

# The Changing World of Dental Implantology



**Michael Jungling >>** +44 20 7996 2247  
Research Analyst  
MLPF&S (UK)  
michael\_jungling@ml.com

**Alex Surla >>** +44 20 7996 0799  
Research Analyst  
MLPF&S (UK)  
alex\_surla@ml.com

## Dental Implant Outlook - Growing Faster than We Thought

Our review of the fairly undiscovered smaller dental implant companies suggests that the **dental implant market is ~20% or US\$400m larger** than we thought. Furthermore, with the 'smaller company' segment showing 30-40% growth, it appears the market is growing 1-2% points faster at 18-19% compared to our previous forecast of 17%. This clearly shows that the 'smaller segment', which often competes on price, is able to capture market share and is worth US\$530m.

## Nobel Biocare - Really Gaining Unit Market Share?

While strong revenue growth at NOBE may suggest market share gains, we believe a large portion is driven by price/mix increases and Procera. As a result, we believe **NOBE may not be gaining unit market share**, which in our view is an important predictor of sustainable future growth. Furthermore, recent feedback from U.S. dental bodies make us nervous about the company's aggressive marketing practices for recruiting general dentists. The next 24 months will show whether its marketing strategy will prove long-term success and compensate for the loss in revenues from some of its high volume surgeon customers.

## Increase in General Dentist Regulations - May Slow Growth

Strong growth ambitions by a number of dental implant companies is fuelling general dentist recruiting through questionable 2-3 day training courses, which drive short-term sales (i.e. starter kits with implants) but may have more serious long-term implications, from an increasing number of patient complaints. As a result industry bodies such as UK's **General Dental Council** and US's **Institute of Dental Implant Awareness** are rolling out more onerous guidelines to make dentists aware of the legal liability of placing implants with limited experience, by not satisfying the **elevated standard of care expected from surgeons**.

## Industry Consolidation - Likely to Pick Up

Over the intermediate term we see potential M&A activity between **Straumann and 3i**. Although the intentions of AstraZeneca remain unclear, we would not rule out a possible combination between **Zimmer Dental and Astra Tech**. We believe M&A activity amongst the smaller companies will intensify and result in a number of larger and stronger entities with sales comfortably exceeding +US\$50m.

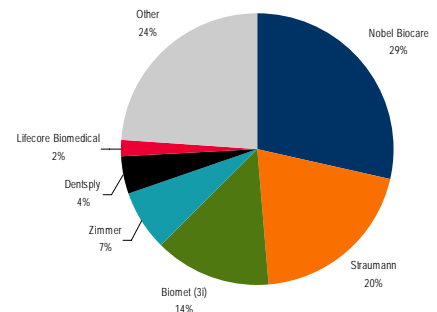
## Medtronic Moves into Dental Implants

Although it may be many years before any market impact will be felt from Medtronic's investment in Neoss, it will take away some market bid speculation that the U.S based company is interested in making a bid for Nobel Biocare.

## Investment Conclusion

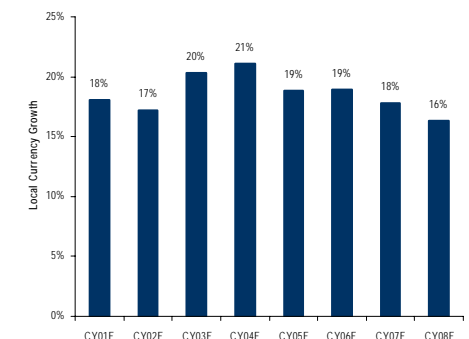
While we continue to like the prospects of the dental implant market, we retain our **'Neutral'** stance on **NOBE** and **STMN**, due to company specific concerns.

Chart 1: Dental Implant - Market Share (FY06E)



Source: Merrill Lynch estimates

Chart 2: Dental Implant - Market Growth Rates



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## Contents

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<b>EAO Congress - Update</b>	<b>3</b>
<b>Dental Implant Outlook</b>	<b>3</b>
Industry Growth Rates - Faster Than We Thought	
Market Model - Size Larger Than We Thought	
<b>Key Themes at Congress</b>	<b>5</b>
The Winner is Astra Tech	
Industry Consolidation	
Risk of Increasing Regulation	
Image Guided Surgery - Growing In Importance	
<b>Nobel Biocare - Growth May Slow</b>	<b>14</b>
NobelDirect - Medical Products Agency	
Sales Force Feedback - Changing Business Model	
Finland - Dental Implant Register	
<b>Medtronic Makes Entry into Dental Implants</b>	<b>16</b>
<b>Product Launches Low Key</b>	<b>17</b>
Nobel Biocare	
Straumann	
Biomet (3i)	
Zimmer Dental	
Dentsply (Friadent)	
Astra Tech	
Other Tid Bits	
<b>Investment Conclusion</b>	<b>20</b>
Nobel Biocare - Neutral	
Straumann - Neutral	

## EAO Congress - Update

The 15<sup>th</sup> annual meeting of the *European Association of Osseointegration (EAO)* kicked off on 5 October 2006 in Zurich, Germany. This year's congress was again a relatively weak clinical program compared to previous meetings as well as a low level of new product launches/updates. As a result, we allocated most our time towards identifying emerging themes and market conditions by talking to a broad range of dental implant manufacturers and clinicians. Our findings are highlighted below.

## Dental Implant Outlook

### Industry Growth Rates - Faster Than We Thought

Based on our discussions with all of the major dental implant manufacturers it appears consensus for current industry market growth rates lie in the 17-19% range, which is in line with our current thinking.

#### Europe: 14-16%

It appears that most European countries are growing in the high teens, with a number of exceptions including Germany. Despite the improvements in the dental reimbursement system over the past 18 months, it appears that Germany continues to show relatively uninspiring growth rates of 10-12%.

#### North America: 20-25%

The North American market continues to do very well with the growth rate feedback in the 20-25% range, helped by the lower penetration rates compared to Europe as well as greater willingness by general dentists to look into dental implant treatment compared to Europe. Furthermore, the referral based model (i.e. a dentist refers a patient to the oral surgeon for surgery while the restorative work is then returned to the dentist) seems to currently allow for faster growth rates compared to Europe.

#### Asia: 25-30%

Although the Asian market remains small compared to Europe and North America, various countries show very strong growth rates. This appears to include Taiwan, Korea, Indonesia, Hong Kong, Japan and to a lesser degree Australia and New Zealand.

Table 1: Worldwide Dental Growth Rates - FY07E

Region	Growth Rates
Europe	14%
North America	20%
ROW	27%
<b>Total</b>	<b>18%</b>

Source: Merrill Lynch estimates. Note: growth in local currency.

Table 2: Market Growth Rates – Current View

Market	Constant Currency Growth
Europe	14-16%
North America	20-25%
Asia	25-30%
<b>Total</b>	<b>17-19%</b>

Source: EAO Company Feedback

However, it is our view that the industry **may be underestimating industry growth rates**, driven by the significant momentum we are starting to see from many of the smaller manufacturers, which are increasingly making up a larger share of the dental implant market. Based on our informal survey of a large number of smaller companies, it appears that this segment may be making up +24% of the market and growing at 20-40%. While we recognize that the information from smaller companies is often difficult to obtain, we estimate that the overall dental implant market may be growing as fast as 18-19% in constant currency and faster than current estimates.

**Table 3: 'Other Companies' – Estimated Growth Rates**

Company	Estimated Sales (CY06E)	Constant Currency Growth
Astra Tech	140	Over 40%
BioHorizons	40	Over 30%
BioLok	10	Over 30%
Camlog	70	Over 30%
Danaher	30	Over 20%
MIS	40	Over 30%
NEOSS	20	Over 50%
Ossstem	120	Over 40%
<b>Total</b>	<b>470</b>	<b>Over 30%</b>

Source: Merrill Lynch estimates

### Market Model - Size Larger Than We Thought

Provided below is our revised worldwide dental implant market model, which includes additional detail on the 'Other Category'. Our revised model suggests that the dental implant market may be ~20% bigger at US\$2.2bn compared to our previous forecast of US\$1.8bn, driven by greater clarity on the size of the smaller dental implant manufacturers, which over the years have amassed a sizeable portion or 24% of the market.

**Table 4: Worldwide Dental Implant Market**

Dec Y/E (US\$m)	CY01E	CY02E	CY03E	CY04E	CY05E	CY06E	CY07E	CY08E
Nobel Biocare	226	256	329	420	517	641	767	891
Growth (%)	12%	13%	28%	28%	23%	24%	20%	16%
LC Growth (%)	17%	12%	19%	22%	25%	24%	20%	16%
Straumann	137	165	249	320	386	447	519	598
Growth (%)	22%	20%	51%	29%	20%	16%	16%	15%
LC Growth (%)	24%	23%	24%	21%	15%	15%	16%	15%
Biomet (3i)	136	158	194	238	270	310	357	410
Growth (%)	15%	16%	23%	23%	13%	15%	15%	15%
LC Growth (%)	15%	16%	18%	19%	12%	15%	15%	15%
Zimmer (Centerpulse)	71	78	98	116	138	158	182	207
Growth (%)	111%	10%	25%	18%	19%	15%	15%	14%
LC Growth (%)	5%	18%	16%	22%	18%	15%	15%	14%
Dentsply (Friadent)	49	56	64	75	87	100	114	130
Growth (%)	18%	15%	15%	18%	15%	15%	14%	14%
LC Growth (%)	18%	15%	15%	18%	15%	15%	14%	14%
Lifecore Biomedical	22	24	29	34	39	46	53	61
Growth (%)		12%	19%	18%	14%	17%	15%	15%
LC Growth (%)	9%	12%	17%	15%	14%	14%	15%	15%
Other	143	186	241	314	408	530	689	896
Growth (%)	30%	30%	30%	30%	30%	30%	30%	30%
LC Growth (%)	30%	30%	30%	30%	30%	30%	30%	30%
<b>Total</b>	<b>784</b>	<b>923</b>	<b>1204</b>	<b>1518</b>	<b>1844</b>	<b>2232</b>	<b>2680</b>	<b>3193</b>
Growth (%)	27%	18%	31%	26%	22%	21%	20%	19%
LC Growth (%)	18%	17%	20%	21%	19%	19%	18%	16%

Source: Merrill Lynch estimates. LC = local currency.

For **CY06E** we have lifted our local currency growth from 18% to 19% driven solely by a faster growing 'Other' segment. For **CY07E** our growth rate has been increased from 17% to 18% for the same reasons as above.

## Key Themes at Congress

During the EAO we have identified the following facts/themes, which include growing interest in Astra Tech, industry consolidation, risk of increasing regulation and imaged guided surgery.

### Attendee Interest - the Winner is Astra Tech

As at every EAO Congress, the founding gold sponsors provide opening symposia where they can provide updates on new product launches or highlight clinical data as well as other developments. Unlike the previous three EAO congresses, where Nobel Biocare has been the clear winner, we have seen a material shift in attendee numbers, towards other implant companies.

Table 5: Gold Sponsor Course Attendance

Company	Number of Attendees
Astra Tech	350-400
Straumann	200-250
Nobel Biocare	180-230
Dentsply	100-120

Source: Merrill Lynch estimates

To our surprise, Astra Tech has been the outright attendee winner with an estimated 350-400 participating during their symposium, followed by Straumann at 200-250. Next in line was Nobel Biocare with 180-230, followed by Dentsply at 100-120. Based on our discussions with Astra Tech attendees, it appears the strong attendance was driven by the following key factors:

- **Astra Tech has Momentum** – attendees thought that Astra Tech was doing an excellent all round job in product development and customer service and also offered the most interesting program;
- **New Nobel Biocare** – it appears that clinicians are starting to view Astra Tech as the new ‘old Nobel Biocare’ driven by the view that the company uses evidence based product development and design, a culture that is driven and enforced by its parent AstraZeneca; and
- **Prof. Tomas Albrektsson** – attendees wanted to listen to Albrektsson speak on the topic of “The importance of serious documentation and liability issues regarding implant treatment”, which amongst other implants focused on the poor clinical outcomes of Nobel Biocare’s NobelDirect and NobelPerfect implants.

In our view the lower attendance of Nobel Biocare’s symposium may largely be driven by the fact that the company may have seen many of the EAO attendees during their World Tour and thus attendees decided to take the opportunity to listen to the product offering of other implant companies.

**Overall the feedback we are getting on Astra Tech is very positive and we estimate that the company can continue to take market share both in volume and value over the next 2-3 years. Furthermore, we believe Astra Tech may benefit from the void that has been created by Nobel Biocare and become recognized as a company that continues to focus on solid research and development in conjunction with well supported clinical research.**

## Industry Consolidation

We believe further industry consolidation is likely to pick-up in 2007 and involve all three tiers of the dental implant market. Provided below is our segmentation of the industry participants by sales, with Tier 1 referring to companies with dental implants sales greater than US\$200m, Tier 2 greater than US\$50m and Tier 3 and less than US\$50m.

- **Tier 1 Companies (> US\$200m in Sales)** – with Biomet currently undergoing a strategic review with the help of Morgan Stanley, one can not rule out the possibility of an asset break-up including the sale of its dental implant business, 3i. It is our view that Straumann could seriously be interested in 3i, providing an instant solution to its relatively weak U.S. position, while at the same time becoming the largest dental implant provider globally. Furthermore, with increased resources it could more aggressively develop the under penetrated dental implant market;
- **Tier 2 Companies (> US\$50m in Sales)** – we also believe that a number of Tier 2 players are seriously interested in consolidation including Zimmer and AstraTech. Interestingly, for Zimmer a strong geographic fit would be AstraTech, while AstraTech could clearly be interested in 3i to strengthen its worldwide geographic presence.
- **Tier 3 Companies (< US\$50m in Sales)** – in this segment we are typically referring to companies with less than US\$50m in dental implant sales, which are looking for critical mass or geographic reach. Companies which fall into this category include Danaher (Sybron Dental), Lifecore Biomedical and Thommen Medical.

The pick-up in industry consolidation is driven by our view that dental implant companies are increasingly scrambling for position in the underlying attractive dental implant market, helped by significant **geographic holes** at many of the Tier 2 as well as some Tier 1 companies. It should also be noted, that we see it as likely that the cost of doing business will increase as the market shifts its growth ambitious to the higher number of general dentists which are typically lower volume users but lots of them compared to the traditional segment of oral surgeons. Hence as the demand for education, training and service increases for the larger number of general dentists wishing to perform dental implant procedures, so will the pace for industry consolidation to benefit from greater economies of scale. Furthermore, we believe the industry is starting to move towards the area of **orthobiologics** as a way for future product differentiation, which is likely to make future R&D programs significantly more expensive.

## Conclusion

Within the Tier 1 segment we see potential M&A activity between Straumann and 3i. Although the intentions of AstraZeneca remain unclear, we would not rule out a possible combination between Zimmer Dental and Astra Tech. We believe M&A activity within Tier 3 is likely to intensive and will result in a number of stronger entities with sales exceeding US\$50m.

## Risk of Increasing Regulation

Following the recent news flow on Nobel Biocare's recent product launches of NobelDirect and NobelPerfect, which may have been based on limited clinical data, we have started to witness increased discussion as to whether the dental implant market may need to be subject to stricter regulations. Furthermore, a number of dental bodies have highlighted the risks about aggressive marketing techniques/tactics for recruiting general dentists to do implant procedures.

### Medical Device Regulation

The interest in this topic appears to be quite strong, driven by the EAO attendance during Professor Tomas Albrektsson's presentation on the topic:

*"The importance of serious documentation and liability issues regarding dental implant treatment"*

In his presentation he highlighted that we can no longer accept the current poor control environment and provided a number of suggestions/guidelines that should be used to prevent manufacturers from launching products too soon and to quickly that may in the end have a detrimental impact on the health of the patient. The questions that need to be asked in identifying a novel implant and whether clinical documentation is needed are as follows:

- **A Major Change** – does the implant represent a major change to previous established research. If it is, one would need a controlled, randomized clinical trial before accepting company claims;
- **A Moderate Change** – does the implant represent a moderate change, which may include extending the rough surface in soft tissues. In these situations may need to have 1 year clinical data before marketing to show maintained bone levels; or
- **A Minor Change** – does the implant only contain a minor change, which may include an increase of the implant diameter or hydrophilic surfaces or nano-indentations instead of ordinary surfaces. This category typically represents low risk as it is unlikely that such surfaces are more risky than ordinary documented surfaces.

It was further highlighted that the industry should take proactive steps in self regulation to prevent products such as NobelDirect entering the market too early and thus avoid the risk of seeing an increase in government regulation. Clearly self regulation over government regulation seems a more desirable approach.

### Training Regulations for General Practitioners

It appears this not only applies to the manufacturing and marketing of new products but also increasingly to the quality of training of general dentists starting dental implant procedures. Some of the more recent developments in the UK and the US are highlighted below:

#### UK - New Guidelines

In March 2006 the General Dental Council (GDC) convened a working group to consider training standards for general dental practitioners who wish to practice implant dentistry. The remit of this group was to consider:

- What training standards would be necessary for a general practitioner before practicing implant dentistry;
- To publish those standards; and
- To periodically review these standards in the light of new developments.

The GDC highlighted that such standards could be used not only by practitioners but also by the GDC in the **consideration of patient complaints against dental practitioners** who, allegedly, practice implant dentistry beyond the limits of their competence. While we do not want to bore the reader, we highlight the following requirements expected from a general dentist, which may suggest that many of the training courses offered by dental implant companies (often a 2-5 day program) to recruit new customers, may be insufficient:

**Table 6: GDC Standards - Placement of Implants without Major Bone Augmentation**

Requirement #	Description
2	Have detailed knowledge of and have been trained in infection control and practical surgical aseptic techniques as applied to implant dentistry
6	Understand the techniques involved in harvesting bone from oral sites for minor augmentation during implant placement
7	Understand the use of exogenous bone or bone substitutes for minor augmentation in the placement of implants
9	Understand the clinical assessment of a patient's suitability for implants, and the medical conditions that could preclude a patient from implant techniques or complicate surgery
10	Understand the main implant options available and their indications and contraindications for certain patient groups
12	Understand the clinical and laboratory techniques used to restore implants including: 1] ability to demonstrate experience and understanding of advanced restorative dental procedures; 2] recognition of technical and cosmetic limitations of implant dentistry in certain situations; and 3] proficiency in clinical and laboratory techniques in using implant superstructures

Source: General Dental Council

For the placement of implants with **major bone augmentation** and/or modification of anatomical structures, the requirement becomes more stringent and includes that general dentists must have attended courses which specifically train in these techniques.

In comparison we provide an overview of *"The Unique, Worldwide Training & Educational Program 2006"* from **Nobel Biocare** (we have only sited this company because it has the most complete training material readily available on their website for us to have a look at), which includes programs titled *"Starting with implants"*. These aforementioned courses are marketed for dentists who are **new to placing implants** and want to incorporate them into their clinic. Interestingly, the *Start-Up* program consists of 5 days, of which 3 days is spent on implant placement and 2 days on the prosthetic treatment.

**Table 7: Nobel Biocare – Start-Up Program for Dental Implants**

Time Period	Objective	Course Description
3 Days	<u>Tapered Implants or Parallel Wall Implants</u>  Achieve sufficient knowledge to place NobelReplace tapered implants or parallel implants with Immediate Function and prosthetic treatment  Achieve sufficient knowledge to start placing and creating prosthetics for Nobel Direct	<u>Course content includes:</u> 1. Treatment planning & patient selection 2. Surgical techniques - NobelReplace, NobelDirect & Branemark 3. Introduction to NobelGuide 4. Component and system knowledge 5. Practice management 6. Lectures, live surgery, video and hands on training 7. Planning on own case
2 Days	<u>Prosthetic Treatment</u>  Gain sufficient knowledge to do implant prosthetic treatment on cases ranging from single teeth to full jaws	<u>Course content includes:</u> 1. Treatment planning & patient selection 2. Procera solutions on implants 3. Component and system knowledge 4. Lectures and hands-on training 5. Planning on own cases

Source: Nobel Biocare: "The Unique, Worldwide Training and Educational Program 2006"



When we compare Nobel Biocare's 3 day dental implant training course, it seems that several of the criteria by the General Dentist Council may not be satisfied. Specifically the training program makes no reference to techniques for harvesting bone or the use of exogenous bone substitutes; furthermore one has to wonder whether after 3 days a general dentist will be able to have show the level of competence required by the GDC.

#### United States - Emerging Guidelines

It seems that similar concerns surrounding general dentists performing dental implant treatment are arising in the United States. Recently the **Institute of Dental Implant Awareness**, which is a non-profit corporation founded in 1997 to provide independent, authoritative and objective information on the benefits of dental implants as an alternative treatment option for tooth replacement, highlighted the following in their publication, which went to **3,800 periodontists** on 8 September 2006 and to **5,900 oral surgeons** on 18 September:

*"Since at this point dental societies have not yet promulgated standards for training, the alternative for maintaining the integrity of implant dentistry is for surgical specialists to become proactive. They should consider providing proper education for their referring dentists in risk management and counsel them regarding appropriate minimum requirements for surgical training should they wish to place their own implants. Equally they should address the breadth of potential complications associated with the surgical placement of dental implants. Exposure to the realities of dental implant liability claims and preventive risk management generally deters most dentists from becoming implant surgeons until they have reasonable training for patient safety."*

This statement was made on the basis that dental implant companies are now directly selling surgical kits and implants to general dentists without the training required to comply with the Standard of Care. Specific reference has been made to Nobel Biocare, where the Institute stated that:

*"The goal of the company-sponsored surgical training courses is to make implant surgery appear easy to as many new surgical customers as quickly as possible. Since these are one and two day courses there is not enough time to address risk management or how to handle complications. Indeed the limited formats inherent in such constrained programs cannot provide in-depth training on the surgical procedures or exposure to treatment of complications."*

This issue was also addressed recently, by Dr. Jay Malmquist, president of the **American Association of Oral and Maxillofacial Surgeons** (AAOMS) in his inaugural speech and later again in the January/February 2006 issue of AAOMS, where he stated the following:

*"Moreover, these companies never mention that professional liability legal standards require all practitioners providing a service to meet the highest standard of care expected of any other surgeon or face potential malpractice litigation . . . Unhappily for patients, course participants, believe that they are now trained after just one or two weekends, return to their practice to perform their recently learned skills in the operatory. The results of their misconceptions may be seen in the **caseloads of the state boards, where the number of complaints filed by the patients injured or otherwise harmed by dental professionals who lacked the necessary training to perform a particular procedure is increasing**"*

Table 8: Institute of Dental Implant Awareness - Advisory Board

Dr. David Anson  
 Dr. Jay Beagle  
 Dr. Bruce Johnson  
 Dr. Paul Korb  
 Dr. Aldo Leopardi  
 Dr. Jay Malmquist  
 Dr. Dennis Shanelec  
 Dr. Rich Stuart  
 Dr. Clark Taylor  
 Dr. Stephen Wheeler

Source: IDIA

Attorney Arthur Curley who consults to the Institute of Dental Implant Awareness highlighted in September of 2006, that in his experience, having represented the dental community for over 30 years:

*“Many general dentists do not seem to be aware of the potential liability of placing implants, particularly after taking a one or two-day training course with minimal clinical experience. Unfortunately, not having more extensive training can leave dentists ill-prepared to handle the full variety of complications and failures can occur. [I] have been too often been asked to defend general dentists who had performed surgical procedures based upon courses with inadequate training. The late diagnosis and treatment of complications often results in much more injury to a patient than the mere loss of an implant. Typical cases involve permanent nerve injury, significant infections, sinus perforation or loss of adjacent teeth. **The potential problems can be increased when a general dentists relies on an implant manufacturer’s marketing representation that 1-2 training courses are fully adequate.**”*

It was further highlighted that ideally the dental specialty societies should establish guidelines for the minimum amount of training required for implant surgery. Such a standard would cause the implant industry to revamp its curriculum for surgical procedures into their practices while maintaining appropriate standards of care. It was concluded that unfortunately, if these warnings are not heeded, it will be the legal profession of attorneys, judges and juries that will create and mandate the standards for training in implant procedures. As a result the **Institute of Dental Implant Awareness** is currently putting together training & education guideline for general dentists, which is likely to make it more onerous for general dentists to move into placing dental implants.

### Conclusion - Industry May Become More Regulated

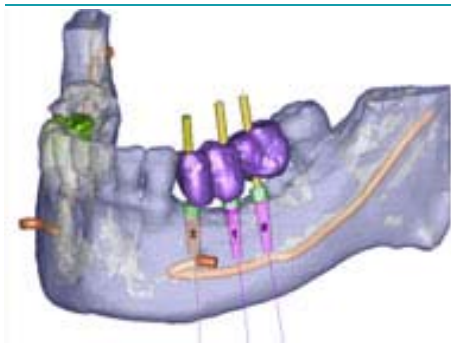
We believe the strong sales growth targets set by the management of large listed dental implant companies such as Nobel Biocare (i.e. > 20%), has the potential to result in new dental implant designs being launched to quickly without sufficient clinical data, increasing the risk of complications or undesirable side effects such as poor esthetics. Furthermore, the strong growth ambitions is also fuelling the recruiting of general dentists to do dental implant procedures, by potentially hyped 2-3 day training courses that may drive short-term sales (i.e. through starter kits with implants) but may have more serious long-term implications on the industry. Although, we continue to see general dentists as a very appealing long-term growth opportunity, we feel the current training practices by some dental implant companies may be too short sighted. As a result, we believe long-term investors should take into consideration what implications such aggressive marketing techniques can have on the dental implant industry, with respect to industry regulation and growth rates over the intermediate term.

## Image Guided Surgery - Growing in Importance

Since the introduction of NobelGuide by Nobel Biocare during its World Congress in 2005, we have seen increasing interest in image guided surgery at the EAO meeting. Although Nobel Biocare may not be the pioneer of this technology (we believe the honor goes to Materialise), it is the company's vision which has clearly raised the interest within the dentist and oral surgeon community. While the technology is generally considered too expensive, particularly if one includes the manufacturing of the implant guide, the interest is driven by the possibilities it creates, which include:

- **Avoid bone augmentation techniques** – using image guided surgery may allow the use of implants in patients without doing an expensive and long-dated bone regeneration procedure; and
- **Useful for general dentists** – newcomers may find added comfort in doing dental implant procedures using image guided surgery, as it can substantially reduce the risk of incorrect placement.

Chart 3: Materialise – SimPlant Software



Source: Materialise

Interestingly, Materialise which continues to be the industry leader with an estimated 60% market share (4,7000 clinicians now utilize the SimPlant) has decided for an open platform and can handle a wide range of dental implant systems, while Nobel Biocare has chosen to develop it is own platform. It appears that Dentsply is also seeing strong growth prospects, with the company recently acquiring a 40% shareholding in Materialise Dental for EUR20m. At the same time we have seen Astra Tech announced a licensing agreement with Materialise for its own labeled product called *Facilitate*.

### Materialise vs. NobelGuide

On 14 July 2006 Belgium based company Materialise announced that it is suing NOBE for the alleged patent infringement for the use of a method for making so called dental drill guides, with a court decision expected in **mid 2007**. These dental drill guides are acknowledged as a very promising improvement for implant treatment and hence Materialise has therefore filed a patent infringement action at the Düsseldorf district court in Germany. It should be noted that NobelGuide is an important growth driver for the company and represents a key ingredient for the company's dental implant sales strategy.

#### Patent in Question - EP 0 756 735

NOBE is sued for infringement of the method which is protected by **Claim 1 of European Patent 0 756 735** granted to the company Materialise on 26 October 1995. Materialise points out that it launched its dental drill guide system back in 1999 under the name of SurgiGuide, while NOBE did not introduce its NobelGuide system until 2005. Materialize has highlighted that 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. Materialise asserts that NOBE 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 presented at open conferences for clinicians.

### Field of Invention

The patent highlights that the invention concerns a **method for making a medical model on the basis of digital image information of a part of the body**, according to which this image information of a part of the body is converted, by means of what is called rapid prototyping technique and thus with a processing unit and a rapid prototyping machine, into a basic model of which at least a part shows the positive or negative form of at least a portion of the part of the body. Rapid prototyping technique should be understood as all techniques whereby an object is built layer by layer or point per point by adding or hardening material. The best known techniques of this type are stereo lithography, selective laser sintering or fused deposition modeling.

The models produced before Materialise's invention were devices that were an exact copy of the part of the body, for example a piece of bone, and upon which a surgery operation can be practiced, or it can be a prosthesis which fits perfectly to the part of the body. However, the models produced up to now **do not take advantage of all the information contained in the image information. They form a perfect copy of the part of the body, but they do not contain any additional functional elements.**

### What is Claim 1 of EP 0 756 735

While **European Patent 0 756 735** makes a number of claims, it appears that only Claim 1 is in question, which reads:

*"In a method of making a medical model from digital information corresponding to a part of a human body wherein the digital information is used to generate information for rapid prototyping of the model, the improvement comprising: adding to the digital information data related to at least one artificial functional element having a useful function related to a physical parameter and based on image information in the form in which all medical data are visible and including grey value image information, before segmentation; carrying out the rapid prototyping of the model using the digital information with the added data whereby the medical model includes said artificial functional element."*

### SurgiGuide & SimPlant

Materialise's 3D implant planning system for predicable treatment planning for dental implant systems consists out of two key components. The SimPlant planning software which uses data from a CT scan to find suitable locations for the dental implants on the 3D image. Once the dentist is finished with his pre-planning, the data is then used to create SurgiGuide, which is later used to physically position the dental implants in the patient's jaw bone. Provided below is a visual comparison between SurgiGuide and NOBE's NobelGuide.

Chart 4: Materialise – SurgiGuide



Source: Materialise

Chart 5: Nobel Biocare – NobelGuide



Source: Nobel Biocare

### Dentsply Gets Involved

On 8 August 2006 the dental division of the Materialise Group became a separate company and Dentsply International (market capitalization of ~US\$5bn) acquired a 40% shareholding in Materialise Dental for EUR20m. The transaction also provides the opportunity for Dentsply to acquire and the other shareholders to sell the remaining interest in Materialise Dental to Dentsply over time. It should be noted that Dentsply made the investment following their own patent review.

As expected both companies agreed to keep the SimPlant product as an open platform for computer guided technology, compatible with all implant brands. In our view the investment by Dentsply is driven by Materialise's strong position, which according to the Belgium based company equates to a global market share in excess of 60% for 3D Digital Dentistry in dental implants, with over 4,700 clinicians now utilizing the SimPlant Platform.

Before Dentsply's investment, it was our view that Materialise's primary objective for the patent infringement case was to obtain royalties from NOBE, driven by its relatively small size (FY05 revenues of EUR30-35m). However, with Dentsply becoming a key investor, its dominance in the dental market may have changed to motive behind the patent infringement case from royalties to one of injunction.

### Conclusion

Due to Nobel Biocare's foresight the relevance of computer guided surgery is likely to increase substantially over the next 5 years and we would expect this technology to receive strong demand particularly from general practitioners thinking of moving into dental implant treatment. However, with this also comes a challenge for Nobel Biocare and that is a successful defense against Materialise/Dentsply. Although this matter will go to court in mid 2007, with a decision probably later in the year, we believe this matter may take several years to resolve due to the appeals process. As a result, we believe it is too early to perform a scenario analysis on the various financial outcomes. However, we do believe it is worth mentioning that the NobelGuide concept is an important future growth driver for NOBE and as a result this patent infringement case may pose as a meaningful uncertainty / deterrent should a large Medical Device company be interested in acquiring the company.

## Nobel Biocare - Growth May Slow

Provided below is additional feedback on Nobel Biocare following the EAO meeting and includes comments on NobelDirect, sales force feedback and comments on unit market share gains.

### NobelDirect - Medical Products Agency

We continue to believe that the Swedish Medical Products Agency is on track to make a decision by the end of October 2006, as to whether NobelDirect should be withdrawn from the market due to safety and efficacy concerns.

### Sale Force Feedback - Changing Business Model

We had the opportunity to talk to a number of Nobel Biocare sales people who recently left Nobel Biocare and have received the following feedback:

- **Sales Force Turnover** – it appears that there has relatively large sales force turnover (e.g. numbers cited where 30-40%) over the past 2 years. It appears that Nobel Biocare has shown surprisingly little interest in retaining experienced sales people as a result of competitive hiring. Instead it appears the company seems to be replacing the lost sales people (who can be quite expensive) with two less experienced sales people for roughly the same cost. As a result, the company is better positioned to pursue new general practitioner accounts to gain business. While this has the potential to grow the business, we were told that it has reduced the level of specialist sales service to existing high volume users, which has resulted in the loss of some high volume customers. This appears to be a change to the old fashioned sales force business model in dental implants and it will be interesting to see whether the market leader has correctly foreseen the future development of the dental implant market;
- **Not Outgrowing Market in Units** – further feedback from sales people suggested that Nobel Biocare's growth has been strongly benefiting from strong price increases and positive mix shift across its product portfolio. It was further highlighted that the underlying dental implant unit growth does not suggest that Nobel Biocare is gaining market share. As a result, in order to sustain the current growth momentum of +20% it was suggested that the company must find new avenues of price increases, which they believe will be fueled through a new product launch cycles; and
- **Procera Gaining Momentum** – group growth has been strongly augmented by its Procera crown and bridge offering, which has gained strong momentum over the past 2 years.

### Finland - Dental Implant Register

Further evidence that Nobel Biocare may not be outgrowing the dental implant market, is supported by the Finnish dental implant statistics (the only country known to us that publishes unit data for dental implants) as highlighted in the 2005 Dental Implant Yearbook. While we recognize that Finland is a small part of the dental implant market, it nevertheless is in Northern Europe, in which Nobel Biocare typically holds a strong market position.

Provided in Table 9 below is a summary of implant units placed by dental implant manufacturer from 1994 to 2005. The data clearly shows that Nobel Biocare has lost market share since 1998 and more recently has managed to maintain its unit market share at 14% despite the company showing strong revenue growth.

**Table 9: Finland - Total Implants Placed by Manufacturer**

Year	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Straumann	1,138	1,903	2,047	2,086	2,950	3,413	3,767	3,599	4,126	4,487	5,307	5,388
Astra Tech	439	624	897	974	1,211	1,501	1,746	1,863	2,040	2,058	2,175	2,776
Nobel Biocare	525	803	911	1,596	1,596	1,408	1,549	1,254	1,544	1,368	1,532	1,688
<b>Total</b>	<b>2,659</b>	<b>4,217</b>	<b>5,128</b>	<b>6,063</b>	<b>7,463</b>	<b>8,686</b>	<b>9,534</b>	<b>9,377</b>	<b>10,364</b>	<b>10,310</b>	<b>11,222</b>	<b>12,374</b>
Market Share	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Straumann	43%	45%	40%	34%	40%	39%	40%	38%	40%	44%	47%	44%
Astra Tech	17%	15%	17%	16%	16%	17%	18%	20%	20%	20%	19%	22%
Nobel Biocare	20%	19%	18%	26%	21%	16%	16%	13%	15%	13%	14%	14%

Source: The 2005 Dental Implant Yearbook

More recently Astra Tech has been able to gain market share, which is line with the overall strong revenue growth that we are sensing at the company.

## Conclusion

While the strong constant currency revenue growth rates at Nobel Biocare suggest material market share gains, we believe a material portion is driven by price increases on existing products as well as recently launched products such as *Groovy*. As a result, we believe the company may not be gaining material market share in units, which in our view is a clearer predictor of sustainable future growth. In addition, we believe the company is also benefiting from its very compelling Procera prosthetic range (the company should be congratulated on picking this trend), which in our view is helping Nobel Biocare grow faster than some of its competitors. However, with the risk that Nobel Biocare may need to slow down its launch rate for new products, to allow it to accumulate more long-term data, we feel the company sales growth rate may slow in 2H CY07, as the price benefit from its *Groovy* technology of 10-15% (i.e. including the healing cap) fades. Furthermore, we also believe that the next 12-24 months will show whether company's strategy of aggressively pursuing general practitioners, particularly in the U.S., will prove a success and compensate for the loss in revenues from some of its high volume surgeon customers, who feel unhappy with the Nobel Biocare's strategy.



Chart 6: Neoss Implant System



Source: Neoss

## Medtronic Makes Entry into Dental Implants

We understand that Medtronic has recently entered the dental implant market, with a +10% equity stake in UK based Neoss. We estimate the stake cost Medtronic £5m or US\$8.8m. Other investors include MMC Ventures and Delta Partners.

### Neoss Description

Neoss, which was founded in 2000, is the designer and distributor of a new system of dental implants. The two founders are a UK academic, Prof Neil Meredith, Chair in Biomaterials at Leeds Dental Institute and Fredrik Engman, a former senior product developer at the market leader, Nobel Biocare. The company believes its competitive position includes its simplicity; currently many of its competitors have up to 2,000 different components in their product catalogues, meaning that dental implantology is a difficult and specialist area. However, Neoss believes that its design allows for a fully functional product suite containing under 100 components. This simplicity reduces production costs and allows both general dentists to place implants and specialist implantologists to increase their productivity. Neoss has also devised an interesting method of packaging the implements which should further reduce costs and complexity for dentists.

### What Next?

We believe the investment by Medtronic at this stage is only at 10%, to avoid the company from consolidating what continues to be a loss making business, driven by the investment in its direct sales force. We would not be surprised to see Medtronic take full ownership of Neoss over the coming years and leverage its BMP2 rights for a long-term competitive advantage. For many market observers, an investment in a relatively insignificant company does not appear to follow Medtronic's style, which typically makes market leading acquisitions to enter into a new area of medical devices. Examples of this is the AVE acquisition to enter into interventional cardiology, Sofamor Danek for a move into orthopaedic spine and MiniMed for insulin pump therapy.

### Conclusion

Although it may be many years before any market impact will be felt from Medtronic's investment in Neoss, it will take away some market bid speculation that the U.S based company is interested in making a bid for Nobel Biocare.



## Product Launches Low Key Nobel Biocare

During the EAO, the world's largest dental implant company launched new products that extended the Procera product line. Details of the Nobel Biocare launches are highlighted in the table below:

Table 10: Nobel Biocare – Product Launches

Product	Description
Procera Implant Bridge Zirconia	The world's only CAD produced implant bridge in zirconia for screw retained solutions
Procera Bridge Alumina	Densely sintered Alumina bridge
Procera Bridge Zirconia	Now up to 9 units
Procera Bridge Titanium	Can now be prepared with Procera Forte scanner
Procera Abutment Zirconia & Titanium	Extended the range to also include AstraTech and Camlog implants
NobelRondo Gingiva Zirconia	Six types of pink ceramic shades

Source: Nobel Biocare

We believe the company will launch a whole range of new products at its World Conference 2007 that will be held on 20-24 May in Las Vegas and may include a one piece ceramic implant. It will be interesting to see, what length of human clinical data Nobel Biocare will have on its new implantable products. We hope the company has learnt from its current regulatory investigations surrounding NobelDirect and NobelPerfect and will invest more strongly in the future to ensure long-term product efficacy and safety.

## Straumann

During the EAO Straumann launched its Narrow Neck implant with its SLActive surface. As a reminder, the SLActive surface reduces the time of osseointegration (i.e. bone growing into the rough surface for implant stability) and was launched at the 2005 EAO meeting in Munich.

Table 11: Straumann – Product Launches

Product	Description
Narrow Neck SLActive	Narrow neck implant is now available with new SLActive surface
BoneCeramic	BoneCeramic sizes has been extended from 0.25g and 0.5g to the new size of 1.0g for large defects

Source: Straumann

In addition the company provided an extension to the unit size for its BoneCeramic from 0.25g and 0.5g to 1g. Although the company is secretive about its products launches over the next 12 months, we believe Straumann could be launching a new sloped implant design at the ITI World Congress 2007. Furthermore, it appears the company is extremely comfortable with its mid-term product pipeline.

## Biomet(3i)

3i, the dental implant subsidiary of Biomet, launched a line extension to its PREVAIL implant range, including a new straight collar design compared to its existing range of an expanded collar; we understand the price premium is US\$15 or around 5% selling at US\$329. In addition 3i launched OSSIX Plus, a new porcine based collagen membrane to accommodate for the heightened concern about bovine based material due to mad cow disease.

**Table 12: Biomet (3i) – Product Launches**

Product	Description
PREVAIL Straight Collar	Line extension of the PREVAIL implant range to include straight collar
OSSIX Plus	New porcine collagen membrane.

Source: Straumann

It seems the company is very excited about its pending NanoTite surface launch, which the company believes results in substantial acceleration in bone healing. To date the company has done a limited marketing release to 150 clinicians worldwide. It seems the roll-out will gain momentum in January 2007 when NanoTite will be released to its Platinum customers, with a full launch at the AO meeting on 8 March 2007.

## Zimmer Dental

Zimmer Dental, subsidiary of the world's largest orthopedics company Zimmer, launched its one-piece implant, which is based on the same CoreVent body (except on the 3mm implant) and does not require in situ preparation like Nobel Biocare's NobelDirect implant. Over the next 2 years we believe Zimmer Dental may be in a position to launch a tribecular based dental implant system. We also believe the company is looking into digital dentistry for impression less solutions.

## Dentsply (Friadent)

Friadent, subsidiary of one of the world's largest dental companies, also had some low key product launches including a new power unit, a contra-angle hand piece and new single-patient drills. In addition, we also saw the launch of zirconium oxide abutments, but customized versions are still some time away.

**Table 13: Dentsply (Friadent) – Product Launches**

Product	Description
FRIOS Unit S	Power unit specifically dedicated for placing dental implants
FRIOS Handpiece	New contra-angle hand pieces
Disposable Drills	New single-patient drills

Source: Dentsply

Far more interesting is the company's success from STEEPS Direct, which is a step-by-step business practice marketing and promotional program for dentists wishing to move into dental implants. This program was launched in March 2006 and has worked well in Germany, Switzerland, France, Italy and the U.S. Over the short to intermediate term we believe Dentsply will leverage its recent investment in Materialise in image guided surgery and perhaps even force Nobel Biocare to rethink its strategy, should the Courts enforce the company's belief that NobelGuide has infringed its patents.

## Astra Tech

Astra Tech, which is a subsidiary of the AstraZeneca Group, announced the launch of *Facilitate*, its new computer guided surgery kit. *Facilitate* is an Astra Tech branded solution that is based on Materialise's Simplant 3D Planning System for accurate and predictable planning of dental implants. We estimate that SimPlant is currently the industry leading planning software for dental implants, with an estimated market share of 60% and well ahead of Nobel Biocare's NobelGuide. Although we believe that *Facilitate* gives Astra Tech a very strong dental implant offering, we are somewhat confused by the fact that its competitor Dentsply has recently acquired 40% of Materialise, with an option to increase its stake. As a result, one has to wonder how long Astra Tech will be able to market *Facilitate* before Dentsply attempts to reduce Astra Tech's competitive advantage.

## Other Tid Bits

**Innova**, which is part of Sybron Dental, launched the Anatomic Implant System, which is the very first asymmetric dental using a press-fit design (i.e. tapped in). The press-fit design substantially improves implant placement compared to other claimed high-esthetic implants such as NobelPerfect, which is difficult to place due to its thread design.

Our field checks suggest that we are seeing the emergence of a strong Korean competitor; **OSSTEM** seems to have established many marketing leading positions in Asia such as Korean (50% market share), Indonesia (35%), Taiwan (10%) as well as Saudi Arabia and Pakistan. It has also moved into Europe with a direct sales force in Germany and Russia, while it uses distributors in Spain, Portugal and Italy. It also has a subsidiary in the United States and is growing rapidly, driven by what many industry commentators suggest are good quality products at a reasonable price.

## Conclusion

Based on the various product updates by Astra Tech, Biomet (3i), Dentsply (Friadent), Nobel Biocare, Straumann and Zimmer Dental, we feel product innovation within the dental implant industry is currently not at a high level. While we saw the launch of some new implant surfaces last year, including Straumann's SLActive surface, it appears that product differentiation is a little more difficult to come by. Moving forward, we believe the premium companies will attempt to drive product differentiation through the use of orthobiologics to accelerate bone healing as well as image guided surgery to make their product offering more appealing to general dentists.

## Investment Conclusion

Following our attendance at the EAO meeting in Zurich, we continue to believe in the attractive nature of the dental implant market due to its low penetration rates in Europe, U.S. and Asia, which we currently estimate at 19%, 12% and 8% respectively or ~15% worldwide. We continue to believe that the dental implant market can grow in the high-teens over the intermediate term and thus consider this area as one of the most exciting fields in European MedTech. Nevertheless, everything has its price and we feel that the strong interest in dental implants over the years has rightfully pushed up the valuations sharply for Nobel Biocare and Straumann. While we continue to see positive returns over the long-term, we feel the current CY06E P/E valuation range 30-31x does not allow for any material uncertainties.

### Nobel Biocare (NBCHF, B-2-7, EUR302) - Neutral

We continue to believe that the uncertainties surrounding NobelDirect are not yet resolved (unlike consensus) and thus we retain our **'Neutral'** recommendation, pending the Swedish MPA ruling on the safety of this implant. As we are unable to form a conclusive view on how the agency will decide, we again highlight our previously published scenario analysis. Our analysis suggests that a **positive decision** would value NOBE at **CHF364 per share**, a **NobelDirect label change** would bring this to **CHF340**, while a **product withdrawal** and the resulting uncertainties would bring this to **CHF268**.

In addition, while the strong constant currency revenue growth rates at Nobel Biocare may suggest material market share gains, we believe a material portion is driven by price increases on existing products as well as recently launched products such as *Groovy*. As a result, we believe the company may not be gaining material market share in units, which in our view is **a clearer predictor of sustainable future growth**. However, with the risk that Nobel Biocare may need to slow down its launch rate for new products, to allow it to accumulate more long-term data, we feel the company sales growth rate may slow in 2H CY07, as the price benefit from its Groovy technology of 10-15% (i.e. including the healing cap) starts to fade. Furthermore, we also believe that the next 12-24 months will show whether company's strategy of **aggressively pursuing general practitioners**, particularly in the U.S., will prove as a success and compensate for the loss in revenues from some of its high volume surgeon customers, who feel unhappy with the Nobel Biocare's strategy.

### Straumann (SAUHF, B-2-7, CHF271) - Neutral

For highly rated dental implant stocks, such as Straumann, we believe the valuation requires both high-teens sales growth and margin expansion of 100 basis points, to result in +20% EPS growth. STMN is unlikely to approach the required high-teens organic sales growth through new product launches (despite SLActive) and is unlikely to show meaningful margin expansion, due to a strong infrastructure expansion cycle in North America and new product launch costs. These developments are likely to equate to a transition year for STMN in CY06E and CY07E. Furthermore, Straumann's sales growth has looked relatively pedestrian over the past 12 months compared to Nobel Biocare, which in our view is driven by a far more conservative strategy in pursuing general practitioners. Whether this strategic conservatism will prove correct, will show over the coming 12-24 months. We retain our **'Neutral'** stance.

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