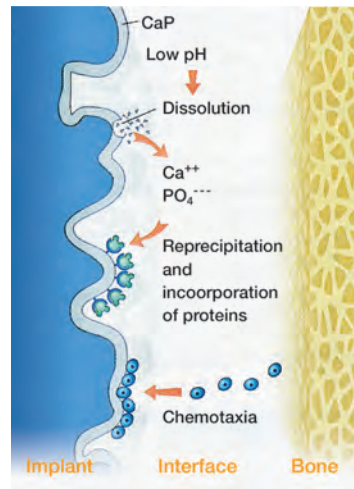


## Clinical results



Source:  
Søren Overgaard:  
Calcium phosphate coatings  
for fixation of bone implants.  
Evaluated mechanically and  
histologically by stereological  
methods.  
Acta Orthopaedica  
Scandinavica, suppl. no. 297,  
vol. 71, December 2000

## Bibliography

Since BONIT® was first marketed in 1995, more than 700,000 orthopaedic and dental implants have been coated with BONIT® coatings.

Animal studies and clinical trials have provided impressive proof of the efficacy of BONIT® coatings. Accelerated implant healing, increased bone formation and improved mechanical implant anchoring have been observed especially in the early post-implant phases. This means that the load bearing properties of the implant are robust at an early stage.

BONIT® coatings are completely resorbed in a controlled way (approximately six to twelve weeks following implantation) and are simultaneously replaced by bone.

The coatings are well tolerated and no inflammatory or rejection processes have been reported.

- Schwarz ML et al., *Histomorphometrical and mechanical Evaluation of various Surfaces on Titanium Testbodies placed into Femora of the Göttinger Minipig. Can a resorbable Ca-P Coating increase the Osteointegration?*, 49th ORS New Orleans 2003; Poster 1378
- Schwarz ML et al., *Effect of a resorbable CaP coating on Bone-Implant Contact and Density in a Gap Model after 4 and 8 weeks. An experimental Study in Göttinger Minipigs*, 52th ORS Chicago 2006; Poster 0869
- Szmukler-Moncler S et al., *From Microroughness to Resorbable Bioactive Coatings*, In: Ellingsen JE & Lyngstadaas SP (Hrsg.), *Bio-implant interface:improving biomaterials and tissue reactions*, Boca Raton, London, New York, Washington D.C.: CRC Press LLC 2003:73-100
- Wood PL, Deakin S, *Total ankle replacement, The results in 200 ankles*, JBJS 2003; 85-B : 334
- Reigstad O et al., *In vivo biomechanical comparison of Ti6Al4V implants with and without an electrochemically deposited CaP coating*, Biomaterials 2003; 4 : 143
- Pimenta L et al., *Clinical experience with the new artificial cervical PCM (Cervitech) Disc*, The Spine Journal 2004; 4 :3155
- McAfee PC et al., *SB Charité Disc Replacement, Report of 60 Prospective Randomized Cases in a U.S. Center*, J Spinal Disord & Techniques 2003; 16 : 424
- McAfee PC et al., *Analysis of Porous Ingrowth in Intervertebral Disc Prostheses*, Spine 2003; 28 : 332
- Lichtinger TK et al., *Osseointegration of Titanium Implants by Addition of Recombinant Bone Morphogenetic Protein 2 (rhBMP-2)*, Mat.-wiss. u. Werkstofftech. 2001; 32 : 937
- Link HD et al., *Choosing a cervical disc replacement*, The Spine Journal 2004; 4 : 294S
- Becker P et al., *Resorbable calcium phosphate composite coatings*, Key Engineering Materials 2002; 218-220 : 653
- Becker P et al., *Cellular investigation on electrochemically deposited calcium phosphate composites*, J Mater Science: Mater in Medicine 2004; 15 : 437
- Zeggel P, Becker P, *Innovative Beschichtungsverfahren für zementfreie Hüftpfannen*, in: Effenberger H et al., *Hüftschäfte*, Grieskirchen 2006; MCU-Verlag 53:56

# Accelerated healing through the use of electrochemically deposited CaP BONIT® coatings



DOT GmbH  
Charles-Darwin-Ring 1a  
18059 Rostock  
Germany

Tel: +49 (0) 381 - 4 03 35-0  
Fax: +49 (0) 381 - 4 03 35-99  
info@dot-coating.de  
www.dot-coating.de

**DOT**  
medical implant solutions

DOT is one of Europe's leading providers of medical coating solutions for orthopedic and dental implants and instruments and also their cleanroom packaging.

We also manufacture implants and products for regenerative medicine for dental and orthopedic applications.

Our comprehensive supply chain concept makes us an ideal medical technology partner. Our activities help restore the health of patients worldwide and thus make a major contribution to the improvement of their quality of life.

**DOT**  
medical implant solutions



# Osseointegration par Excellence

## Background



The success parameters for joint replacement implants include rapid healing, optimal fixation, and long-term compatibility. Another key factor is osseointegration, whose rapidity and durability are determined by implant design, materials used and surface structure. Consequently, over the past few decades not only surface topography but also surface chemistry have been the major areas of focus for implant designers and users. In order to be deemed optimal, implant surfaces today must be macroporous and at the same time compatible with osteogenesis. This is where thin, bioactive calcium phosphate (CaP) coatings come into their own.

They imitate the mineral components of bone tissue, thus enabling these coatings to be integrated seamlessly into the bone tissue development process. As the boundary layer between the bone and implant, these coatings play an instrumental role in bridging the gap between them. The coating aids the healing process in osteoporotic bone. CaP coatings optimise osseointegration even in lower quality bone and increase implant tolerance to micro movements. These characteristics make calcium phosphate coatings a helpful catalyst in connecting the patient's tissue with the implant.

## Technologies



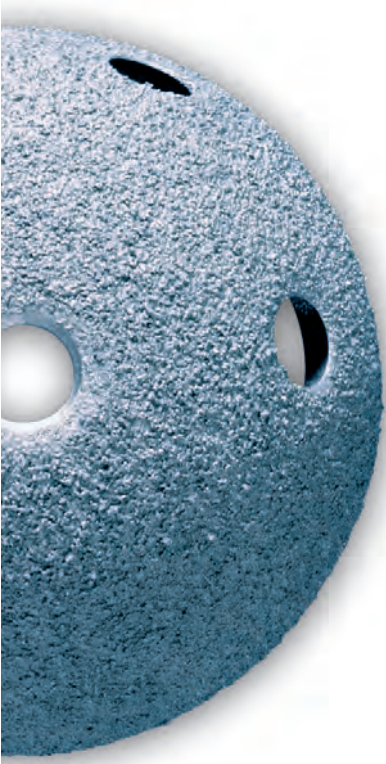
effect on coating quality. In addition, the so called "line of sight" spraying process is unsuitable for porous surfaces and complex implant geometries as only the external surfaces directly facing the spray gun are coated. These factors, in addition to the limited bonding capaci-

ty and inhomogeneous solubility of these coatings, led implant developers to the realisation that for CaP coatings to provide long-term stability plasma sprayed coatings may not be necessary or even desirable. It has since been discovered that bioactive coatings on implant surfaces only need to last as long as it takes for implant osseointegration to be completed. Once this has occurred, the coating has fulfilled its purpose and should biodegrade to make way for new bone. Thin, fully biodegradable and electro-deposited CaP coatings, are a further,

essential development on plasma sprayed hydroxyapatite coatings. They, providing that they are endowed with good bioactive properties, eliminate the long term risks that are currently associated plasma sprayed coatings. The fluid-phase BONIT® coating process allows for the realisation of thin (approximately 20µm) coatings with an even and complete coverage on structured surfaces and complex implant

geometries. The electro deposition process produces a microporous structure with outstanding solubility and resorption characteristics. The electrodeposited BONIT® coating is manufactured at room temperature. Unlike poorly soluble, highly crystalline, plasma-sprayed hydroxyapatite coatings, electrocoating technologies provide a microcrystalline structure that rules out the release of coating particles.

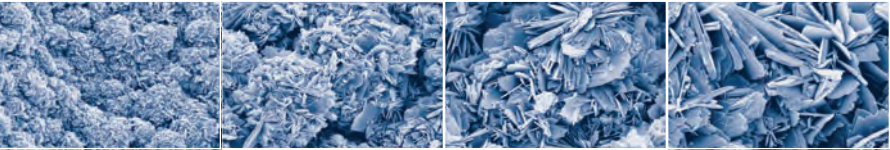
## Properties



BONIT® is a composite of two thin microcrystalline CaP phases that have differing solubility characteristics. The more soluble phase (brushite) promotes short term bone synthesis, whereas the inner phase (microcrystalline hydroxyapatite) is resorbed more slowly and releases ions over a relatively long period. This promotes bone formation. The coordinated bioactivity of these two phases greatly improves the healing process and fosters long-term implant tolera-

bility. The closely packed and almost perpendicular CaP crystals offer a large, open implant surface with a potent capillary effect on blood, beneficial for the adsorption of growth factors and for the attachment of bone cells.

The BONIT® coating process modifies the properties of the implant surface but has no effect on the chemical and physical properties or the biomechanical functionality of the implant material itself.



REM pictures of BONIT® coated surface

Coating thickness	20 ± 10 µm
Ca/P ratio	1.1 ± 0.1
Phase composition	Brushite and hydroxyapatite
Fatigue strength	BONIT® has no measurable impact on this parameter
Biocompatibility	Heavy metal content lower than ASTM F 1185 and ASTM F 1609 standards

## Advantages at a glance

- Outstanding biocompatibility
- Thin coating
- Microcrystalline structure, large open surface
- High solubility and controlled resorption area
- 100 percent and even coverage of porous surfaces and complex implant geometry
- Non-line of sight process
- No particle shedding or flaking