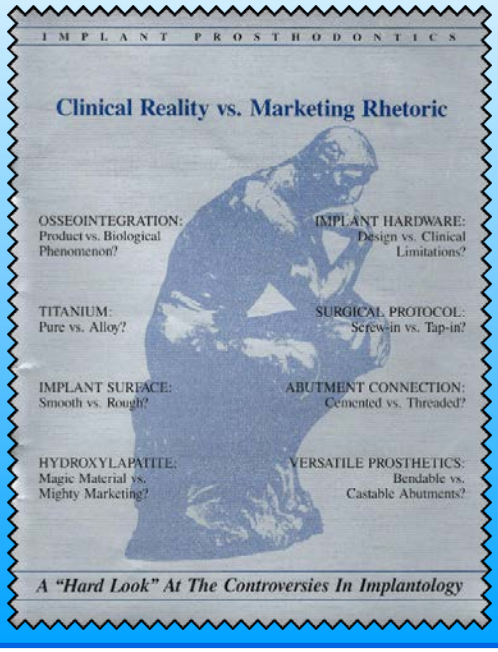
Recently NobelBiocare ("Nobel") posted a video of its president, Patrik Eriksson, announcing "2021 is the 40th anniversary of the founding of our original company by Prof. P-I Branemark" and asking dental professionals to trust Nobel's new products based on its 40 year history of producing "game changing, even life changing treatment never seen before.

In the video Eriksson states:
"Looking forward to decades to come, our exciting innovations continue to offer the best possible treatment at every step. From the chemistry of our new surface innovation with Zeal and TiUltra …. And most exciting, the new NobelBiocare N1 System, a completely new way of improving the treatment experience of both clinicians and most importantly, of patients. On this anniversary, we thought it would be a good time to take a look back

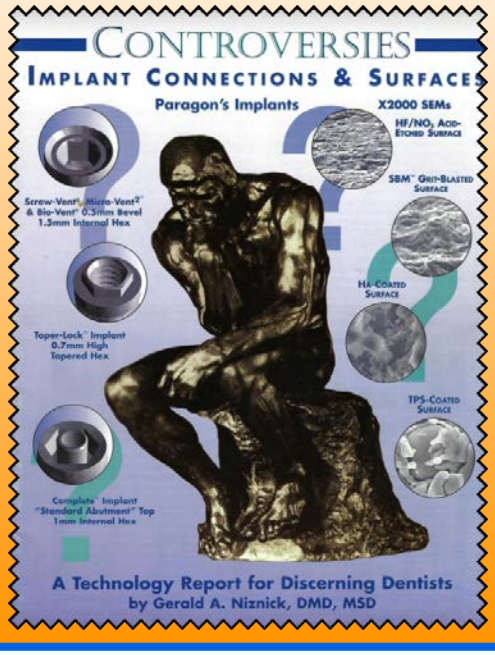
The purpose of Nobel's president, Mr. Eriksson, extolling Nobel's heritage over the last 40 years is to give credibility to Nobel's marketing claims related to its new products. The purpose of this 14 page documentation of Nobel's conduct in the implant industry over the last 40 years, and the history of its product developments, is to give dentists a better frame of reference for evaluating Nobel's marketing claims of its new products and surfaces.

Over the last 40 years since I developed and launched the Core-Vent System, I have published a number of articles, letters to editor, open letters to professionals and booklets all dealing with controversies in implant dentistry. On my website www.niznick.com, I have a section where these documents are archived including 24 Linkedin and Facebook postings on controversial topics since 2018. With about 250 implant companies competing for dentists' business, there seems to be an unlimited number of Unique Selling Propositions by which companies try to differentiate their products. This is quite often with exaggerated claims of success and/or superiority based on company sponsored research reports to support their claims of simplicity, versatility and value.

1988 - I published a 42 page booklet on Surfaces, Materials & Connections
Clinical Reality vs. Marketing Rhetoric.



1998 - I published a 28 page booklet with 71 references on Controversies over
Implant Connections and Surfaces



On Nobel's invitation to look at its 40 year history, let's look at it all….The good, the bad and the ugly. This report chronicles my experiences and interactions with Nobel in the 40 years since Nobel and Core-Vent Corporation brought osseointegrated implants to North America in 1982. I write this report with the hope that in the future, dental professionals become more discerning about what influences their selection of dental implants for their patients. Let's look over these last 40 years to examine the questionable business tactics and acquisitions used by Nobel in its efforts to become the global market leader in the implant Industry, a position today held by Straumann implant company.

Nobel's President states:

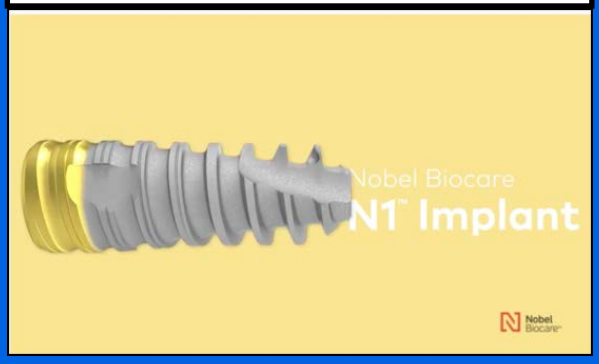
> "Looking forward to decades to come, our exciting innovations continue to offer the best possible treatment at every step from the chemistry of our new surface innovation, Zeal and TiUltra, …and most exciting, the new NobelBiocare N1 System."

Below are my recent postings on Nobel's "new surface innovation, Zeal and TiUltra" which Nobel claims promotes "mucointegration" and Nobel's new N1 System.

I have posted on the Controversies Section of www.niznick.com, my challenges to Nobel's claims regarding these new "exciting innovations [that] offer the best possible treatment ".

Nobel's Mucointegration Claims
1. Anodizing Titanium:Method and Reality
2. Unsubstantiated Claims: TiUltra & Zeal

Nobel's N1 Implant System Claims
1. Achilles heel of the N1 Implant design
2. Drill minimizes noise and vibration



Nobel's President invites us to "take a look back at [Nobel's] heritage" assuming that to do so would ensure confidence in its new product offerings. Let's start with Mr. Eriksson's claim that Branemark discovered osseointegration.

> ***"Our founding father, Professor P-I Branemark, the discoverer of Osseointegration…"***

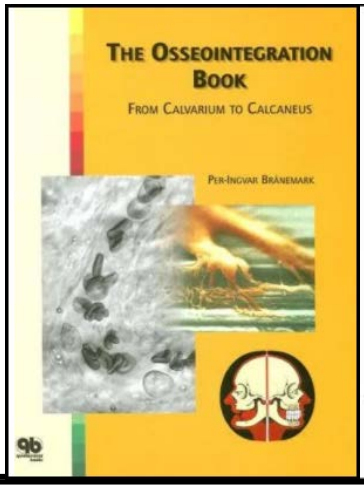
FACT: Branemark observed that a titanium chamber used in a rabbit experiment on blood flow, became firmly attached to bone but he was not the first to make such an observation or to understand its significance. Branemark's 1977 textbook references a 1951 article Titanium, A Metal For Surgery by Gottliev. S. Leventhal in the J. BONE JOINT SURG. This was a year before Branemark did his rabbit study where he observed bone attaching to the titanium chamber.

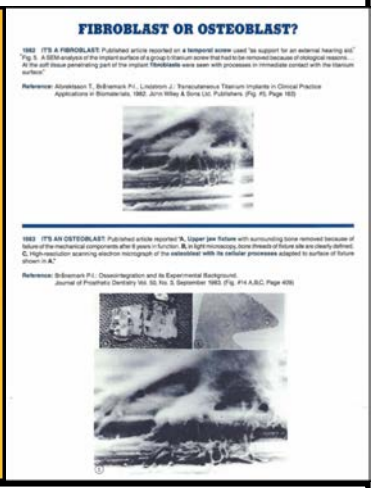
FACT: Branemark's Wikipedia Biography confirms that he was a " professor of Anatomy at Gothenburg University (not an orthopedic surgeon as some claim) and further acknowledges that:

> ***"The phenomenon of osseointegration was first described by Bothe et al. in 1940 (Bothe, RT; Beaton, KE; Davenport, HA (1940). "Reaction of bone to multiple metallic implants". Surg Gynecol Obstet. 71: 592–602.) and later by Leventhal et al. in 1951. Brånemark's studies, and his subsequent coining of the phrase osseointegration, occurred a year after Leventhal."***

Nobel's Unique Selling Proposition has been its claim to the heritage of Branemark's clinical studies using pure titanium, external hex screw implants for the restoration of edentulous jaws, dating back to the 1960s. One of Branemark's fellow researcher at the University of Gothenburg was Tomas Albrektsson who Nobel has used extensively to promote the use of pure titanium as the material of choice, and the superiority of the Branemark System through articles and lectures. Albrektsson and his associate, Lars Sennerby, primarily became Nobel's "attack dogs," publishing articles critical of almost all of Nobel's competitors and especially Core-Vent.

In 1989, I discovered further evidence that brings into question, Branemark's and Albrektsson's scientific veracity. They used the same SEM picture in two articles, one purporting to be a fibroblast from skin around an ear implant and the other claiming to be an osteoblast attached to titanium of a maxillary Branemark implant. This SEM of a dubious origin was colorized by Nobel and used in its advertisements as well as appearing on the cover of Dr. Branemark's last book shown here.





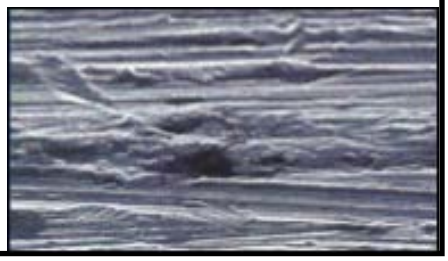
The Branemark Implant started out as Grade1 CP Titanium but, as Adell's published 15 and 20 year reports showed, a number of implants fractured (16% of Maxillary implants followed for 15 years). Also there was a relatively high failure rate in the soft bone of the maxilla, eventually attributed to the relatively smooth machined surface. The only thing that changed in the 1980s and 1990s was that Nobel started using stronger grades of CP Titanium which did not solve all the fracture and hex stripping problems. The problem was that changing the design, surface and/or material of the Branemark implant would have compromised its Unique Selling Proposition of being the implant system with 20+ years of clinical research. **When Nobel bought SteriOss in 1998 and introduced TiUnite anodized surface in 1990, Nobel repeated the mistake of not correcting an obvious shortcoming of having the porous TiUnite extend to the top of the implant which has been reported to encourage bone loss if/when exposed. After 20 years of selling implants with TiUnite to the top, Nobel developed a marketing story to justify creating a smooth neck. They anodized their abutments and neck of the implants gold, (Zeal and TiUltra) and claimed a "New Era" of soft tissue attachment which they called mucointegration. This came at a $21 price increase for a NobelActive from $499 to $520.**

1965 Branemark Implant System developed by Swedish P.I Branemark MD
- 3.75mmD Screw with 4.1 mm External Hex Platform made from CP Titanium.
- Made from Commercially Pure Titanium
- A machined, relatively smooth surface
- Developed in Sweden and after 15 years of clinical documentation,
- Introduced to the North American market at the 1982 at the Toronto University Symposium on Osseointegration.
- **Osseointegration Definition Changed from 1982 to 1988** as Nobel sought to make it specific to its Branemark Implant.
- Branemark implants manufactured and sold by Swedish Company called Bofores, later changed to Nobelpharma and again to NobelBiocare.

CpTi

Material	Modulus (GPa)	Ultimate Tensile Strength (MPa)	Yield Strength (MPa)	Elongation (%)
Cp Ti grade I	102	240	170	24
Cp Ti grade II	102	345	275	20
Cp Ti grade III	102	450	380	18
Cp Ti grade IV	104	550	483	15
Ti-6Al-4V- ELI	113	860	795	10

Branemark Machined Surface



1984 - Both Nobelbiocare ("Nobel") and Core-Vent Corporation (a USA company founded by Gerald Niznick DMD, MSD) had been on the market for 2 years. Nobel's implant sales were restricted to Oral Surgeons and their training programs restricted to Oral Surgeons and Prosthodontists at a fee of $1500 per person. The starting costs of a Branemark System was about $20,000 whereas the cost for a comparable inventory of implants, instruments and an electric motor from Core-Vent was about $4500. By contrast, a two-day live surgical course at Core-Vent teaching centers was $600 with Core-Vent sales and training programs being available to all dentists. The didactic portion of these courses included a review of Branemark's published research on Osseointegration and documentation that confirmed Core-Vent implants achieved osseointegration.

1982 - Core-Vent Implant System

Inventor and President of Core-Vent Corporation was Gerald Niznick DMD, MSD (Prosth).

•Hollow Basket with an internal hex for insertion and for cement abutments. Three threads projecting above basket. Design was a combination of Straumann basket & screw implant

•Made from Ti6Al4V alloy (same as orthopedic hips) with 40% increased strength vs TiCPGrade4

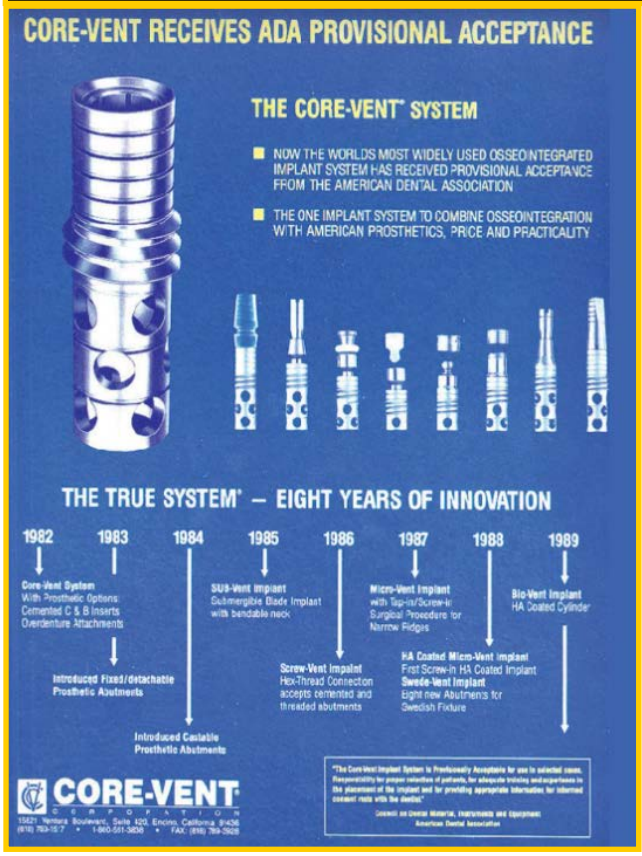
•Surface texture created by blasting with AlO2 Medium Grit followed by Acid Wash.

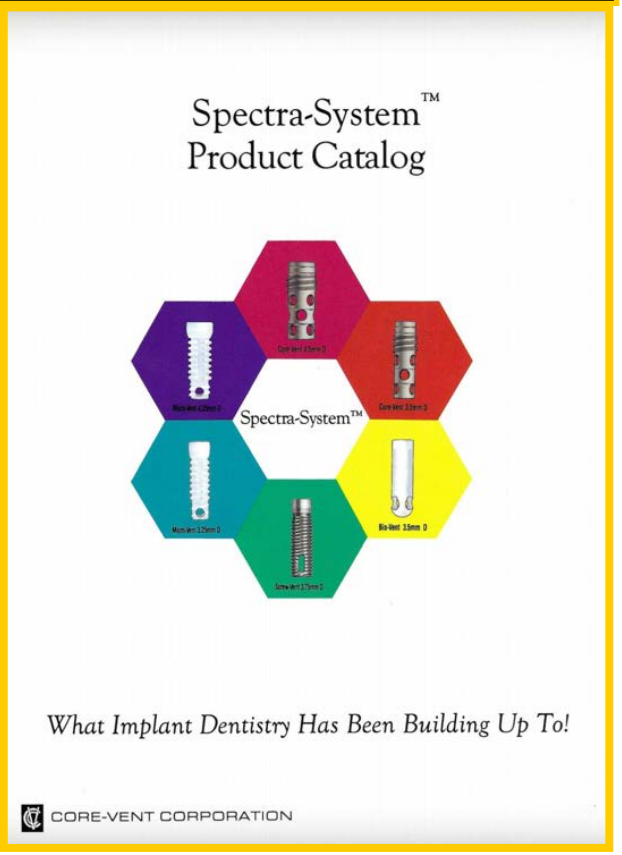
- First System with simplified surgical procedures - 3 Diameters & 4 Lengths.

•First System with Application Specific Abutments

•First Article documenting free-standing implants retaining an overdenture .

By the end of the 1980s Core-Vent Corporation's implants were the most widely used in the world. The Screw-Vent was introduced in 1986 with its patented, internal hex and 45 deg. lead-in bevel (conical connection). By 1990, Core-Vent added the Micro-Vent Screw/Ledge (first narrow implant) and Bio-Vent cylinder implants, both with HA coating. In 1999 the Tapered Screw-Vent was developed, eventually obsoleting the other designs. Today, it is the flagship product of Zimmer Biomet (bought C-V 2001).





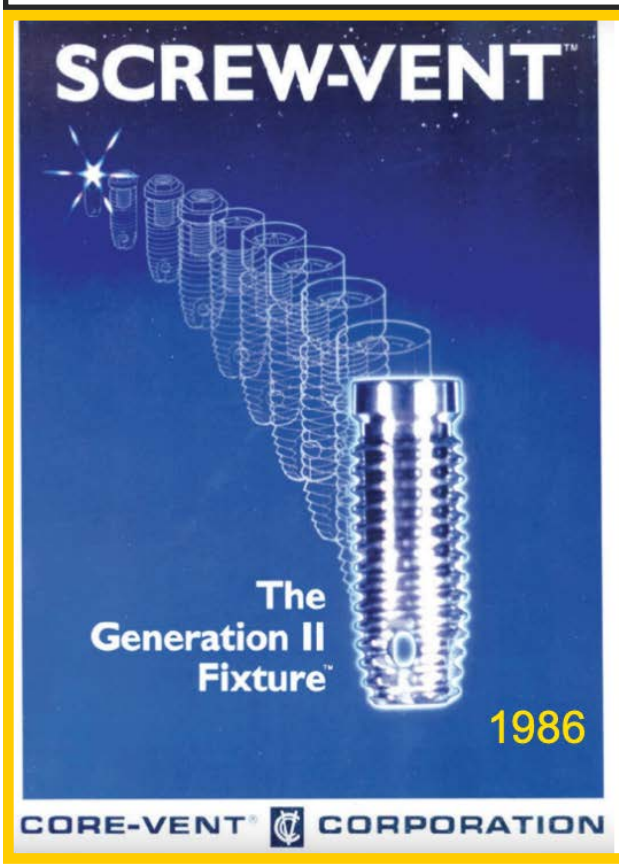
1984 - Nobel sent out an open letter to all Oral Surgeons attacking Core-Vent for extrapolating Branemark's published research on osseointegration. Core-Vent's respond to Nobel's "Open Letter" pointing out that the Branemark research did not compare different materials (Pure Titanium vs Titanium Alloy) or different designs (Screw vs Basket). All it proved was that if an implant achieved firm attachment to bone following a surgical protocol that avoided overheating of the bone, (termed osseointegration by Branemark) and maintained this anchylosis for one year in function, the implant most likely had long-term predictability. Core-Vent's Titanium Alloy, hollow basket implants had met those criteria.

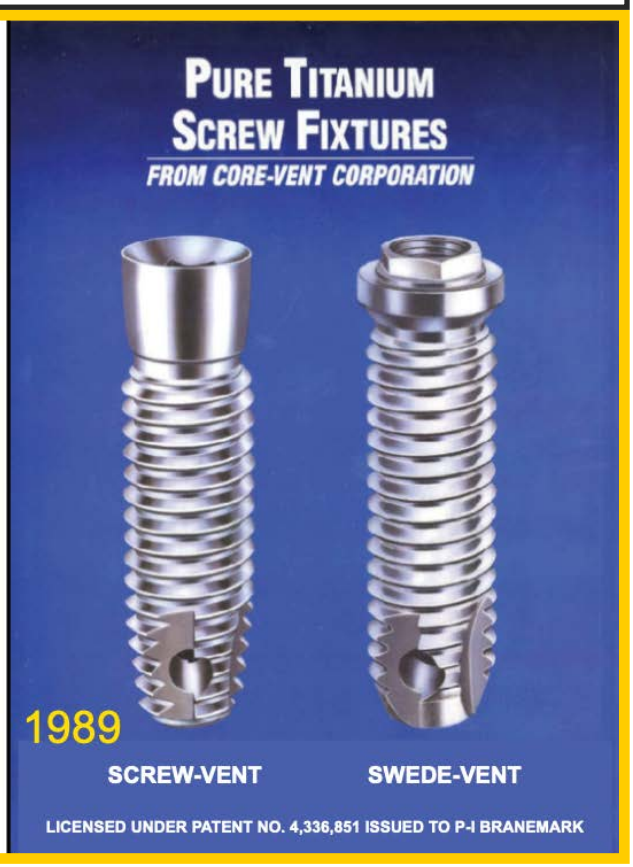
1986 - Nobel initiates Patent Infringement litigation against Core-Vent on a Patent Nobel and Branemark filed in 1979 in Sweden and with the U.S. Patent and Trademark Office (PTO) in 1980. The U.S patent, issued in 1984, claimed a dental implant

> ***"made of titanium and have a network of particularly-sized and particularly-spaced 'micropits'. These micropits, which have a diameter in the range of about 10 to 1000 nanometers or, preferably, 10 to 300 nanometers, allow a secure tissue connection to form between the implant and growing bone tissue through a process called 'osseointegration'"***

Pits of the claimed size are inherent in all machined titanium including the bar stock used in the manufacturer of dental implants. They can neither be intentionally made nor intentionally avoided. Branemark's 1977 Textbook shows SEMs of the Branemark Implant's machined implant surface that exhibited such micropits. This prior art publication alone would invalid the Branemark patent filed in 1980….Which was why Nobel and Branemrk never disclosed this book to the US PTO.

1986 - Core-Vent Corp. introduced the Screw-Vent implant having an internal hex below a 45 degree lead-in bevel (Niznick US Pat. # 4,960,381). The Screw-Vent, with the first conical connection, is considered the cornerstone of modern implant design. The Screw-Vent, made from Grade4 CP Titanium, matched the Branemark implant in thread design and dimensions but instead of leaving the machined surface, it was subjected to treated with HFl acid to create a super-clean, textured surface.
1989 - After Core-Vent settled the Nobel patent litigation by licensing Branemark's micro-pit patent, Core-Vent introduced the Swede-Vent with an external hex matching the Branemark implant.





1989 - After three years of very expensive litigation, rather than undertake the expense of a trial Core-Vent settled the case with Nobel, agreeing to pay 10% for a license on pure titanium implants for the remaining 6 years of the patent's life. During the litigation, Dr. Niznick and his attorney traveled to Sweden to depose Branemark and his Swedish patent lawyer, Barnieske. They learned that Branemark's 1977 prior art book was referenced in the initial draft of the patent but removed when the patent was filed.
1991 - Nobel sued Implant Innovations ("3i") on the same patent — 3i litigated for years and then went to trial. Dr. Niznick testified for 3i about the missing book. The jury ultimately found that the Branemark patent was invalid by fraud on the U.S. Patent Office. Nobel lost its appeal to this ruling and was ordered to pay 3i $3.3M which was tripled for fraud, plus almost $5M in attorney fees. The millions Core-Vent had to pay on Nobel's fraudulently gained patent of an ordinary machined surface necessitated price increases to its customers, which made Core-Vent less competitive benefiting Nobel.

NOBELPHARMA BRANEMARK IMPLANT SURFACE PATENT OBTAINED FRAUDULENTLY

This article was originally published in The Gray Sheet

16 May 1994 | **NEWS**

Executive Summary

NOBELPHARMA BRANEMARK IMPLANT SURFACE PATENT OBTAINED FRAUDULENTLY, a jury in the U.S. District Court in Chicago ruled May 4. The verdict stems from a patent dispute with Implant Innovations, Inc. (3i) relating to titanium dental implants manufactured by both firms. The "verdict and a decision by the court invalidates" the patent, 3i said in a May 10 release. 3i was awarded $9.9 mil. in damages from Nobelpharma, which was found guilty of antitrust violations based on the fraud.

The Appeals Court upheld the verdict: "the jury could properly have inferred that Branemark had the requisite intent to defraud the PTO" by not disclosing his 1977 Book

NOBELPHARMA AB v. IMPLANT INNOVATIONS, INC.
Cite as 141 F.3d 1059 (Fed. Cir. 1998)

Excerpts from Court Ruling

After trial limited to the antitrust issue, the jury found in special verdicts, inter alia, that 3I had proven that (1) "the inventors or their agents or attorneys obtained the '891 patent through fraud," (2) NP "had knowledge that the '891 patent was obtained by fraud at the time this action was commenced against 3I," and (3) NP "brought this lawsuit against 3I knowing that the '891 patent was either invalid or unenforceable and with the intent of interfering directly with 3I's ability to compete in the relevant market." The jury awarded 3I approximately $3.3 million in compensatory damages, an amount the court trebled

Third, the record indicates that a reasonable jury could have found that NP brought suit against 3I with knowledge of the applicants' fraud. A reasonable jury could have found that two of NP's then-officers, Dr. Ralph Green, Jr. and Mr. Mats Nilsson, were aware of the fraud based on Green's testimony that Nilsson told him: "[I]f the Patent Office did not receive a copy of [the 1977 Book], and if that were true, then we would have a larger problem and that was fraud." Green's testimony also indicates that NP was aware that the 1977 Book was highly material and, in fact, likely rendered the patent invalid.

Fabrication of "Research" Findings to Discredit a Competitor of the Branemark System

Nobel funded, directly or indirectly, a number of false and/or misleading studies critical of Core-Vent's implants. They were all written by clinicians associated with Branemark System Teaching Centers (UCLA and University of Western Australia) or Swedish academics who were paid consultants to Nobel (Allbrektsson & Sennerby). They were mostly published in JOMI, the editor of which was also associated with a Branemark System Teaching Center (Mayo Clinic). Dr. Niznick responded to these articles with Letters to the Editor most of which were not printed. Ultimately, Core-Vent deposed several of the authors and Nobel consultants to learned the full nature of the deception of these published studies and articles which were repeatedly mischaracterized by Albrektsson and Sennerby while ignoring references to any of the positive published research on Core-Vent implants. This was obviously done in an attempt to discredit Core-Vent. Below are excerpts from Dr. Niznick's responses to these bias and misleading articles. The links to the Controversies Section of www.niznick.com provide the full text of Dr. Niznick's analysis and responses.

Responses to Kinni ME et al.: Force transfer by osseointegration implant devices, Int J Oral Maxillofac Implants 1987;2(1):11-14) ***(UCLA)***

Figure 5 examining the "unstressed models" shows the full length of the Biotes and Core-Vent implants. Figure 6, showing "stress patterns observed with 40 lb. axial load" cropped the top of the picture of the Biotes implant while it shows the full length of the Core-Vent implant. In fact, none of the figures show the top of the Biotes implants under stress. The Biotes implant, which is wider at the top, will result in undesirable high stress concentrations in the area of the crest of the ridge.

Response to Henry PJ: Comparative surface analysis of two osseointegrated implant systems (Pp 23-27). ***(University of Western Australia.)***

Dr. Henry's article compares the grit-blasted surface of the Core-Vent implant to that of the smoother machined surface of the Biotes implant and tries to prove the superiority of the smoother surface. One only has to read the article in this same issue of the JOMI by Steven D. Cook et al., proving that osseointegration was more likely to occur on a grit-blasted surface than on a smooth surface.

Response to UCLA Comparative Study of Core-Vent vs. Branemark Implants:

Moy P., Buemer J., and Lewis S. Abstract, Second International Congress on Pre-Prosthetic Surgery, was presented at Palm Springs, Calif, May 1987 by Dr. Moy. The tittle states "Comparative Analysis of 100 Consecutively Placed Core-Vent to 100 Consecutively Placed Biotes [Branemark] Implants."

This ***study containing false and misleading information uncovered during 11 days of Moy's deposition. Dr. Peter Moy's deposition testimony revealed the full extent of the intentional misinformation he and his UCLA colleagues presented at a Palm Springs UCLA scientific meeting in 1997. This abstract was subsequently referenced (and mischaracterized) by Nobel's paid consultants, Albrektsson and Sennerby, while ignoring 3 other presentations at that meeting documenting very high success rates with Core-Vent implants.***

1. **Of the first 100 "consecutively placed" Branemark implants included in Moy's comparison study, 11 failures where intentionally not reported.**
2. ***Of the first 100 "consecutively placed" Core-Vent implants included in Moy's comparison study, 4 implants where counted as failures that had not even been placed.***
3. ***Moy created an arbitrary criteria of "projected failures" based on bone loss measured from the top of the implant that was applied to the Core-Vent implants but not the Branemark implants. This did not take into consideration that Core-Vent implant's surgical protocol required that the top 1 mm of the Core-Vent implant was left projecting above the bone at insertion to make uncovering easier.***
4. ***Core-Vent Success Rate: Based on actual failures, his success rate with Core-Vent Implants was 90% in the upper jaw and 89% in the lower jaw (including two implants removed because they were placed in the mandibular canal) rather than the 58% maxillary or 68% mandibular success rate reported by Moy in his abstract presented at the UCLA symposium and republished by Nobel and its paid consultants.***
5. ***Branemark Success Rate: Dr. Moy's Branemark implant actual success in the maxilla including the 15 implants he had excluded, 11 of which failed, was 28 out of 41 for a success rate of 68.2% and if you include the two he projected would fail, it dropped to 63.4%.***
6. ***Prior to giving this paper, Dr. Buemer, professor of Prosthodontics at UCLA had solicited Nobel for a $700,000 donation to establish an implant center. Following the presentation UCLA received the funds.***

Response to Albrektsson's Attacks Against Titanium Alloy used in Core-Vent Implants.

Letter to Editor RE: Albrektsson T, Jacobsson M: Bone-metal interface in osseointegration. J Prosthet Dent 1987;57(5):597-607.

Albrektsson's false and misleading article claims medical grade titanium alloy (90% titanium 6% aluminum-4% vanadium) used in Core-Vent dental implants is **a potential health hazard and, as yet, unproven to achieve osseointegration**. Furthermore, the article raises the issue of **neurotoxicity** relative to the aluminum leaching from the alloy and that Core-Vent implants **"lack proper evidence of a bony integration."**

As of the date of this article extensive histologic and clinical evidence had been published proving the efficacy of Ti6Al4V medical grade titanium used by Core-Vent implants and that they osseointegrated:

- .Dan Laskin, editor of the JOMFS, reported on the results of five independent dentists having placed 609 Core-Vent implants with a 96.6% incidence of osseointegration. ***Laskin D. Presentation 1986 AAOMS national meeting. New Orleans.***
- University of Pacific professors placed Core-Vent implant in dogs and reported that" the bone metal interface involved almost the entire surface of the embedded implant." ***Lum L, Beirne R. Viability of the retained bone core in the Core-Vent dental implant. J. Oral Maxillofac Surg 1986;44:341-5.***
- An article evaluating the surface of a Core-Vent demonstrated an overall bone-implant interface at both the light and scanning electron microscopic level. ***Niznick G. Destinations Magazine, 1986;10.***
- A study of various types of implants, including the Brånemark and Core-Vent, confirmed histomorphometrically that the degree of mineralization, as tested at six points on the bone/metal interface, was equivalent. ***Chase D., Comparative evaluation of endosseous implant systems in edentulous dogs. Presentation at AAOMS meeting, Anaheim, Calif, Sept 1987.***
- A study compared Core-Vent with Brånemark implants loaded in monkeys and reported "light microscopic examination revealed that both the Brånemark and the Core-Vent implants were in direct contact with bone." The surface contact area appeared to be the same. ***Lum L, Beirne R. [Abstract]. Second International Congress on Preprosthetic Surgery, Palm Springs, Calif., May 1987.***

1989 - Following the litigation settlement and licensing agreement, Nobel and Core-Vent sent out a **Joint Announcement of the Settlement .** In 1988, faced with being sued on a patent that it believed to be invalid and fraudulently gains, Core-Vent introduced the Swede-Vent, a clone of the Branemark Implant. In keeping with Core-Vent's marketing strategy, it sold the Swede-Vent for $96, representing a 44%-57% savings for Nobel customers. The Swede-Vent surface, like that of the Screw-Vent, was CP Titanium with micro-pitted surface created by acid etched with HFl to remove machining contaminants. Nobel offered Core-Vent a license in court just before trial was to start and Core-Vent accepted a 10% royalty on pure titanium implants only. Core-Vent had recognized that it could gain a marketing advantage besides price by focusing on its greater precision between the mating implant and abutment. Besides saving the cost of a trial, Core-Vent saw the marketing opportunity of being able to reference the license to the Branemark patent in its **advertising of its Swede-Vent Branemark implant clone while also showing its better fit.** Once Nobel realized the marketing advantage it had given Core-Vent by allowing it to reference Branemark's patent in its ads, a Second Announcement was sent out attempting to negate any marketing benefits from Core-Vent's reference to the Branemark patent. **Core-Vent Responded.**

Nobel'a Letter Claimed: "*the patented invention involves only a particular type of micro-pitted surface on certain implants"*.

Core-Vent's Response: *"P-I Brånemark's years of experimentation and development*" also led to filing in 1979 of his application for U.S. Patent No. 4,330,891, the claims of which cover a micro-pitted titanium implant with a threaded surface and an apical vent. The Swede-Vent Implant from Core-Vent Corporation matches the "standardized" Brånemark implant in design, material and dimensions and **now provides the patented micro-pitted surface that Brånemark's Patent No. 4,330,891 states will give "inextricable anchoring in the living bone tissue."** Core-Vent's implant surfaces from 1986-1991 were acid etched with HFl acid, creating a "METALLURGICALLY IMPROVED" micro pitted surface compared to the Branemark implant's machined surface (see **Taussig Metallurgical Engineers Report #74305-1/August 27, 1987 funded by Nobel**)

Nobel'a Letter Claimed: "the decision to license Core-Vent does not in anyway represent an endorsement of Core-Vent's products."

Core-Vent's Response: Core-Vent neither wants nor needs Nobelpharma's endorsement. The only endorsement Core-Vent believes is important is from the world dental community.

February 20, 1989, - Unhappy with Core-Vent's response above, Nobel sent out a second post-settlement Disclaimer Letter falsely stating "the Swede-Vent's surface may be both sandblasted and acid etched." **Core-Vent responded in great detail citing an independent Metallurgical Study done by Taussig Metallurgical Engineers** in the presence of a Nobel representative, examining the contamination left on the surface of a Branemark Machined implant. This study, funded by Nobelpharma, found that machined titanium surfaces **"are not metallurgically satisfactory and can detract from the suitability of the implants for service."** The report by Taussig Metallurgical Engineers strongly recommended Nobelpharma to wash their implants in acid

NOBELPHARMA STUDY CONFIRMS ADVANTAGES OF ACID ETCHING SURFACE

Taussig Metallurgical Engineers Report #74305-1/August 27, 1987 examined Nobelpharma implants that "had been packaged in sealed glass containers" with "a representative of the Brånemark Company being present." Examination using "scanning electron microscope and Energy Dispersion X-ray Analysis of two samples representing titanium dental implants" revealed the following:

It appeared that the grinding of the surface of the implant produced a number of titanium particles that were partially dislodged, and/or folded over onto the surface of the implants.

- Energy Dispersion X-ray Analysis of this dark appearing particle revealed that the primary element was lead. In addition, there was a significant amount of tin. Other elements present were silicon, aluminum, magnesium and iron.
- This particle is primarily a piece of silicon and magnesium oxide.
- This particle is primarily iron.

THE NOBELPHARMA SURFACE ANALYSIS REPORT CONCLUDED:

"Brånemark implants exhibited evidence of nonmetallic particles on the surface of the implants while the implants had been sealed in glass containers. Even though the implants have been rendered biologically sterile, the contamination of the metal surface by metallic particles had resulted in the implants being not sterile from a metallurgical point of view. It is our opinion that the metallic particles and nonmetallic particles that we observed on the Brånemark implant surfaces, as well as the numerous areas where the apparently ground surfaces have been folded over, are not metallurgically satisfactory and can detract from the suitability of the implants for service. The titanium surface can be and should be passivated (acid washed) similar to that process performed on stainless steel to eat out any metallic particles and to help reinforce the passive oxide film on the surface of the titanium. The dentist, periodontist or oral surgeon has every right to expect that the surfaces of the implants that they are inserting are clean and free from any particles that could possibly adversely affect the serviceability of that implant."

1990 - Response to Malmqvist JP and Sennerby L: Clinical report on the success of 47 consectuively placed Core-Vent® Implants followed from 3 months to 4 years. Int J Oral Maxillofac Implant 1990;5(3):53-60.

Lars Sennerby

Dept Oral & Maxillofacial Surgery, Inst Odontology, , University of Gothenburg, Sweden

dental implants bone healing bone augmentation

Why was Sennerby, a paid Nobel Consultant, sent from Sweden to Portland to evaluate charts of patients who had received 47 Core-Vent implants (43 documented with 4 lost to follow-up). The authors admit to not using standardized radiographic techniques: Panoramic and sometimes periapical radiographs were available.

Based of the same set of criteria used to evaluate the Brånemark implant (i.e., osseointegration), the results with Core-Vent implants placed in the lower jaw **is 88% success - 33 implants with 4 being removed**. By misapplying Albrektsson's criteria for success the mandibular success rate was artificially reduced by 15.6%.

Albrektsson's proposed criteria specifically requires that bone loss due to surgical trauma and bone loss due to remodeling under function not be included in the measurement. Only the amount of annual bone loss "following the implant's first year of service" is to be measured. Malmqvist and Sennerby did not have adequate radiographs to evaluate how much of the change in height from the top of the implant to the level of crestal bone had occurred during the submerged period and in the one year following prosthesis attachment, so they arbitrarily allowed 2 mm. Not only is this speculative, it does not even take into consideration the fact that the Core-Vent surgical protocol called for the implant to be placed 1 mm above the crest, as can be seen from the radiographs in Figures 1, 2 and 4 of the article.

The authors blame the design of the Core-Vent implant for the bone loss without considering that the most obvious cause was the surgeon's selection of too wide an implant for the ridge. The authors do not consider that the failures were due to anything other than the "inexact surgical technique" which they claim to be "unavoidable...when inserting the Core-Vent implant." This anecdotal report of 43 implants represents the learning curve of one oral surgeon with his first attempt at osseointegrated implants, and must be put in perspective by comparing it with the 5-year report of 1,605 Core-Vent implants with overall success of 96% by Drs. Patrick, Lubar, Zosky and Buchs (Oral Implantology Vol XV, No 2, 1989). The Malmqvist-Sennerby article does acknowledge having reviewed the Patrick et al. abstract, but attempts to negate its significance by falsely stating: "no success criteria or follow-up routines have been reported." The Patrick et al. abstract clearly states how the patients were followed up: "During the study, 81 implants were lost to follow-up. The remaining implants and prostheses were recalled annually **for clinical and radiographic examinations to check for osseointegration, gingival health and bone loss.**" The Patrick et al. abstract unmistakably states what criteria of success were followed: "implants that had failed to achieve osseointegration [or lost osseointegration] were removed and the successful implants were placed in function."

Response to Albrektsson T and Sennerby L: Direct bone anchorage and experimental considerations of the concept of osseointegration. International Journal of Prosthodontics 1990; Vol. 3, No. 1.

LETTER TO THE EDITOR: International Journal of Prosthodontics 1990, Vol. 3, No. 6, Pages 583-584
The authors reach a number of conclusions in this article that are not supported by the published articles they reference or a number of articles they conveniently fail to reference.

Osseointegration or Bone Loss as Criteria of Success: Albrektsson, in an earlier article (JOMI, Vol. 1, No 1, 1986), stated what is clearly the legacy of the Brånemark research: "The Brånemark results...clearly underscore the basic concept of osseointegration as being the major, if not the exclusive reason for a successful long-term dental implant attachment."

- **Albrektsson and Sennerby then attempt to negate the clinical significance of this fact by applying a set of criteria proposed by Albrektsson, Zarb, et al. (JOMI 1986;1:11-25) that included: "That vertical bone loss be less than 0.2 mm annually following the implant's first year of service."**
- **Based on this parameter, the authors conclude: "For osseointegrated implants, it seems clear that the Brånemark fixtures meet the success criteria...Core-Vent Implants do not meet these criteria for success, and it is uncertain if the IMZ and the Calcitek hydroxyapatite-coated implants will pass..."**
- **A review of the literature clearly demonstrates that the Brånemark Implant success rates were based on fixture stability and fixture survival, not bone loss.**
- **Selective use of References. - Albrektsson and Sennerby state: "To date, the present authors are unaware of any scientifically controlled studies supporting the verbal claims of excellent success rates of the Core-Vent and IMZ, two frequently used osseointegrated oral implant systems."**
- **They failed to reference an article by Kirsh and Ackerman (Dent Clin North Am, October, 1989) on a 10-year follow-up of 2,284 titanium plasma-sprayed IMZ implants, which Albrektsson was certainly aware of, as he had referenced it in a previous article. Furthermore, in criticism of Core Vent implants, the authors relied on an unpublished abstract of Moy with 100 Core-Vent implants that demonstrated 84% to 87% success rates (Maxilla-Mandible). Albrektsson and Sennerby reference Moy's projected failure rates to predict a final success rates of 58% to 68%. This projected success rate was based on subjective criteria created by Moy and were never confirmed as becoming actual success rates in any subsequent published article. Albrektsson and Sennerby incorrectly referred to these unsubstantiated, projected rates as the "actual success rate." Furthermore, they failed to mention three other abstracts presented at the same meeting as Moy's presentation that reported very favorable Core-Vent results: Lubar with 100 consecutively placed Core Vent Implants, all over 4 years, reported 95% success; Zosky with 200 Core-Vent's reported 93% success (96% in the Maxilla alone); English, who conducted a survey of 672 Core-Vent users, reported a success rate of 93% with 15,150 Core-Vent implants.**

Response to De Bruyn H, Collaert B, Linden U, Johansson C, Albrektsson T: Clinical outcome of Screw Vent implant. Clin Oral Impl Res 1999;10:139-148. July 29, 1999

This False and Misleading Clinical Study by DeBruyn and Albrektsson compares the Branemark to the Screw-Vent Implant by applying a different and arbitrary criteria of success to the Screw-Vent Implant.

INACCURATE REFERENCE #1: De Bruyn 1999 Article States:

"The short-term clinical survival of Screw-Vent implants (Core-Vent company Encino, USA) was first reported by De Bruyn et al. (1992). They reported 1-year failures of 11% in the maxilla with Screw-Vent versus 6% with Branemark fixtures."

FACT: De Bruyn 1992 Article States:

The characterization of the difference in maxillary success rates of the 1-year data from the De Bruyn 1992 article is misleading by not including the information that 37 of 62 (60%) Screw-Vent implants placed in the maxilla were of the 7-10mm length (7mm = 6; 10mm = 31) in contrast to only 13 of 56 (23%) Branemark implants (7mm = 0; 10mm = 13).

The De Bruyn 1992 study acknowledged more short implants as the cause of higher failures:

"We believe that the failure rate is more influenced by the implant length." - the majority of all Screw-Vent implants in the upper jaw are 10mm or less...it is tempting to conclude that the large proportion of short Screw-Vent implants versus the large number of long Branemark fixtures highly influenced the absolute failure rates of the present study."

November 1989: Regulation of the Implant Industry and Misinformation from Nobelpharma

In a calculated effort to promote its own products by casting aspersions on Core-Vent Corporation, its most successful competitor, Nobelpharma USA has been circulating copies of an FDA Regulatory Letter received by Core-Vent Corporation in November, 1989. The background to this incident is clearly explained in the attached excerpts from a medical device trade publication (Devices & Diagnostics Letter, November 17 and 24, 1990). Although Nobelpharma understandably chooses not to mention it, the substantive issues raised by FDA have all been addressed by Core-Vent Corporation. Furthermore, other than awaiting approval of the requested 510 (k) applications, we have been advised by the FDA that its files on this matter have been formally closed. The simple fact is that Core-Vent has never been subject of FDA regulatory enforcement action. Nobelpharma's recent effort to "smear" the reputation of Core Vent products demands a factual response.

Once again, Core-Vent Corporation finds it necessary to set the record straight regarding issues that affect the field of Implantology. Despite Nobelpharma's persistent and misleading efforts to cast aspersions on our U.S. made implant products through the distribution of a single FDA Letter, while at the same time conveniently ignoring the problems associated with its own foreign-made implant products, as set forth in this response letter, we believe that American dentists cannot be so easily fooled. We challenge Nobelpharma to compete with us fairly in the marketplace, based on product versatility, quality, customer service and price rather than on who can make the most accusations!

1990 - Response to False and Misleading Advertising by NobelBiocare in the JADA and the JPD

Nobel's advertisements ask the legitimate question, "Which Implant System Gives You and Your Patients the Most Security?" It then lists a number of marketing statements, referring to them as "FACTS," claiming that with the Branemark System, "The Weight of Evidence is On Your Side!" This report will analyze a number of research studies, including the publication of the 20-year results with Brånemark implants at the University of Gothenburg (Adell[2], JOMI, Vol. 5, No. 4, 1990). **It is time the profession took a hard look at the research rather than rely on Nobelpharma's slick marketing images and carefully worded implications. If a company has a tendency to exaggerate some facts, its future claims should be closely scrutinized.**

EXAMPLE: Nobelpharma falsely claimed that the Brånemark fixture is "the only implant system that uses osseointegration as a method of achieving a dental prosthesis permanently to the jawbone itself." This statement appeared in a 1988 Nobelpharma brochure and was so blatantly untrue that Nobelpharma retracted it in a letter to hundreds of dentists in this country. This brochure is still in circulation in Japanese and Spanish language versions without correction.

February 1992: FDA Bans Importation of Nobelpharma Implants

Following Nobel's efforts to disparage Core-Vent by referencing its FDA inspection Report (see above), the FDA held Nobel accountable for its "serious violations in Good Manufacturing Practices."

"The FDA, in its February 21, 1992, Warning Letter to Nobelpharma AB Sweden, ruled that, due to serious violations in Good Manufacturing Practices (GMP), Nobelpharma's endosseous implants shall be banned from importation into the United States. The FDA Warning Letter states that this ban will remain in effect until Nobelpharma provides an adequate written response to the charges and the FDA has an opportunity to conduct another inspection of the Swedish facilities to verify the implementation of the corrections. Due to Nobelpharma USA's lack of candor with its customers, the full text of the FDA Warning Letter is being sent to you. Nobelpharma's response letter to its customers failed to even mention that it is banned from shipping endosseous implants to the United States for an indeterminate period of time."

> ***"Given the serious nature of these violations of the Act, all endosseous implants manufactured by Nobelpharma AB, Bohusgatan 15, Gothenburg, Sweden, and Nobelpharma Produktion AB, Dimbovagen 2, Karlskoga, Sweden, will be refused entry into the United States until these violations are corrected. Until these violations are corrected, Federal agencies will be informed that the FDA***

Albrektsson's recurring theme is that Commercially Pure Titanium (CPTi) is more biologically acceptable compared to the medical grade Titanium Alloy (Ti6Al4V ELI) used by Core-Vent and the orthopedic industry. The Branemark implant originally was made of Grade1or 2 CPTi but over the years moved to the stronger Grade4 which is still 40% weaker than Titanium Alloy. It is therefore more prone to fracture and to having the internal or external wrench-engaging surfaces deform during insertion. Nobel fully understood that the use of CP Titanium increases the risks of implant fractures because Adell, in his 20 year report on the Branemark implant documented that after 15 years, 16% of the maxillary implants and 4% of the mandibular implants had fractured.

Nobel's use of Commercially Pure Titanium for its implants rather than Ti6Al4V Eli Medical Grade titanium alloy, which is at least 40% stronger than Grade4 CPTi, was determined by 2 marketing factors:

1. **Nobel's unique selling proposition when it launched the sale of the Branemark implant in the U.S. in 1982 was that only Nobel could cite to studies of an implant with 15 years of clinical documentation, irrespective of what that research showed. Nobel fully understood that the use of CP Titanium increases the risks of implant fractures. Fractured Branemark implants, reported on in Adell's 1981 publication of the 15 year results, documented a number of fractures which were still being counted as successes if the fixation screw could engage the fractured apical part of the implant. In 1990, Adell published the 20 year followup of Branemark implants reporting that after 15 years, 16% of the maxillary implants and 4% of the mandibular implants had fractured.**
2. **Around 2000, Nobel finally acknowledged that the failure rates in soft bone with machined surface implants could be reduced by using a textured surface. Instead of switching to an AO2 or SBM blasted surface like most of its competitors, Nobel copied the anodized surface of a German Company, called Ticer, and called the rough, porous surface "TiUnite". This further committed Nobel to using CP Ti titanium because TiUnite, created by an Anodic Spark Deposition process, will not form on Ti. Alloy.**

7 OUT OF 10 BRANEMARK IMPLANTS FRACTURE IN ONE PATIENT RESULTS IN LITIGATION
From 1989-1994, Dr. Dennis Tarnow placed 10 Branemark implants in a female patent. Dr. Tarnow was head of a post-graduate program in implants at NYU at the time and has a double specialty in both periodontics and prosthodontics. Nobel was sued after 7 out of 10 Branemark implants fractured in Dr. Tarnow's patient.
Around 2000, Nobel added a porous surface (TiUnite) which is an anodized surface developed by the German Company, Ticer, in process called Anodic Spark Deposition developed for CP titanium implants, Since Nobel's marketing relies on research articles documented over the last 20 years with the TiUnite to the top of its implant and this anodizing process will not produce the same surface texture when applied to Ti Alloy, Nobel is firmly committed to continue using CP Titanium.

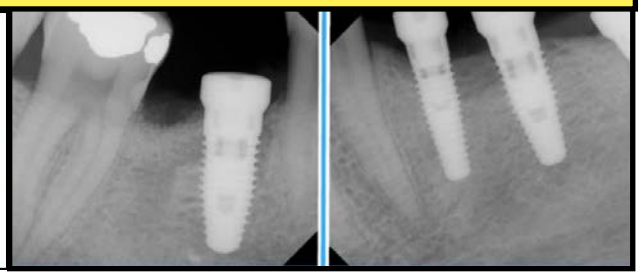
Nobel's introduction of its new selective surface treatment, called TiUltra, was an acknowledgement that the porous TiUnite surface should have been kept a few mm distance from the top of the implant to avoid risks from exposure to soft tissue. The email below from one of Nobel's customers in 2011 confirms this. Using creative marketing, Nobel anodizes the machined neck gold, claims "mucointegration" & adds $21.

Email to Nobel's Sales Reps RE: "early bone loss" from Replace Implants with TiUnite to Top

Subject: Crestal bone loss
Date: 11/11/2011 5:49 A. A. Pacific Standard Time
From: murray.arlin@utoronto.ca
To: Kishores.Pranjivan@nobelbiocare.com, Kevin.McAuley@nobelbiocare.com, gniznick@aol.com

Hi Guys: Here is unfortunately a "typical example" of what I see too often with the Replace design. Pass these along if you like. I have not made an attempt at a comprehensive analysis but I would estimate that at least 25% of my cases are showing unacceptably high degrees of early bone loss.

Murray Arlin, Periodontics and Implant Dentistry, Toronto
http://www.MurrayArlin.com



NobelBiocare claims competitive advantages of product innovation with the motto "We Follow No One."

- **1998 Nobel bought the U.S Company, Steri-Oss, for $97M and Steri-Oss's RePlace Implant with its internal tri-lobe connection, became Nobel's flagship product line.**
- 2008 Nobel bought the Israeli Company Alpha BioTec for $95M whose implants all use the Internal Conical Connection Patent (Niznick Patent Filed 1987; Issued 1990; Expired October 2007)
- 2008 Nobel modified Alpha Bio's tapered screw implant connection by increasing the lead-in bevel from 45 deg. To 78 deg., which would have still been covered by Niznick's Internal Conical Connection Patent.
- 2021 Nobel introduces the N1 Implant with a "Trioval" neck similar to the triangular neck of the MIS V3 Implant introduced in 2018. Neither offer clinical benefits while reducing initial titanium contact at the neck.
- 2020 Nobel introduces the "TiUltra" selective surface with a smooth anodized neck - **The Selective Surface design with a smooth neck and rougher body was patented by Niznick in 1994.** Nobel should have realized over a decade ago that extending the porous TiUnite surface to the top of the implant was a bad idea.
- 2020 Nobel introduced "Zeal" surface on healing collars and abutments. Anodizing components a gold color is nothing new. What is new is Nobel's unsubstantiated claims that anodizing creates "Mucointegration".

Judging from the 3 obsoleted implants listed below, Nobel has been following the wrong people.

OBSOLETED

2003 - NobelBiocare Launches NobelPerfect implant developed by Dr. Peter Worley. Nobel claimed it "*is the first implant that effectively eliminates the "black triangle" often encountered with conventional implants. … Heliane Canepa, President & CEO of Nobel Biocare, says, "For the first time, a manufacturer has addressed the problem of bone degradation between two implants thereby replicating the natural anatomy. This is actually the first time in many years that this industry has launched a completely new implant design, thereby solving a clinical problem that was impossible to treat before. "*

2014 - Posting on Dental Lab Network - NobelPerfect Obsoleted

"Hello, I am a Prosthodontist trying to restore a Nobel Perfect implant. These implants have been discontinued and Nobel does not have any abutments left. The only thing they offer is a custom milled abutment for $1200, which quite frankly, I feel is a rip off. Does anyone know where I may be able to get ahold of an existing stock abutment for this implant? Any suggestions appreciated!"

OBSOLETED

2004 - Nobel Biocare introduced the NobelDirect implant line developed by Dr. Dragoo. Three years later, independent research from the Sahlgrenska Academy in Sweden showed that 8% of the implants were lost 3 years after implantation. In January 2008, Nobel issued a safety notice claiming any bone loss was due to incorrect placement of dental screws and updated the instructions it sent to dentists.

2010 - Dr. Jason Yamada filed a class action lawsuit against Nobel and 1000 dentists joined the class. The plaintiffs contend that Nobel's dental implant design is defective and the company's supposedly simpler, 1-step device actually leads to gum loss, bone erosion and total implant failure, according to court documents.

2013 - **The NobelDirect Class Action law suit was settled for $1.3M** with the attorney who filed the lawsuit seeking $4M in legal fees. **The product was taken off the market.**

OBSOLETED

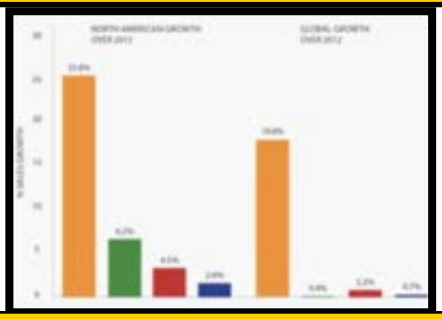
2008-At the same time Nobel introduced the NobelActive, it also introduced the **NobelActive External with a tap-on, Morse Taper connection.**

The "active" concept with these two implants was that the sharp apical end to allow a change of trajectory after the insertion process was initiated. The purpose of using a pilot drill and guide pins is to establish the trajectory of the implant insertion before the osteotomy is enlarged to accept the implant. The last thing you want to be doing is forcing a change in the trajectory during insertion of the implant. The 1.5 degree Morse Taper on the head of the NobelActive External implant necessitated the needed to parallel the external connections of this implants for multi-unit implant restorations, which was why the sharp apical end was included in the design. It became clear very quickly that the tap-on abutment created a ledge or undercut which, when the crown was cemented, would trap the cement subgingivally. As a result, this implant was obsoleted by Nobel within a year of first introducing it.

Factory Tour

Implant Direct ("ID") was founded in 2004 by Gerald Niznick, DMD, MSD (pros.) who remained ID's president through the end of 2013. During that time, he received numerous patents on its products. In December 2010, he sold 75% of ID to Danaher and his remaining 25% in January 2014. Danaher then bought NobelBiocare in December 2014. By 2017 ID's operational management was under Nobel's control. By 2019, ID's products were being shipped out of Nobel's offices in Yorba Linda California. In 2020, ID's successful operations in E.U were shut down. ID's Canadian office in Vancouver was also shut down and all Canadian ID salespeople let go. Implant Direct's success was due in part to its customer service provided by over 50 inside sales and customer support personnel. As of this year, the number of inside sales and customer support people has been reduced to 18 and many of the most experienced outside sales people having been replaced. Since 2016 ID's marketing department has not produced any product brochures explaining the features and benefits of its implant systems. Most, if not all, implant brochures, articles and graphic videos have been removed from ID's website. ID's sales people have been discouraged from approaching Nobel customers, denying those doctors the opportunity of learning about the technical advantages of ID's patented implant designs including RePlant and InterActive that are compatible with NobelReplace and NobelActive at >65%% cost savings with All-in-1 Packaging for added value.

In 2013, the last year Dr. Niznick was president of Implant Direct, it had 26.5% U. S. growth and 18.6% Global Growth compared respectively to NobelBiocare's growth of with 4.3% and 2.3%.



In 2013, Implant Direct's customer satisfaction was rated the highest compared to 7 other companies with NobelBiocare ranking fourth, level with the mean of all 7 companies.

In the video commemorating Nobel's 40th Anniversary, its President claims that in "looking forward to decades to come, [Nobel's] exciting innovations continue to offer the best possible treatment at every step."

After reviewing the information in this document, dentists should dispute Nobel's claim that it offers "the best possible treatment at every step." Many ID customers in the U. S. have stayed loyal to ID's high quality, patented products. Nobel could be promoting these product if it really wanted "to offer the best possible treatment." Instead, it has undermined ID's sales to sell Nobel's more expensive products.