DS

DEGRADABLE SOLUTIONS AG

From Orthopaedics to Dentistry

Dear Reader

Research findings on bone regeneration are progressing. So are the methods and optimal use of bone grafts and their substitutes. Whilst in the past scarcely anything other than autologous bone was used, nowadays more and more bone graft substitutes have found their way into the clinics. Granules from xenogenic, human or synthetic origin are used for treating bone defects using GBR technique. The broad availability and clinically proven effectiveness of these products has enabled the dentist to achieve better and reproducible results. With *easy-graft*™ and its stunningly easy handling, DS has significantly contributed to the suitability for daily use of bone graft substitutes and has been a door opener to new therapeutic possibilities.

SWISS TECHNOLOGY AWARD 2004

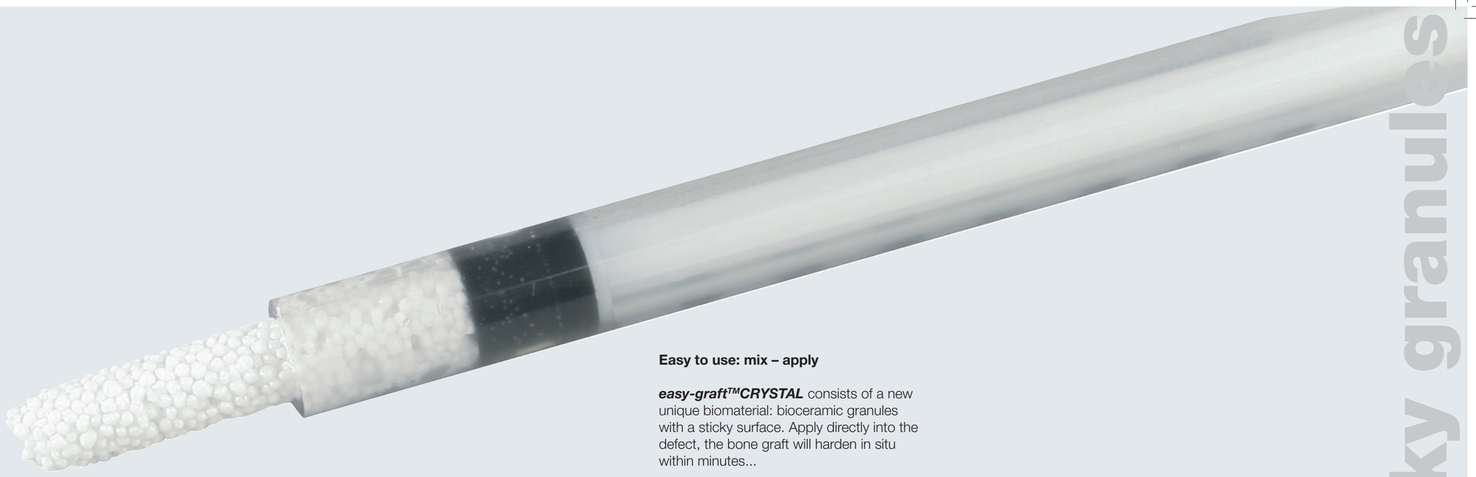
Now, we have made a further step towards differentiation. Not every material is suitable for every indication. Especially in large defects and for indications, which are prone to high atrophy, bone graft substitutes that degrade slowly or only partially may prove to be advantageous.

For such uses, DS recommends biphasic, porous calciumphosphate-granules. This material has been successfully used in orthopaedics for years and consists of hydroxyapatit and ß-TCP. The ß-TCP resorbs, releases calcium ions and forms porous channels that function as a guiding structure for bone regeneration. The crystalline structure of the hydroxyapatit has an optimal surface for osteoconduction and remains in place for years. Therefore, it supports the long-term preservation of bone volume. The new biphasic granules are available with the award-winning *easy-graft*™ application technique.

Profit from over 15 years of experience in development of bone graft substitutes and test ***easy-graft™CRYSTAL***.
You will not be disappointed!

Faithfully yours, Kurt Ruffieux

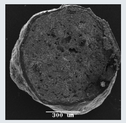
easy-graft™ CRYSTAL

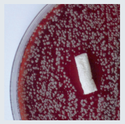


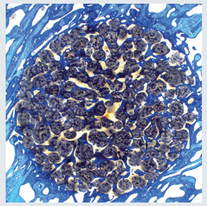
bionic sticky granules

The innovative concept

- High porosity due to bionic structure of granules
- Injectable putty due to fast resorbing polylactic acid coating
- Initial antibacterial properties
- Prevention of bacterial ingrowth due to coating
- No loss of granules due to solid body formation in situ
- High biocompatibility demonstrated in histological sections
- Direct bone contact promotes tissue ingrowth
- Blood uptake and tissue ingrowth due to porosity between granules
- Bone formation in parallel to partial degradation of bone graft substitute







Histological analysis

Two months after filling of an 8 mm drill defect in a sheep humerus with biphasic calcium phosphate granulate (BCP). After the toluidine blue staining, bone appears blue. Bone has grown through the entire supercritical defect confirming the good osteoconductivity of the material. The violet staining of the granulate suggests that bone penetrated into the granules. The osteointegrated hydroxyapatite remains in the bone resulting in long-lasting volume preservation. The intimate contact between BCP and bone indicates an excellent biocompatibility of the material.

Indications

The high osteoconduction and the long-term stability makes *easy-graft™CRYSTAL* especially suitable for

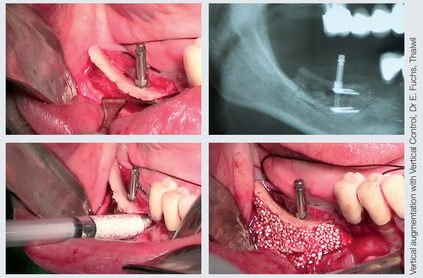
- Large bone defects
- Regions that are prone to bone atrophy
- Patients with reduced bone regeneration potential

Possible uses are

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

The advantages of *easy-graft™CRYSTAL* are

- Time & cost savings due to simple handling and shortend surgical procedure:
  - injectable
  - easy modelling in the pocket
  - In-situ hardening
  - In most cases no membrane needed
- accelerated osteoconduction
- long-term volume preservation
- 100 % synthetic (60 % HA / 40 % ß-TCP)



Vertical augmentation with Vertical Control, Dr E. Fuchs, Thalwil

Vertical alveolar ridge augmentation
easy-graft™CRYSTAL was used to fill the void below the mobilized layer of cortical bone in a vertical augmentation procedure. The hardening of the material resulted in a good primary stability.

Dr A. Huber, Erlang

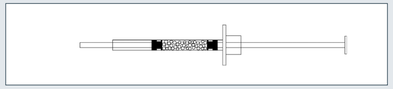
Horizontal spreading and implantation
Support for implant insertion and horizontal bone spreading, optimal stabilization of the mobilized lamellae.

Easy to use: mix – apply

easy-graft™CRYSTAL consists of a new unique biomaterial: bioceramic granules with a sticky surface. Apply directly into the defect, the bone graft will harden in situ within minutes...

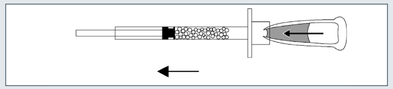
Step by step...

Open the pouch with the syringe containing ***easy-graft™CRYSTAL*** granules, open the pouch with the Biolinker.

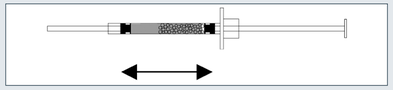


Fill the Biolinker into the syringe.

Mix both components and discard excess Biolinker.



The granules are now sticky and may be applied directly into the bone defect.

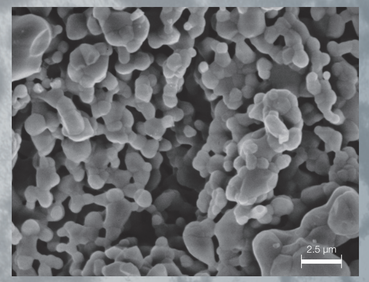


Literature about biphasic calcium phosphate (BCP) and DS biomaterials

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. - Dacuisi, 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 CO2 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 calcium phosphates 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.

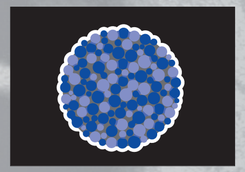
High osteoconduction and long-term volume preservation

easy-graft™CRYSTAL achieves an accelerated osteoconductivity thanks to its high micro- and macroporosity as well as its optimally balanced material formulation. The ß-TCP (40 %) resorbs slowly while the hydroxyapatit (60 %) remains in the defect and functions as a highly porous scaffold ensuring long-term volume preservation.



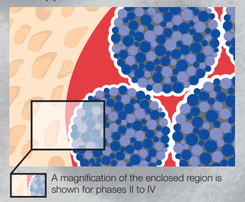
Detail of an *easy-graft™CRYSTAL* granule (electron-microscopic image)

Cross section through an *easy-graft™CRYSTAL* granule (schematic representation)



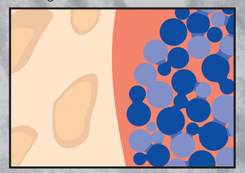
- Hydroxyapatite (HA)
- ß-Tricalcium phosphate (ß-TCP)
- Polylactide coating (PLGA)
- Bone
- Blood

Phase I
after application into the defect

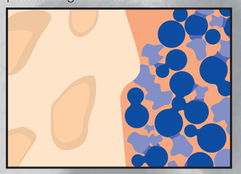


A magnification of the enclosed region is shown for phases II to IV

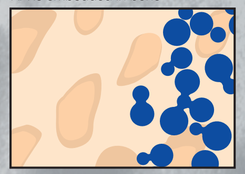
Phase II
after degradation of the polylactide coating



Phase III
proceeding bone formation



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



easy-graft™CRYSTAL

Reference no.	C15-012	C15-013	C15-002	C15-003
Units	3 x 0.15 ml	6 x 0.15 ml	3 x 0.4 ml	6 x 0.4 ml
Granule size	450 – 630 µm	450 – 630 µm	450 – 1'000 µm	450 – 1'000 µm
Material	Biphasic calcium phosphate (60 % HA / 40 % ß-TCP)			
Indication	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			

easy-graft™CLASSIC

Reference no.	C11-012	C11-013	C11-002	C11-003
Units	3 x 0.15 ml	6 x 0.15 ml	3 x 0.4 ml	6 x 0.4 ml
Granule size	500 – 630 µm	500 – 630 µm	500 – 1'000 µm	500 – 1'000 µm
Material	Pure phase ß-tricalcium phosphate (>99 %)			
Indication	Small defects in oral surgery, implantology, socket preservation, and sinus floor elevation			

calc-i-oss™

Reference no.	A02-103B	A02-103C	A02-103D
Units	3 x 0.5 g	3 x 1.0 g	3 x 2.0 g
Granule size	315 – 500 µm	500 – 1'000 µm	1'000 – 1'600 µm
Material	Pure phase ß-tricalcium phosphate (>99 %)		
Indication	General bone defects in oral surgery and implantology		

DS
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