

Accelerated healing by using electrochemically deposited CaP coating BONIT[®]



Principles

The parameters essential for the success of joint replacement implants are known to be rapid healing, optimal fixation, and long-term compatibility. Another key parameter is osseointegration whose rapidity and durability is determined by implant design, materials used and surface structure. Consequently, studies have focused on surface topography and surface chemistry over the past years. For an implant surface to achieve the optimal performance, it must offer a suitable (macroporous) structure and provide biocompatibility in order to facilitate bone metabolism.

Thin, bioactive calcium phosphate (CaP) coatings fulfill these requirements. They imitate the mineral components of bone tissue, thus enabling the coatings to be integrated seamlessly into the developing bone tissue. Acting as a boundary layer, the coatings play an instrumental role in bridging the gap between bone and implant. They also aid the integration of low-quality bone and increase implant tolerance to micro movements. Calcium phosphate coatings can be regarded as a vital link between the living organism and implant.

Technology

The first CaP coatings that were placed on the market in the 1980s consisted of relatively thick (50 μm) and compact hydroxyapatite layers that were applied to the implant surface using the plasma spray technique.

Unfortunately, this process induces thermal degradation, which has an adverse effect on coating quality. In addition, the "line-of-sight" spraying process is unsuitable for porous surfaces and complex implant geometries.

As a result of these factors, the limited adhesion and inhomogeneous solubility, a new line of thought was directed to the long-term stability of plasma sprayed CaP coatings. It is now common knowledge

that bioactive coatings are only required on the implant surface until implant osseointegration is achieved. Once it has occurred, the coating has fulfilled its purpose and should biodegrade to make way for new bone.

Thin, fully biodegradable and electrochemically-deposited CaP coatings, are an essential, further development after plasma sprayed hydroxyapatite coatings. They are able to retain their good bioactive properties and eliminate long term risk factors that are still present.

The fluid-phase of the BONIT[®] coating process allows for thin application (approximately 20 μm) and covers structured surfaces and complex implant geometries evenly and completely.

The microporous surface, which has outstanding solubility and resorption characteristics, is formed by electrodeposition. BONIT[®] is deposited at room temperature. Unlike highly crystalline, poorly soluble, plasma-sprayed hydroxyapatite coatings, a microcrystalline structure is created by using electro-coating technologies. The formation of hard particles and coating delaminations can be ruled out when this technology is used.

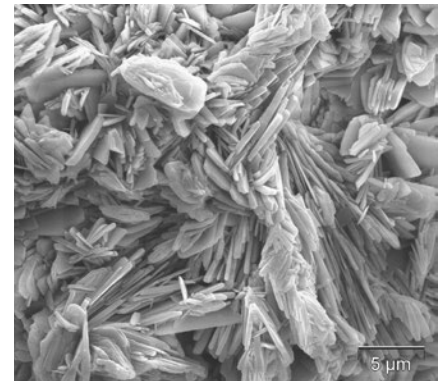
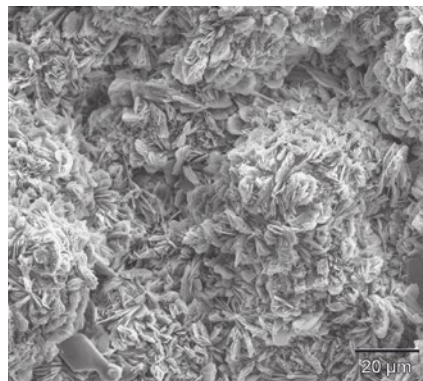
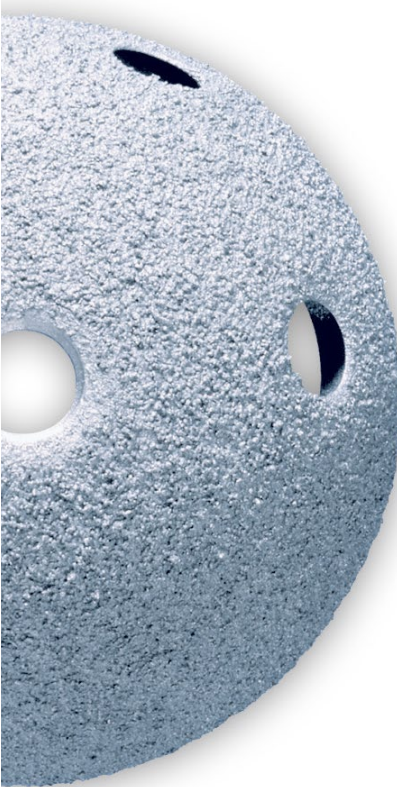


Properties

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

The closely packed, almost perpendicular CaP crystals and the large, open surface offer the implant surface a potent capillary effect on blood that is 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.



SEM pictures of BONIT® coated surface

Coating thickness	20 ± 10 μm
Ca/P ratio	1.1 ± 0.1
Phase composition	Brushite + HA
Fatigue strength	BONIT® has no measurable impact on this parameter
Elemental analysis	Heavy metal content lower than ASTM F 1185 and ASTM F 1609 standards
Biocompatibility	Biocompatible (DIN EN ISO 10993-1)

Advantages

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

Clinical results

More than 4,700,000 orthopedic and dental implants have been coated with BONIT® since it was first placed on the market in 1995.

Animal studies and clinical trials have provided impressive evidence to demonstrate the efficacy of BONIT® coatings. Accelerated implant healing, increased bone formation and improved mechanical implant anchoring have been observed in

the early post-implantation phases, leading to implant loading at an early stage. BONIT® coatings are completely resorbed in a controlled manner (approximately six to twelve weeks following implantation) and are simultaneously replaced by bone. BONIT® is well tolerated. Incidents stemming from inflammation or foreign body reaction to products coated with BONIT® have not been observed.

Literature

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We look forward to talking with you!

DOT GmbH
A Member of Eifeler Holdings
Charles-Darwin-Ring 1a
18059 Rostock

Phone: +49 381 40 33 50
Fax: +49 381 40 33 599
info@dot-coating.de
www.dot-coating.de

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medical implant solutions

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