Straumann launches new Roxolid

At the 2009 annual meeting of the American Academy of Periodontology (AAP) in Boston, Straumann announced the full market launch in North America of its new high-performance dental implant material Roxolid™.

Straumann Ø3.3 mm Bone and Tissue Level implants are now available in the new material in the United States and Canada, offering customers a new level of confidence with small diameter implants. Ø3.3 mm implants currently generate approximately 15 percent of the company’s global implant sales.

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 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 perform better than with pure titanium (grade 4).

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.

Roxolid’s largest prelaunch clinical program to date
Engineered and developed by Straumann, Roxolid has been undergoing a broad program of clinical trials in nine countries, the first of which began nearly two years ago.

Involving 60 centers and more than 500 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 95 percent. In addition, Roxolid has been made available to 450 selected specialists in a controlled release program, in which more than 6,300 implants have now been distributed.

Initial clinical reports have already been presented by lead investigators at recent major congresses, including a review of the scientific evidence and clinical application by Prof. Hans-Peter Weber (chair of the Department of Restorative Dentistry and Biomaterials Sciences at Harvard School of Dental Medicine) at the AAP.

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.

According to published research, 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.

Furthermore, TAV cannot accommodate the sophisticated microstructuring processes required for Straumann’s third generation SLActive® surface technology, which enhances osseointegration.

(Source: Straumann)