

Media Release

Straumann launches Roxolid™, a new high performance material for dental implants

- ✎ *New material increases the choice of treatment options with small diameter implants*
- ✎ *Roxolid combines higher tensile and fatigue strengths¹ with excellent osseointegration² and is designed to increase reliability and confidence with small diameter implants*
- ✎ *Less invasive treatment using smaller implants is expected to increase patient acceptance of implant solutions*
- ✎ *More than 6300 Roxolid implants in controlled release program and international clinical trials*
- ✎ *Roxolid Ø3.3mm Bone and Tissue Level implants are now available in the US and Canada; European launch to follow in the coming weeks*
- ✎ *Allograft bone augmentation material launched in US; FDA approves Straumann® Emdogain for combined use with various bone graft materials¹⁵*

Basel/Boston 14 September 2009: At the 2009 Annual Meeting of the American Academy of Periodontology (AAP) currently taking place in Boston, Straumann announced the full market launch in North America of its new high performance dental implant material Roxolid™. Straumann Ø3.3mm Bone and Tissue Level implants are now available in the new material in the US and Canada, offering customers a new level of confidence with small diameter implants. Ø3.3mm implants currently generate approximately 15% of the company's global implant sales.

Higher tensile and fatigue strengths combined with the excellent osseointegration of SLActive

Roxolid™ is an alloy of titanium and zirconium and has been designed specifically for dental implants. Its name conveys the concept of natural physical strength combined with solidity (osseointegration).

Rigorous tests in Straumann laboratories have shown that the new material has higher fatigue and tensile strength than pure titanium (grade 4 annealed and cold worked), the current material of choice for dental implants. In addition, preclinical study results have indicated that bone integrated with Roxolid better than with pure titanium (grade 4)³.

The combination of enhanced strength and osseointegration opens the door for a new generation of small diameter implants, which may be particularly advantageous in situations where there is limited space between teeth, and when preserving existing bone and vascular supply is important. A further potential advantage could be the use in thin alveolar bone.

Straumann's largest prelaunch clinical program to date

Engineered and developed by Straumann, Roxolid has been undergoing a broad program of clinical trials in 9 countries, the first of which began almost 2 years ago. Involving 60 centers and more than 300 patients, this is one of the largest clinical research programs ever undertaken by a dental implant company prior to market launch. Based on reports to date, the implant survival rate exceeds 99%. In addition, Roxolid has been made available to 450 selected specialists in a controlled release program, in which more than 6300 implants have now been distributed.

Initial clinical reports have already been presented by lead investigators at recent major congresses^{4,5,6,7}, including a review of the scientific evidence and clinical application by Professor Hans-Peter Weber (Chair of the Department of Restorative Dentistry and Biomaterials Sciences at Harvard School of Dental Medicine) at the AAP, currently taking place in Boston.

Although Straumann obtained regulatory clearance several months ago, the company chose not to launch Roxolid until the available data from preclinical and clinical trials, including 12-month results from completed studies, had been reviewed by a Clinical Advisory Board of independent experts. On the basis of their unanimous recommendation, Straumann is proceeding with a full market launch, beginning in North America, the world's largest market for dental implants. Roxolid will also become available to doctors and patients in Europe in the coming weeks.

The need for high performance materials

Pure titanium is well known for its biological compatibility with the human body and its resistance to corrosion. The discovery that bone integrates with titanium (osseointegration) opened the way for its use in orthopedic surgery and subsequently in implant dentistry, where its physical properties were also important in order to bear the very strong forces of chewing. However, the mechanical properties are limited in the case of small diameter implants or parts, which are needed for narrow spaces. This prompted the use of alternative materials, such as titanium alloys (e.g. Ti-6Al-4V, 'TAV'), but additional strength came at the price of impaired osseointegration due to inferior biocompatibility and surface characteristics^{8,9,10,11}.

According to published research⁴, titanium and zirconium are the only two metals commonly used in implantology that do not inhibit the growth of osteoblasts, the bone forming cells that are essential for osseointegration. In contrast, the alloy of titanium and vanadium (TAV) has been shown to compromise osseointegration^{10,11}. Furthermore, TAV cannot accommodate the sophisticated microstructuring processes required for Straumann's third generation SLActive[®] surface technology, which enhances osseointegration.

Excellent osseointegration with the SLActive surface

Surface texture, purity and hydrophilicity are important contributors to optimal osseointegration and successful implant outcomes. In 2005, Straumann introduced its third generation implant surface technology SLActive, which cut implant osseointegration times in half to 3-4 weeks from 6-8 weeks, which was the benchmark established by SLA^{®12}. Since its launch, more than a million SLActive implants have been sold and it has set a benchmark for enhanced osseointegration.

Initial results from large clinical program

In a prospective pilot clinical trial, which is still ongoing, Ø3.3mm Roxolid implants were placed in 22 patients. One-year data were presented at the Europerio Congress in Stockholm, including bone level measurements, which showed bone gain in 50% of the patients¹³.

A multicenter double-blind randomized study also is underway in 8 European centers with more than 90 patients. The one-year follow-up data, which are currently being evaluated, will be presented at forthcoming scientific meetings.

A non-interventional clinical study is also underway with more than 400 implants placed in 230 patients in Europe and North America. More than 50% of the patients in this study have been followed for 6 months or more.

The potential of smaller implants

In the future, high strength, small diameter implants with enhanced osseointegration properties are expected to offer a number of advantages to dental professionals and patients, including: enhanced esthetics, broader treatment options, shorter treatment times and reduced costs. This is important as patients often fear implant treatment because of the associated pain, time, and cost. Straumann believes that Roxolid will therefore increase the general acceptance of implant dentistry and will contribute to further enhancing confidence among practitioners placing implants.

Additions to regenerative portfolio

The company also used the AAP as a platform for the US introduction of Straumann® Allograft, the oral bone augmentation material supplied through Straumann's partnership with LifeNet Health®. The latter is the world's largest provider of bio-implants and organs for transplantation and the longest accredited tissue banking organization in the world.

Allograft materials make up more than 50% of the dental bone augmentation market in the US, which was estimated to be worth USD 97 million in 2008¹⁴. Straumann Allograft complements the company's fully synthetic BoneCeramic, which was launched in the US in 2005.

Additionally, Straumann announced that it has received FDA approval for a new indication of Emdogain, the company's flagship regenerative product. Emdogain can now be used in the US with a number of bone graft materials¹⁵, in wide defects where additional soft tissue support is needed.

With these new offerings, Straumann continues its commitment to providing dental professionals in the US with a range of treatment options as part of a comprehensive portfolio of products for restorative, replacement and regenerative dentistry.

About Straumann

Headquartered in Basel, Switzerland, the Straumann Group (SIX: STMN) is a global leader in implant and restorative dentistry and oral tissue regeneration. In collaboration with leading clinics, research institutes and universities, Straumann researches, develops and manufactures dental implants, instruments, prosthetics and tissue regeneration products for use in tooth replacement and restoration solutions or to

prevent tooth loss. Straumann currently employs approximately 2200 people worldwide and its products and services are available in more than 70 countries through its broad network of distribution subsidiaries and partners.

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Photographs and further information

Photographs for journalistic use and further information are available on request from Straumann Corporate Communication.

¹ Compared with grade 4 annealed and cold worked titanium; data on file, comparing material with specifications from standard ASTM F67

² Thoma D et al. ‘Evaluation of a new titanium-zirconium dental implant. A comparative radiographic study in the canine mandible’ Oral presentation at the 24th Annual meeting of the Academy of Osseointegration (AO), San Diego

³ Gottlow J et al. Preclinical data presented at the 23rd Annual meeting of the Academy of Osseointegration (AO), Boston, February 2008, and at the 17th Annual Scientific Meeting of the European Association for Osseointegration (EAO), Warsaw, September 2008

⁴ Stone P. Experience new confidence and freedom with small diameter implants. European Federation of Periodontology 6th Congress, Stockholm, Sweden, 4-6 June 2009.

⁵ Thoma DS. Evaluation of a new titanium-zirconium dental implant. A comparative radiographic study in the canine mandible. Academy of Osseointegration 24th Annual Meeting, San Diego, CA, USA, 26-28 February 2009; Abs. SO4.

⁶ Gottlow J. Make a difference with the next generation implant properties. European Association for Osseointegration 17th Annual Scientific Meeting, Warsaw, Poland, 18-20 September 2008.

⁷ Barter S. New reduced diameter implants for wider clinical options. European Association for Osseointegration 17th Annual Scientific Meeting, Warsaw, Poland, 18-20 September 2008.

⁸ Steinemann S. *Periodontol* 2000 1998;17:7-21

⁹ Wong M et al. *J. Biomed Mater Res* 1995;29:1567-1575

¹⁰ Stenport VF, Johansson CB. *Clin Implant Dent Relat Res.* 2008, 10:191-9

¹¹ Johansson CB et al. *Int J Oral Maxillofac Implants* 1998;13:315–321

¹² Oates TW et al. Int J Oral Maxillofac Implants 2007;22:755-760

¹³ Stone P. Clinical data presented at the EuroPerio 2009, Stockholm, June 2009

¹⁴ Millennium Research

¹⁵ Autograft, allograft, bone derived xenograft, B-tricalcium phosphate, and bioactive glass