

Blog on Nobel Biocare's Credibility and TiUnite

Nobel Smile?

Can Nobel Biocare finally smile again? Last week Sweden's Medical Products Agency (MPA) gave Nobel the green light to continue selling its NobelDirect and NobelPerfect implants. The condition is simply that Nobel Biocare must rewrite instructions for the NobelDirect and NobelPerfect dental implants to inform customers and dentists of a possible bone loss problem and how to prevent it, the Swedish Medical Products Agency said. The company must explain by Jan. 8, 2007 how it plans to rewrite the instructions and cannot market the product until the new information is available.

Reaction to the MPA ruling was unquestionably positive. "Without a product withdrawal, we believe many of the potential material risks have been avoided," Michael Jungling, an analyst at Merrill Lynch, said in a report. As a result, it's unlikely that Nobel Biocare "will face U.S. litigation or that its customer reputation will be tarnished."

However, it is important to note that a ban of the product is still possible. "We just don't have enough data to pull the product off the market at the moment,"

Lennart Philipson, the agency's director for medical devices, said at a press conference in Uppsala, Sweden. The shortcomings in the instructions could explain the increased risk of a breakdown of the jawbone, the agency said.

What are your thoughts on this latest twist in Nobel saga? Has fortune once again smiled upon Nobel?

December 12, 2006 in [Dental Implant News](#), [Nobel Biocare](#) | [Permalink](#)

Comments

- 1) One-part implants have been used for many decades. It seems that NOBEL has simply forgotten the clinical procedures how to apply them successfully.
- 2) The recommended protocol is clearly insufficient.
- 3) NOBEL Direct is obviously more a marketing thing than a clinical concept fitting NOBEL's product / knowledge concept and portfolio.
- 4) I found their communications during this event rather weak and unprofessional - not what I would expect from the market leader.

Posted by: mac | Dec 12, 2006 11:27:55 PM

Are there Nobel Direct and Nobel Perfect the only two Nobel implants with bone loss concerns?

What about the other Nobel implants like the TiUnite?

Any dentists experience bone loss with the TiUnite?

Posted by: TD | Dec 13, 2006 1:01:56 PM

I love the Groovy implants - that one rabbit study really gives me confidence...

Posted by: Doc Albert | Dec 13, 2006 5:18:42 PM

"That one rabbit study..."

Enough said

Posted by: | Dec 14, 2006 7:45:15 AM

The Ti Unite surface is the gold standard surface in implant dentistry. Huge evidence

Posted by: Sergio Callamand | Dec 15, 2006 6:46:30 AM

Anyone finding a bacterial microgap problem (i.e. bone loss) with the TiUnite?

Posted by: TD | Dec 15, 2006 7:25:21 AM

"The Ti Unite surface is the gold standard surface in implant dentistry. Huge evidence"

I would challenge that on so many levels. The first being that there is not "huge evidence" directly comparing different surfaces.

On what basis is TiUnite better than any other surface?

Posted by: DL McGraw | Dec 15, 2006 11:46:12 AM

Getting back to the Nobel Direct issue that this thread started with.

What Nobel is being called on - quite rightly- is the fact that when Nobel Direct was launched, they pitched it as the answer for inexperienced surgeons and promoted a flapless surgery. I remember because I still have the flyer and the letter from them.

Most of the cases in the Direct clinical trials were done with a flap, by experts. Now they're saying that it's really an implant for experienced users.

So it all comes down to, "Can I trust what Nobel's marketing is telling me?" I know, like any other company, they want to sell product. I don't mind marketing. But there's a big difference between making a splash and making false claims about a product.

Go to Nobel's website and you'll see all sorts of new claims: Beautiful teeth NOW; Soft tissue integration, groovy, immediate function. All of these claims are based on paper-thin evidence.

As mentioned above by 'Doc Albert' the whole basis for the claims of the "Groovy" implants is one rabbit study. I'm supposed to confidently offer immediate function to my patients based on one rabbit study? And that's on their own website!!

I hope my fellow dentists will at least acknowledge these distortions, just as the Swedish agency has.

Posted by: Simon | Dec 15, 2006 12:05:10 PM

Anyone who proclaims the TiUnite as being the golden standard is ignorant.

I have used the groovy and the Nobel direct with variable results. I don't feel these implants are as versatile as they have been marketed.

More long-term multi-center unbiased studies are required with less company backed pseudo scientific studies.

Posted by: | Dec 15, 2006 5:20:11 PM

Lets recall all the Gold Standards Nobel has claimed over the years and where they are now:

1) Branemark Machined Surface (remember high failures in soft bone because it

was too smooth). Nobel claimed a Branemark Pit Patent covered it...but that was declared invalid by fraud by the US Federal Court of Appeals after Nobel lost its patent suit against 3i. Nobel did effectively push the price of its competitors' implants up with this type of frivolous litigation.

2) Pure Titanium (remember high number of fractures)

3) External Hex (remember screw loosening and bacterial percolation from gapping margins)

4) Nobel Perfect with the speed bumps preserving interproximal bone and thus the papilla.... that didn't turn out to be true

5) NobelDirect being so simple anyone could place them with guaranteed success (that was one of the statements Nobel can no longer say because of bone loss)

6) TiUnite...invented by Nobel. In fact Ticer Implants in the 1980s had this surface.

7 And the biggest lie of them all.... Branemark discovered osseointegration. The fact is that Branemark's 1977 book acknowledged a French Orthopedist named Levinthal as the first to report on bone bonding to titanium but then conveniently forgot that when the marketing started. I sued Nobel for false advertising in the late 1980's and for a while they changed to saying Branemark "observed" osseointegration, but then went back to the big lie in their literature and again credited Branemark.

Finally, here is a little lie that many may not know about. The SEM (Albrektsson JPD Article 1983) colorized for use in Nobel's marketing literature claiming it represented an osteoblast with its cell processes extending over a titanium implant in the upper jaw, turned out to be the same SEM from a 1981 Albrektsson article referred to as a fibroblast from skin around the ear implant. So much for Albrektsson's credibility as he now speaks for Astra claiming indignation at Nobel's failure to research the NobelDirect.

Posted by: [Jerry Niznick](#) | Dec 22, 2006 11:55:10 PM