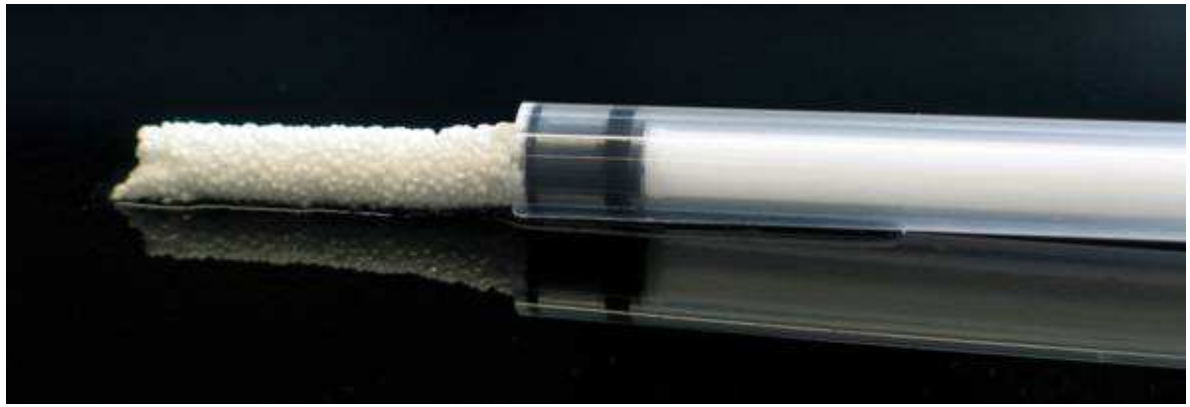
easy-graft™CRYSTAL

Overview

- **Advantages**
- *easy-graft*™: principle & application
- Material & studies
- Indications
- *easy-graft*™*CRYSTAL & CLASSIC*
- Degradable Solutions AG

Advantages of *easy-graft™CRYSTAL*



Easy handling:

- Injectable
- Modelling in the defect
- In-situ hardening
- In most cases no membrane needed

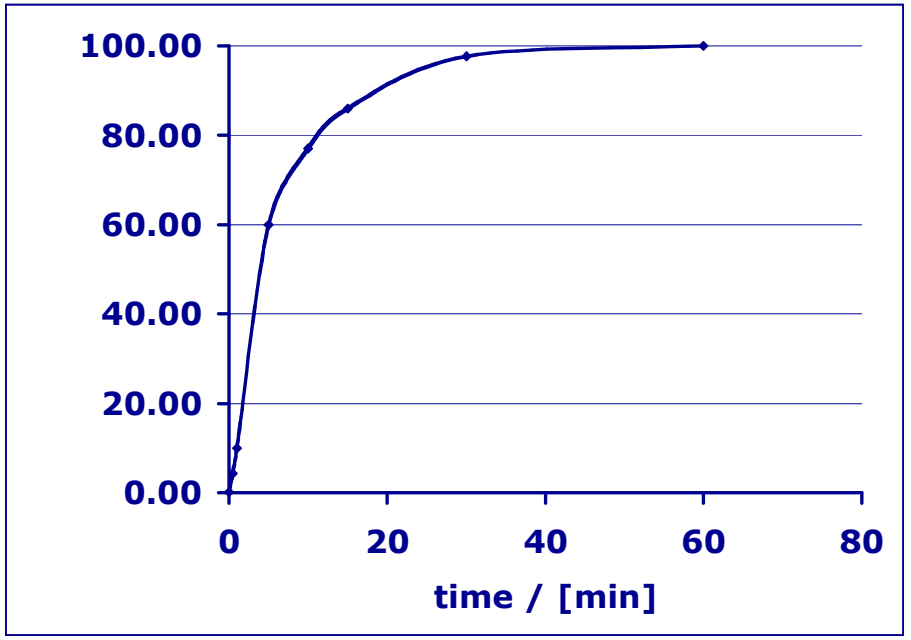
➔ Time & cost savings due to simple handling

Advantages of *easy-graft™CRYSTAL*

In-situ hardening:

- Hardening starts only in contact with body fluids
- No temperature increase
- Hardens within 30 - 90 seconds* in situ
- Stabilization of defect due to mechanical stability
- No dislocation of granules

* Depending on size of defect and amount of blood in defect



Advantages of *easy-graft™CRYSTAL*

Unique material properties:

- High osteoconductivity
- Long-term volume preservation
- 100% synthetic

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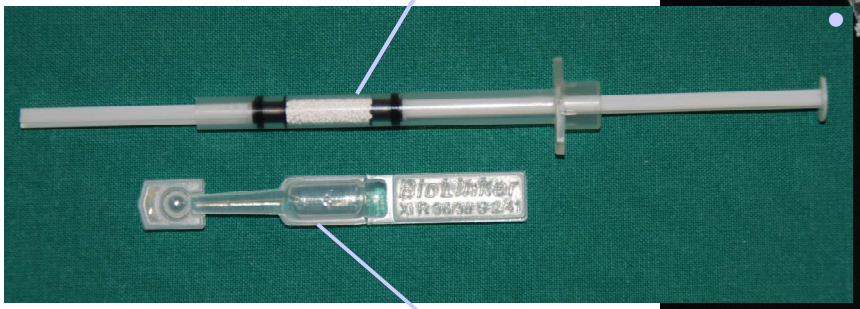
Biomaterial

easy-graft™ CRYSTAL



Coated granules

- 90% biphasic calcium phosphate (**BCP**)
- 10% **polylactide** (coating)

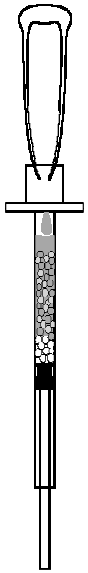
BioLinker™

- Organic solvent (NMP), used in several medical implants

Application

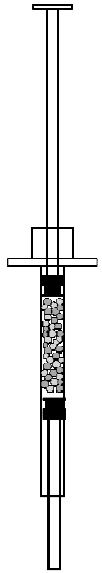
easy-graft™ CRYSTAL

1



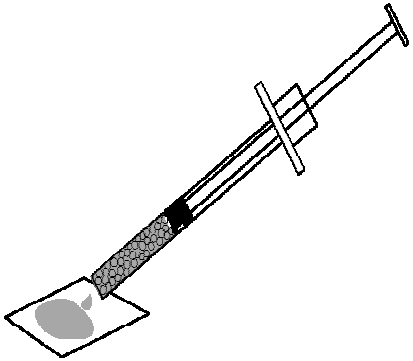
Transfer BioLinker™ into funnel shaped opening of syringe

2



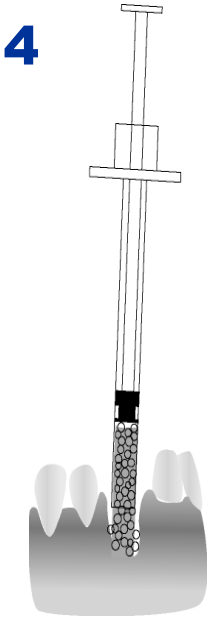
Push BioLinker™ through granules, incubate for approx. 20s

3



Remove excess BioLinker™

4

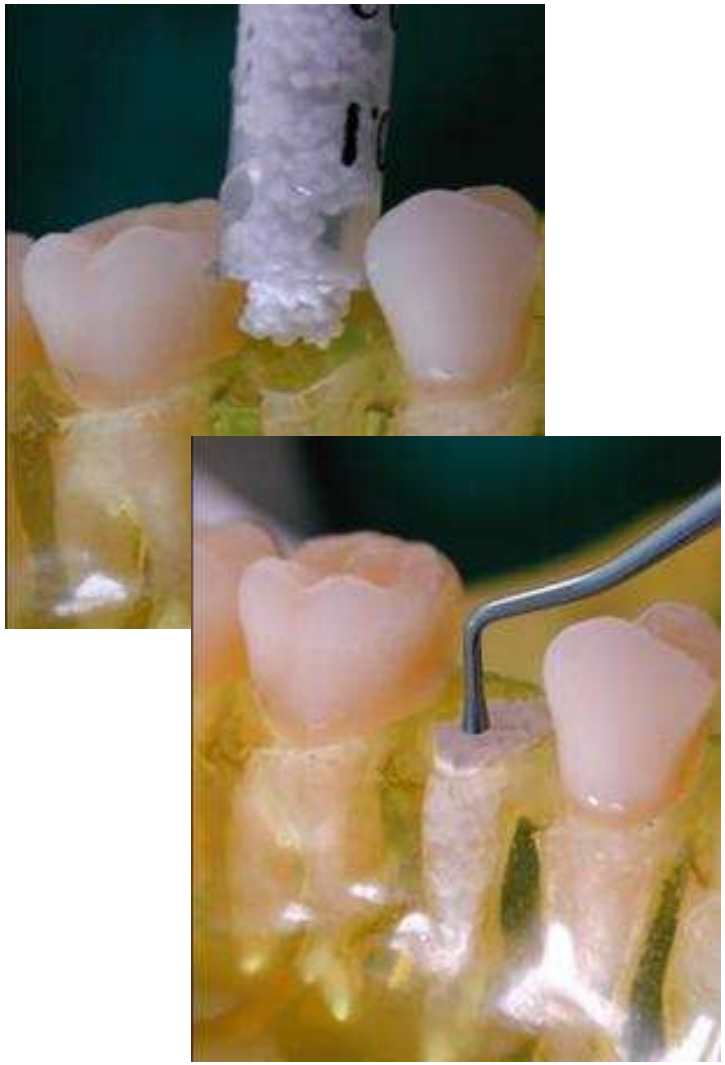


Apply *easy-graft™* directly from the syringe into the defect

Function & Application

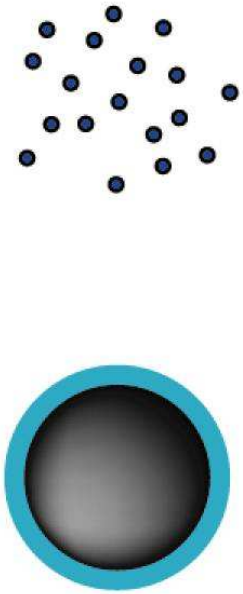
easy-graft™ CRYSTAL

- BioLinker™ penetrates coating
  → sticky granules
- *easy-graft™CRYSTAL* can be applied directly into the defect and modelled in situ
- *easy-graft™CRYSTAL* hardens in situ when in contact with body fluid
- In most cases no membrane is needed

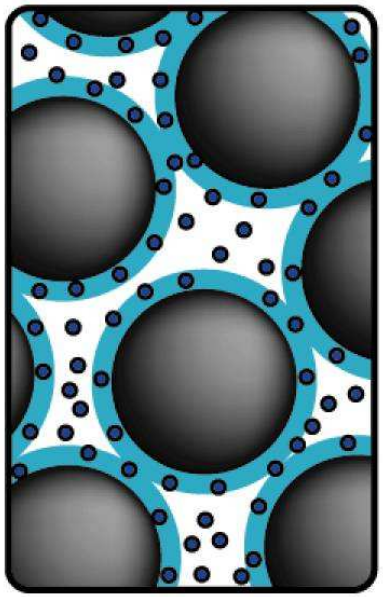


easy-graft™ Principle

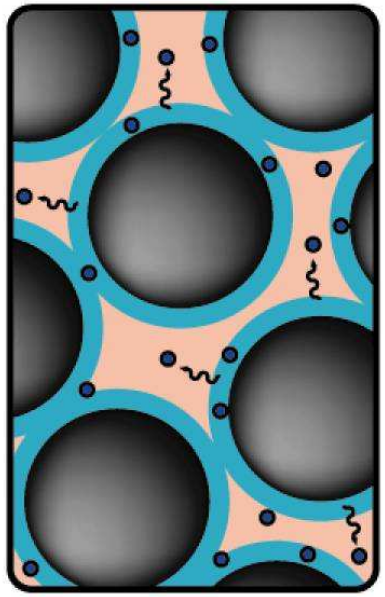
easy-graft™ CRYSTAL



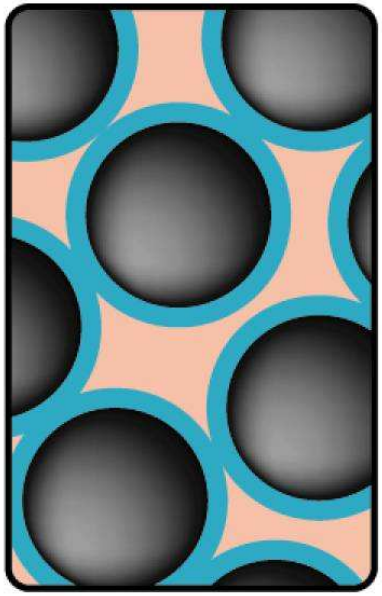
BioLinker™
+
coated
BCP granule



adhesive
granules:
modeling in-situ



In situ: extraction
of BioLinker™,
material hardens
in contact with
body fluids



formation of a
porous, solid
body

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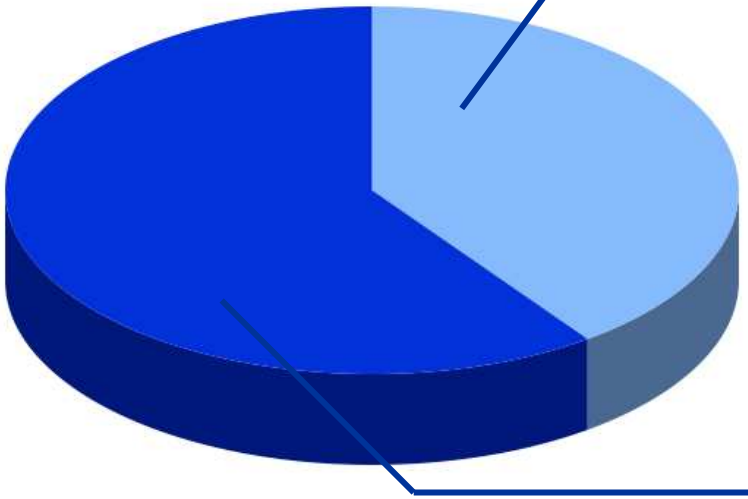
Composition of BCP

easy-graft™ CRYSTAL

Biphasic calcium phosphate (**BCP**)



40% ß-tricalcium phosphate (ß-TCP)

Slow degradation of ß-TCP increases the porosity, calcium and phosphate ions are released for bone formation

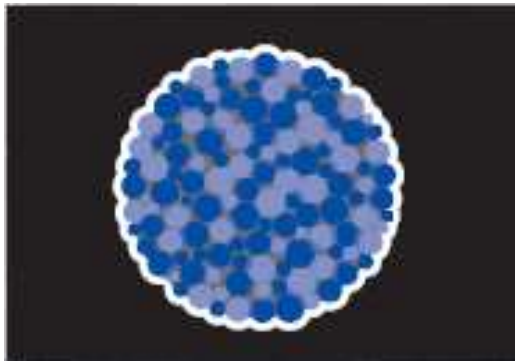
60% hydroxyapatite (HA)

Remains in the defect, serves as an osteoconductive scaffold

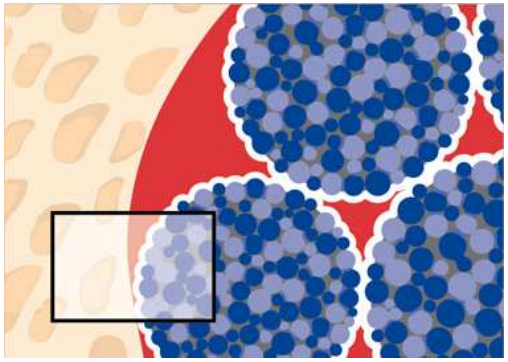
Behaviour of BCP in the Body
Schematic Representation

easy-graft™ CRYSTAL

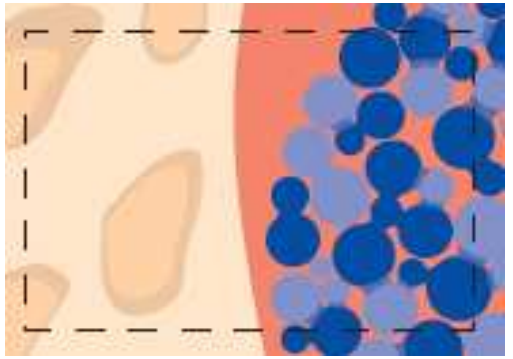
Cross section through an *easy-graft™CRYSTAL* granule



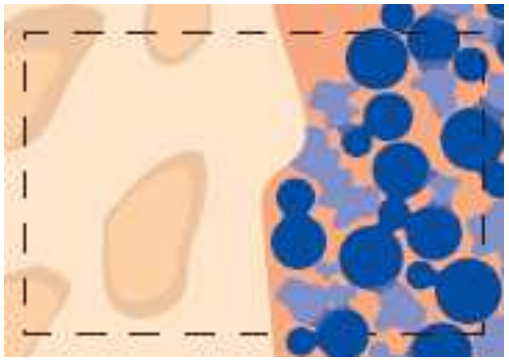
Phase I
after application into the defect



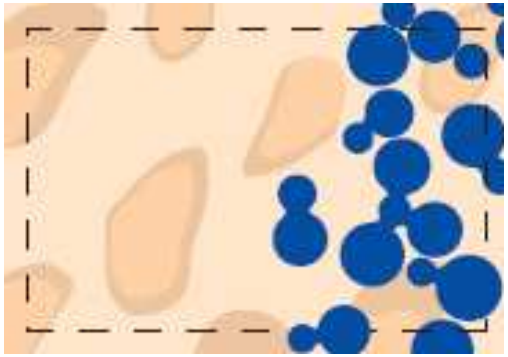
Phase II
after degradation of polylactid coating



Phase III
proceeding bone formation



Phase IV
β-TCP part has been degraded, HA is embedded in bone



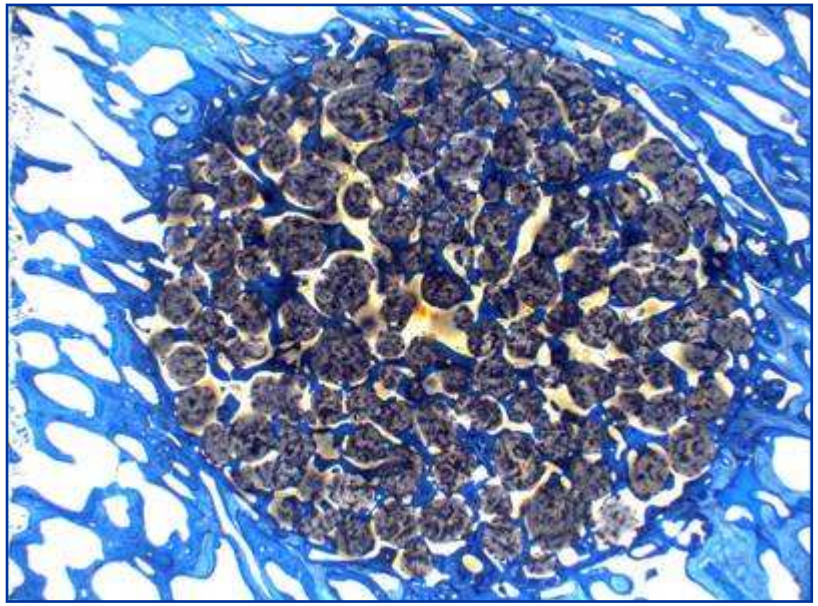
- Hydroxylapatite (HA)
- β-tricalcium phosphate (β-TCP)
- Polylactide coating (PLGA)
- Bone
- Blood

Comparison
easy-graft™CRYSTAL & ß-TCP

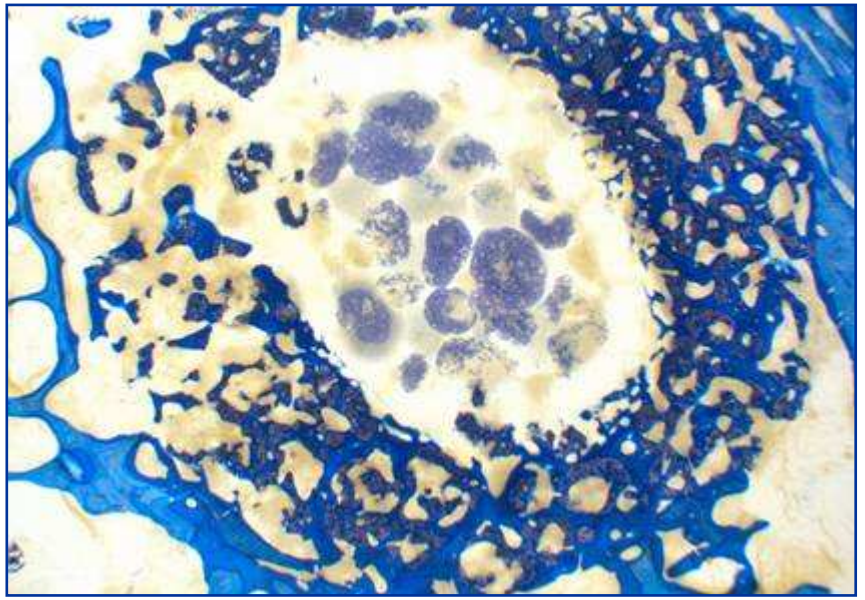
easy-graft™ CRYSTAL

Fast osteoconduction with *easy-graft™CRYSTAL*

easy-graft™CRYSTAL partly remains in defect



easy-graft™CRYSTAL



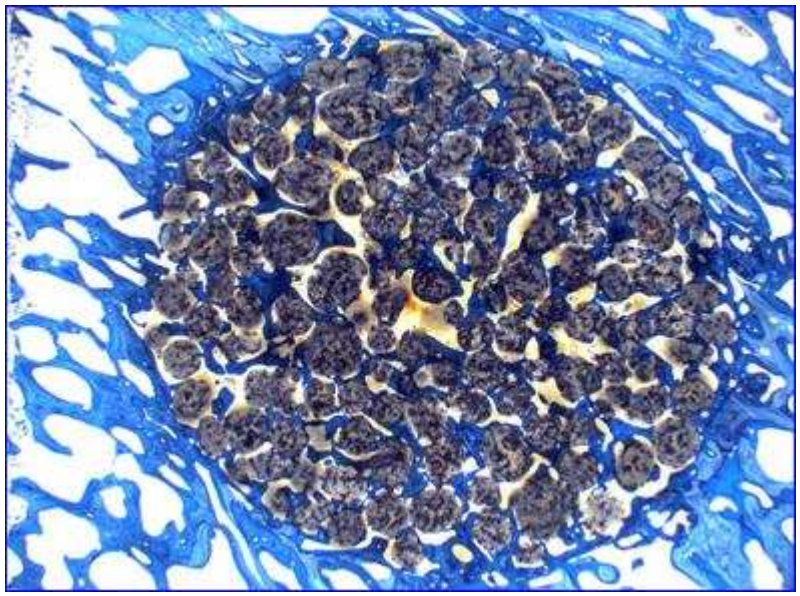
ß-TCP

8 mm defect in femur & humerus of a sheep after 2 months. Toluidine blue staining, bone appears blue.

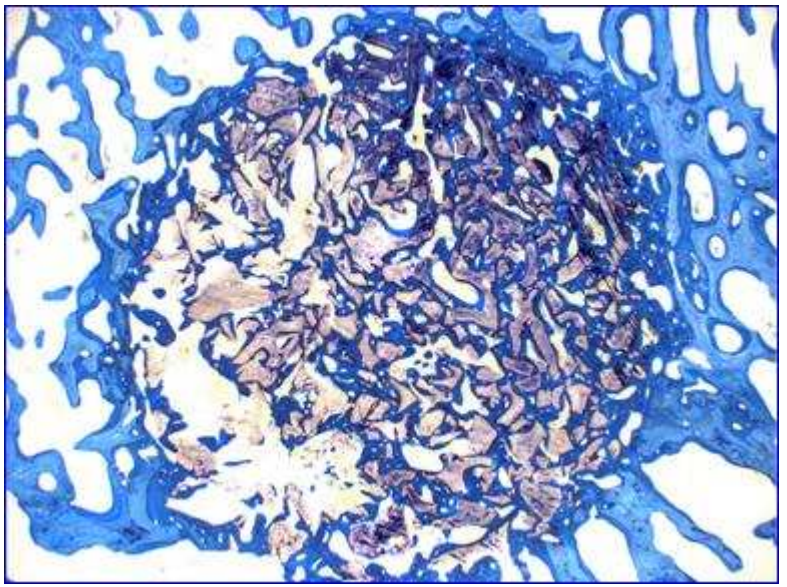
Comparison
easy-graft™CRYSTAL & Xenogenic Material

easy-graft™CRYSTAL und xenogenic material remain in defect.

easy-graft™CRYSTAL granules are penetrated by tissue.



easy-graft™CRYSTAL

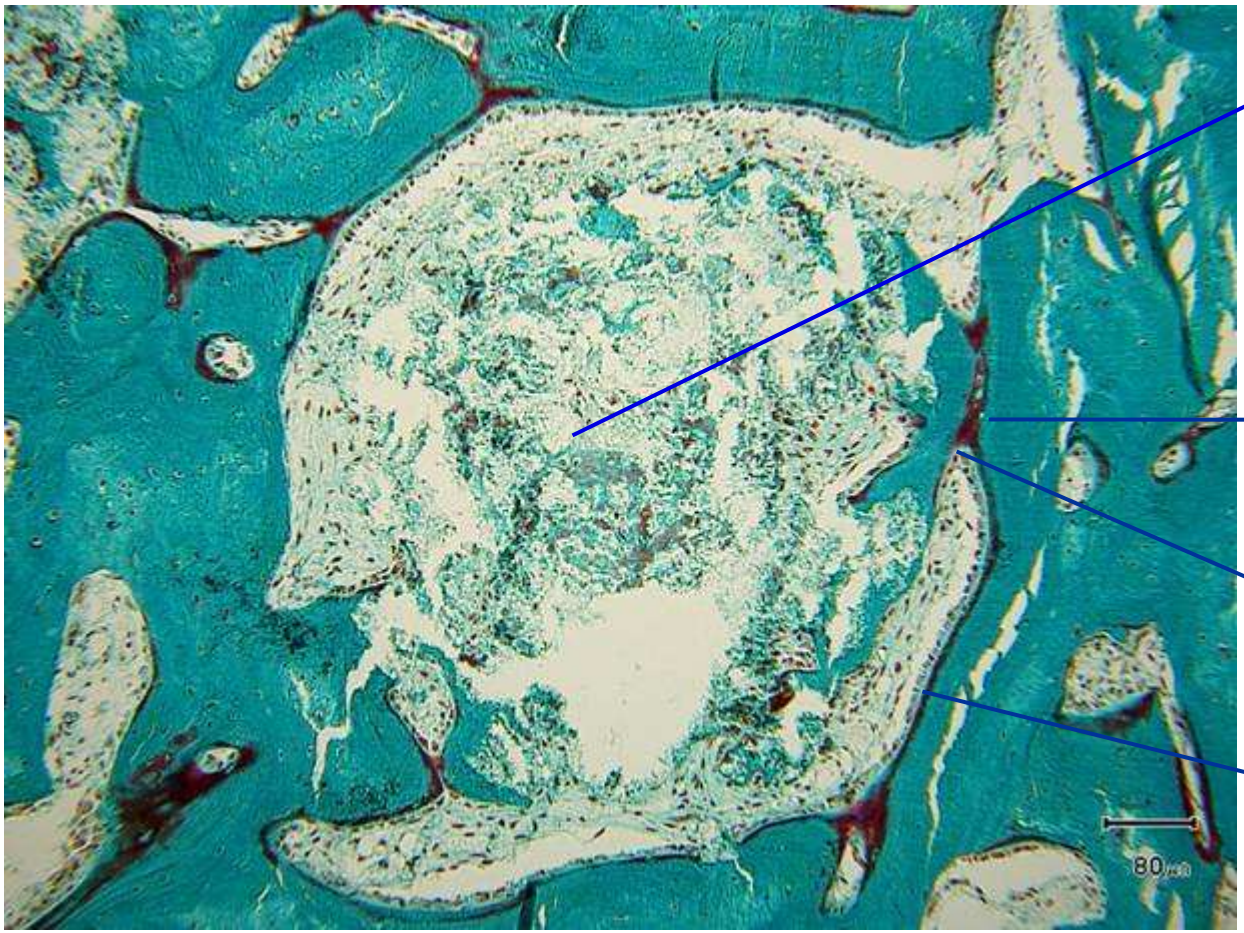


xenogenic bone graft substitute

8 mm defect in femur & humerus of a sheep after 2 months. Toluidine blue staining, bone appears blue.

Osteoconductivity

easy-graft™ CRYSTAL



easy-graft™CRYSTAL is penetrated by bone

Bone (turquoise)

Osteoid (red)

Osteoblasts

easy-graft™CRYSTAL in cranial defects of rabbits after 4 weeks.
Masson-Goldner staining.

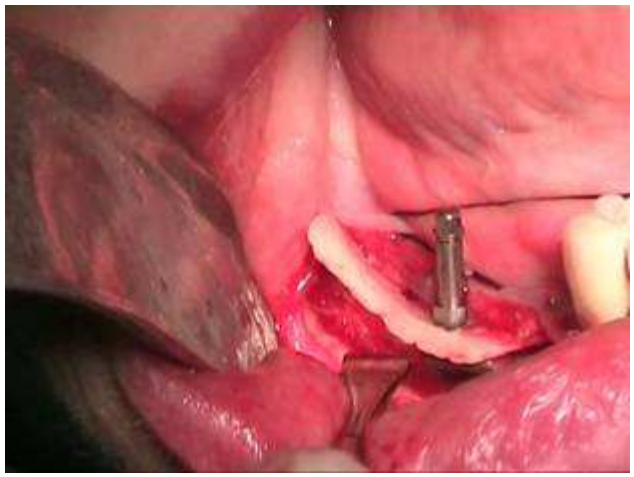
Clinical Application

easy-graft™ CRYSTAL

Clinical application
Vertical augmentation

Dr. E. Fuchs, Thalwil

With Vertical-Control from
Hager & Meisinger GmbH



Studies & Publications

easy-graft™ CRYSTAL

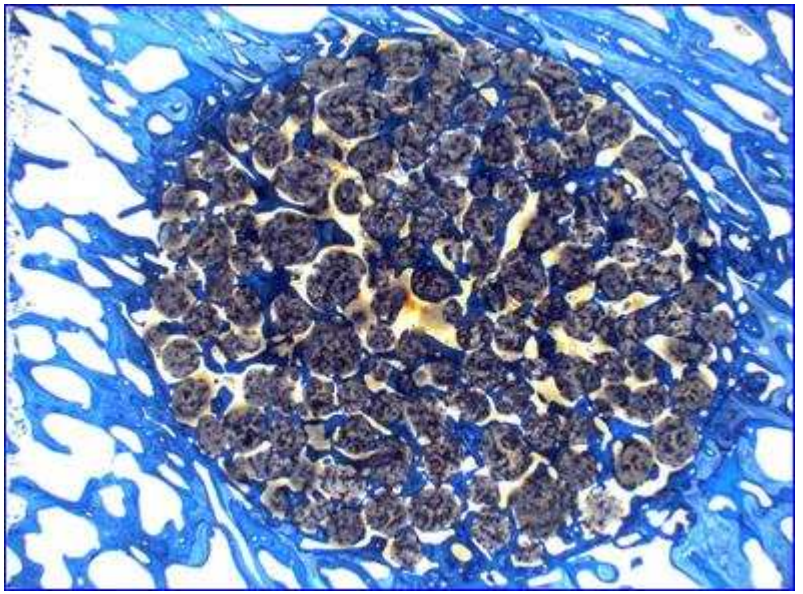
- Studies exist to the following topics:
  - Biocompatibility/efficacy of *easy-graft™CRYSTAL* in an animal model
  - Biphasic calcium phosphate in dental applications (socket preservation, bone cysts, periodontal defects, sinus floor elevations)
- Further clinical studies in 2010

Studies & Publications

easy-graft™ CRYSTAL

Key findings:

- BCP is biocompatible
- BCP is osteoconductive
- BCP remains in the defect



Studies & Publications

easy-graft™ CRYSTAL

Literature about biphasic calcium phosphate (BCP) and DS biomaterials

Lee, J. H, et al., 2008 Histologic and clinical evaluation for maxillary sinus augmentation using macroporous biphasic calcium phosphate in human. Clin Oral Implants Res 19(8): 767-71. - Habibovic, P., M. et al., 2008 Comparative in vivo study of six hydroxyapatite-based bone graft substitutes. J Orthop Res 26(10): 1363-70. - Zafiropoulos, G. G. et al., 2007 Treatment of intrabony defects using guided tissue regeneration and autogenous spongiosa alone or combined with hydroxyapatite/beta-tricalcium phosphate bone substitute or bovine-derived xenograft. J Periodontol 78(11): 2216-25. - Daculsi, G., O, et al., 2003 Current state of the art of biphasic calcium phosphate bioceramics J Mater Sci Mater Med 14(3): 195-200. - Piattelli, A., et al., 1996 Clinical and histologic aspects of biphasic calcium phosphate ceramic (BCP) used in connection with implant placement. Biomaterials 17(18): 1767-70.- Passuti, N., et al., 1989 Macroporous calcium phosphate ceramic performance in human spine fusion. Clin Orthop Relat Res(248): 169-76.

Schug, J., 2009. Langzeitstabilität eines Implantats nach Alveolarprävention mit beta-Tricalciumphosphat und einem internen Sinuslift: eine Fallstudie. Submitted - Gläser, R., 2009. Ästhetische Rehabilitation im Frontzahnbereich dank erfolgreichem Kieferkammerhalt und 3D-Planung – ein Fallbericht mit histologischer Analyse. Submitted - Gacic, B. et al, 2009. The closure of oroantral communications by application of the alloplastic material PLGA-coated beta-TCP. Submitted. - Gläser R. 2009 Innovative Geweberegeneration durch formstabiles, defektkongruentes beta-TCP-Composite. Implantologie Zeitung, (1):12-15. - Thoma, K. et al. 2006. Bioabsorbable root analogue for closure of oroantral communications: A prospective case-cohort study. Oral Surg Oral Med Oral Pathol Oral Radiol Endod, 101(5): 558-64. – Nair, P.N. et al, 2006. Biocompatibility of beta-tricalcium phosphate root replicas in porcine tooth extraction sockets - a correlative histological, ultrastructural, and x-ray microanalytical pilot study J Biomater Appl 20(4):307-324 - Nair, P.N. et al. 2004. Observations on healing of human tooth extraction sockets implanted with bioabsorbable polylactic-polyglycolic acids (PLGA) copolymer root replicas: A clinical, radiographic and histological follow-up report of 8 cases. Oral Surg Oral Med Oral Pathol Oral Radiol Endod, 97: 559-69, May. - Schmidlin, P. et al. 2004. Alveolarkammprävention nach Zahnextraktion – eine Literaturübersicht, Schweiz Monatsschr Zahnmed, 114: 328-336, April. Schug, J. et al. 2002. Prävention der Alveolarkammatrophie nach Zahnextraktion durch Wurzelreplikas. DZW, 47: 14-15, Feb. - Maspero, FA et al. 2002. Resorbable defect analog PLGA scaffolds using C02 as solvent: Structural characterization, J Biomed Mater Res, 62: 89-98. - Heidemann, W. et al. 2001. Degradation of poly(D,L)lactide implants with or without addition of calciumphosphates in vivo. Biomaterials, 22: 2371-2381.

- Suhonen, J., et al., 1996. Polylactic acid (PLA) root replica in ridge maintenance after loss of a vertically fractured incisor. Endod Dent Trumatol, 12: 155-160. - Suhonen, J. et al. 1995. Custom made Polyglycolic acid (PGA)-root replicas placed in extraction sockets of rabbits. Dt. Z Mund Kiefer Gesichts Chir. 19: 253-257.

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Indications

easy-graft™ CRYSTAL

The fast osteoconduction and the long-term stability make *easy-graft™CRYSTAL* especially suitable for:

- Large bone defects
- Regions that are prone to bone atrophy
- Patients with reduced bone regeneration potential

Possible uses are:

- Cystectomy
- Socket preservation
- Sinus floor elevation
- Bone spreading
- Guided bone regeneration (GBR)
- Periodontal defects
- Periimplantitis

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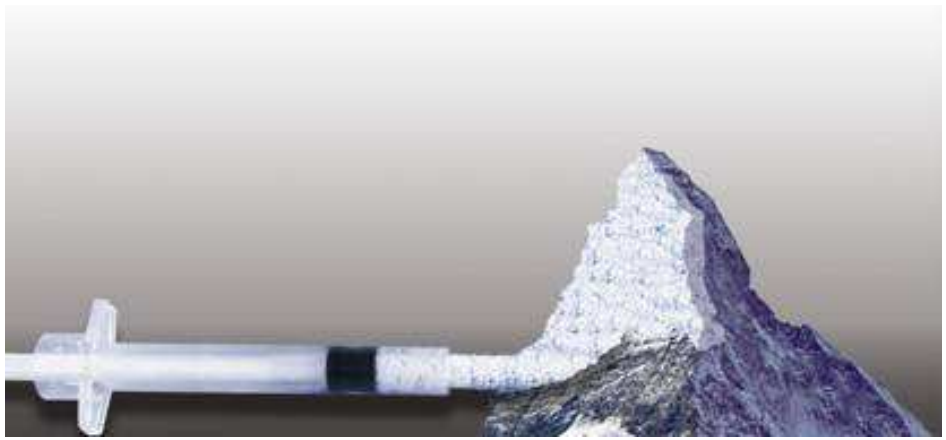
easy-graft™CRYSTAL & CLASSIC

easy-graft™ CRYSTAL

easy-graft™ CRYSTAL

partial resorption

easy-graft™



full resorption

easy-graft™ CRYSTAL & CLASSIC

easy-graft™ CRYSTAL

	easy-graft™ CRYSTAL	easy-graft™
Material	Biphasic calcium phosphate (60% HA / 40% β-TCP)	Pure phase β-tricalcium phosphate (>99%)
Properties	• Fast osteoconduction • Long-term volume preservation	• Degradation parallel to bone formation • 100% degradable
Indications	Large bone defects and patients with reduced bone regeneration potential, e.g. in cystectomy, socket preservation, sinus floor elevation, bone spreading, guided bone regeneration (GBR), periodontal defects, periimplantitis	Small defects in oral surgery, implantology, socket preservation, and sinus floor elevation

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Degradable Solutions AG

Degradable Solutions AG is a global leader in the development and production of degradable implants for

- Dentistry
- Spine surgery
- Sports medicine
- Traumatology

15 years experience guarantee for innovative products with high customer benefits.

easy-graft™CRYSTAL is produced and sterilized in Switzerland according to rigorous quality standards.

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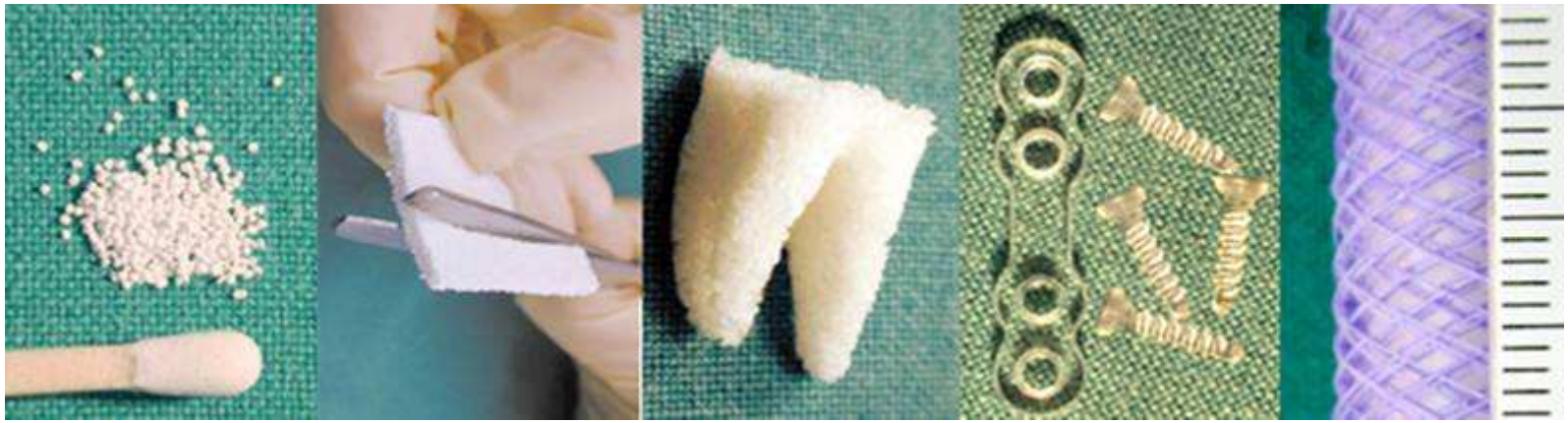
Degradable Solutions AG

easy-graft™ CRYSTAL

leading edge biomaterial implants

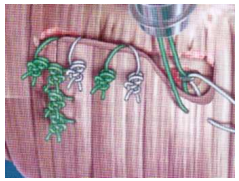


synthetic bone graft innovations swiss made

Degradable Solutions AG

easy-graft™ CRYSTAL

Sutures
engineering

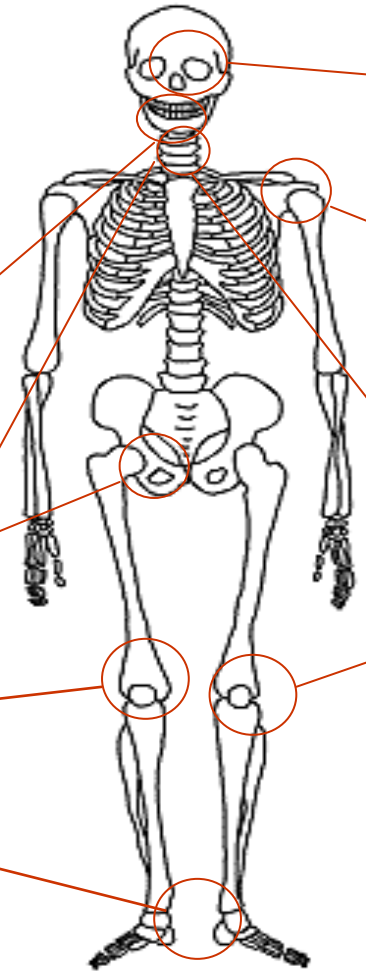


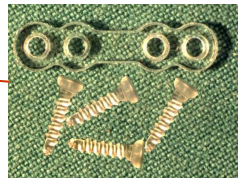
Dental membranes

Bone augmentation biomaterials

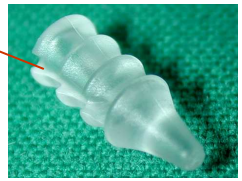
Meniscus fixation

Fixation devices for foot surgery



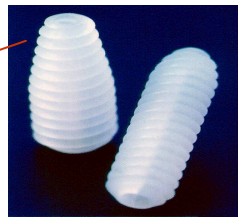


Fixation devices for maxillo-facial surgery

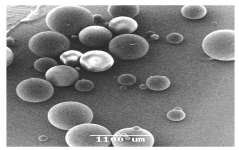


Suture anchors

Cervical cages



Screws for knee surgery



Drug release systems