

*One Nano Step For Man,  
One Giant Leap For  
Implant Dentistry...*

*The Bone Bonding®\*  
NanoTite™ Implant*

*Nano In Size,  
Profound In Effect*

\*The interlocking of the newly formed cement line matrix of bone with the implant surface.

2007

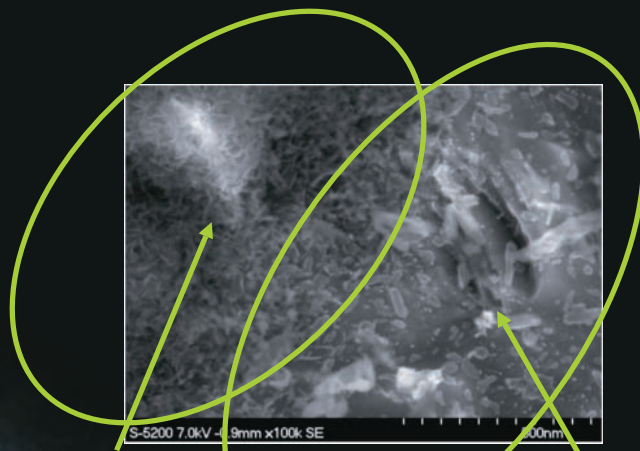
FROST & SULLIVAN

European Dental Implant Customer Service  
Leadership Award

## **The Revolutionary NanoTite™ Implant – A Bone Bonding® Surface**

- Microtopography Of The OSSEOTITE® Implant Combined With A Nanometer-scale Discrete Crystalline Deposition (DCD™) Of Calcium Phosphate (CaP) Creates A More Complex Surface Topography. This Renders The NanoTite Implant A Bone Bonding Surface By The Interlocking Of The Newly Formed Cement Line Matrix Of Bone With The Implant Surface<sup>1, 16</sup>
- Preclinical Studies Demonstrate A Substantial Improvement On The Rate And Extent Of Osseointegration For The NanoTite Implant Versus The OSSEOTITE Implant Leading To Implant Stability<sup>12</sup>
- NanoTite Implants May Be Used For Immediate Function On Single Tooth And/Or Multiple Tooth Applications When Good Primary Stability Is Achieved, With Appropriate Occlusal Loading, In Order To Restore Chewing Function

### **Interface Of Cement Line Matrix And DCD Treated Implant Surface**



**De novo Bone**

Photo Courtesy Of:  
John E. Davies,  
BDS, PHd, DSc, FSBE

**Nano Crystals**

## Why NanoTite™?

BIOMET 3i's OSSEOTITE® Surface has more than a decade of clinical use and evidence based research to support its efficacy, so why is another surface needed?<sup>2-9</sup> As treatment protocols get more advanced and dental implants are placed in more challenging clinical scenarios, there could be a benefit to a surface that provides a greater rate and extent of osseointegration on a more predictable basis. Potential scenarios where such an implant might be beneficial to patient and practice might include the following:

- Immediate And Accelerated Loading Protocols
- Immediate Replacement In Extraction Sockets
- Simultaneous Grafted Sites And Implant Placement
- Aesthetic Areas Where Bone Preservation Is Critical
- Implant Placement In Poor-Quality Bone
- Locations Requiring Short Or Wide Implants

Implants typically demonstrate good primary stability at the time of placement – in principle, a mechanical phenomenon. As bone remodels in subsequent weeks, there can be a reduction in implant stability that might impact early or immediate loading protocols.\*

Now with the next generation surface technology, the NanoTite Implant incorporates the complex architecture at the nano-scale, which renders it a Bone Bonding® Surface.† Preclinical studies have shown that the surface on the NanoTite Implant results in significantly enhanced integration compared to OSSEOTITE Control Implants.<sup>12</sup> This enhanced osseointegration is occurring at early time points.<sup>15</sup> BIOMET 3i is actively investigating via resonance frequency analysis the ability for the NanoTite Implant to produce a more Steady State Stability™‡ Condition in the early phases of healing.

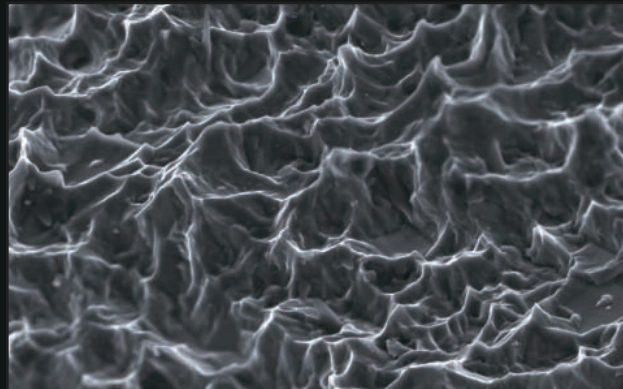
\* Adapted from: Raghavendra S, Wood MC, Taylor TD. Early wound healing around endosseous implants: a review of the literature. *Int J Oral Maxillofac Implants*. 2005 May-Jun;20(3):425-31.

† Bone Bonding is defined as the interlocking of the newly formed cement line matrix with the implant surface.

‡ BIOMET 3i defines Steady State Stability as maintaining the primary stability achieved at the time of surgery with minimal to no drop-off in implant stability due to bone remodeling.

## It All Starts With The Proven OSSEOTITE® Surface...

For more than 10 years, with documentation from numerous global multicenter clinical evaluations, the OSSEOTITE Surface has proven to be a predictable and well-researched surface<sup>2-9</sup>. Clinical studies on the OSSEOTITE Surface continue to document the benefits of increased contact osteogenesis, especially in poor-quality bone.<sup>6</sup>



OSSEOTITE Surface at 20,000x magnification

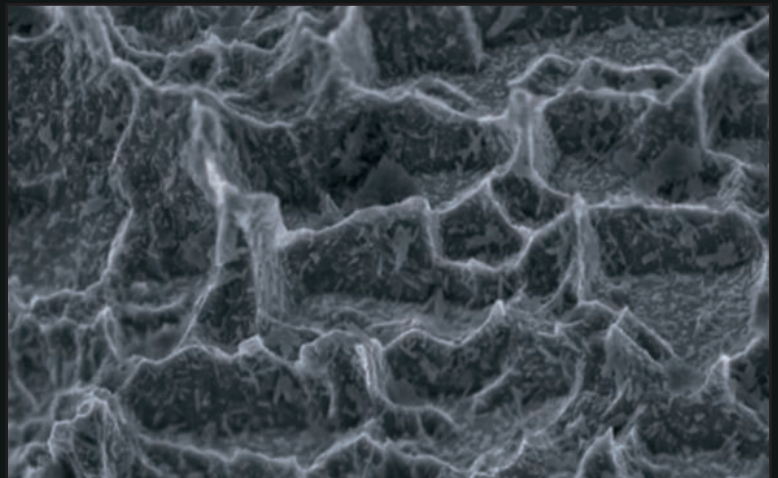


**...And It Gets Better With The Nano-Scale  
Discrete Crystalline Deposition (DCD™) Process**

**An Innovative Implant Surface Technology**

**The Unique Patented Process:**

1. Nanometer-scale, ultra small particles of highly Crystalline Calcium Phosphate (CaP) are suspended in the solution
2. These particles are then prompted to “Self-Assemble” onto the implant titanium oxide surface
3. This results in discrete crystal deposits of 20-100 nanometers in length on the dual acid etched OSSEOTITE® Implant Surface. The shear strength of crystal attachment to the OSSEOTITE Surface exceeds the minimum shear strength value of 34.5 MPa set by the ASTM standard (F 1609-03) for attachment of traditional HA coatings to implant surfaces<sup>11</sup>



*NanoTite™ Surface at 20,000x magnification*

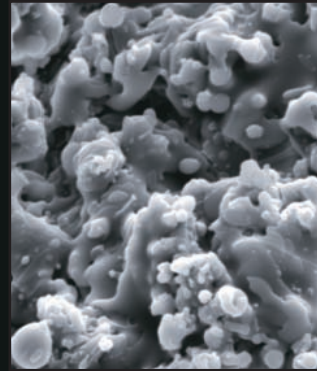
## Using The Best Of Both Worlds

The NanoTite™ Implant builds on the success of the OSSEOTITE® Surface by creating a more complex surface topography and maximizing the potential biological benefits of calcium phosphates (CaP).

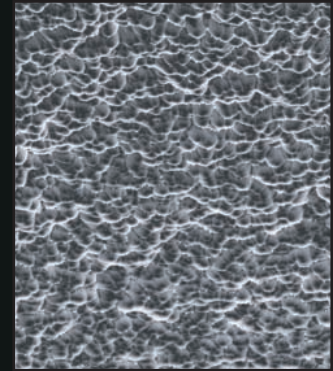
Traditionally, CaP has been plasma sprayed on the implant surface, creating a coating thickness typically in the range of 50-100 microns. The nature of plasma sprayed coatings makes them susceptible to events such as delamination or dissolution of the amorphous content of the coating.\* Hence the positive attributes of CaP may be offset by certain risk factors.

The NanoTite Implant is different. The CaP is not applied via a plasma sprayed process but rather a solution based form of self-assembly. It is not a continuous coating but consists of actual deposits of discrete crystals that occupy approximately 50% of the OSSEOTITE® Surface. The total amount of CaP material on a NanoTite Implant is so small that it weighs less than 20 micrograms (or about one-third the weight of one grain of ordinary table salt). This is in contrast to the 20,000 micrograms of CaP on the typical plasma sprayed surface – a one thousand fold difference.

The dissolution of DCD™ on a NanoTite Implant is extremely low in physiologically neutral pH given the highly crystalline nature of the CaP crystals. This provides implants with a more consistent and stable phase of CaP, allowing the implant site to capitalize on the positive attributes of this biomaterial. In addition, the DCD Process increases the micro-surface area by 200%, providing greater microcomplexity.



HA Surface  
at 2000x magnification

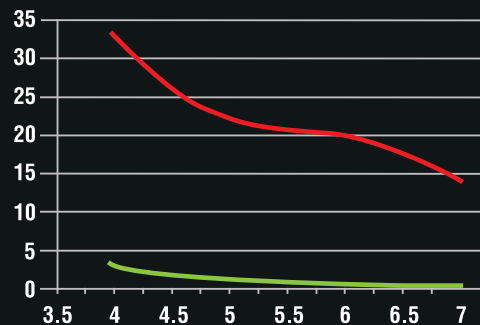


NanoTite Surface  
at 2000x magnification

*At 2000x magnification, the contiguous coating is clearly evident with a plasma-sprayed implant, while at the same magnification, there is no visible change in the microtopography of a NanoTite Implant. At 20,000x magnification, these nano-scale discrete deposits become visible. (See image opposite page)*

### Dissolution Of Discrete Calcium Phosphate Crystals vs. Plasma Sprayed HA<sup>10</sup>

(Micrograms Of Ca Dissolution At Various pH)



■ NanoTite - Surfaced Implants  
■ Plasma Sprayed Implants

NanoTite Implant vs. HA Plasma Sprayed Implant						
	APPLICATION METHOD	ADHESION STRENGTH <sup>11</sup>	CRYSTALLINITY <sup>12</sup>	IMPLANT COVERAGE <sup>12</sup>	SURFACE AREA INCREASE OVER OSSEOTITE <sup>13</sup>	AMOUNT OF CaP <sup>13</sup>
NanoTite Implant	Nano crystal self assembly	>40x ASTM standard	>95% pure crystalline HA	50% of the OSSEOTITE Surface	200% greater surface area	3.6-22.8µg
HA Plasma Sprayed Implant	Plasma sprayed	ASTM standard of 34.5 MPa	Variable crystallinity: typical amorphous content	100% on Grit-blasted Surface	N/A	20,000µg

\* Adapted from: Ong JL, Chan DC. Hydroxyapatite and their use as coatings in dental implants: a review. Crit Rev Biomed Eng. 2000;28(5-6):667-707.

## Researchers Are Seeing Impressive Results

### Benchtop Testing

Both quantitative and qualitative benchtop performance tests demonstrate superior adhesion strength of the nano-scale crystals to the OSSEOTITE® Implant

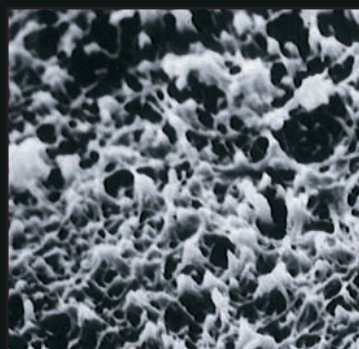
Study Center	Evaluations	Findings
BIOMET 3i	Quantitative Analysis of Nano-Scale Shear Strength/Stress	The average crystal-surface adhesion shear strength was three orders of magnitude greater than the average implant-bone shear stress <sup>11</sup>
BIOMET 3i	Qualitative Analysis of Nano-Crystal Adhesion	Field Emission Scanning Electron Microscope imaging indicated that the nano-crystals did not become dislodged during implant placement and removal <sup>12</sup>

### Preclinical Studies

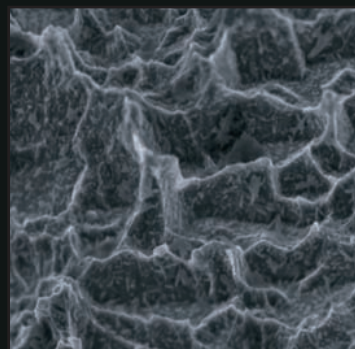
A comprehensive series of animal studies were performed on the NanoTite™ Surface in various animal models. Further, these studies conclusively demonstrated that the NanoTite Surface results in a greater rate and extent of osseointegration as compared to the OSSEOTITE Surface alone. The micro-topography of the OSSEOTITE Surface combined with the nanometer-scale architecture created with the NanoTite Surface Treatment renders it a Bone Bonding® Surface by the interlocking of the newly formed cement line matrix of bone with the implant surface.

Study Center	Evaluations	Comparisons With OSSEOTITE	Healing Time
UCLA	Rat Push-in	Up to 129% push-in force difference <sup>14</sup>	14 days
SkeleTech	Rabbit Pull-out	109% increase in pull-out force <sup>12</sup>	14 days
University of Toronto	T Plant Histology	160% increase in Bone-To-Implant-Contact (BIC) <sup>15</sup>	9 days
University of Toronto	Tensile 1	700% detachment force difference <sup>16</sup>	9 days
University of Toronto	Tensile 2	>1,000% detachment force difference <sup>16</sup>	9 days

*Bone that has undergone osteoclastic resorption demonstrates a unique surface complexity not all that dissimilar from the NanoTite Surface complexity. The nanoscale topography of the NanoTite Implant is thought to play a significant role in the osseointegration potential of this implant.*



Osteoclastic Resorption Image  
Courtesy of J.E. Davies, BDS, PhD, DSc,  
FSBE University of Toronto

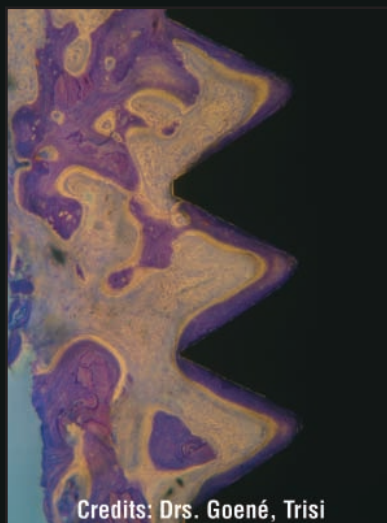


NanoTite Surface  
at 20,000x magnification

## Ongoing Preclinical And Clinical Studies

Numerous prospective human trials have been initiated with the NanoTite™ Implant and global evaluation of the product has been in progress since June of 2006. These human protocols were specifically designed to assess the comparative performance of the NanoTite Implant in more challenging clinical indications to include immediate loading. Human histology has also been procured demonstrating a substantive increase in Bone-To-Implant-Contact (BIC) with the NanoTite Surface.

Study Center	Evaluations	Comparisons With OSSEOTITE®	Healing Time
15 Study Centers	Immediate loading of single tooth restorations and short span bridge cases (Human)	Prospective study: One year follow-up, 343 implants placed; 95% cumulative success rate	Provisionalized in ≤48 hours
BIOMET 3i Clinical Registry	All evaluators provided early access to NanoTite Implants (Human)	Prospective study: At study close (Dec 2007), 1057 implants placed in 664 patients; 98.8% cumulative success rate	Varied
The Department of Stomatology and Oral Science at the University G. d'Annunzio, Chieti – Pescara	Trephined mini-implant (Human)	15 pairs NanoTite / OSSEOTITE; 70% increase in BIC. <i>J Periodontol</i> 2007;78;209-218.	8 weeks
Dr. Ronnie J. Goené, Amsterdam Dr. Tiziano Testori, Como Dr. Paolo Trisi, Pescara	Trephined mini-implant (Human)	9 pairs NanoTite / OSSEOTITE - 197% increase in BIC at 4 weeks - 148% increase in BIC at 8 weeks. <i>Int J Periodontics Restorative Dent</i> 2007;27:211-219	4 and 8 weeks
The Sahlgrenska Academy at Göteborg University	Soft and Hard Tissue (Animal)	In-life phase complete – under histological analysis	2/4 weeks
Universidad Complutense de Madrid	Soft and Hard Tissue (Animal)	In-life phase complete – under histological analysis	4 hours and 1, 2, 4, 8 weeks



### Bone-To-Implant-Contact Outcome At Eight Weeks Of Healing

Human histological sections have demonstrated an impressive amount of bone to implant contact around the NanoTite Surface, further supporting its unique potential for osseointegration.

## Surface And Design Technology That's Out Of This World



- **The NanoTite™ PREVAIL® Implant** incorporates integrated platform switching and an internal connection with the OSSEOTITE® Surface and nano-scale crystals to the top of the collar, creating a continuous bone-loading surface



- **The NanoTite Straight Collar PREVAIL Implant** provides users the benefits of the PREVAIL Implant in a straight collar design to allow for flexibility in tight interdental spaces or where ridge width is limited



- **The NanoTite Tapered PREVAIL Implant** includes benefits of the PREVAIL Implant in a tapered design for indications where a natural tooth root shape is preferred and early stability is desired



- **The NanoTite Tapered Implant** closely approximates the shape of a natural tooth root with the OSSEOTITE Surface and nano-scale crystals to the base of the implant collar



- **The NanoTite Certain® Implant** provides an internal connection and has coverage of both the OSSEOTITE Surface and nano-scale crystals to the base of the implant collar



- **The NanoTite External Connection Implant** has coverage of both the OSSEOTITE Surface and nano-scale crystals to the base of the implant collar



## What Your Peers Are Saying About The NanoTite™ Implant

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**Dennis Tarnow, DDS, New York, NY**

“It’s very exciting to us as clinicians and as academicians because this discrete deposited nano technology allows for the best of both worlds. Without having a full coating on the implant, you now have a surface that will integrate... that’s the regular OSSEOTITE®...combined with something that acts as an attractor to the bone and in fact might allow for actual deposition of bone on the electron microscope level.”



**Robert Emery, DDS, Washington, D.C.**

“We try to stay at the cutting edge of oral and maxillofacial surgery and especially implant dentistry because we do such a large amount of implant surgery. To stay at the cutting edge you have to evaluate new products and see if they improve patient care. This “DCD™” Technology or the Nano Calcium Phosphate is probably the biggest improvement that’s hit implant dentistry in the past few years. It’s a big step forward.”



**Markus Hürzeler, DMD, PhD, Munich, Germany**

“We have already treated patients in one day. We placed implants and we immediately placed some teeth on those implants and we had a pretty good success rate. But now, with this new technology, I am pretty sure that in the future, we will have an even better success rate with this approach and if you have the opportunity to give the patient...that you come in the morning to the office and get implants... you get the teeth right away...in the same day...this I think is a big advantage and a big effect for the patient.”



**J. E. Davies, BDS, PhD, DSc, FSBE, Toronto, Canada**

“Certainly these results are incredible. I don’t think it’s because we’ve discovered a new phenomenon in biology, but certainly the interface which has been created between bone and this particular implant surface is quite different from anything ever seen before.”

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**Nano Fact:**

The planet earth is approximately one billion times larger than a soccer ball – the same correlation of a meter to a nanometer.

# NanoTite™ Implant Ordering Information

## NanoTite Certain® PREVAIL®

Length	3/4/3mm(P)	4/5/4mm(P)	5/6/5mm(P)	4/3mm(P)	5/4mm(P)
8.5mm	NIIOS3485	NIIOS4585	NIIOS5685	NIIOS4385	NIIOS5485
10.0mm	NIIOS3410	NIIOS4510	NIIOS5610	NIIOS4310	NIIOS5410
11.5mm	NIIOS3411	NIIOS4511	NIIOS5611	NIIOS4311	NIIOS5411
13.0mm	NIIOS3413	NIIOS4513	NIIOS5613	NIIOS4313	NIIOS5413
15.0mm	NIIOS3415	NIIOS4515	NIIOS5615	NIIOS4315	NIIOS5415

## NanoTite Tapered Certain PREVAIL

Length	4/3mm(P)	5/4mm(P)	6/5mm(P)
8.5mm	NIITP4385	NIITP5485	NIITP6585
10.0mm	NIITP4310	NIITP5410	NIITP6510
11.5mm	NIITP4311	NIITP5411	NIITP6511
13.0mm	NIITP4313	NIITP5413	NIITP6513
15.0mm	NIITP4315	NIITP5415	NIITP6515

## NanoTite Tapered Certain

Length	3.25mm(D)	4mm(D)	5mm(D)	6mm(D)
8.5mm	NINT3285	NINT485	NINT585	NINT685
10.0mm	NINT3210	NINT410	NINT510	NINT610
11.5mm	NINT3211	NINT411	NINT511	NINT611
13.0mm	NINT3213	NINT413	NINT513	NINT613
15.0mm	NINT3215	NINT415	NINT515	NINT615

## NanoTite Certain

Length	3.25mm(D)	4mm(D)	5mm(D)	6mm(D)
8.5mm	NIO SM385	NIO SS485	NIO SS585	NIO SS685
10.0mm	NIO SM310	NIO SS410	NIO SS510	NIO SS610
11.5mm	NIO SM311	NIO SS411	NIO SS511	NIO SS611
13.0mm	NIO SM313	NIO SS413	NIO SS513	NIO SS613
15.0mm	NIO SM315	NIO SS415	NIO SS515	NIO SS615
18.0mm	NIO SM318	NIO SS418	N/A	N/A

## NanoTite Tapered

Length	3.25mm(D)	4mm(D)	5mm(D)	6mm(D)
8.5mm	NNT3285	NNT485	NNT585	NNT685
10.0mm	NNT3210	NNT410	NNT510	NNT610
11.5mm	NNT3211	NNT411	NNT511	NNT611
13.0mm	NNT3213	NNT413	NNT513	NNT613
15.0mm	NNT3215	NNT415	NNT515	NNT615

## NanoTite External Connection

Length	3.25mm(D)	4mm(D)	5mm(D)	6mm(D)
7.0mm		NOSS407	NOSS507	NOSS607
8.5mm	NOSM385	NOSS485	NOSS585	NOSS685
10.0mm	NOSM310	NOSS410	NOSS510	NOSS610
11.5mm	NOSM311	NOSS411	NOSS511	NOSS611
13.0mm	NOSM313	NOSS413	NOSS513	NOSS613
15.0mm	NOSM315	NOSS415	NOSS515	NOSS615
18.0mm	NOSM318	NOSS418	NOSS518	NOSS618

**D = Diameter**  
**P = Restorative Platform**



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