

March 6, 2008
Domenico Scala
President and CEO
Nobel Biocare

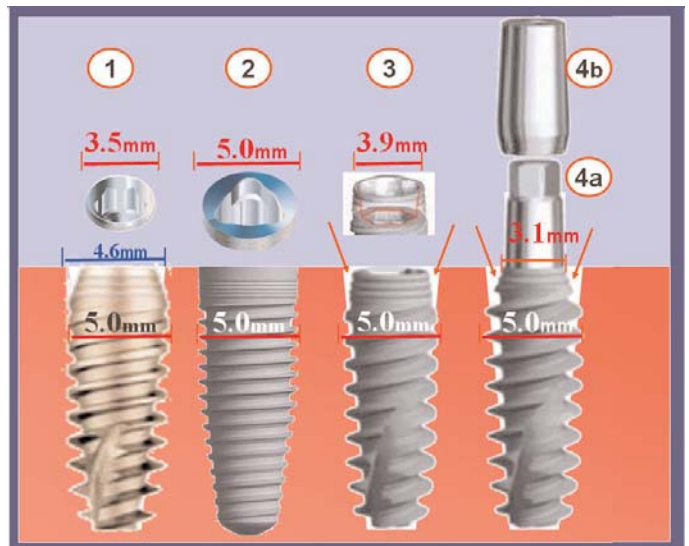
Dear Mr. Scala:

You talked at the February 11, 2008 analyst's meeting, about doing multi-center clinical studies on the NobelActive implants and requiring training as part of a careful and responsible launch. Yet, it is clear from Nobel Biocare's marketing at the Academy of Osseointegration meeting in Boston, that Nobel is not waiting to see the long-term results of any independent studies before advocating the use of this implant as the "Implant of the Future." Nobel Biocare (Nobel) received 510K marketing approval (K061003), June 30, 2006 for two implants referred to as "SFB" and "CFB". This application cites Nobel Biocare's (Replace) Groovy implant as the predicate device, essentially claiming that these implants are substantially equivalent. I am not familiar with any implant called "CFB" but an implant designated as "SFB" appears in the catalog of Alpha Bio Tec, the Israeli company Nobel has announced it is acquiring. The SFB implant is very similar to the NobelActive Internal hex implant. Nobel received 510K marketing approval (K071370) on August 3, 2007 for the NobelActive Internal implant, citing the June 2006 510K implants (SFB and CFB) as the predicate devices. I believe that the differences, cited in detail below, between the SFB/NobelActive implants and the Nobel Groovy implant predicate device, are clinically significant enough that one can not rely on the results of the Groovy in projecting similar clinical success with the NobelActive Internal implant. I can not find any 510K approval for the NobelActive External Hex implant although that may be what is designated as "CFB" implant. If that is the case, the NobelActive External implant is even more dissimilar to the Groovy than the SFB implant, Both notifications are attached to this letter with highlighted notes added.

As can be seen below, the top portion (neck) of the Replace Groovy implant is straight, maintaining the major diameter of the implant at the top surface where it penetrates the crest of the bone. By contrast, the necks of the SFB/NobelActive implants taper inward in the area of the crest of the ridge for the 4.3mmD and 5.0mmD implants. I believe the tapered vs straight neck represents a clinically significant difference in design between the two implants of such a magnitude that the clinical performance of the SFB/NobelActive can not be predicted from the clinical results experienced with the Replace Groovy implant. This is because the straight neck and platform of the Replace Groovy implant will result in a sealed junction between bone and implant when placed into a socket prepared with drills and will minimize the amount of gap between implant and bone, when inserted into an extraction socket. This is in contrast to the tapered necks of the SFB/NobelActive 4.3mmD and 5.0mmD implants which are narrower than the final sizing drills sold by Nobel for inserting this implant in medium to dense bone (see chart on next page). The result is that a the gap or ditch will exist between the implant and the bone whether the implant is inserted into freshly prepared site or into an extraction socket. This could result in down growth of soft tissue precluding bone formations in this critical area. This type of ditching around the top of the implant can lead to soft tissue complications, progressive bone loss and ultimately, to the loss of the implant itself. The closed circuit, live surgery demonstrations performed by Dr. Fromovich, the president of Alpha Bio, at Nobel symposiums, showed routine use of bone graft material to fill the gap created by the coronally tapered neck of the NobelActive implant. In at least one case, he showed the need to remove soft tissue from the patient's palate for use as a soft tissue graft to hold the hard tissue graft in place. The fact that the design of the NobelActive routinely requires such extra procedures, indicates further that it is not substantially equivalent to implants like the Nobel Groovy which fill the socket and does not need secondary procedures. If routinely required for the NobelActive, use of bone graft material should be included in the "Indications for Use."

The picture to the right shows 4 implants each 5.0mm in Diameter at their widest part, overlaying the same white, tapered trapezoid, simulating a surgical socket prepared with a 4.6mmD drill recommended in the NobelActive drill guide for dense bone..

- 1: 5mmD SFB Implant from Alpha Bio. This implant is the subject of Nobel's June 2006 510K application
2. 5mmD Tapered Groovy Replace™ - This is the predicate device cited in Nobel's June 2006 510K application. The widest diameter is maintained in the top half of the implant and in particular, at the very top of the implant to provide a seal at the junction of the crest of the ridge and the socket created in the bone with drills.
- 3: 5mmD NobelActive™ Internal (hex). This implant tapers in towards the top, creating a gap between the bone and the walls of the implant starting several millimeters below the top of the implant.
- 4a: 5mmD NobelActive™ External (hex) - This implant tapers in towards to 3.1mmD at the top for all three diameters of this implant, creating a gap between the bone and the implant starting several millimeters below the top.
- 4b: Tap-on Abutment, required for NobelActive External Implant, creates undercut that could trap cement if the crown is not cemented on the post prior to tapping the abutment on the tapered post.



Placement of the NobelActive implants in an immediate extraction site will usually accentuate the gap. The use of bone graft material which will then require a membrane or soft tissue graft to hold it in place, seems to be Nobel's recommended procedure for filling this gap, although it could be avoided by use of the Nobel Groovy.- #2.

As can be seen by the drill chart, in Dense Bone, the hole cut will be wider than the top of both the 4.3 and 5.0 NobelActive implants. In Medium Dense bone, the hole is wider than the 3.5, 4.3 and 5.0 NobelActive External implants. The neck of the 3.5mm NobelActive External is narrower than the drills recommended by Nobel the 4.3 and 5.0 implants. NobelBiocare claims that inserting the NobelActive implant into an undersized socket will result in the cortical bone "rebounding" to close over the top thread. In my experience, forcing wide threads into an undersized socket will expand the opening to the socket just as it expands the socket itself as the wider threads pass through the narrow opening to the socket.. Where the final drill is wider than the neck diameter, there can be no question that the surgical protocol creates a gap around the neck of the bone following insertion. **Nobel makes a number of marketing claims related to the**

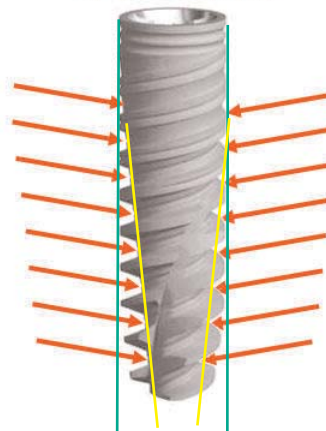
This drill sequence is recommended to ensure optimal primary implant stability when applying Immediate Function™.

Implant Ø	Soft Bone Type IV	Medium Bone Type II-III	Dense Bone Type I
Ø 3.5	2.0 (2.4/2.8)	2.0 2.4/2.8 (2.8/3.2)	2.0 2.4/2.8 2.8/3.2
Ø 4.3	2.0 2.4/2.8 (2.8/3.2)	2.0 2.4/2.8 3.2/3.6	2.0 2.4/2.8 3.2/3.6 (3.8/4.2)
Ø 5.0	2.0 2.4/2.8 3.2/3.6	2.0 2.4/2.8 3.2/3.6 3.8/4.2	2.0 2.4/2.8 3.2/3.6 3.8/4.2 (4.2/4.6)

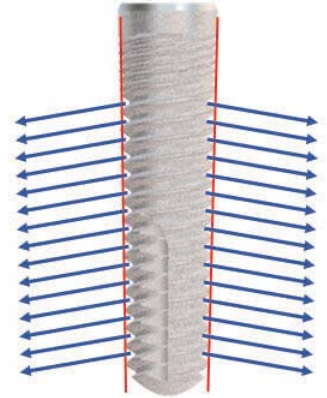
Note! All data is stated in mm.

Drills within brackets (- -) denote widening of the cortex only, not drilling to the full drilling depth.

**NobelActive
Progressive Deepening
of Wide Threads**



**ScrewPlant
Consistent Thread Depth of
Tapered Implant**



• Continue inserting the implant to final position, while gradually changing the angulation.

performance of the NobelActive implants which I question:

CLAIM #1. "bone-condensing - expands indication range and gives even higher initial stability."

COMMENT: As shown in the diagram with the colored arrows, deep threads provide space for the bone to passively fit between as the implant is screwed to place. Standard "V" threads (0.6mm pitch) allow for more threads and provide greater surface area to compress the bone when inserted into an undersized socket.

CLAIM #2. "ability to change direction during surgery:

COMMENT: This can be done with any screw implant in soft bone, but it is against established surgical procedures for implant insertion. Manipulating the implant in soft bone to align it for esthetics or parallelism could cause compression or fracture of bone and contribute to a loose initial fit necessary for osseointegration, especially in immediate load cases. The location and angle of the implant is established by treatment planning and drill guidance with templates, not free-hand tipping.

CLAIM #3. "Unique press-fit connection of abutment - removes risk of excess cement."

COMMENT: The NobelActive External connection creates an undercut ledge that could make cement removal more difficult than with abutments having a more natural emergence profile. The Tap-in abutment connection allows cementation of the crown on the abutment before seating to allow extra-oral removal of cement but this requires a change from conventional restorative procedures and, as Nobel notes, "extra-oral cementation of multiple connected units should not be performed."



external_connection

NobelActive™ External connection

NobelActive™ External abutment connection allows extra-oral cementation of final crown to abutment avoiding excess cement under the gingiva.

- one-piece implant with a unique combination of design features that enables easier insertion and promises extremely high initial stability
- one-piece implant design with two-piece flexibility
- smaller body makes it preferred choice in narrow bone ridges
- available in 3.5, 4.3, 5.0 mm implant diameters and 10, 11.5, 13, 15 mm lengths



Unique prosthetic connection

- abutments are connected by a locking tapered interface which eliminates the bone-level micro-gap, micro-movements, and the use of an abutment screw
- external abutment interface (implant pillar) is a consistent 3.1 mm diameter
- this external configuration of NobelActive™ External takes advantage of all the mechanical and biological benefits of a narrow one-piece implant while maintaining the flexibility of a two-piece system.
- abutments are friction secured to the implant pillar by tapping with a mallet and removed from the implant using a special driver – the Removal Driver NobelActive™ External.
- the friction connection allows the use of a screwless abutment and extraoral cementation of the final crown. This eliminates the risk of excess cement contaminating the implant site and soft tissue.

Note: extra-oral cementation of multiple connected units should not be performed; standard intra-oral cementation procedures should be followed

CLAIM #4. "NobelActive Internal and External implants don't cut through bone like conventional implants, they press through like a corkscrew."

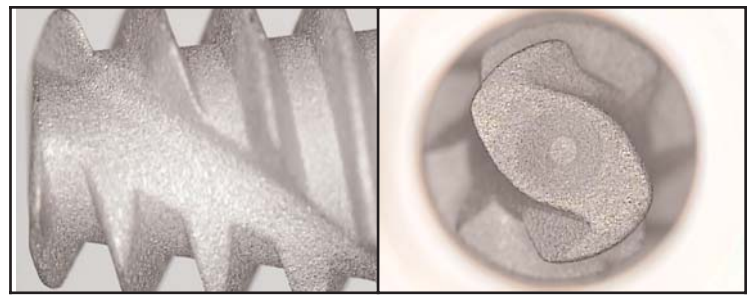
COMMENT: Pictures to right are of Alpha Bio 5mm X 10mm Implant with a similar apical design as NobelActive implants. Nobel Claims this design is "self-drilling" and allows change of direction during insertion from the trajectory created by the drills. It also advises that the socket can be drilled short of the intended depth and the implant will "cut through bone like a corkscrew." This presents several potential clinical problems: (1) Once the end-cutting drills create the socket at the desired depth and trajectory, the dentist can inadvertently change direction or screw the implant into the bone too far. The normal guidance provided by the direction and depth of the prepared socket can be inadvertently overridden by the narrow apex and sharp cutting blades cutting a new pathway.. (2). Penetration into the maxillary sinus by the sharp, cutting blades could result in tearing the membrane, whereas the rounded end of the Nobel Replace and Implant Direct implants can penetrate the sinus floor and lift the membrane.

Nobel claims that the NobelActive implant is "bone-condensing... and gives even higher initial stability." An article [Achieving Osseointegration in Soft Bone: August 2000 Canadian Journal of Oral Health, G. A. Niznick](#); documents the increased stability achieved by inserting a tapered Screw-Vent implant into an undersized socket. Deep, sharp threads would not enhance this process. Implant Direct's Spectra-System, Legacy and RePlus systems duplicate the even tapered body and standard "V" threads of the Screw-Vent (developed by Niznick/sold by Zimmer Dental) with its drills that provide the option of bone expansion in soft bone and self-tapping insertion (without need for bone-taps) in dense bone. [Implant Direct's new tapered Tri-lobe implant, called ReActive](#), has slightly deeper threads, combining benefits of compression, increased surface area and more aggressive self-tapping.

The NobelActive Internal and External hex implants have significant differences in body, thread and connection design as well as surgical protocol and cementation procedures to the Nobel's Replace Groovy implant. I believe these differences will impact clinical outcome. Prospective, multi-center studies over a 3-5 year period, by independent researchers, reporting the results in both soft and hard bone and in situations where the floor of the maxillary sinus is penetrated, would reveal if these concerns are justified. This study needs to document the use of this implant by both

experienced and inexperienced clinicians and report on crestal bone changes as well as prosthetic complications. While Nobel claims that the NobelActive is the "Implant of the Future", it is ironic that after two decades of claiming the Branemark Implant's external hex connection was the "gold standard," Nobel now launches "the Implant of the Future," with a lead-in bevel and internal hex connection, introduced in 1986 and covered by [Niznick US Patent #4,960,381](#) that expired October, 2007.

I have clearly demonstrated in this document and in the slide series on Implant Direct's website, "[A Critical Analysis of the NobelActive Implant](#)", the many differences between the NobelActive and Nobel Replace Groovy implant (NobelActive's 510(K) predicate device). Recent Nobel product launches have failed to live up to their marketing claims. Articles critical of the NobelDirect and NobelPerfect Implants have spawned a solicitation for litigants on the website www.lawyersandsettlements.com. Dental professionals expect and deserve high quality, intelligently designed, reliable implant products to continue to build on the public's confidence in dental implants. Nobel Biocare should take a hard look at whether the NobelActive implants can realistically be expected to achieve equivalent results to implants with more conventional designs that have proven successful. I hope you find this information of value in guiding your decision regarding the mass marketing of the NobelActive implants for all indications.



implant design

revolutionary design expands treatment options

The self-condensing abilities of NobelActive™ deliver advantages in all types of bone and in compromised situations, especially in softer bone.

The self-drilling ability of NobelActive™ allows it to be inserted into sites prepared to a reduced depth. This is useful where sites are close to vital anatomical structures: the mandibular nerve canal or the maxillary sinus, and nose cavity for instance. This means you can be confident of accurate placement while having a minimally invasive procedure.



The unique combination of design features of NobelActive™ is derived from thorough investigation into the bio-mechanical dynamics of hard and soft tissues surrounding dental implants.

This revolutionary implant design has already been in use since 2004 and in thousands of cases. By combining the clinically documented 98% success rate ([Scientific Evidence](#)) with the outstanding track record of TiUnite™, NobelActive™ promises to change how implant restorations are performed.

NobelActive™ offers unique advantages

- potentially fewer drilling protocol steps, depending on bone density and quantity
- minimal osteotomy with minor trauma to bone and surrounding tissues
- extremely high stability in fresh extraction sites and sites with thin sinus floors
- ability to change direction during surgery gives full flexibility for optimal placement
- a narrow neck designed to preserve marginal bone
- grooves on threads and scientifically proven TiUnite™ surface

NobelActive™ expanded indications

The unique self-drilling and bone-condensing capabilities of NobelActive™ facilitate placement in clinically demanding situations, by offering:

- excellent stabilization in soft bone - using gradual condensing of bone in all dimensions throughout the entire length of the implant, even with as little as 3 mm of bone at the neck of the implant
- adjustment to small changes for parallelism - using the self-drilling capacity it is possible to change direction of the implant during implant placement
- immediate placement in the esthetic region, even when buccal bone plate is very thin
- excellent stabilization in wide sockets - using minimal osteotomy, even with as little bone as 3 mm at the bottom of freshly extracted sockets



NobelActive Type Spiral Implant (Picture of Alpha Bio SFB Implant)
Coronal taper creates gap at crest (Magenta)
Sharp, "Self Drilling" cutting blades could tear sinus membrane

