

Patent Suit Against Nobel Biocare

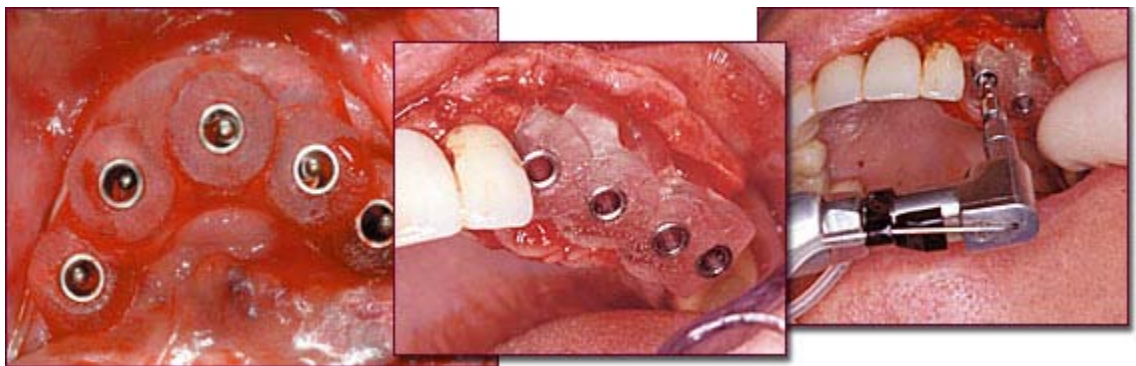
Dental solutions provider Materialise sues multinational
for unauthorized copying of a method for successful implant dentistry

Düsseldorf (Germany) / Leuven (Belgium), July 14, 2006.

The Swedish medical technology enterprise Nobel Biocare (Göteborg / Sweden) is alleged to use a method for making so called dental drill guides. These dental drill guides are acknowledged as a very promising improvement for implant treatment. Materialise has therefore filed a patent infringement action at the Düsseldorf district court (Germany).

Nobel Biocare is sued for infringement of the method which is protected by Claim 1 of European Patent (EP) 0 756 735 granted to the company Materialise (Leuven). Materialise points out that it launched its dental drill guide system back in 1999 under the name of SurgiGuide, while Nobel Biocare did not introduce its NobelGuide system until 2005.

Dental drill guides transfer the surgical implant planning to the actual surgery. The principal allegation refers to a method for making medical models, including guides for dental surgery, that involves the use of grey value images and rapid prototyping. *"We would prefer not to resort to litigation, but we must protect our intellectual property and patented technology, wherever it is infringed,"* stated Materialise CEO Wilfried Vancraen. *"Our solution was the result of years of development work and a basis for further developments, continuously providing cutting-edge technology that contributes to the success of implant dentistry."*



The Materialise patent refers to the priority date of April 19, 1994, and since then has gathered considerable clinical experience with it. According to the company, further research has yielded groundbreaking results leading to the 1999 introduction of the first (bone-supported) version of SurgiGuide. It was followed in 2001 by a SurgiGuide version for zygomatic implants, in 2002 by a mucosa-supported SurgiGuide, and in 2003 by a tooth-supported SurgiGuide version. Materialise asserts that Nobel Biocare as well as diverse dental experts and opinion leaders in the industry were very well aware of the development of the SurgiGuide drill guides, which were

the industry were very well aware of the development of the SurgiGuide drill guides, which were presented at open conferences for clinicians.

When Nobel Biocare, the Swedish market leader, unveiled its NobelGuide system to a large public in 2005, Materialise resolved to take legal action. *“Customers,”* says Vancraen, *“have been shocked about the launch of the NobelGuide system and the Procera software from Nobel Biocare without the involvement or the acknowledgement of the rights of Materialise.”* He adds that *“our customers need to know they can rely on Materialise. Our products are based on extensive research and supported by a large R&D team.”*

Materialise is represented in the action against Nobel Biocare by the international law firm Bird & Bird.

SurgiGuide drill guides and Nobel Biocare, the full story ...

Wilfried Vancraen, CEO of Materialise, reports:



Materialise has been active in the development of medical image based applications of stereolithography, a rapid prototyping technology, since **1991**, shortly after its founding in 1990. We very soon realized the importance and impact that this technology could have for dental applications, especially in the area of dental implantology.

In **1992** Materialise launched the first project to develop stereolithographic models as a master for the production of titanium foils under which bone regeneration could be stimulated in collaboration with the company CEKA NV. This technology allowed controlled, computer-guided bone augmentation of mandibular and maxillary dental arches. It was during the evolution of this project that we first were in contact with Professor Daniel van Steenberghe at the Catholic University of Leuven, Belgium.

During the course of **1993**, Materialise devoted considerable resources to manufacturing of extremely accurate medical models based on CT images. That same year Materialise started testing and developing the very first concepts relating to the manufacture of surgical drill guides for accurate implant placement. This landmark work resulted in a patent application referring to the priority date of April 19, **1994**. Soon afterward we informed Professor Daniel van Steenberghe about the concept, his interest in the use of CT information for oral implant planning being known to us. He was aware of the innovative product called “SimPlant”, a software application for dental implant planning based on CT data. After the launch of SimPlant, he wanted to start developing a more advanced three-dimensional oral implant planning software with the aid of the medical imaging group of the University of Leuven.

SimPlant was already commercially available back in the early nineties. Its first users, including Dr. Scott D. Ganz, Dr. Alan Rosenfeld and Dr. Richard Mecal, gathered extensive experience with it. They shared this experience in visionary national and international podium presentations at events such as the AO, EAO, ICOI, AAID(1-3), etc and publications in the years **1995**(4) and **1996**(5). Those presentations and publications gave the first proof of a scientific approach to prosthetic-driven implant placement. This is an issue that has been considered very important in connection with the further development of the SimPlant software and SurgiGuide drill guides.

In the meantime, we continued to invest in the technology by studying the accuracy of medical models. In

resin that could be used in contact with the patient's body during surgery. In 1995, this research resulted in the first resin for medical grade stereolithography that permitted clinically safe production of surgical drill guides, with the ability to add colorable indices for locating nerves and tooth roots. Further toxicological tests and approval of the curing process followed.

Materialise was still a very small, evolving company at the time, and therefore endeavored to do much of its development work within the framework of collaborative research projects involving other companies and universities. Professor Daniel van Steenberghe, who also held the Professor P-I Brånemark Chair in Osseointegration sponsored by Nobel Biocare, advised us to contact Nobel Biocare to investigate the possibility of collaborating. In 1995 we presented our ideas for the "SurgiGuide" CT-based drill guide to Nobel Biocare, asking them to participate in a new collaborative research project to develop the SurgiGuide technology further. They wrote an endorsement letter expressing their interest in the project, but never participated in the project or supported it in any other way.

As Professor Daniel van Steenberghe still had not tested the SurgiGuide technology by **1997**, we finally distanced ourselves from the possibility of working with him. At that time he was investigating the use of navigation systems for oral implantology. That same year, Materialise was introduced to another clinician, Dr. Luc Vrielinck, an oral surgeon who realized the potential of the SurgiGuide technology. Under the advice and direction of Dr. Vrielinck, in the summer of 1997 the researchers at Materialise proceeded to implement the first clinical applications of SurgiGuide. From then on, the SurgiGuide drill guide technology went through several improvement cycles and multiple accuracy studies.

Because Materialise wished to properly document its research and development activities utilizing proper scientific protocols, the first studies comparing planning and post-operative CT were performed not internally but at the medical imaging group of the University of Leuven. It was this same group that collaborated with Professor Daniel van Steenberghe. It is now surprising to see that precisely those clinical cases and studies are not mentioned in the scientific publications that present the history of the development of the drill guide technology as referred by Professor van Steenberghe in JOMS⁽⁶⁾.

On June 11, 1997 Materialise researchers filed a patent application on the use of an additional (micro-) CT scan that included information on the dental cast or prosthesis and posed an alternative to optical scans in combination with the patient's radiography data. This patent was the precursor for the mucosa and teeth-supported SurgiGuide, which requires anatomical information on the patient's soft tissues.

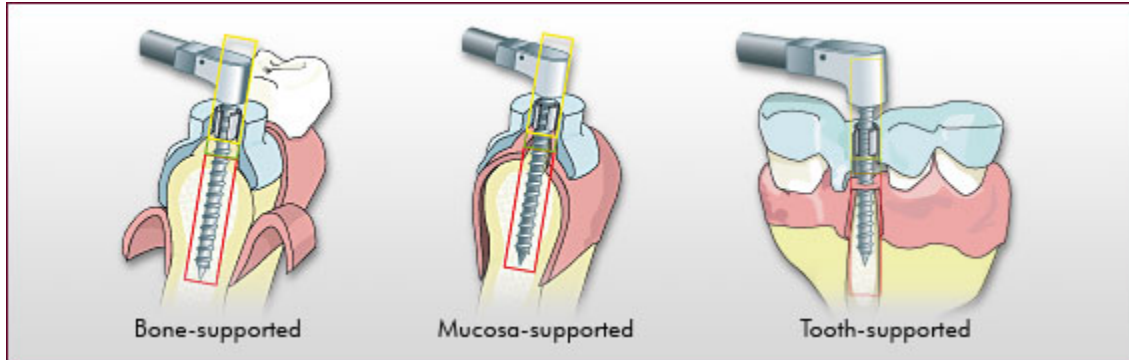
During **1998** and **1999** the first patients were treated with SurgiGuide drill guides by several of the early adopters in Europe: In Belgium, Dr. Vrielinck (7-8), Dr. Defrancq and Dr. Thevissen; in France, Dr. Tardieu and Dr. Caillon; in The Netherlands, Dr. Poukens, Dr. Haex and Dr. Verdonck; and in the United States, Dr. Erickson, Dr. Sarment and Dr. Kircos.

These first users were big believers in the potential of our technology, which could have a highly beneficial impact on the treatment of many implant patients. These first users were big believers in the potential of our technology, which could have a highly beneficial impact on the treatment of many implant patients.

The first article describing the use of CT-based surgical guides in collaboration with Nobel Biocare was not published until September / October **2002**, appearing in an issue of *The International Journal of Oral and Maxillofacial implants* (Vol. 17, no. 5, **2002**). Prior to that time, articles (9) appeared on second-generation developments in SurgiGuide drill guide technology, and a full description (10-11) of the SimPlant software and SurgiGuide drill guides was published as long ago as 2001. A full description of Zygoma implants placed with SurgiGuide SAFE System on bone was also published in August 2002. (12)

In multiple contacts with Nobel Biocare management at the headquarters of Materialise, as well as at major implant conferences and meetings, the Nobel Biocare executives expressed great interest in collaborating with Materialise, but the initiative never moved beyond the pronouncement phase. Materialise continued to intensify its research and development efforts in SurgiGuide technology and launched the first generation of commercially marketable products in **2000**. According to the results of patent searches, that was also the year that Nobel Biocare filed the first patent application that mentions CT-based guide technology: on December 29, 2000, ref. no. SE522958.

On October 25, **2002**, Materialise unveiled the “Mucosa-Supported SurgiGuide”, at its New York symposium. This innovative surgical guide was the breakthrough for flapless surgery. Multiple beta users presented their research results at this meeting and published articles around the same time (13). It was not until 2004 that the first articles appeared on flapless surgery in combination with the Nobel Biocare technology.



It is our conclusion that, apart from direct infringement of the patent, for each step in developing SurgiGuide technology there is clear proof that the clinicians collaborating with Materialise were years ahead of those who now claim that the underlying research concepts were originated by Nobel Biocare or professors affiliated with it.
