 C11-102	C15-112 C15-172 C15-102

Key information and
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 easygraft 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.

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.

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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).

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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).

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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.

More information at
www.guidor.com

Please refer to the Instructions for Use for description, indications, contraindications, warnings, precautions and other important information. A surgeon must always rely on his or her own professional clinical judgement when deciding whether to use a particular product when treating a particular patient. Availability of these products might vary from one given country or region to another as a result of specific local regulatory approval or clearance requirements for sale in such country or region. MS1327 Rev A

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