

SciComm Bulletin

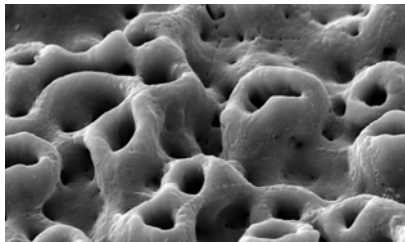
ZURICH, SWITZERLAND – 2009-08-21

TiUnite®

TiUnite is a moderately rough implant surface that enhances the speed at which implants osseointegrate, by stimulating rapid bone growth, and reduces the risk of implant failure during the early healing phase.¹ Pre-clinical and clinical results up to 8 years demonstrate that TiUnite implants offer safe and predictable treatment outcomes.

Key messages / definition

Nobel Biocare launched its patented TiUnite surface after pre-clinical and clinical testing. Today, it is one of the most clinically documented implants surfaces on the market:²

<p><i>Key messages</i></p> <ul style="list-style-type: none"> ▪ Tenth anniversary of the development and testing: <ul style="list-style-type: none"> – Developed and tested in 1998/1999 – Market launch in 2000 ▪ Enhanced osseointegration¹ ▪ Predictable treatment outcome² ▪ Osseoconductive – promotes bone growth¹ ▪ Excellent clinical results² 	<p><i>Definition</i></p>  <ul style="list-style-type: none"> ▪ Titanium oxide (TiO₂) surface ▪ Highly crystalline and phosphate-enriched ▪ Produced by spark anodization ▪ Pores in low micrometer range ▪ Proprietary cold-worked, commercially pure Grade 4 titanium base metal
--	--

TiUnite promotes faster osseointegration

Compared to machined implants, TiUnite offers significant advantages:

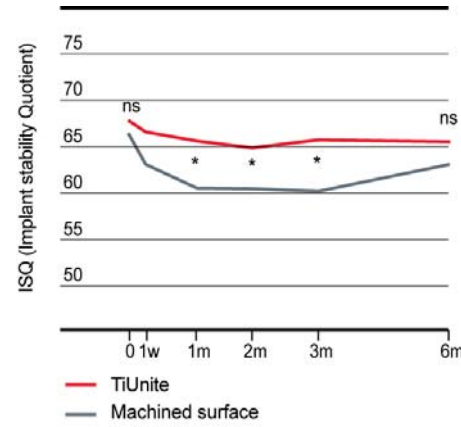
<p><i>Key messages</i></p> <ul style="list-style-type: none"> ▪ TiUnite is osseoconductive, resulting in faster implant osseointegration ▪ Osseoconductivity of TiUnite is equal to, or even better, than for calcium phosphate enriched surfaces 	<p><i>Evidence</i></p> <ul style="list-style-type: none"> ▪ Different bone formation patterns on – and near – the two surface types have been demonstrated. TiUnite stimulates rapid bone growth by osseosynthesis directly on and along the implant surface: <ul style="list-style-type: none"> – Osseoconductive properties result in a higher bone-to-implant contact already during the early healing phase and contribute to faster integration of the implant in the surrounding bone (Zechner et al. 2003, Ivanoff et al. 2003) ▪ The osseoconductivity of the TiUnite surface is on par with, or even exceeds, that of a calcium phosphate surface (Poulos et al. 2009, Xiropaidis et al. 2005)
---	---

¹ Compared to implants with machined surfaces (Glauser et al. 2001)

² A complete list of clinical references is available upon request

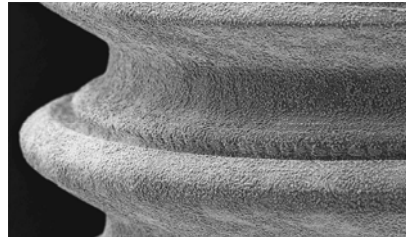
TiUnite reduces the time at risk

Compared to machined implants, TiUnite offers significant advantages, during the early healing period:

<p><i>Key messages</i></p> <ul style="list-style-type: none"> ▪ Bone begins forming in the early phase of healing ▪ Higher mechanical stability during critical healing phase ▪ Initial drop in implant stability is reduced, thereby reducing the risk of early implant failure 	<p><i>Evidence</i></p>  <p style="font-size: small;">Stability measurements using resonance frequency analysis (RFA). Mean value for TiUnite and machined implants. * = $p \leq 0.05$, ns = non significant.</p> <ul style="list-style-type: none"> ▪ The mechanical stability of the implant can be maintained at a higher level throughout the critical healing phase: <ul style="list-style-type: none"> – This implies shortened time at risk after implant insertion, which is particularly important in regions with soft bone and/or high occlusal loads, and for immediate function protocols (Glauser et al. 2001)
---	---

Macroscopic grooves enhance TiUnite effectiveness

The effectiveness of TiUnite implants has been further increased by the addition of macroscopic grooves to the thread flanks. Pre-clinical testing demonstrated:

<p><i>Key messages</i></p> <ul style="list-style-type: none"> ▪ Faster osseointegration ▪ Higher implant removal torque values ▪ Potentially more predictable treatments, especially in situations of suboptimal bone and/or immediate loading 	<p><i>Evidence</i></p>  <ul style="list-style-type: none"> ▪ Histological studies have demonstrated that bone grows more rapidly within and along the groove at groovy TiUnite implants compared to TiUnite thread flanks without a groove (Hall et al. 2005)
---	--

TiUnite promotes the soft tissue interface

Stable soft tissues around the dental implant and/or abutment greatly enhance esthetics and long-term function:

<p><i>Key messages</i></p> <ul style="list-style-type: none"> ▪ TiUnite allows for soft tissue attachment 	<p><i>Evidence</i></p> <ul style="list-style-type: none"> ▪ Histological observations of soft tissues around experimental one-piece dental implants with TiUnite, showed substantial structural and functional similarities with the gingiva around natural teeth in humans: <ul style="list-style-type: none"> – Ultra-structural analyses of the junctional epithelium indicate the presence of a direct attachment to TiUnite – Functionally oriented collagen fibrils of the connective tissue extending into TiUnite have been observed (Schübach & Glauser 2007)
--	--

Textured or machined collars according to customer preference

Nobel Biocare offers TiUnite implants with either textured or machined collars depending on patient treatment specifications and dental professional preferences:

<p><i>Key messages</i></p> <ul style="list-style-type: none"> ▪ Extensive follow-up data (5-7 years) exists for TiUnite implants, with good clinical outcomes ▪ Machined and textured collars demonstrate good tissue response 	<p><i>Evidence</i></p> <ul style="list-style-type: none"> ▪ Seven-year follow-up data from a prospective study on immediately loaded Brånemark System TiUnite implants, placed predominantly in regions of soft bone (Glauser et al. 2009) ▪ Prospective five-year follow-up data on immediately loaded single lower molars on Brånemark System TiUnite, wide platform, implants (Calandriello & Tomatis 2009) ▪ Five-year follow-up data on immediately and early loaded Replace Select TiUnite implants with machined collars (Mura 2009) ▪ A recent pre-clinical study showed equally good soft tissue health when comparing machined and textured collars (Replace Select & NobelReplace) (Allegrini et al. 2008) ▪ A prospective follow-up study of NobelReplace Tapered implants with textured collars placed in immediate function showed stable soft tissue and bone levels over time (Kielbassa et al. 2009) ▪ A radiographic evaluation of implants, in a controlled, split-mouth study, comparing machined versus textured collars has demonstrated changes in crestal bone levels during healing and under functional loading in favor of the NobelReplace Straight implant textured collar (Nickenig et al. 2009)
--	--

TiUnite implants demonstrate excellent clinical results

Clinical efficacy of TiUnite is supported by clinical data, with cumulative survival rates (CSR) in the upper ninetieth percentiles:

<i>Key messages</i>	<i>Evidence</i>
<ul style="list-style-type: none"> ▪ 97.1% CSR and stable marginal bone levels over time 	<ul style="list-style-type: none"> ▪ Seven-year follow-up data from a prospective study on immediately loaded Brånemark System TiUnite implants, placed predominantly in regions of soft bone (Glauser et al. 2009)
<ul style="list-style-type: none"> ▪ 95.0% CSR and stable bone levels over time 	<ul style="list-style-type: none"> ▪ Prospective five-year follow-up data on immediately loaded single lower molars on Brånemark System TiUnite, wide platform, implants (Calandriello & Tomatis 2009)
<ul style="list-style-type: none"> ▪ 100.0% CSR with a good treatment soft tissue and marginal bone response 	<ul style="list-style-type: none"> ▪ Five-year follow-up data on immediately and early loaded Replace Select TiUnite implants with machined collars (Mura 2009)
<ul style="list-style-type: none"> ▪ 97.1% and 98.4% CSR – two groups of TiUnite implants 	<ul style="list-style-type: none"> ▪ Five-year cross-sectional retrospective follow-up study comparing TiUnite and machined surface implants (Friberg & Jemt 2009)
<ul style="list-style-type: none"> ▪ 99.3% CSR with stable bone levels over time 	<ul style="list-style-type: none"> ▪ Up to three-year follow-up of Replace Select Tapered implants placed in compromised maxillary bone (Bahat 2009)
<ul style="list-style-type: none"> ▪ 100% CSR for TiUnite implants versus 97.5% CSR for machined surface implants; marginal bone levels for both groups were nearly identical 	<ul style="list-style-type: none"> ▪ One-year follow-up of Brånemark System machined surface implants versus Brånemark System TiUnite implants (Friberg & Jemt 2008)

References

- Allegrini S, Jr., Allegrini MR, Yoshimoto M, Konig B, Jr., Mai R, Fanghanel J, Gedrange T. Soft tissue integration in the neck area of titanium implants – an animal trial. *J Physiol Pharmacol* 2008;59 Suppl 5:117-32.
- Bahat O. Technique for placement of oxidized titanium Implants in compromised maxillary bone: prospective study of 290 implants in 126 consecutive patients followed for a minimum of 3 Years after loading. *Int J Oral Maxillofac Implants* 2009; 24: 325-334
- Calandriello R, Tomatis M. Immediate occlusal loading of single lower molars: five-year clinical follow-up from a prospective multi-center study using TiUnite implants. *Europerio* 6, 2009, Stockholm, abstract #403.
- Friberg B, Jemt T. Rehabilitation of edentulous mandibles by means of five TiUnite implants after one-stage surgery: a 1-year retrospective study of 90 patients. *Clin Implant Dent Rel Res* 2008;10(1):47-54
- Friberg B, Jemt T. Clinical experience of TiUnite implants: a 5-year cross-sectional retrospective follow-up study. *Clin Implant Dent Relat Res* 2009, accepted for publication.
- Glauser R, Portmann M, Ruhstaller P, Lundgren AK, Hämmerle C, Gottlow J. Stability measurements of immediately loaded machined and oxidized implants in the posterior maxilla: a comparative clinical study using resonance frequency analysis. *Appl Osseointegration Res* 2001;2:27-9.
- Glauser R, Zembic A, Ruhstaller P, Windisch S. Five-year results of implants with an oxidized surface placed predominantly in soft quality bone and subjected to immediate occlusal loading. *J Prosthet Dent* 2007 Jun;97(6 Suppl):S59-68. Erratum in *J Prosthet Dent* 2008;99(3):167. AO 2009, San Diego, oral presentation with seven-year follow-up data.
- Hall J, Miranda-Burgos P, Sennerby L. Stimulation of directed bone growth at oxidized titanium implants by macroscopic grooves: an in vivo study. *Clin Implant Dent Relat Res* 2005;7 Suppl 1:76-82.
- Ivanoff CJ, Widmark G, Johansson C, Wennerberg A. Histologic evaluation of bone response to oxidized and turned titanium micro-implants in human jawbone. *Int J Oral Maxillofac Implants* 2003;18(3):341-8.
- Kielbassa AM, Martinez-de Fuentes R, Goldstein M, Arnhart C, Barlattani A, Jackowski J, Knauf M, Lorenzoni M, Matorana C, Mericske-Stern R, Rompen E, Sanz M. Randomized controlled trial comparing a variable-thread novel tapered and a standard tapered implant: interim one-year results. *J Prosthet Dent* 2009;101:293-305.
- Mura P. Immediate and early loading of Replace Select Tapered TiUnite implants placed in post-extractive sockets and healed sites. Retrospective analysis of the 5-year clinical outcome. EAO 2009, Monaco, abstract accepted.
- Nickenig HJ, Wichmann M, Schlegel KA, Nkenke E, Eitner S. Radiographic evaluation of marginal bone levels adjacent to parallel-screw cylinder machined-neck implants and rough-surfaced micro-threaded implants using digitized panoramic radiographs. *Clin Oral Implants Res* 2009, epub March 2009.
- Poulos N, Rodriguez N, Lee J, Rueggeberg F, Schüpbach P, Hall J, Susin C, Wikesjö U ME. Evaluation of a novel calcium phosphate coated titanium porous oxide implant surface: a study in rabbits, *Clin Implant Dent Relat Res* 2009, submitted for publication.
- Schüpbach P, Glauser R. The defense architecture of the human peri-implant mucosa: a histological study. *J Prosthet Dent* 2007;97:15-25.
- Xiropaidis AV, Qahash M, Lim WH, Shanaman RH, Rohrer MD, Wikesjö U ME, Hall J. Bone-implant contact at calcium phosphate-coated and porous titanium oxide (TiUnite)-modified oral implants. *Clin Oral Implants Res* 2005;16:532-9
- Zechner W, Tangl S, Fürst G, Tepper G, Thams U, Mailath G, Watzek G. Osseous healing characteristics of three different implant types. *Clin Oral Implants Res* 2003;14(2):150-7.