**Media release**

# Green light for Straumann's oral tissue regeneration products in the US

- *Emdogain®, a product used as an adjunct to periodontal surgery and surgical treatment of gum recessions is available again for US customers*

- *US surgeons and patients have access again to Straumann's clinically-proven, fully-synthetic alternative for jawbone augmentation*

**Basel, 5 August 2008:** Straumann announced today that the import detention on Biora products in the US, which has been in place since the beginning of 2007, has been lifted following a re-inspection of the Group's Biora facility in Sweden by the FDA (US Food and Drug Administration). As a result, Straumann can now supply its range of oral tissue regeneration products to dental professionals and their patients in the US again. The company's US subsidiary is taking orders and the products concerned – Straumann Emdogain, PrefGel® and BoneCeramic – will be available shortly.

As no other countries have been affected by the US import detention, availability elsewhere has been uninterrupted and global sales have continued to develop positively, reflecting the fact that these products help to meet healthcare needs both in tooth preservation and oral bone augmentation.

**About periodontal disease and regeneration**
Periodontal disease is a major cause of tooth loss because it destroys the tissues that anchor the tooth root. Mild to moderate periodontitis affects most adults at some time in life, while 5–20% of any population suffer from severe forms of the disease. Demographic developments indicate that periodontal disease will continue to be a major issue.[1,2] Therapy involves controlling the causative bacteria and inflammation and then restoring the lost tissue structures in order to regain tooth attachment.

The decision to rescue or remove a compromised tooth requires careful consideration by the treating clinician. The Straumann Regenerative System offers treatment options to support both tooth preservation and oral bone augmentation.

**Straumann Emdogain** is an effective therapy that helps to stabilize teeth and improve the outcome of periodontal surgery by regenerating the tissue structures that anchor the tooth. Specifically, Emdogain is used as an adjunct to periodontal surgery as a topical application onto exposed root surfaces, and is indicated for the treatment of intra-bony defects due to moderate or severe periodontitis, as well as the surgical treatment of gum recessions.[3]

Since its introduction in 1996, Emdogain has been used in more than a million patients worldwide and continues to be a leading product for periodontal regeneration. The wealth of scientific evidence supporting the product continues to grow. In the past 12 months alone, more than 40 new scientific articles have been published in peer

reviewed journals, including a systematic review of 18 studies on the treatment of gum recessions.[4] This showed that Emdogain can increase the predictability of surgical outcomes by achieving equal or better root coverage and attachment.

Other recently published studies have indicated that less post-surgical discomfort is reported with Emdogain.[5,6]

**Straumann PrefGel** is a convenient gel which is used to remove the smear layer on the tooth surface prior to application of Emdogain.[3] Straumann is now introducing PrefGel in the US in an easy-to-use pre-filled syringe, which has been has been well received by clinicians in Europe, where it has been available for some time.

**Bone augmentation and regeneration**

One of every five dental implants needs bone augmentation either prior to or concurrent with implant placement. The patient's own (autologous) bone, from the jaw or elsewhere is the preferred material for this procedure. However, limited quantities are available and the procedure can result in pain and complications at the donor site. Furthermore, autologous bone is readily resorbed and may not provide the required bone volume in the long term.

One of the most commonly used commercial bone augmentation materials is sourced from bovine bone, while another commonly used material is sourced from human cadavers. Being fully synthetic, **Straumann® BoneCeramic** is a very attractive alternative.[3]

Two of the key benefits offered by Straumann BoneCeramic are that it supports the regeneration of – and is gradually substituted by – the patient's own bone, while at the same time preserving bone volume, which is important for achieving esthetic results.

Over the past 12 months data from multiple clinical trials have been published in peer reviewed journals.[7,8,9] In a prospective, blinded, multicenter, randomized, controlled clinical trial, Straumann BoneCeramic was compared head to head with the market leader, which is bovine derived. Histomorphometric examination revealed that Straumann BoneCeramic achieved equivalent new mineralized bone and more vital tissue after 6-8 months, but with less residual graft.[10] Other findings have confirmed vital bone formation and show active remodelling as well as increasing bone volume over time.[11] In one study published in 2007, Straumann BoneCeramic combined with autologous bone achieved significantly better outcomes than autologous bone alone.[9]

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**Concerning forward looking statements**
This release contains certain "forward-looking statements", which can be identified by the use of terminology such as "will", "shortly", "can", "to meet needs", "improve outcome", or similar wording. Such forward-looking statements reflect the current views of management and are subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of the Group to differ materially from those expressed or implied. These include risks related to the success of and demand for the Group's products, the potential for the Group's products to become obsolete, the Group's ability to defend its intellectual property, the Group's ability to develop and commercialize new products in a timely manner, the dynamic and competitive environment in which the Group operates, the regulatory environment, changes in currency exchange rates, the Group's ability to generate revenues and profitability, the Group's ability to realize its expansion projects in a timely manner and the Group's ability to recruit and retain key employees. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this report. Straumann is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in it as a result of new information, future events or otherwise.

**About Straumann**
Headquartered in Basel, Switzerland, the Straumann Group (SWX: 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. The Group manufactures implant system components and instruments in Switzerland and the US, CAD/CAM prosthetics in Germany, and dental tissue regeneration products in Sweden. Straumann also offers comprehensive training and services to the dental profession worldwide, including training and education, which is provided in collaboration with the International Team for Implantology (ITI). Altogether, Straumann employs approximately 2150 people worldwide and its products and services are available in more than 60 countries through the Group's 21 distribution subsidiaries and broad network of distribution partners.



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