



## Media release

### **Biora responding to 'warning letter' from US Food and Drug Administration**

**Basel, 19 January 2007:** In the course of a routine inspection of Biora AB, Straumann's oral regenerative product company in Sweden, in October 2006, a US Food and Drug Administration (FDA) investigator made a number of observations predominantly concerning maintenance of quality system documentation and procedures associated with the company's products. Biora has received a 'warning letter' from the FDA, which indicated that its 'dental bone grafting materials' are on import detention in the US, until the inspectional observations are resolved. No other countries apart from the US are affected.

The company is fully confident that its products continue to meet specifications and can be used safely. FDA has not requested that Biora recall product in the US. The company also believes that current supplies will meet customer and patient needs for the immediate future.

Straumann and Biora take the concerns of regulatory authorities very seriously and are committed to operating in full compliance with the FDA's regulations. Biora has already responded in detail to the observations raised by the inspection and will work with the FDA to resolve the issues in the warning letter as quickly as possible.

The products concerned are: Straumann BoneCeramic, Emdogain, and PrefGel.

BoneCeramic was introduced in North America in 2005. It is a fully synthetic alternative to human or animal derived bone substitutes and is used for bone augmentation in implant dentistry.

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. Since its introduction in 1996, Emdogain has been used to treat more than one million patients and has been the subject of more than 300 scientific publications. PrefGel is convenient gel used to remove the smear layer on the tooth surface prior to application of Emdogain.

**About Straumann**

Headquartered in Basel, Switzerland, the Straumann Group (SWX: STMN) is a global leader in implant dentistry and oral tissue regeneration. In collaboration with the International Team for Implantology (ITI), leading clinics, research institutes and universities, the Group researches and develops implants, instruments and tissue regeneration products for use in tooth replacement solutions or to prevent tooth loss. The Group manufactures implant system components and instruments in Switzerland and the US and oral tissue regeneration products in Sweden. Straumann also offers comprehensive training and services to the dental profession worldwide. Altogether, Straumann employs approximately 1544 people worldwide and its products and services are available in more than 60 countries through the Group's 18 distribution subsidiaries and broad network of distribution partners.

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