

Press release  
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## **Nanolevel topographic modifications on the OsseoSpeed™ fluoride modified implant surface provide additional mode of action for documented bone response**

**When the fluoride modified OsseoSpeed™ implant was launched in 2004 it was based on solid pre-clinical and clinical documentation and in order to fully understand and utilize the full potential of OsseoSpeed, Astra Tech has continued to search further.**

Scientific results from in vitro studies show that human mesenchymal stem cells (hMSC) grown on the OsseoSpeed™ surface differentiate to a larger extent to osteoblasts. The gene expression further shows that the cells that grow on OsseoSpeed mineralize. Similarly, significantly higher expression of bone formation markers have also been identified in the tissue close to OsseoSpeed implants in vivo, demonstrating that the bone response to this implant surface is favorable and can be identified.

“The original idea for fluoride treatment of titanium wasn’t conjured out of the air” says Professor Jan Eirik Ellingsen, University of Oslo, the inventor of the OsseoSpeed surface. He continues:

“It was based on established theories on the reaction between fluoride and titanium and possible biological consequences. Even before we started with these studies, we tried to figure out what mechanisms might be involved. Results from numerous research projects in this area ended up with the OsseoSpeed surface. One important finding is that the fluoride treatment brings about a topographical change at a nanoscale level. When we examine surface characteristics at the usual magnifications, we don’t see any difference between the OsseoSpeed surface and the control. But looking at a higher resolution at nanolevel (500 nm) you can see that the surface has a modified topography and nanoscale structures are created. This unique nanoscale topography can only be created through the OsseoSpeed surface modification.”

“What we have observed is a physical-chemical effect of the OsseoSpeed surface leading to the improved adsorption of calcium phosphate to the surface. For patients and doctors this means that OsseoSpeed is

demonstrated to result in more bone formation, stronger bone integration and faster bone healing” Ellingsen concludes.

### **OsseoSpeed™, short facts**

- The first-ever fluoride-modified titanium implant surface with a unique nanoscale topography
- More and earlier bone formation
- Increased bone-to-implant contact ratio
- Stronger bone-to-implant interface
- More than 800 patients enrolled and treated in clinical trials
- Superior maintenance of stability during the early healing phase
- High survival rates for implants placed in soft bone

### **The FOCUS project**

The FOCUS project evaluates the treatment success of OsseoSpeed when used in a general population under conditions found in daily practice. More than 150 dentists in 14 countries are involved in the project.

- Follow-up: 3 years
- Study status
  - Treated patients: 541
  - One year follow-up: 187 patients
  - Last patient out: 2011
- Results
  - 57% poor bone quality (III/IV)
  - 98.7% survival rate with up to one year follow-up
  - Few complications, mainly associated with prosthetic issues

- >80% of the patients were satisfied or very satisfied with the overall result of the treatment (QoL) one year after being restored.

## **Predictable results using an early loading protocol in the posterior maxilla and mandible (YA-OSS-0001)**

### **Maxilla**

- Countries: Germany and USA
- Follow-up: 5 years
- One stage, early loading (6-7 weeks)
- Study status
  - Treated/planned patients: 47/45
  - Last patient out: 2011
- Results
  - 80% soft bone quality (III/IV)
  - 52% with osteotome technique
  - 93.9% survival rate with up to one year follow-up

### **Mandible**

- Countries: Germany and USA
- Follow-up: 5 years
- One-stage, early loading (6-7 weeks)
- Study Status
  - Treated/planned patients 45/45
  - Last patient out: 2010

- Results
  - 20% poor bone quality (III/IV)
  - 100% survival rate after two years follow-up

**Encl.**

Scientific Review, OsseoSpeed™

Why accept bone loss? (The Astra Tech BioManagement Complex™)

For further information, please contact:

Kerstin Wettby, Head of Market Communication Dental, Astra Tech AB

Phone: +46 31 776 30 00/32 02, cell phone +46 705 16 32 02

E-mail: kerstin.wettby@astratech.com

Janie Shen, Director Corporate Communications, Astra Tech Inc., USA

Phone: +1 781 890 6800/6605

E-mail: janie.shen@astratech.com

*Astra Tech, a subsidiary of the pharmaceutical company AstraZeneca, develops and produces dental implants and advanced medical devices. With these products, Astra Tech aims to improve treatment results, facilitate procedures, reduce health care costs and enhance the quality of life for patients.*

*Astra Tech's headquarters, located in Mölndal, Sweden, house facilities for research and development as well as production. The company has 15 subsidiaries in Europe, North America and Asia/Pacific and is represented by local partners in other selected markets.*

*Astra Tech had sales of \$360 million in 2006 and employs approximately 1,800 people.*

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