The **Osseotite®** Implant

Documented Success

ZIMMER BIOMET

The Osseotite Implant Overview

Proven Clinical Success

The Osseotite Surface has more than 10 years of documentation from numerous global multi-center clinical studies[1-6] and meta-analyses.[7-8] Clinical studies on the Osseotite Surface continue to document the benefits of increased contact osteogenesis, especially in poor-quality bone.[6]

The Osseotite Implant features an acid-etched surface designed to facilitate osseointegration.

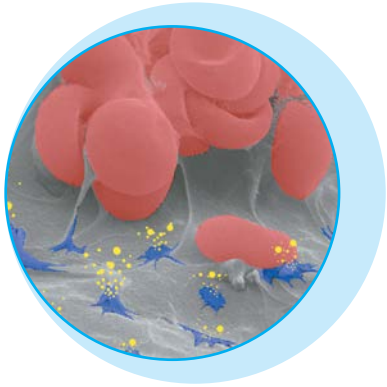
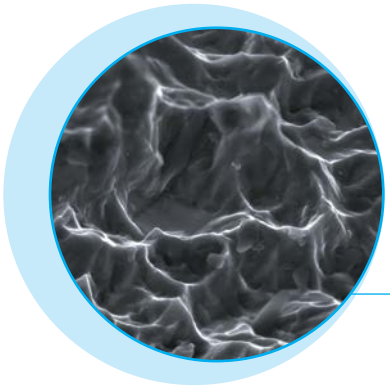


Image courtesy of Jun Y. Park, The Bone Interface Group.

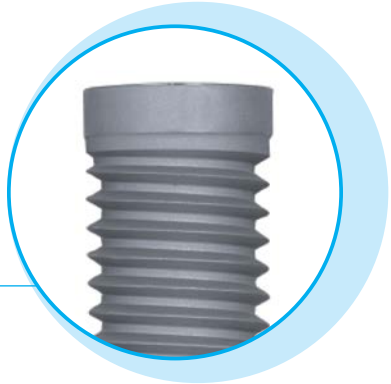


Osseotite Surface at 20,000x magnification

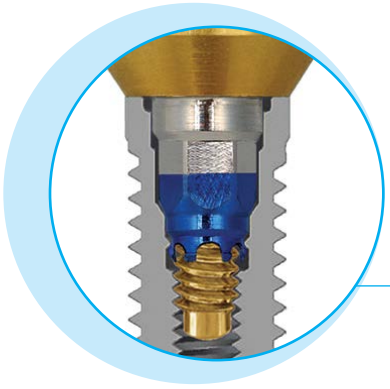
The Osseotite Surface

- Facilitates the osseointegration process
- Demonstrates high contact of implant with new bone
- One of the most well-researched dental implant surfaces on the market today
- Numerous studies report 98% cumulative success rates[6]

- Five-year study[10] showed no increased risk of peri-implantitis vs. a Zimmer Biomet hybrid implant
- Bone remodeling with integrated platform switching



Full Osseotite Surface



Certain Connection

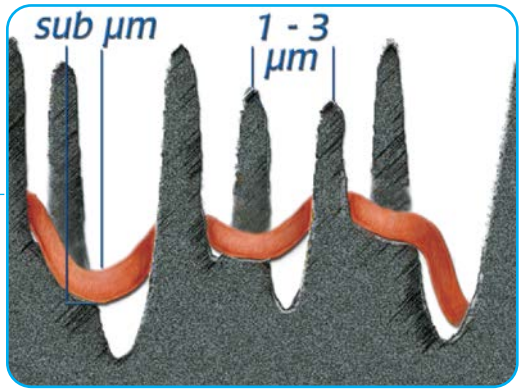
Certain Connection

- Seal Integrity provided by a stable, tight implant/abutment interface[14]
- Gold-Tite® Screw increases implant/abutment clamping force[17]

The Osseotite Surface and the Healing Process

Blood Clotting and Implant Attachment

A blood clot attaches to an implant when its fibrin strands become intertwined in an implant's micro-surface features. The strength of the clot/implant attachment depends on how tightly the fibrin strands are entangled in the surface. Fibrin strands are typically sub-micron in diameter. Therefore, for the strongest bond, the implant surface features should create a maze of slightly larger spaces that can tightly capture the fibrin strands. Characterized by a 1 to 3 micron peak-to-peak surface created by a unique acid-etch process, the Osseotite Surface features are precisely sized to entangle the fibrin strands of the blood clot.



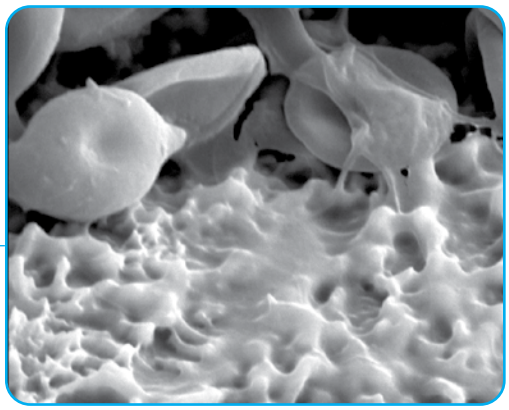
The Osseotite Surface Features Are Precisely Sized To Entangle The Fibrin Strands

Platelet Aggregation

Platelet Activation Up-Regulates Healing Response

Osteogenic cell migration will occur through the blood clot and can be expected to be influenced by the release of cytokines and other growth factors from activated cellular components of the blood clot. In a study of red blood cell (RBC) and platelet interactions with implant surfaces, the amount of RBC agglomeration on the Osseotite Surface was 54% greater than as seen on a smooth-machined surface.[11]

In addition, platelet adhesion onto the Osseotite Surface was enhanced by 110% in comparison to a smooth-machined surface.[11] RBC agglomeration is known to enhance blood clot permeability, which can lead to enhanced wound healing. Increased platelet activity can also lead to enhanced wound healing by the release of cytokines and growth factors.[12] Taken together, both platelet adhesion and RBC agglomeration can therefore result in increased bone formation on the Osseotite Surface.

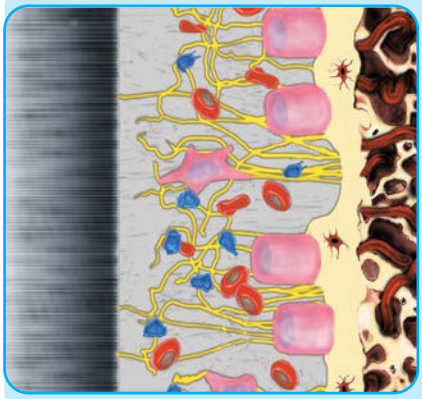


Enhanced microscopy image of the Osseotite surface showing platelet activation.

The Osseotite Surface and Bone Contact

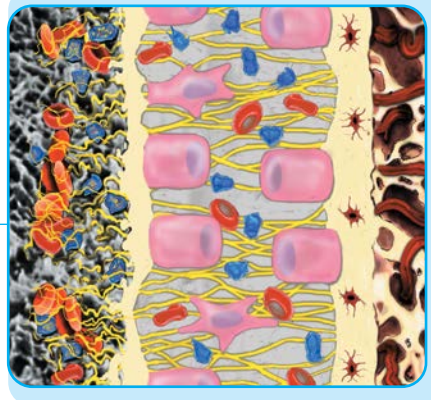
Clot Attachment Increases Contact Osteogenesis

Contact Osteogenesis Facilitates Bone Healing
Bone heals around an implant through two distinct and overlapping phenomena: distance osteogenesis and contact osteogenesis. The rate and extent of healing around an implant is dependent on the degree of contact osteogenesis that occurs at the implant surface. The migration of osteogenic cells through the clot matrix causes contraction of the fibrin strands in the clot matrix, which can detach the strands from smooth-machined implant surfaces, disrupting or stopping contact osteogenesis and osteoconduction.[13]



Smooth - Machined Implant | Healing Bone | Existing Bone

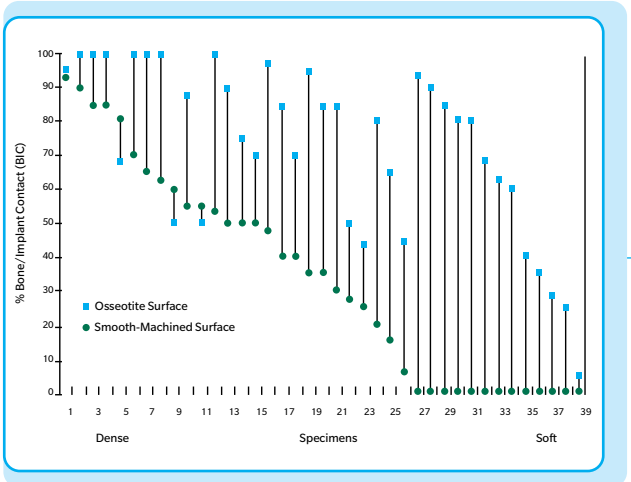
Distance Osteogenesis – A gradual process of bone healing inward from the edge of the osteotomy toward the implant. Bone does not grow directly on the implant surface.



Osseotite Implant | Healing Bone | Existing Bone

Contact Osteogenesis – The direct migration of bone-building cells through the clot matrix to the implant surface. Bone is quickly formed directly on the implant surface.

Human Histology Matched Smooth-Machined and Osseotite Surface Pairs



Human Histologic Data

In a study on the effect of implant surface features on bone healing, human histologic data confirmed the increase in osteoconduction and contact osteogenesis with the Osseotite Surface as compared to a smooth-machined surface. Two 1-millimeter diameter screws, each having on one side an Osseotite Surface and on the other side a smooth-machined surface, were placed in the posterior maxilla and removed after six months of healing.

The thirty-nine histologic sections prepared showed a mean percent bone/implant contact for the Osseotite surface of 72.96% as compared to 33.98% for the smooth-machined surface.[9]

Full Osseotite Implants and Peri-Implantitis

Full Osseotite Surface

A Five-Year Study

A five-year prospective, multicenter, randomized-controlled study of the incidence of peri-implantitis for hybrid-DAE and fully-DAE implants.[10]

Considerations for potential benefits of extending the DAE surface to the seating surface led to this prospective randomized-controlled study designed to assess the risk and incidence of peri-implantitis for fully-DAE-surfaced implants (Full Osseotite/FOSS).

Study implants, fully-DAE-surfaced "test" implants and hybrid-DAE "control" implants, were placed in a single-stage approach with the seating surface level with the crestal margin of the alveolar bone. The implants were allowed to heal for two months and were then provisionalized. Final restorations were placed at six months and patients were followed for five years at annual intervals. Follow-up evaluations included Sulcus Bleeding Index scores (SBI), probing for suppuration, assessments for mobility and periapical radiographs to identify radiolucencies and crestal bone levels.

Control Implant: hybrid-DAE

Test Implant: fully-DAE

One hundred twelve patients were enrolled and 165 test and 139 control implants were placed supporting 127 prostheses. No substantial differences in mucosal health outcomes between test and control groups were observed throughout the five year follow-up. For both groups, the bleeding-on-probing scores were no different. There was one case of peri-implantitis reported over the five years of observation and this was for a hybrid implant.

Radiographic analysis of crestal bone regression demonstrated that the mean change from baseline (provisionalization) is less for test implants in comparison to control implants (P<.01). The results of this five-year study showed no increased risk in adverse soft-tissue outcomes or peri-implantitis for fully-DAE-surfaced implants versus the control implants in this study.

Integrated Platform Switching

Bone remodeling with integrated platform switching

Integrated platform switching medializes the implant/abutment junction (IAJ) inward, creating a biologic width between connective tissue and the IAJ, helping to maintain bone levels.[19]

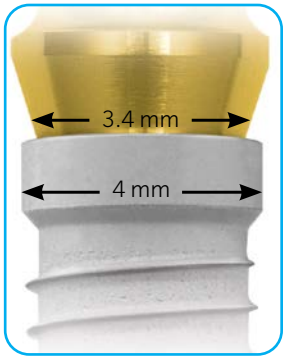
Reduced crestal bone loss

Studies show implants with the integrated platform switching feature demonstrated crestal bone loss as low as 0.37 mm.*[,20]

Image courtesy of Dr. Xavier Vela†, Spain.

Reduction in crestal bone remodeling vs. non platform-switched implants[21]

A medialized implant/abutment junction provides support for connective tissue, reducing the potential for recession by 50%.*



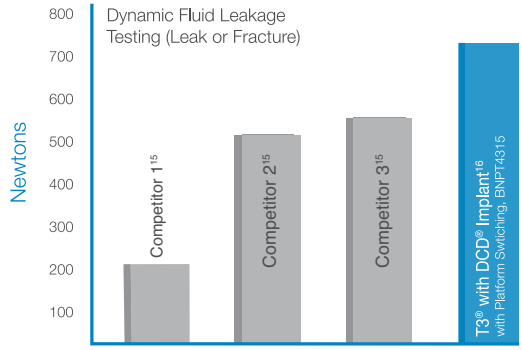
* Results are not necessarily typical, indicative or representative of all recipient patients.

Certain Connection

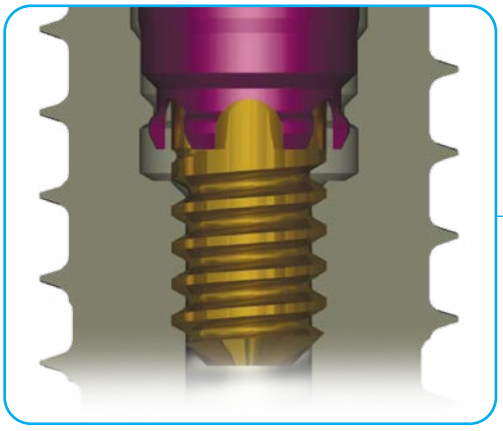
Seal Integrity

A stable, tight implant/abutment interface minimizes abutment micromotion and reduces potential microleakage.[14]

- Seal integrity test was performed by Biomet 3i July 2011 - June 2012. In order to test the implant systems, a dynamic - loading leakage test was developed and executed. The test set-up was adapted from ISO14801, Dentistry - Implants - Dynamic Fatigue Test for Endosseous Dental Implants.
- Five samples each of the three competitive implant systems were evaluated.
- The mean seal strength (N) at which each of the systems leaked or fractured is detailed in the graph.
- Bench test results are not necessarily indicative of clinical performance.



Results of preclinical testing are not necessarily indicative of clinical performance.



Implant/abutment seal strength

Designed to reduce microleakage through exacting interface tolerances and maximized clamping forces.

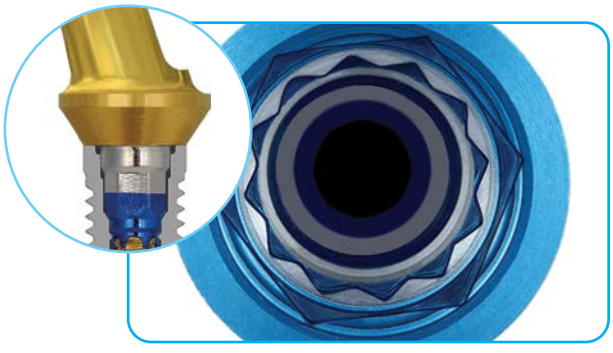
Implant/abutment clamping force

Use of the Gold-Tite® Screw increases Certain® Implant/abutment clamping force by 113% vs. a non-coated screw.[17]

Proprietary Gold-Tite Surface lubrication allows the screw to rotate further, increasing clamping force and maximizing abutment stability.[18]

The 6/12 hex inside the internal connection incorporates both a

- 6-point single and a 12-point double hex. The 6-point single hex is designed for two functions: engaging the driver tip for mountless delivery during implant placement and providing anti-rotation for all straight abutments.
- The 12-point double hex is designed to provide 30º rotational positioning for pre-angled abutments.



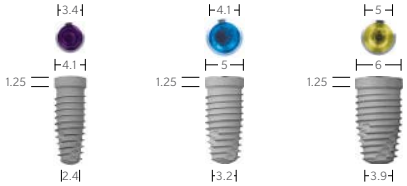
QuickSeat® Connection:

It Clicks! The Certain Implant and Abutment Systems feature the QuickSeat Connection. This unique connection produces an audible and tactile "click" that confirms placement of impression copings and abutments.

Abutment fingers cause the "click" and also provide retention for the prosthetic components in the implant before the screw is placed. A screw is needed to fully seat the components when the restoration is being tried in or definitively placed.

Ordering Information

Full Osseotite Tapered Certain PREVAIL
Commercially Pure Titanium

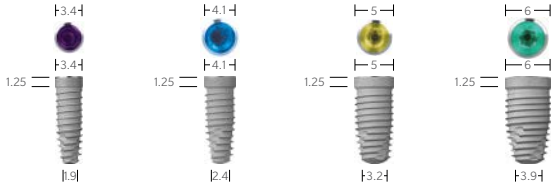


Length	4/3 mmP	5/4 mmP	6/5 mmP
8.5 mm	XIITP4385	XIITP5485	XIITP6585
10 mm	XIITP4310	XIITP5410	XIITP6510
11.5 mm	XIITP4311	XIITP5411	XIITP6511
13 mm	XIITP4313	XIITP5413	XIITP6513
15 mm	XIITP4315	XIITP5415	XIITP6515

Cover Screw Flat (included)			
			
	IMCSF34	ICSF41	ICSF50

*Non-Flared 4.1 mmP Cover Screw ICS400 is also available.

Full Osseotite Tapered Certain
Commercially Pure Titanium



3.25 mmD	4 mmD	5 mmD	6.0 mmD
XIFNT3285	XIFNT485	XIFNT585	XIFNT685
XIFNT3210	XIFNT410	XIFNT510	XIFNT610
XIFNT3211	XIFNT411	XIFNT511	XIFNT611
XIFNT3213	XIFNT413	XIFNT513	XIFNT613
XIFNT3215	XIFNT415	XIFNT515	XIFNT615

			
IMCSF34	ICSF41	ICSF50	ICSF60

References:

1. Sullivan DY, Sherwood RL, Porter SS. Long-Term Performance of OsseotiteImplants: A Six-YearClinical Follow-up.Compendium Contin Edu Dent. 2001 Apr;22(4):326-334.
2. Davarpanah M, Martinez H, Etienne D, Zabalegui I, Mattout P,Chiche F†, Michel J. A prospective multi-center evaluation of 1,538 3i implants: 1 to 5-year data. Int J Oral Maxillofac Implants. 2002 Nov-Dec;17(6):820-828.
3. Feldman S, Boitel N, Weng D, Kohles SS, Stach RM†. Five-Year Survival Distributions of Short-Length (10mm or less)Machined-Surfaced and Osseotite Implants. Clin Implant Dent Relat Res. 2004;6(1):16-23.
4. Sullivan D, Vincenzi G, Feldman S. Early Loadingof OsseotiteImplants 2 Months After Placement in the Maxilla and Mandible: A 5-year Report. Int J OralMaxillofac Implants 2005 Nov-Dec;20(6):905-912.
5. Stach RM†, Kohles SS. A Meta-Analysis Examining the Clinical Survivability of Machined-Surfaced and Osseotite Implants in Poor-QualityBone. Implant Dent. 2003;12(1):87-96.
6. Testori T†,Wiseman L, Woolfe S, Porter SS†. A ProspectiveMulticenter Clinical Study of the OsseotiteImplant: Four-Year InterimReport. Int J OralMaxillofac Implants. 2001 Mar-Apr;16(2):193-200.
7. Gaucher H, Bentley K, Roy S, Head T, Blomfield J, Blondeau F,NicholsonL, Chehade A, Tardif N, Emery R†. A Multi-Centre Study of OsseotiteImplants Supporting Mandibular Restorations: A 3-YearReport. J Can Dent Assoc (Tor). 2001 Oct;67(9):528-533.
8. Testori T†, Fabbro MD, Feldman S, Vincenzi G, Sullivan D, Rossi R, Anitua E, Bianchi F, Francetti L,WeinsteinRL. AMulticenter ProspectiveEvaluation of 2-months LoadedOsseotite Implants Placed in the Posterior Jaws: 3-year Follow-upResults. Clin Oral Implants Res. 2002 Apr;13(2):154-161.
9. Zetterqvist L, Feldman S, Rotter B, Vincenzi G,WennströmJL, Chierico A†, Stach RM†, Kenealy JN†. A Prospective,Multicenter, Randomized-Controlled Five-Year Study of Hybrid and Fully-etchedImplants for the Incidence of Peri-implantitis. J Periodontol. 2010 Apr;81(4):493-501.
10. Lazarra RJ†, Testori T†, Trisi P, Porter SS†,WeinsteinRL. A Human Histologic Analysis of Osseotite and Machined Surfaces Using Implants with TwoOpposing Surfaces. Int J PeriodonticsRestorativeDent. 1999 Apr;19(2):117-129.
11. Park JY, Davies JE†. Red Blood Cell and Platelet Interactions with Titanium Implant Surfaces. Clin Oral Implants Res. 2000 Dec;11(6):530-539.
12. Gemmell CH, Park JY. Initial Blood Interactions with Endosseous ImplantMaterials. International bone engineering workshop; Bone engineering; 1999; Toronto, Canada. Chapter 9 in Bone Engineering (ed. Davies JE†); Em Squared Inc. 2000 108-117pp.
13. Davies JE†. Mechanisms of Endosseous Integration. Int J Prosthodont. 1998 Sep-Oct;11(5):391-401.
14. Lazzara R.† Dental implant system design and the potential impact on long-term aesthetics: A review of the T3 Tapered Implant. ART1193EU Biomet 3i White Paper.
15. Biomet 3i, Palm Beach Gardens, Florida, USA. http://biomet3i.com/Pdf/EMEA/ART1193C_T3%20Implant_White_Paper_EU.pdf
16. Suttin et al††. A novel method for assessing implant-abutment connection seal robustness. Poster Presentation: Academy of Osseointegration, 27th Annual Meeting; March 2012; Phoenix, AZ. http://biomet3i.com/Pdf/Posters/Poster_Seal%20Study_ZS_AO2012_no%20logo.pdf
17. Suttin Z††, Towse R††. Dynamic loading fluid leakage characterization of dental implant systems. ART1205EU Biomet 3i White Paper. Biomet 3i, Palm Beach Gardens, Florida, USA. http://biomet3i.com/Pdf/EMEA/ART1205EU%20Dynamic%20Loading%20T3%20White%20Paper.pdf
18. Suttin Z††, Towse R††. Effect of abutment screw design on implant system seal performance. Presented at the European Association for Osseointegration, 20th Annual Scientific Meeting; October 2012; Copenhagen, Denmark. http://biomet3i.com/Pdf/Posters/P-450_Effect_of_Screw_Design_on_Implant_Seal.pdf
19. Byrne D, Jacobs S, O'Connell B, Houston F, Claffey N. Preloads generated with repeated tightening in three types of screws used in dental implant assemblies. J. Prosthodont. 2006 May–Jun;15(3):164-171.
20. Lazzara RJ, Porter SS. Platform switching: A new concept in implant dentistry for controlling postrestorative crestal bone levels. Int J Perio Rest Dent. 2006;26:9-17.
21. Östman PO,† Wennerberg A, Albrektsson T. Immediate occlusal loading of NanoTite prevail implants: A prospective 1-year clinical and radiographic study. Clin Implant Dent Relat Res. 2010 Mar;12(1):39-47.
22. Boitel N, Andreoni C, Grunder U†, Naef R, Meyenberg K†. A three year prospective multicenter, randomized-controlled study evaluating platform-switching for the preservation of peri-implant bone levels. Poster Presentation P83: Academy of Osseointegration, 26th Annual Meeting: 2011 March 3-5; Washington DC. http://biomet3i.com/Resource%20Center/Publications%20of%20Interest/Platform_Switching_for_the_Preservation_of%20Peri_Implant%20Bone%20Levels.pdf

† Clinicians have or had a financial relationship with Zimmer Biomet Dental resultingfrom speaking engagements, consulting engagements and other retained services.

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