The Inside Story on Nobel BioCare's Marketing Strategy in North America

Forbes Business News July 27, 2007

"Major losers include ... Nobel Biocare, shedding 3.3pct or 12.25 sfr to 364.50, amid speculation CEO Heliane Canepa could be replaced, possibly by former Syngenta CFO Domenico Scala due to the dental implant maker's lack of success in the US market."

30-07-2007 Nobel Biocare appoints Domenico Scala as new CEO

Nobel Biocare Initiates Campaign of Disinformation

Mr. Keven Mosher, VP and General Manager of Nobel Biocare North America, failed to comply with Implant Direct's demand that Nobel cease making false and misleading claims about the surgical compatibility of Implant Direct's RePlant Implant with NobelReplace Drills

This Report provides Implant Direct's Response to Nobel's False Claims

Implant Direct's RePlant™ vs. Nobel's *Replace Tapered Groovy

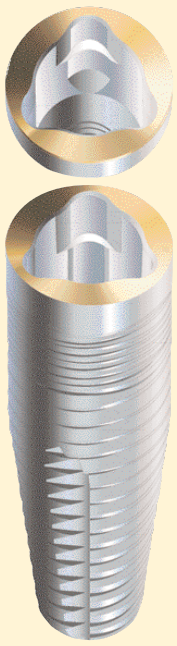
RePlant Implant is inserted with Nobel Replace* Surgical Instruments
RePlant Platform is Compatible with Nobel Replace* Abutments

RePlant Made of TiAlloy vs CP for TiUnite - Increases Strength by 15-20%

Abutment/Implant Instability: RePlant < 0.5° ; Nobel Replace > 1.5°

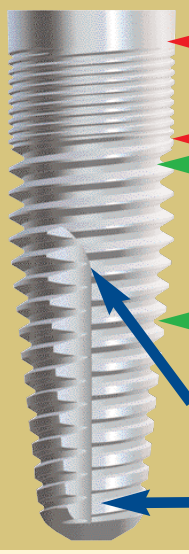
Implant Direct RePlant Implant
U.S. PRICES for Implant includes Cover Screw and Color-Coded Fixture-mount that functions as closed tray Transfer
3.5mmD, 4.3mmD, 5.0mmD 6.0mmD All Same Price
Total Cost $150 Save 65%-67%

Nobel Replace* Tapered Implant
U.S. PRICES for Implant $350 for 3.5, 5.0, 6.0 Diameters & $330 for 4.3mmD
Cover Screw ($45.25) & Transfer ($56.75)
Total Cost $432-$452



RePlant Design Advantages

Ti Alloy for Added Strength
Cover Screw & Transfer Included



*Replace is a Trademark of Nobel Biocare Inc.

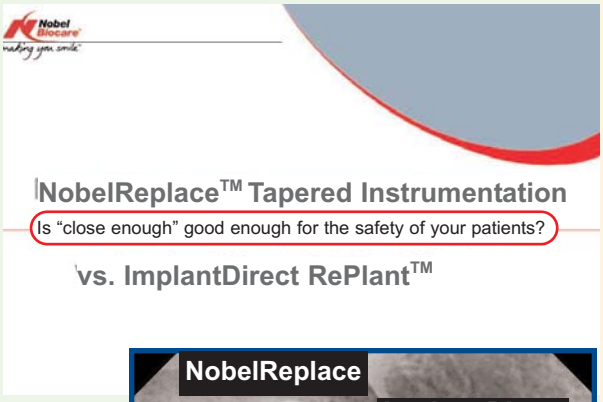
Nobel Biocare's US & Canada's VP and GM Email with 11 Slides

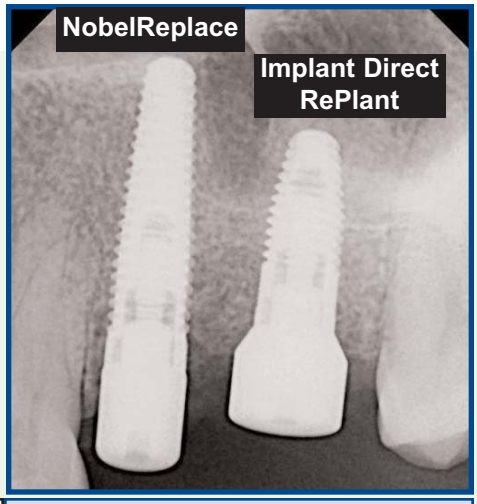
Slide #1: Attempts to raise doubt about the safety of inserting Implant Direct's RePlant Implants using Nobel Replace surgical instruments.. based on thread differences

Dear All,
Steve Hurson showed some information at the WC staff meeting regarding the differences in the Implant Direct RePlant implant and NobelReplace, and demonstrating how our drilling system does not match their design.

With the help of Steve, Dr. Rick Sullivan and Brian Volken, we have put together a presentation that shows these differences, which are very real, and could lead to either breaking the collar of the RePlant implant (as we have heard from a doctor), an implant that is seated too high (as we have heard from a doctor) (possibly causing restor ative problems), or over-tightening (in order to seat properly, which could lead to pressure necrosis). If you look at the attached slides, you will very clearly see why these problems may exist.

If I were a surgical specialist, I would certainly be concerned with whether I was sending a quality product back to my referring dentist, and whether a specialist or an implantologist, I would certainly wonder if I were extending the best care to the patient. Also, what does it say about a company that advertises compatibility with our drilling system, when you clearly see the quite significant differences in implant design???
Regards
Kevin Mosher
Vice President & General Manager
Nobel Biocare North America





Nobel Slides Reproduced in this Report have been Digitally Enhanced for Clarity Replace, NobelDirect and NobelPerfect are Registered Trademarks of Nobel Biocare

A Picture is worth a 1000 words
***Dentist's comments:* "The implants are great! I am a convert now!! Thanks."**

Dr. Gerald. Niznick, President of Implant Direct, Responds Point by Point to Nobel Biocare's False and/or Misleading Claims

Mosher Statement: "differences (in implants are) very real"
Niznick's Response: Differences in thread design are irrelevant - RePlant is self-tapping and has no shoulder

Mosher's Statement: "differences ...could lead to breaking the collar (as we have heard from a doctor)"
Niznick's Response: A number of doctors on Dental Blogs have reported fractures of NobelReplace implants.

OsseoNews Blog - Replace Fractures: "two implants actually fractured at the head...one could not be retrieved (one 4.3 and one 3.5).... I have been told by NB that they had not heard of this happening before."

OsseoNews Blog - Replace Fractures: "I have had 2 fractures on the 3.5 mm. It is happening often"

Dental Town Blog -Replace Fractures: "We also had half a dozen 3.5 fixtures fracture on insertion... (Nobel) blamed (the fractured implants) on 4 different surgeons."

Niznick's Response: A number of fractures of Branemark CP Titanium external hex Implants have been reported. A Patient filed a lawsuit against Nobel and the surgeon claiming 7/10 implants fractured. http://www.implantdirect.com/company/dangers01.html

Mosher's Statement: "differences...could lead to an implant that is seated too high (heard from a doctor)"
Niznick's Response: Nobel is circulating x-ray of Implant (see page 5) with a 3mm Collar, claiming implant is too high

Mosher's Statement: "overtightening (in order to seat properly) could lead to pressure necrosis."
Niznick's Response: Implant Direct studies show it takes 2-3X more torque for bone tap than RePlant insertion

Letter to Mr. Kevin Mosher, VP and GM, Nobel Biocare North America
Response to Nobel Biocare's Misleading Marketing Attack on RePlant Compatibility

Implant Direct Receives FDA Marketing Approval to Claim Surgical Compatibility

Implant Direct's 510(k) Approved Submission States: "The Spectra-System consists of seven implants with external thread configurations consisting of double lead threads over the body of the implant and 2mm-2.5mm of quadruple lead mini-threads near the coronal portion of the implant. … The seventh implant of the Spectra-System, the RePlant, matches the tapered body dimensions and tri-lobe platform of the Nobel Biocare Replace Tapered implants and therefore can be inserted utilizing Nobel Biocare drills."

Dear Mr. Mosher:

I have requested that Nobel Biocare ("Nobel") cease circulating a series of slides claiming that Implant Direct's RePlant™ Implant is not surgically compatible with Nobel's drills for its Tapered Groovy Replace Implant. As seen above, the FDA has approved this marketing claim based on submitted engineering drawings and test results. Furthermore, thousands of RePlant implants have been placed by Nobel's former customers using Nobel's drills without a single complaint to Implant Direct as to a lack of compatibility. Implant Direct does not claim that its RePlant implant is the same as Nobel's Replace implant, only that it can be inserted using NobelReplace drills because the diameters of the collar and threads of both implants are the same. Merriam-Webster Dictionary defines "compatible" as "*designed to work with another device or system without modification*" in contrast to the word "same" that is defined as "*corresponding so closely as to be indistinguishable*". Nobel, apparently unwilling or unable to compete with Implant Direct on product features and prices, has, at your direction, implemented a campaign of disinformation to impede your customers from making an informed judgement about whether they want to spend $452 for a Nobel Replace Implant, cover-screw and transfer or $150 for a RePlant Implant, cover screw and transfer. Since you have only been with Nobel for three years, you may not be familiar with Nobel's history of using questionable marketing claims. The pictures on the right show deception on a very basic level, by representing that a colorized SEM of a Fibroblast from soft tissue around an ear implant was an Osteoblast from an upper jaw Branemark osseointegrated implant. In the early 1990's, Nobel was found liable for Anti-trust violations http://www.implantdirect.com/Pdf/USCourtofAppealsfortheFederalCircuit.pdf enforcing a patent gained by fraud. The Swedish Medical Products Agency has imposed restrictions on Nobel's marketing claims and investigated reports of excessive bone loss around Nobel's Implants http://www.implantdirect.com/speaksout3.htm

AFX News Limited: Nobel Biocare CEO under pressure over dispute with Swedish authorities - report 07.29.07, 11:30 AM ET
ZURICH (Thomson Financial) - Nobel Biocare AB chief executive Heliane Canepa has come under fire over allegations that the Swedish-Swiss dental implant maker has issued misleading statements regarding the safety of its NobelDirect and NobelPerfect implants, Swiss Sunday paper SonntagsZeitung reported.
(On 07.30.07, Heliane Canepa was replaced as CEO of Nobel Biocare)

Albrektsson, Branemark 1982
Clin. Applications in Biomaterials
"Fibroblast ... Soft Tissue"

Branemark et.al: JPD 1983
"Osteoblast ... Upper Jaw Fixture"

Nobel Biocare Website 2007
Claim: History of Osseointegration
Using Non-integrated SEM

Swedish Medical Products Agency Demands Nobel Biocare Improve Instructions

The Swedish Medical Products Agency (SMPA) released a demand for Nobel Biocare to improve the instructions for both its NobelDirect and NobelPerfect Implants. Previously Nobel Biocare had released a response to the recent marketing ban on their NobelDirect Implant following reports that it lost an excessive amount of bone following placement. The SMPA stood by its decision that the firm not be allowed to market the implants until it had carried out the improvement of the instructions. The SMPA stated that the instructional information must be supplemented and further clarified. As an example, the SMPA described Nobel Biocare's Instruction statement: "you don't have to be a specialist to prepare the site for NobelDirect" as inappropriate.

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Nobel Biocare's Real Issue

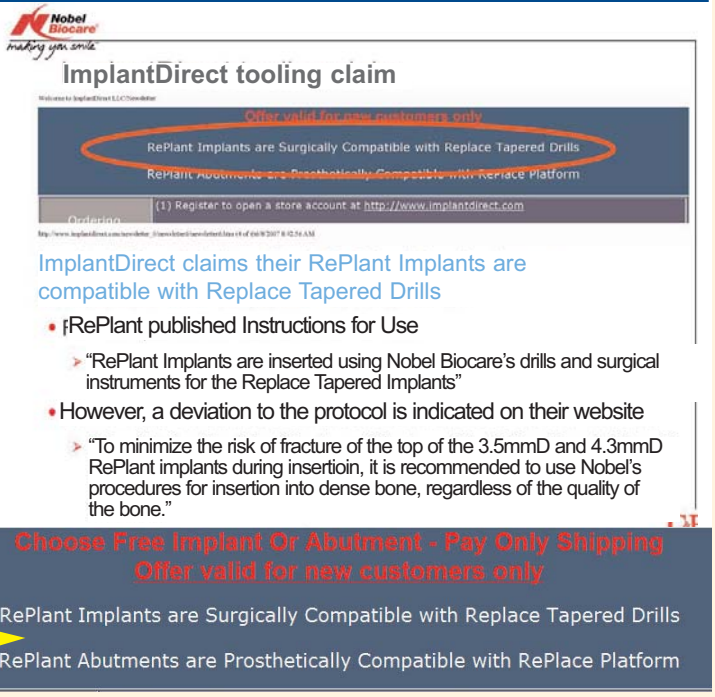
Justifying High Prices in the United States, and even Higher prices in Canada (33% Average Exchange Rate)

Nobel Biocare Dental Implant Products	US List Price	Canadian List Price	Exchange Rate +33% av. on 07/09/07	RePlant from ID US List Price Exact Daily	RePlant from ID Canadian List Price Rate (5%)
Replace Implant + Cover Screw +Transfer	$350.00	$441.00	+26%	$150.00	$157.50
	$ 46.00	$ 61.75	+34%	Included	Included
	$ 56.75	$ 75.00	+32%	Included	Included
Total Cost	$452.75	$557.75	$452.75	$150.00	$157.50
Angled Abutment	$217.00	$247.00	13%	$85.00	$89.25
Gold Engaging Abutment	$202.00	$247.00	27%	$100.00	$105.00
Snappy Straight Abutment	$191.00	$272.00	42%	$85	$89.25

The Newsletter offers free implant or abutment
Dentists can see for themselves the Compatibility

Nobel Biocare Slide #2

Nobel cites to Implant Direct Newsletter reference to compatibility but claims Implant Direct's recommendation for insertion with their instruments is inconsistent



The RePlant Implants' outside thread diameter and taper match's Nobel's Replace dimensions, providing surgical compatibility with Nobel's drills. Differences in thread design are immaterial to insertion, even when using Nobel's bone tap in dense bone, because the RePlant is designed with a vertical, self-tapping cutting groove, unlike the Nobel Replace implant. The Trilobe internal connection geometry and dimensions of the RePlant implants also match the Nobel Replace implants, providing prosthetic cross-compatibility between the two systems. The walls for the 3.5mmD and 4.3mmD RePlant and Replace implants are relatively thin. To minimize the risk of fractures during insertion, Nobel added a warning to the label of the 3.5mmD Replace implant not to exceed 45Ncm of torque during insertion. To avoid the risk of a dentist misinterpreting the density of the bone, Implant Direct suggested using Nobel's dense bone surgical protocol for the small diameter implants, which included use of the bone tap for the shorter implants. This was discretionary and would not significantly compromise initial stability because the RePlant, having a different thread design than the Replace bone tap, was in effect still being inserted self-tapping. Implant Direct's RePlus Trilobe implant utilizes a soft bone and hard bone surgical protocol so that in soft bone, the tapered implant will be inserted into an undersized socket for bone compression and increased stability, a desired factor in immediate loading. This is made possible by the use of straight step drills with an evenly tapered implant, and is not a prescribed protocol for the NobelReplace implants although many dentists elect to use this technique based on their experience. In conducting the insertion torque tests to respond to Nobel's false claims, Implant Direct learned that the combination of a self-tapping implant design made from titanium alloy, and inserted with an aluminum fixture-mount that would strip before damaging the implant, offered the opportunity for optimizing insertion torque regardless if the bone was soft, hard or something in between. This has lead to a revision of the RePlant Surgical Protocol that Nobel cited to as circumstantial evidence of a lack of surgical compatibility. (Refer to the torque and strength chart on page 11). Testing reveals that there is a lower amount of torque required to fracture the RePlant implant if Nobel's insertion tool is not fully seated in the trilobe. Inserting the 4.3mmD RePlant implant using Nobel's dense bone protocol, required only 34.46Ncm of torque using oak (Implant Direct test) and 96Ncm of torque in "foam" (Nobel test). RePlant implants are packaged on aluminum fixture-mounts that engage the Trilobe in the implant and are designed and intended for inserting the implant using a ratchet, drill or handle available from Implant Direct. It also serves as a closed-tray transfer. The aluminum fixture mount for the 4.3mmD RePlant implant can withstand 114Ncm of torque before stripping, substantially below the fracture torque of 145.5Ncm for the 3.5mmD RePlant.

Determination of the quality of bone is subjective. Self-tapping insertion of the RePlant implant can be attempted in all qualities of bone as long as its aluminum Fixture-mount functions as a safety guage. If excessive resistance is met, the aluminum Fixture-mount will strip, protecting the implant. If this occures, unscrew the implant using Nobel's Trilobe insertion tool, enlarge the socket using either the NobelReplace's dense bone dills or bone tap, and re-insert the implant. The Fixture-mount will be unusable as a transfer.

Implant Direct's Surgical Protocol for insertion of RePlant Implants with NobelReplace Instruments:

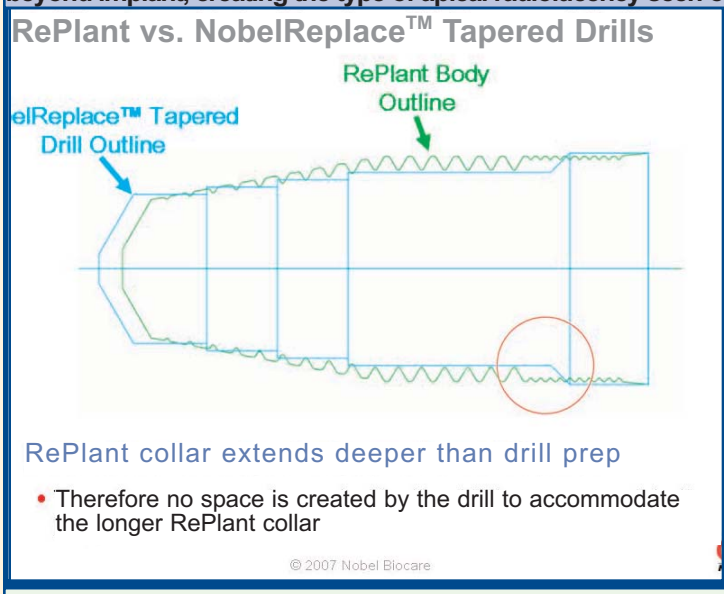
TYPE 4 BONE: In soft bone, only enlarge the socket using Nobel's recommended intermediate drill for the specific diameter implant, followed by self-tapping insertion using the RePlant Aluminum Fixture-mount to protect the implant.

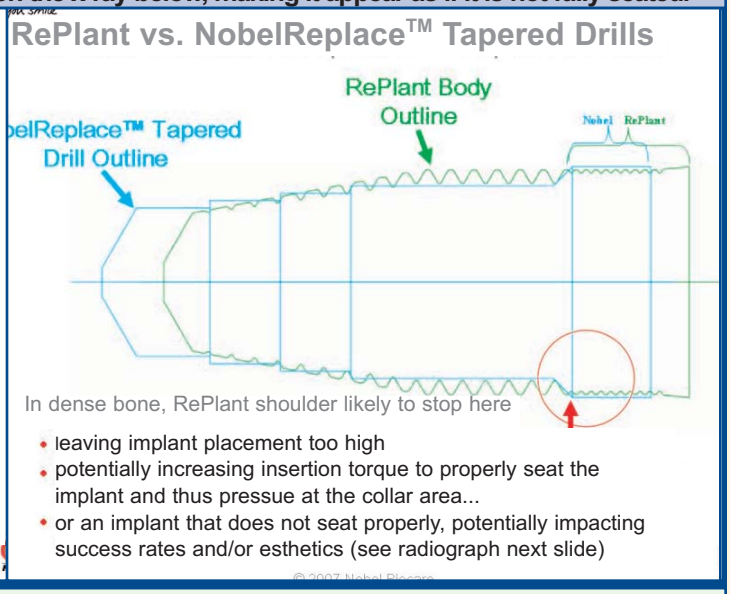
TYPE 2-3 BONE: In medium density bone, enlarge the socket using the recommended final drill for the specific diameter implant, followed by self-tapping insertion using the RePlant Aluminum Fixture-mount to protect the implant.

TYPE 1 BONE: Use NobelReplace's dense bone surgical protocol. Optional Protocol: Insert RePlant self-tapping using the RePlant Aluminum Fixture-mount as a safety gauge. If it strips, unscrew the implant using NobelReplace insertion tools, resize the socket using NobelReplace's dense bone surgical protocol and re-insert the RePlant Implant.

Nobel's marketing strategy is to instill fear, uncertainty and doubt in the minds of its customers to keep them buying Nobel's over-priced products by raising unsubstantiated and unsupported accusations that Implant Direct is misrepresenting its marketing claims to be surgically compatible with Nobel Replace drills. Central to Nobel's argument is that the "RePlant collar extends deeper" when in fact, RePlant has a 1mm collar and Replace has a 2mm collar. The junction at the start of the mini-threads of the RePlant presents no change in diameter that could interfere with full seating of the RePlant in a socket prepared with Nobel drills.

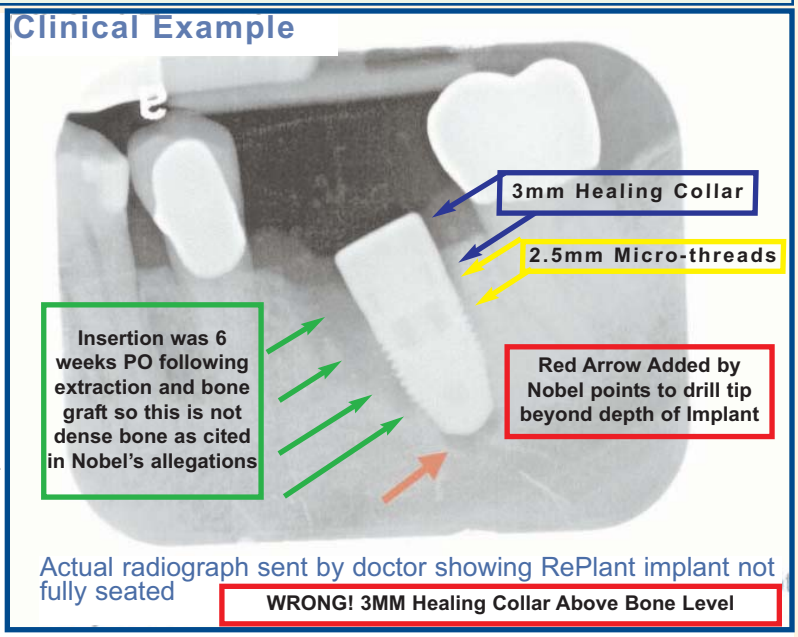
Nobel Biocare Slide 3 & 4: Show differences in thread design between Nobel Replace and Implant Direct's RePlant implant, but does not dispute that both have the same overall body design with the same diameters along their straight and tapered sections. Based on these thread design differences, Nobel spins a story to falsely claim that the RePlant design will result in "implant placement too high" or will require "increasing insertion torque to properly seat the implant and thus (cause) pressure at collar area ." Nobel claims that "in dense bone RePlant shoulder (is) likely to stop... leaving implant placement too high." Nobel states that because the "RePlant Collar extends deeper than drill prep ... no space is created by the drill to accommodate the longer RePlant collar." To support these illogical and unsubstantiated claims, Nobel references a radiograph in the next slide which shows a RePlant implant fully seated in soft bone. Note in Slide #3 that the drill point extends beyond implant, creating the type of apical radiolucency seen on the x-ray below, making it appear as if it is not fully seated.





Nobel Biocare Slide 5: Claims to represent a radiograph "showing RePlant Implant not fully seated." Nobel does not disclose that the implant has a 3mm Healing Collar attached and is seated level with crest.

What Nobel fails to point out is that the RePlant implant shown in this x-ray is actually fully seated with a 3mm Nobel Replace healing collar (note no flare) attached. The RePlant's 2.5mm of Mini-threads are identified between the two yellow arrows starting 1mm below the top of the implant which is level with the crest of the bone on the distal. This x-ray was sent to an OS in Minneapolis along with a copy of the email from the doctor who placed this implant (name was removed). The email stated: "The x-ray was taken 6 weeks after grafting in extraction socket **with a 3mm healing abutment attached**". The dentist wrote Implant Direct saying ***"My partner and I have placed about 15 RePlant fixtures in the past month and have no doubt that the drills/fit/seating is the same." More recently, when the Nobel Representative presented him with the slide series he "told my rep I have my own experience to go on. They are essentially interchangeable to me."*** The surgical compatibility was also confirmed by another former customer of Nobel who was sent this picture for comment: ***He stated: "I am very confident with your system and compatibility wise, I see no issues at all. .... I have placed about 150 Implant Direct implants."*** Nobel Biocare, in an attempt to instill fear, uncertainty and doubt about Implant Direct and its products, is apparently willing to mislead its customers based on a single x-ray of an implant in bone graft material with a 3mm healing collar. claiming it is evidence that RePlant implants will not fully seat in dense bone using NobelReplace's surgical instruments. Based on the very positive response from hundreds of Nobel customers taking advantage of Implant Direct's better products, packaging and prices, Nobel is underestimating the intelligence of its customers.



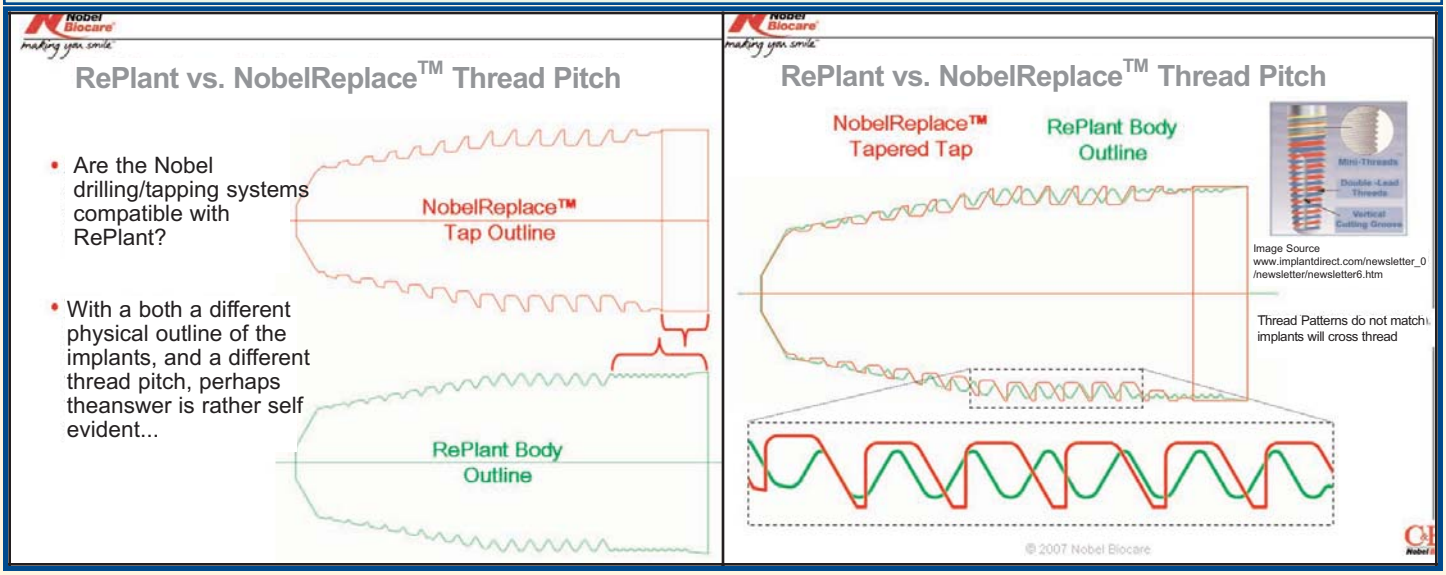
RePlant's thread design eliminates the shoulder at the transition from the threads to the collar of the Replace implant by extending the threads to within 1mm of the top.

Implant Direct does not claim that its RePlant implant is exactly the same in "physical outline" or "thread pitch" as Nobel points out. In fact, the design differences, including its **double-lead threads for faster insertion, quadruple-lead mini-threads for reduced stress distribution and its long self-tapping, vertical grooves are significant improvements** to the NobleReplace Tapered Implant design. These features have been added while matching exactly the Replace's platform and thread diameters as well as the degree and location of its tapered apical end for each length and diameter of implant. This is what allows RePlant to be inserted using NobelReplace's length specific drills. The RePlant maintains the same "V" threads of the Branemark and Screw-Vent implants, with double lead threads on the body for 2X faster insertion. This is in contrast to the flat-topped threads of the Replace, found in orthopedic fixation screws to resist pull-out forces which are not a factor with dental implants. The Mini-threads of the RePlant are an improvement compared to the few horizontal grooves in the collar region of the Replace implant. They engage bone during self-tapping insertion, increasing initial stability and improving stress distribution in immediate load applications, whereas the Replace grooves require bone ingrowth to have any effect. Nobel's arguments against RePlant's surgical compatibility with Replace drills, is based on two elements.

1. Location of a "Shoulder" (Slide #3) or "Collar" (Slide #4): NobelReplace drills create a countersink at a specific depth to accommodate the collar or shoulder of its Replace implant. **Since RePlant has no collar /shoulder this is irrelevant.**

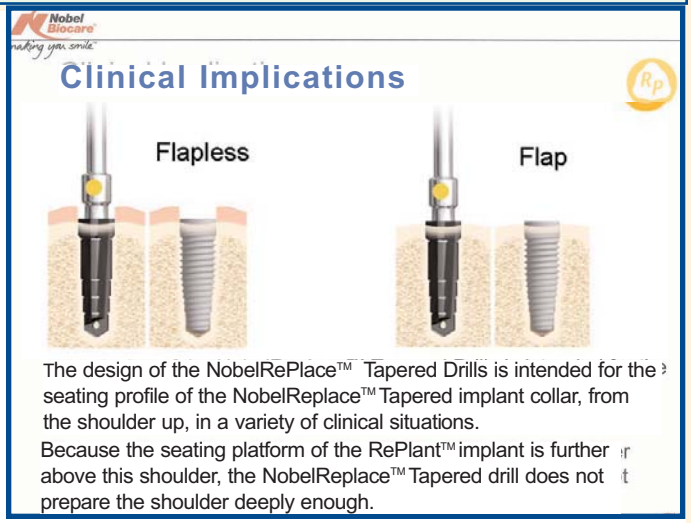
2. Difference in thread design: NobelReplace implants have a different thread pattern than the RePlant and bone taps are part of the hard bone protocol for the 8mm and 10mm implants. **Since RePlant is self-tapping, this is irrelevant.**

Nobel Biocare Slide 6 & 7: Nobel Claims the RePlant "Shoulder" and cross-threading will interfere with Seating



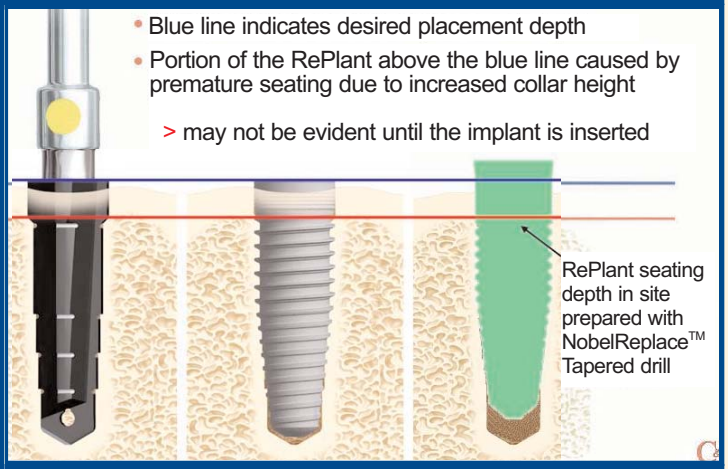
Nobel Biocare Slide #8: Nobel attributes the position of a non-existent "seating platform of the RePlant Implant " as the basis for its argument that "the NobelReplace Tapered drill does not prepare the shoulder deeply enough." This argument is without merit or logic.

As the RePlant's threads engage bone at the base of the 2mm deep countersink created by the NobelReplace drill, continued turning of the implant results in creation of threads in the socket. With the Replace implant in soft bone, these threads are created by compression and in dense bone they are created by the bone tap. With the RePlant implant, whether in soft or hard bone, they are created by the sharp leading edge of the long, vertical grooves cut in the threads similar to the grooves in a bone tap. This groove extends half way up the implant about 4 threads above the start of the tapered end of the implant. Both the Replace and RePlant implants maintain the same major diameter above the tapered end, matching the diameter of the platform at the top of the implant. As soon as the first 4.3mmD thread in the sequence on the next page, pass the base of the countersink in bone, threads are cut to their full depth and all the threads on the implant above that point just follow the threads created in the bone. Therefore, Nobel's argument that the RePlant will hold up at the junction of its two thread types is spurious. If the ledge of bone created by the countersink section of the drill was capable of stopping the self-tapping seating of the RePlant implant, it would do so when the first major diameter thread made contact with the ledge, leaving about half the length of the implant projecting above the opening to the socket.



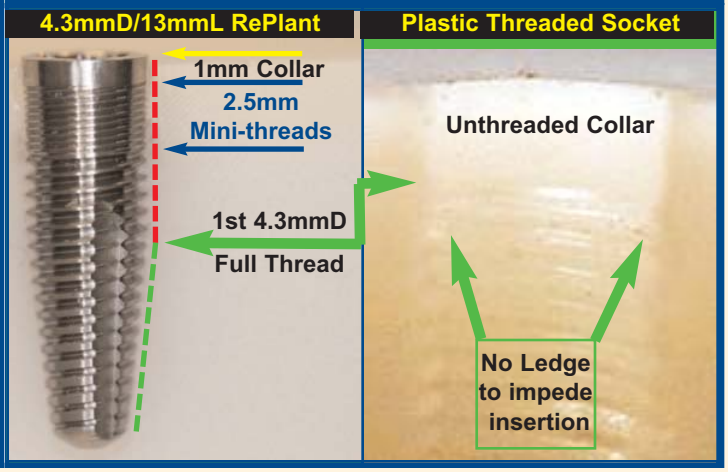
Nobel Biocare Slide #10 states that (1) "Portion of the RePlant above the blue line (representing top of bone) (is) caused by premature seating due to increased collar height." of the RePlant implant. As shown in the pictures below Slide 10, of a RePlant in a plastic block and removed from the block, **this speculation is without basis and is so mis-guided as to be nothing other than intentionally misleading.** Once the first thread is cut in the socket by a bone tap or self-tapping insertion, the threads of the implant follow until the implant bottoms out in the socket. What actually stops the insertion of both the Replace and RePlant implants is the socket itself that is dimensioned and tapered like the implant but slightly smaller than the threaded areas **to provide bone engagement by the threads.**

Nobel Biocare Slide #10: Nobel's representation of the "Clinical Implications" of placing a RePlant implant into a socket prepared by a NobelReplace drill is false and mis-leading. Nobel claims that a "Portion of the RePlant above the blue line (representing the crest of the ridge) (is) caused by premature seating due to increased collar height." **This is fundamentally false** because the RePlant has no ledge to come in contact with the base of the countersink created by NobelReplace drills - it has continuous threads of the same diameter between the double lead body threads and the mini-threads, which blend with the 1mm collar at the top of the implant. The countersink part of a NobelReplace drill provides an untapped section of bone for the 1mm and 2mm collars of the Replace and RePlant.

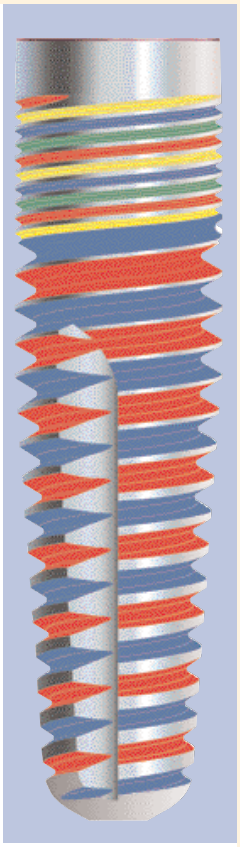


LEFT PICTURE: 4.3mmD - 13mmL RePlant inserted into a Plastic block self-tapping, following site preparation using the appropriate diameter and length Replace drill only.

RIGHT PICTURE: Threads created in the plastic after Implant removed showing unthreaded 2mm collar section. The base of the countersink created by the NobelReplace length-specific drill will be replaced with bone threads as the first major diameter thread of the implant engages bone at the base of the countersink. This applies to self-tapping insertion of the RePlant and to insertion of the Replace with or without use of the bone tap. The depth of the countersink created by the NobelReplace drill has no effect on the depth of the RePlant implant.



Implant Direct does not claim that its RePlant implant will require the same torque to insert its implant in dense plastic as would be required to insert the Replace implant in dense plastic. Implant Direct just claims that its RePlant Implants can be inserted using Nobel's Replace drills, with obvious reference to vital human bone. Nobel's test insertion of the RePlant clearly demonstrated two important facts. (1) The RePlant implant can be inserted using Nobel's Replace drills as it did fully seat at 96Ncm, and (2) The RePlant implant, made from medical grade titanium alloy) can withstand 96Ncm of torque without fracturing. The wall thicknesses for the Replace and RePlant 3.5mmD implants are the same with only 0.009" wall thickness at its weakest point. By contrast, the wall thickness of the 3.7mmD RePlus and ScrewPlant implants are 0.013" and 0.018" respectively. All of Implant Direct's implants are made from **medical grade Titanium Alloy, providing a 20% increase in strength** compared to CP titanium used by Nobel. Nobel's slides cite Implant Direct's recommendation to use of the Nobel Replace dense bone protocol for placement of the RePlant 3.5mmD and 4.3mmD implants. This recommendation was made to further reduce the risk of implant fracture but following the tests conducted for this report, that recommendation has been changed - See Page #4. The new surgical protocol optimizes initial stability by taking advantage of the fact that the RePlant is made of TiAlloy, it includes self-tapping grooves and is provided on an Aluminum Fixture-mount that will strip before the implant can be damaged, even in dense bone. Implant Direct's RePlus Trilobe Implant uses Spectra-System's drills and soft bone/hard bone surgical protocol which does not include use of a bone-tap.



1. One periodontist reported to Implant Direct: **"I placed another 6 of your implants. The self-tapping feature is nice. I had a couple of situations where I know Nobel's Groovy would have bound to the osteotomy, but RePlant kept going."**

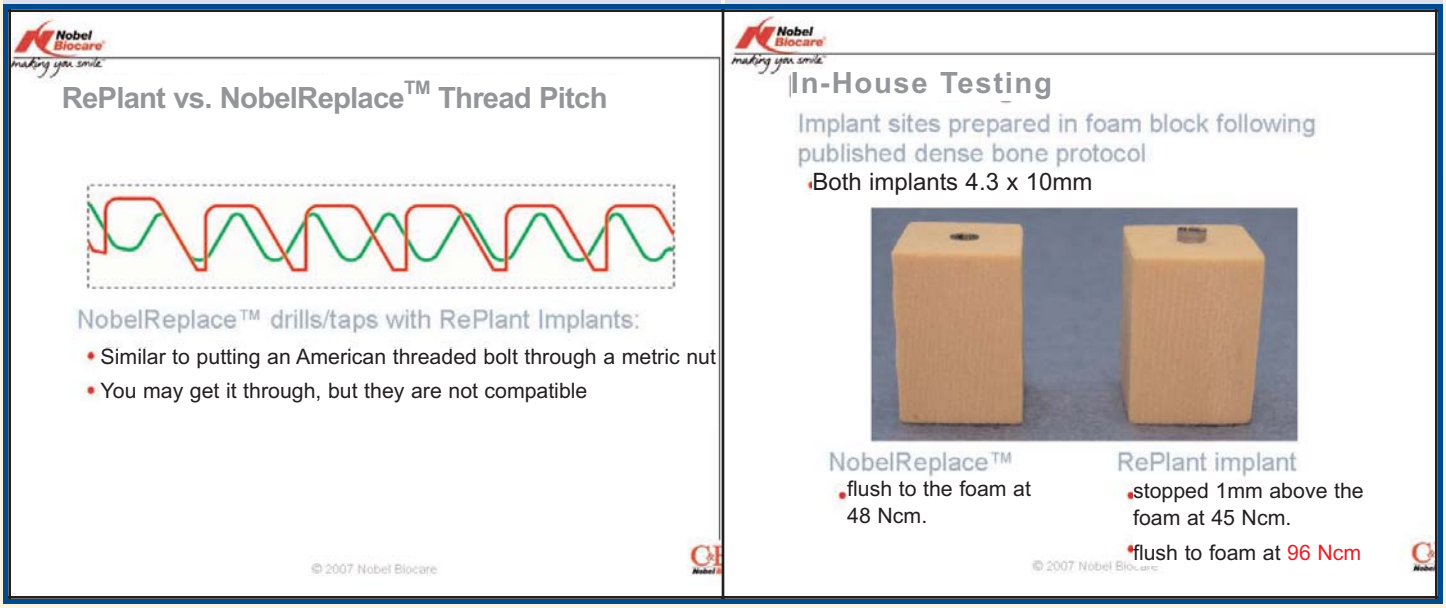
2. Another Periodontist wrote to Implant Direct stating: **"I have placed 5 so far and they are excellent to place. I am very pleased."**

3. A General Dentist provided Implant Direct with the x-ray on page 2 showing side-by-side placement of a Replace and RePlant implant. He wrote: **"Attached are two x-rays of a case I did today with the RePlant system for the first time. The implants are great! I am a convert now!!**

Nobel Replace 4.3mmD Drill Compatible with RePlant Implant	RePlant 4.3mmD Implant - Straight Threads Tap Bone Starting at Crest	Vertical Cutting Groove Self-taps Threads through Ledge Area	Vertical Cutting Groove & 4.3mmD Straight Threads Eliminate Ledge	RePlant Implant Fully Seated in Socket created by 4.3 Replace Drill

Nobel Biocare Slide #8: Superimposes the "V" threads of the RePlant over the flat-topped threads of the Replace implant, The RePlant has self-tapping grooves like a bone tap

Nobel Biocare Slide #11: Insertion torque in plastic. RePlant cut new threads, requiring 2X more torque for increased stability. **RePlant Compatible as it fully seated.**

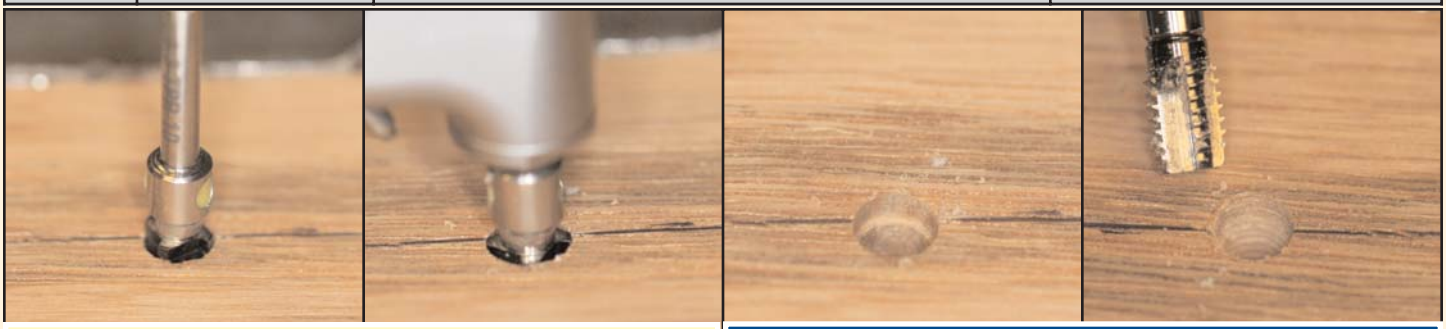


In response to Nobel's circulation to its sales force for use in marketing against Implant Direct, Implant Direct conducted its own comparative insertion torque tests using 10mmL X 4.3mmD NobelReplace Tapered Groovy Implant and Implant Direct's RePlant Implant. By contrast to the picture shown in slide 11 above representing Nobel's "In House Testing" using a "foam block" (dense plastic), Implant Direct used Oak wood as its dense bone replica material because it cuts and threads similar to type 1 or 2 bone. On the opposite page are pictures taken by Dr. Niznick during the tests conducted by two Implant Direct testing and manufacturing engineers, showing the torque readings in inch-pounds which converts to Ncm by multiplying by 11.3. Holes were prepared using the appropriate length and diameter drills and bone tap following Nobel's recommended dense bone surgical protocol for its 10mm long implants (Nobel sells dense bone drills for the 13mm and 16mm long implants but recommends use of the appropriate diameter bone tap for the shorter implants. Implant Direct also recorded the torque required to thread the hole using the Nobel bone tap, which was not reported by Nobel for their test. This is important because of Nobel's claim that higher torque required to insert the RePlant could result in compression necrosis of the bone in a clinical case. This is easily disproved by the fact that the torque needed to thread the Oak was only 40% of the torque needed to cut the threads prior to inserting the RePlant.

The results demonstrate that while the RePlant implant required more insertion torque to seat the implant, the difference was far less than that reported by Nobel, and of no clinical significance. Some difference is to be expected since the threads on the Replace implant just follow the threads created by its bone tap, whereas the self-tapping RePlant Implant cuts new threads in the oak, increasing initial stability. Nobel reported a 100% increase in torque required to fully seat the RePlant compared to the Replace implant (96 vs. 48 Ncm) in contrast to a 45% difference in Implant Direct's test results (34.46 vs 23.55Ncm) placing the RePlant absolutely flush with the top of the wood sample and only 11% difference (26.55 vs 23.73 Ncm) when the RePlant was an insignificant 1/4mm above the wood. To put the RePlant insertion torque numbers in perspective, the higher torque to seat the implant the last 1/4mm is 40% (34.46/82.48Ncm) less than the amount of torque required to tap the threads in Oak. Nobel's claim that the RePlant could potentially cause "pressure at collar area" is therefore without merit because much more pressure was applied by the bone tap. The RePlant creates greater initial stability in dense bone following bone tapping than the Replace implant, as measured by insertion torque. An accepted benchmark for adequate initial stability to immediately load an implant, is 35Ncm of insertion torque, exactly what it took to fully seat the RePlant, a value that is only 17% of the torque required to fracture the implant (34.46 vs 191.7 Ncm). Inserting the NobelReplace Implant into a pre-tapped hole in dense bone for those implant lengths and diameters where dense bone drills are not available, is recommended to reduce the risk of implant fracture. This dense bone protocol may also reduces initial insertion torque values below the recommended 35Ncm, the accepted criteria for immediate loading. The increased strength of the titanium alloy RePlant, allows self-tapping insertion in most situations considered as dense bone. It will also achieve adequate initial stability when inserted into a socket prepared using the NobelReplace bone tap because the RePlant's self-tapping design creates its own threads in the bone, taking advantage of the socket enlargement from the use of the bone tap to reduce required insertion torque to an acceptable level. If the dentist uses the RePlant's aluminum fixture-mount to insert the implant instead of Nobel's Trilobe insertion tool, the softer aluminum will strip before the implant fractures. It acts as a torque gauge to let the dentist know whether the dense bone surgical protocol is needed, thus providing **optimum stability.**

JULY 23,2007 TEST RESULTS IN HARD BONE REPLICA OAK WOOD

TEST #	Test Sample 4.3mmD/10mmL	Test Procedures for Insertion of Bone Tap and Implants in Hard Bone Replica (OAK)	INSERTION TORQUE 1 in/lb = 11.3 Ncm
1.	Replace Bone Tap	Prepare a hole using 4.3mmD Nobel Final Drill and 4.3 RPL Bone Tap. Insert Implant Flush with Top	Tapping Torque 7.30in/lb = 82.48 Ncm
2.	Replace Implant Lot #381709	Prepare a hole using 4.3mmD Nobel Final Drill and 4.3 RPL Bone Tap. Insert Implant Flush with Top	Replace Implant - Flush 2.10in/lb = 23.73 Ncm
3.	RePlant Implant Lot #14395	Prepare a hole using 4.3mmD Nobel Final Drill and 4.3 RPL Bone Tap. Insert Implant 1/4mm above Top	RePlant Implant 1/4mm Above 2.35in/lb = 26.55 Ncm
4.	RePlant Implant Lot #14395	Prepare a hole using 4.3mmD Nobel Final Drill and 4.3 RPL Bone Tap. Insert Implant Flush with Top	RePlant Implant - Flush 3.05in/lb = 34.46 Ncm

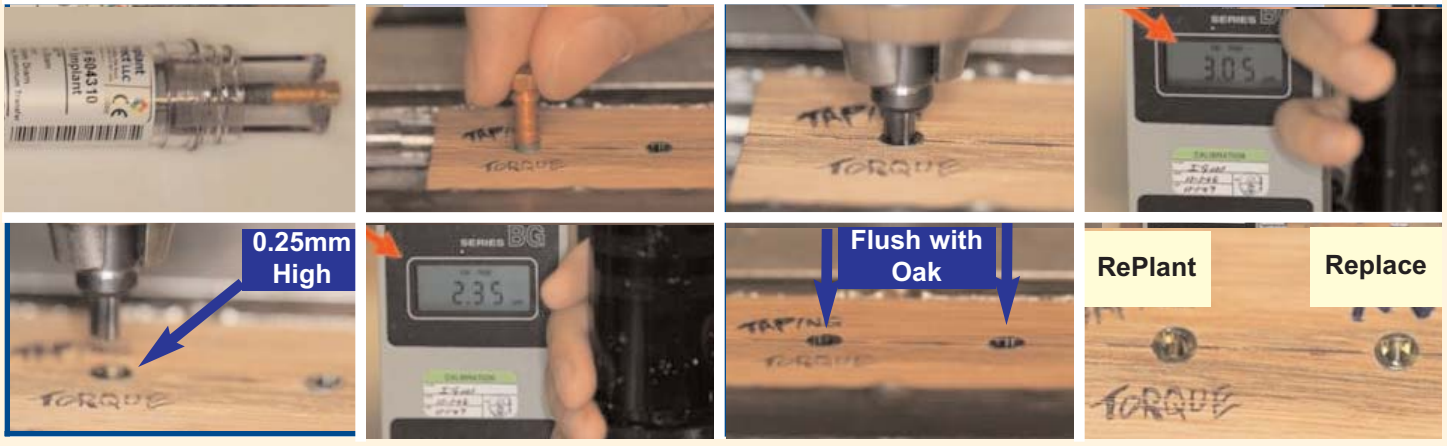


Nobel Replace 4.3mmD/10mmL Insertion Torque
Thread hole in Oak using Replace Bone Tap
Required 7.30in/lb (82.48Ncm)

Nobel Replace 4.3mmD/10mmL Insertion Torque
Insert Implant into Pre-tapped hole in Oak
Required 2.10in/lb (23.73Ncm)

RePlant 4.3mmD/10mmL Insertion Torque
Insert Implant 1/4mm Abve Pre-tapped hole in Oak
Required 2.35in/lb (26.55Ncm)

RePlant 4.3mmD/10mmL Insertion Torque
Insert Implant Flush into Pre-tapped hole in Oak
Required 3.05in/lb (34.46Ncm)

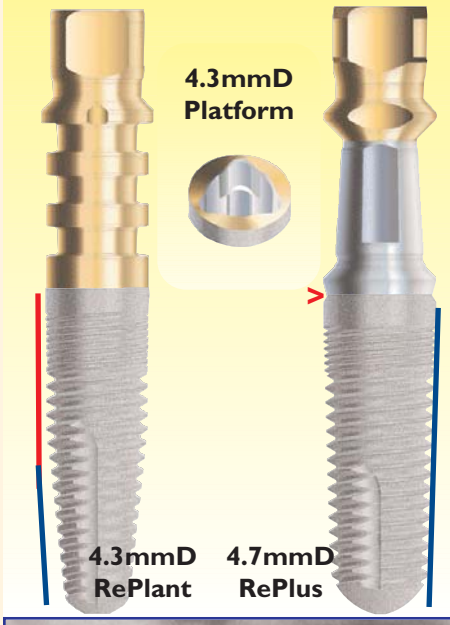


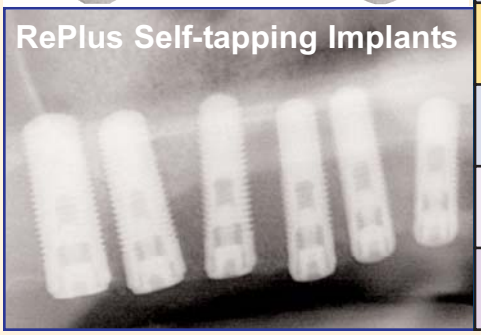
RePlant, RePlus and ScrewPlant Implants from Implant Direct
Made from Titanium Alloy for Increased Strength/ Designed for Self-tapping Insertion

Implant Direct's 3.5mmD RePlant Implant requires about 20% more force (12.88in/lbs vs. 10.90in/lbs) to fracture compared to Nobel Biocare's 3.5mmD Replace Tapered Groovy Implant. The difference is due strictly to the use of stronger Medical Grade Titanium Alloy compared to CP Titanium.. RePlant and Replace implants have the same dimensions with the 3.5mmD implants having a wall thickness of only 0.009" (thickness of two human hairs) and the 4.3mmD implants having a wall thickness of only 0.012". Nobel's TiUnite surface will not form on the Alloy, thus necessitating the use of the weaker CP Titanium but Nobel uses Ti Alloy for it's HA coated Replace Implants. Implant Direct's RePlus Implants match the platforms of the 3.5mmD, 4.3mmD and 5.0mmD RePlant and Replace implants but have the same outside diameters and evenly tapered body design of the ScrewPlant and other Spectra-System implants. This improved design allows for insertion in an undersized socket in soft bone for increased stability. The top 0.3mm of each RePlus implant tapers in to the smaller diameter 3.5mmD, 4.3mmD and 5.0mmD platforms. The wider diameters provide increased strength and the transition to the narrower platform creates room for thicker soft tissue considered by some to be an advantage in the esthetic zone.

IMPLANT	Wall Thickness	Torque in/lbs	Torque N-Cm	Mode of Failure
3.5mmD Replace	0.009"	10.90	123.20	Implant Fractured
3.5mmD RePlant	0.009"	12.88	145.50	Implant Fractured
RePlant 3.5mm Al. Fixture-mount Strips to Protect Implant		5.85	66.1	Tri-lobe Stripped
3.7mmD RePlus	0.013"	15.75	178.00	Implant Fractured
3.7mmD Screw Plant	0.018"	16.03	16.03	Hex Stripped

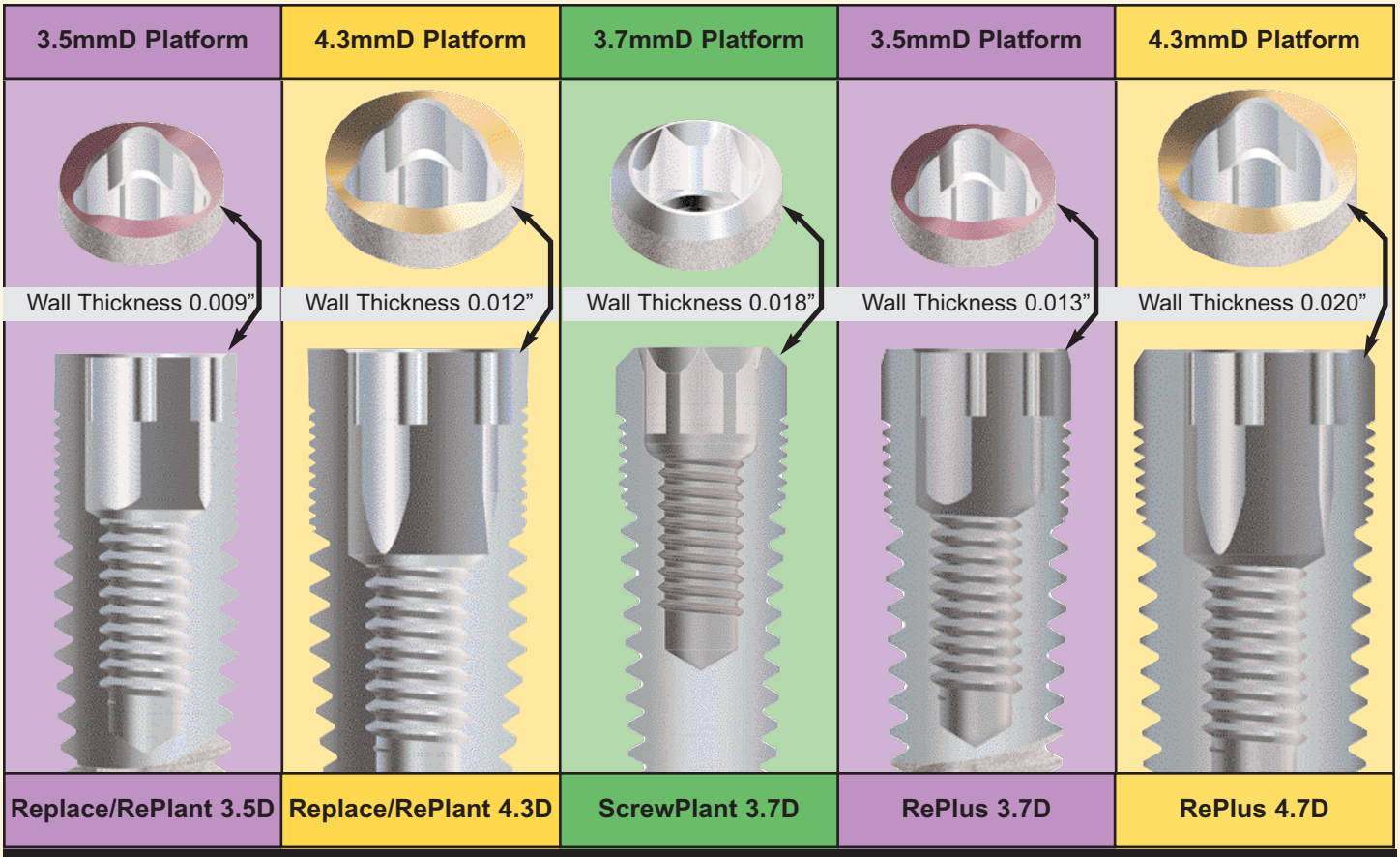
The Even Taper of the RePlus Implant along with the use of Straight Drills allows a Soft-bone/Hard-bone Surgical Protocol that Provides Greater Initial Stability in Soft Bone



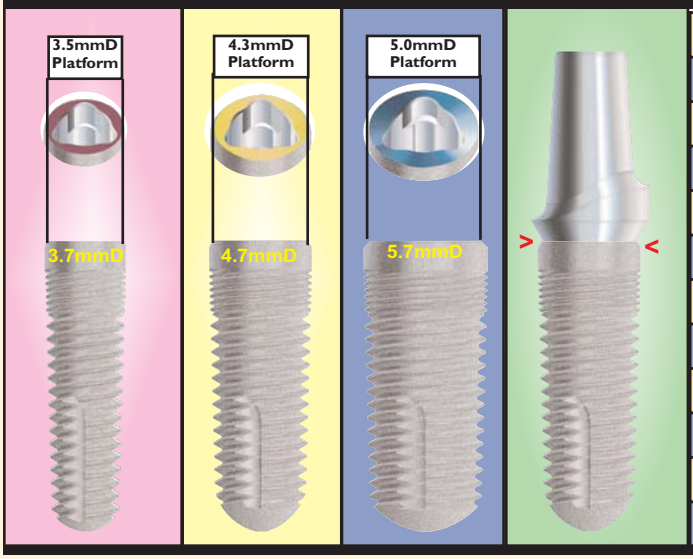


Surgical Protocol for RePlant - insert Self-tapping using Aluminum Fixture-mount

Implant Size and Type	Test Media Balsa or Oak	Socket Preparation	Insertion Torque
Nobel Replace 4.3mmD	Balsa Wood Soft Bone	Nobel 4.3 Drill No Bone Tap	2.25in/lbs 25.4Ncm
Nobel Replace 4.3mmD	Oak Wood Hard Bone	Nobel 4.3 Drill Bone Tap	2.10in/lbs 23.73Ncm
Nobel Replace 4.3mmD	Oak Wood Hard Bone	Nobel 4.3 Drill No Bone Tap	18.65in/lbs 210.7Ncm
ID RePlant 4.3mmD	Balsa Wood Soft Bone	Nobel 3.5 Drill No Bone Tap	3.30in/lbs 37.3Ncm
ID RePlant 4.3mmD	Balsa Wood Soft Bone	Nobel 4.3 Drill No Bone Tap	1.90in/lbs 21.5Ncm
ID RePlant 4.3mmD	Oak Wood Hard Bone	Nobel 4.3 Drill Bone Tap	3.05in/lbs 34.5Ncm
Fixture-Mount 4.3mmD	Test To Failure		10.12in/lbs 114.1Ncm
ID RePlant 4.3mmD	Oak Wood Hard Bone	Nobel 4.3 Drill No Bone Tap	11.81in/lbs 133.5Ncm
ID RePlus 4.7mmD	Balsa Wood Soft Bone	ID 3.8mmD No Bone Tap	3.91in/lbs 44.2Ncm
ID RePlus 4.7mmD	Oak Wood Hard Bone	ID 4.4/3.8mmD No Bone Tap	6.35in/lbs 71.8Ncm



The RePlus Implant uses Implant Direct’s Drills and Surgical Protocols



1	50% stronger Small Diameter Implant
2	Micro-threads for reduced stess near crest
3	Double-lead threads for 2 times faster insertion
4	Self-tapping vertical cutting groove 1/2 the length
5	Soft Bone Protocol: Evenly tapered for Expansion
6	Hard Bone Protocol: No need for bone tap
7	Threaded to the apex for increased stability
8	Straight, step-drills: faster surgery with less drills
9	Five Implant Length Options, including 11.5mm
10	Two Surface Options: HA Coated or Blasted
11	Precision Manufacturing: <0.5° vs >1.5° Rotation
12	All-in-1 Pkg. for 70% *Savings: $200 vs $641

The RePlus Implant is evenly tapered over its entire length, allowing insertion into an undersized socket in soft bone. Research has shown this not only increases initial stability essential for immediate loading, it also results in increased bone attachment and removal torque following osseointegration. In hard bone, Implant Direct’s final step-drills allow insertion without the need for a bone tap. RePlus Implants are available with SBM medium rough surface over their entire length and with HA coating starting 3mm from the top of the implant. The Trilobe, color coded internal connection accepts Nobel’s Replace and Implant Direct’s RePlant abutments. Each RePlus vial includes a cover screw, titanium Fixture-mount/transfer that can be shortened for use as the final “snappy” abutment. A snap-on comfort cap is also provided. The 3.7mmD RePlus implant provides 50% greater strength than NobelRePlace 3.5mmD Implant. The transition from 3.7, 4.7 and 5.7mmD bodies to the 3.5, 4.3 and 5.0mmD Trilobes create platform switching.

*Includes Implant, Abutment, Transfer & CS