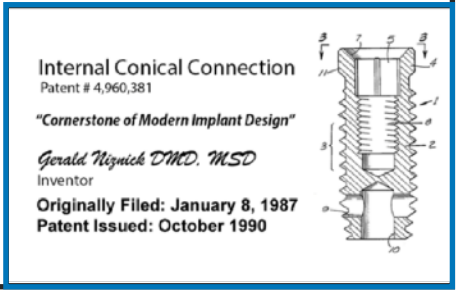
Analysis of the Shortcomings of the Ditron Ultimate Implant

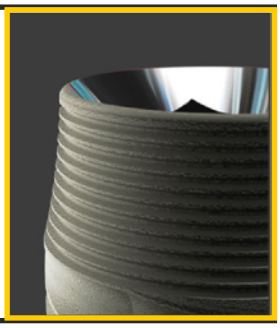
Ditron is a 50 year old Israeli automotive parts company that, for the last 15 years, has also been making dental implants. Its "Ultimate" Implant with a concave, micro-grooved neck, has been on the market for at least 9 years in Europe and Israel before launching in US. Dr. Ole Jensen is listed as the "Founder and Chairman of the Board," of Ditron's US subsidiary which launched in September 2020. The main marketing claim for all Ditron Dental implants and abutments is ***"Welcome to a world of PRECISION,"*** claiming that its manufacturing tolerances ***"reduce micro-gaps to less than 0.5 microns. This reduced micro-gap is too narrow for bacteria to penetrate".*** Dr. Jensen claims this will reduce the risk of peri-implantitis. In fact, the Ditron implant/abutment connection is the same 2.5 mmD platform with a 45 degree lead-in bevel and internal hex first introduced in 1986 on the Screw-Vent for which a US patent was issued to Dr. Gerald Niznick 1990.



CLAIM - MICRO THREAD (All unsubstantiated)

- "Placing micro-threads on the implant neck greatly increases the ability of an implant to resist axial loads, and the mechanical stimulus provided by the micro-threads helps to preserve the peri-implant marginal bone."
- "The Ultimate micro-threads exercise appropriate mechanical stimulation of cortical bone, stimulate the tropism and enhance the speed and quality of osseointegration."

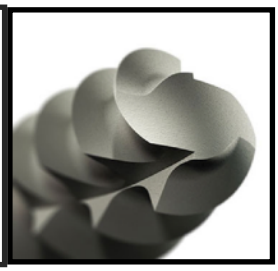
(Problem is the Ultimate, has microgrooves not micro threads)



CLAIM - CUTTING APEX EDGE

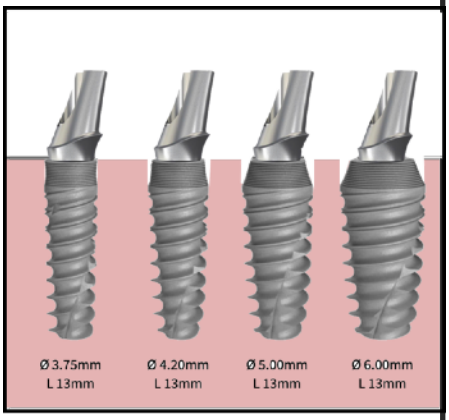
- Provides self drilling and self tapping capacity to the implant
- Offers the possibility of optimizing implant insertion angulation.

Problem is lack of control of implant trajectory and depth since the bottom of the implant is "self drilling". A spade drill is end cutting so it only follows the trajectory established with the pilot drill, and insertion of implants should stop at the depth created by the drill.



The "Ultimate" implant is available in only 4 diameters:

- The narrowest implant is 3.75mmD and Its concave neck further weakens the already thin walls.
- All have the same 3.5mmD internal conical connection, compromising emergence profile on the wider implants.
- As the diameter of the implant increases, the back-taper bevel becomes more pronounced with the 6mmD implant having about a 45 degrees back-taper. Such concavities/back-tapers will leave a gap at the crest of the ridge on insertion requiring bone grafting.
- Dr. Ole Jensen recommends grafting over any exposed metal. An exposed blasted, micro-grooved surface will be a plaque collector that could contribute to peri-implantitis **(so why not start with smooth neck)**



Dr. Ole Jensen, President of Ditron US Gives Bias and Inaccurate Testimonial

Dr. Jensen makes the unsubstantiated claim ***"the Ditron implant, when compared to leading brands, is much more innovative and easier to use."*** The concave, micro-grooved neck adds nothing to initial stability and further thins the walls of the implant increasing the risk of fracture.The concave neck is of no significance in developing an esthetic emergence profile because it is subcrestal. In the two wider diameters, the extreme back-taper leaves a significant gap at the crest of the ridge that will require grafting.

This study compared subcrestal positioning of implants concave neck with placement with the widest part of the implant level with the crest, sealing the opening.

IT CONCLUDED:

"The placement of implants with a hyperbolic convergent profile collar in the subcrestal position resulted in higher buccal bone resorption and more soft tissue recession."

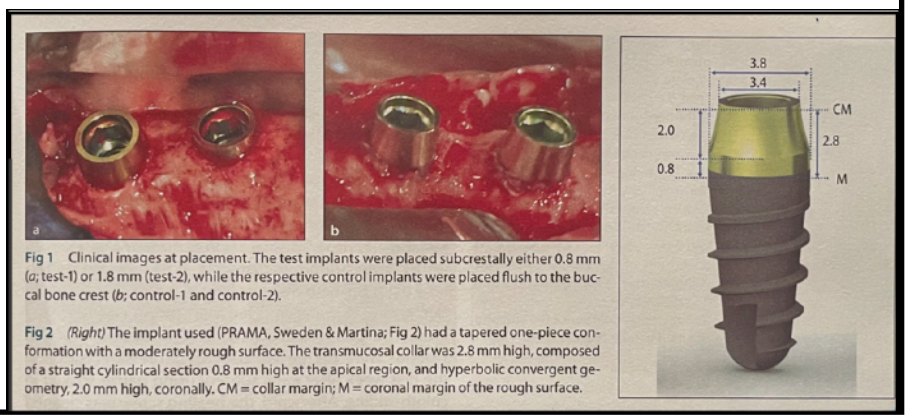


Fig 1 Clinical images at placement. The test implants were placed subcrestally either 0.8 mm (*a*; test-1) or 1.8 mm (test-2), while the respective control implants were placed flush to the buccal bone crest (*b*; control-1 and control-2).

Fig 2 *(Right)* The implant used (PRAMA, Sweden & Martina; Fig 2) had a tapered one-piece conformation with a moderately rough surface. The transmucosal collar was 2.8 mm high, composed of a straight cylindrical section 0.8 mm high at the apical region, and hyperbolic convergent geometry, 2.0 mm high, coronally. CM = collar margin; M = coronal margin of the rough surface.

"Research" does not Support Claim that Micro-gap is too Narrow for Bacteria

DITRON DENTAL
RESEARCH & DEVELOPMENT

Efficacy of a new implant-abutment connection of molecular precision implants to minimize microbial contamination: an in vitro study

DITRON'S STUDY OF BACTERIA GROWTH: The study cited on Ditron's US website to support its claim of zero micro-leakage was conducted by the company, did not include as a control, any other companies' products and was not published in a peer reviewed journal. It consisted of exposing 5 implants, with abutments attached, to a bacteria culture for 48 hours. The results demonstrated bacteria both internally and externally for the first 48 hours with a lower concentration internally. Subsequent to that, the concentration of bacteria internally declined. The investigators thought this was "probably as a consequence of nutrient consumption".

SUMMARY

Purpose: The aim of the present study is to evaluate the effectiveness of Ditron's implant and abutment connection *(IAC)* in sealing the gap between these two parts.

Materials and methods: To identify the efficacy of a new IAC, the passage of genetically modified Escherichia coli across IAC was evaluated. A total of five Ditron implants were used. All implants were immerged in a bacterial culture for forty-eight hours and then the amount of bacteria was measured inside and outside IAC with Real-time PCR. Bacterial quantification was performed by Real-Time Polymerase Chain Reaction using the absolute quantification with the standard curve method.

Results: In all the tested implants, bacteria were found in the inner side with a median percentage of 1.35%. The analysis revealed that, in untreated implants, bacteria grew *(internally and externally)* for the first forty-eight hours, but subsequently, they started to die. Moreover, the difference between outer and inner bacteria concentration was statistically significant at each time point.

Conclusions: Ditron Implant IAC *(MPI, Ditron Dental, Israel)* is effective in reducing bacterial leakage.

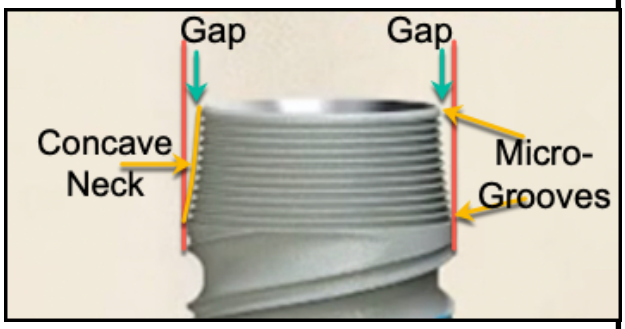
RESULTS

Bacteria quantification is reported in *Table I*. In all the tested implants, bacteria were found in the inner side with a median percentage of 1.35%. The analysis revealed that in both cases *(internally and externally)*, bacteria grew for the first forty-eight hours but, subsequently, they started to die, probably as a consequence of nutrient consumption. Moreover, the difference between outer and inner bacteria concentration was statistically significant at each time point.

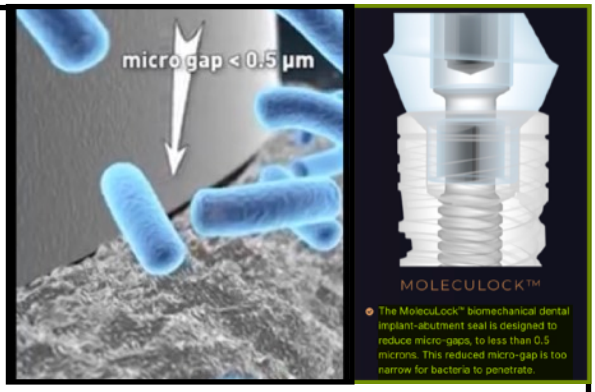
Back-tapering the implant neck weakens the walls and reduces initial stability

Dr. Jensen claims ***"the Ditron implant, when compared to leading brands, is much more innovative and easier to use ."***

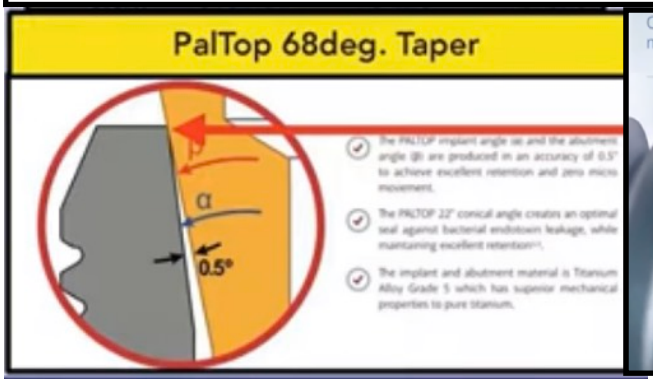
INNOVATION: Dr. Jensen narrated a YouTube post entitled "Lord of the Rings," making the argument that back-tapering the top of the "Ultimate" implant is necessary and beneficial for preserving crestal bone. He makes the valid argument that thinning of the labial plate in narrow ridges will lead to bone resorption and loss of soft tissue support. This argument overlooks the fact that the undesirable thinning of the labial plate in narrow ridges occurs during the bone preparation procedures to widen the socket to accept Ditron's 3.75mmD implant. With a back-tapered neck, the final sizing drill in Type 1 & 2 bone is 3.2mmD. whereas the use of a 3.2mmD Implant would only require the use of a 2.8mmD final sizing drill, thus preserving the labial plate of bone.

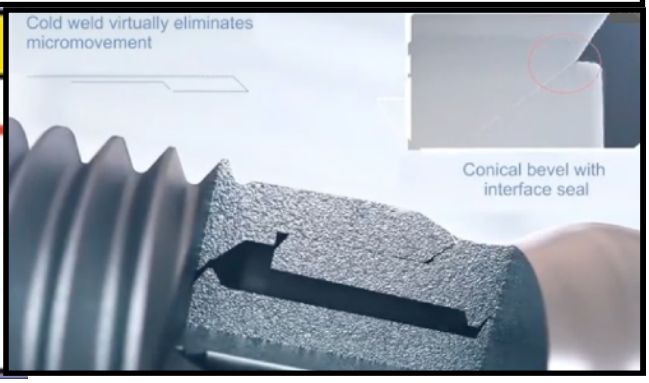


Ditron's claim of precision manufacturing to 0.5 microns is physically impossible. 1 Micron is 0.00004 inches which is about 10X smaller than the tolerances of any CNC screw machines. The optimum seal with an internal conical connection (Niznick Patent 1990) is created by making the abutment's bevel 1/2 degree greater, as measured from the vertical axis, than the lead-in bevel of the implant so that the first point of contact is at the opening of the internal shaft.



The stability of the internal conical connection was enhanced with Friction-Fit connection patented by Dr. Niznick in 1994. The tapered Screw-Vent, developed in 1999, is generally recognized as the "Third Generation" osseointegrated Implant System, popularizing innovative thread design, tapered body and Selective Surface Technology. These patents along with the implant company were purchased by what today is ZimVie who recently celebrated the 20th anniversay of selling the Tapered Screw-Vent and its Friction Fit Abutments





Differentiating Marketing Rhetoric from Clinically Significant Innovations

Dr. Ole Jensen's interviewed on Dentistry IQ

He makes a number of false and misleading statements to promote the sale of Ditron's dental implants, for which Dr. Jensen has secured the US distribution rights. Ditron was an automotive manufacturing company for the last 50 years that started to make dental implant products in the last 15 years.

1. **Dr. Jensen:** "there is a tremendous problem and the problem is peri-implantitis…and that is the major reason I am involved with this new company." **Moderator:** "How does your company address this problem"

2. "What Ditron does it that they make the most accurately well fitting dental implant ***[Dr. Jensen does not cite any comparison study to support this claim).*** *Ditron claims precision of 0.5-1 micron (1 micron = 0.00005") between implant and abutment. This is 10X-20X closer tolerances achievable with CNC machines used to make implant.*

3. **Dr. Jensen:** *"There are three generations of implants generally. The first generation was Branemark's orthopedic implant with a hex head and a relatively machined surface…and a parallel wall. The second generation is kind of what we are in now (starting with the internal conical connection Screw-Vent Implant in 1986). Our Ditron implant is a third generation implant. I would consider for example, NobelActive and Straumann implants as second generation implants. So the implant that we have is a little more modernized than them with different kind of surface characteristics and different kind of mechanics and design architecture. So we call this the Third Generation Implant. Our goal is to go to the Fourth Generation Implant which we think we can do in a couple of years. Presently this implant looks a lot like the NobelActive implant …and the surfaces are kind of an SLA type, sort of like a Straumann type Surface." (the Third Generation implant was the Tapered Screw-Vent 1999)*

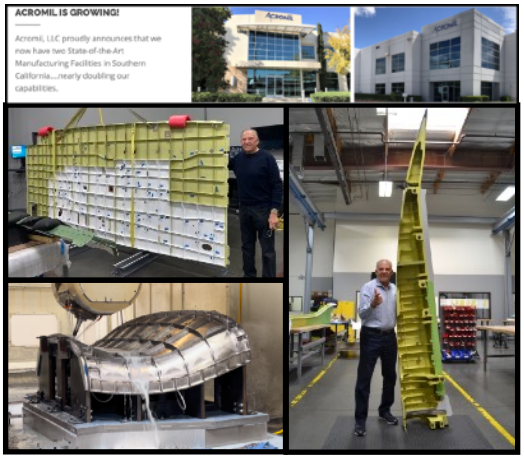
4. *"What we decided to do is to create a value product that has higher quality than all the premium products out there. (claim without substantiation). Our implants are about $150, not a $300 implant." (US List price of Ditron Implants is $230 as of June 1, 2023)*

5. *Dr. Jensen failed to mention that the Ditron Implants, as shown in this picture, from the Zoom interview, uses the same internal hex/bevel connection developed for the Screw-Vent implant in 1986. That was the true "second generation" implant and its conical connection is the cornerstone of all modern dental implants.*

In Dr. Jensen's Dental IQ interview he explains why he is now getting involved with the commercial side of dental implants. He states "dental implant innovations don't come from our offices ….They come from commercial implant companies ….So we wanted to create a cutting edge, very progressive company that is doctor driven….Who better to know what is needed than doctor creators." This statement would be true if the "doctor creators" had acquired manufacturing, design and engineering experience gained over years in the implant industry. This is not the case for Dr. Jensen or his board of dentist advisors. After 3 years of distributing Ditron's implants in the US, the only change Dr. Jenson has made to the 12 year old Israeli designed implant is to raise the price from $169 to $230. By contrast, Dr. Niznick launched Core-Vent Corporation in 1982 after a decade of placing a variety of implants. What followed was 40 years of manufacturing, design and engineering experiences with 33 US Patents related to dental implants and 4 more pending. He built two companies that were sold to major implant companies still selling his products. The flagship product of ZimVie is still the Tapered Screw-Vent acquired with the Core-Vent purchase December 2000. Envista/NobelBiocare is selling Implant Direct's product line acquired 75% in December 2010 and 25% in January 2014.

Dr. Jensen further states that he "was looking for a company worldwide that made the most precision parts and we found one and it was Ditron automotive, aerospace and also dental implants." Manufacturing tolerances in the aerospace industry are something that Dr. Niznick is very familiar with as he has owned Acromil Aerospace since 2003. Its two factories total about 200,000sq. ft., and make parts for many of the prime aerospace companies including Boeing, Lockheed, Spirit and AirBus. According to the VP of Manufacturing at Acromil, tolerances of 0.0005" (12 microns) are required on some bore holes but structural parts that can be 20 feet long usually only require tolerances of 0.003" to 0.010".

If Dr. Jensen thinks having aerospace manufacturing experience is an asset to manufacturing dental implants, then that would apply far more to Dr. Niznick's Paragon Implant Company than to Ditron in Israel. Acromil makes very complex structural parts for variety of airplanes including Lockheed's F 16 and F 35 and Boeing's 737, 787 and 777X airplanes. Paragon's dental implant manufacturing facility in Calabasas was built by Dr. Niznick in 1994 and was leased to Zimmer Dental and Sybron after these companies bought Core-Vent in 2001 and Implant Direct in 2010. Here is a video of this state-of-the-art manufacturing facility in 2007.



GEN5™

PARAGON
IMPLANT COMPANY

40 YEARS OF INNOVATION

NIZPLANT™

* Includes Overdenture Attachment Components

40 YEARS OF INNOVATION

37 PATENTS - 4 SPECIFIC TO GEN5

USE THIS QR CODE TO VIEW THIS DOCUMENT ONLINE AND HAVE ACCESS TO THE LINKS INSIDE

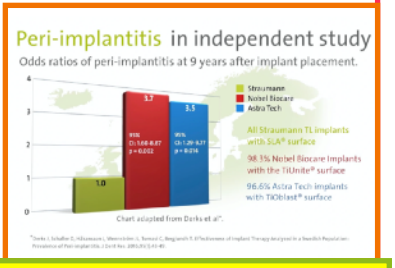
RESEARCH SUPPORTS REDUCTION OF PERI-IMPLANTITIS BY USING A HYBRID DESIGN SURFACE WITH THE IMPLANT-ABUTMENT JUNCTION SUPRA-CRESTAL
Applies to Straumann's TLX implant and Paragon's GEN5 implant BUT not the BLX

Dr. Niznick Article: AO News Vol.33 No. 2, 2022:

"Dr. Buser cites a Swedish 10-year study comparing three implants: Astra, NobelBiocare and Straumann's Tissue Level implant, claiming the latter exhibited significantly less peri-implantitis. Assuming part of the smooth neck of the Straumann TL implant was inserted in bone, this would give it a hybrid bone interface. It also adds the variable that the implant-abutment connection would be supra-crestal… [which] is at least as important a factor in minimizing peri-implantitis as a hybrid surface."

Dr. Michael Dard, Prof. NYU Interview:

1. Explains peri-implantitis and
2. Discusses results of the Derks et al study

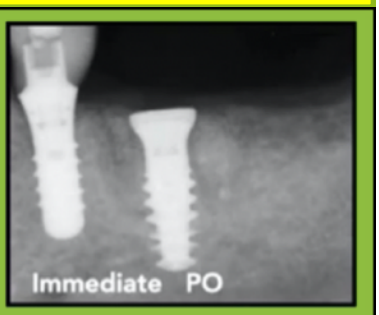


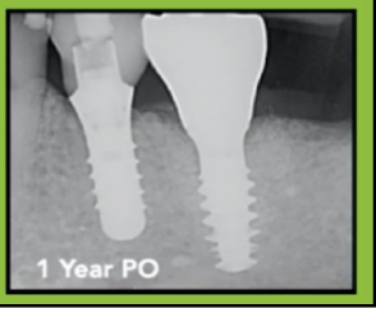
Video Lecture and interview of Dr. Daniel Buser, explaining importance of Hybrid Surface and how he partially submerges smooth neck of "Tissue Level" Implants

Dr. Daniel Buser explains insertion of Straumann's "Tissue Level" implant with 1.8mm of its 2.8mm smooth neck sub-crestal, leaving 1mm and the implant-abutment junction, supra-crestal.

Buser Quote on Straumann's Website:
"The Future of Implant Dentistry is with neck designs combining a smooth surface in the trans-mucosal area with a micro-rough surface inside the bone. As the Derks study showed, moving the micro-gap away from the bone and having a smooth surface in the peri-implant sulcus reduces the risk of peri-implant complications." Derks 9 Year Comparative Study

PARAGON'S GEN5 IMPLANT HAS A 2.5mm ANODIZED, SMOOTH NECK, CONFIGERED TO BE 1mm SUPRA-CRESTAL





Influence of Implant Placement Depth and Soft tissue Thickness on Crestal bone Stability Around Implant with and Without Platform Switching

This case control study measured early crestal bone changes around sub-crestal placed platform-switched implants surrounded by thin soft tissue and compared them with regular, matching-platform implants placed in a supra-crestal position and surrounded by thick soft tissue. After 1 year, mean bone loss was 0.28 mm (SD:0.36 mm; range: 0.1-1.63 mm) in the control group and -0.6 mm (SD:0.55 mm; range: 0.05-1.8 mm) in the test group. Platform-switched implants placed in a subcrestal position in vertically thin soft tissues showed statistically significantly more bone loss than non-platform-switched implants placed supra-crestal with vertically thick tissues.

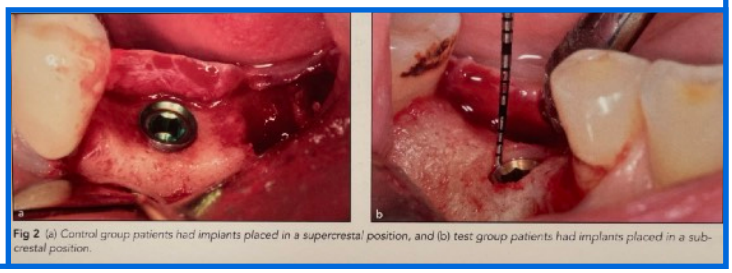
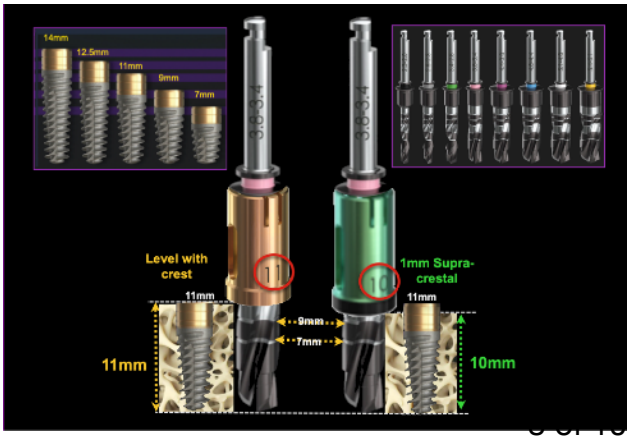
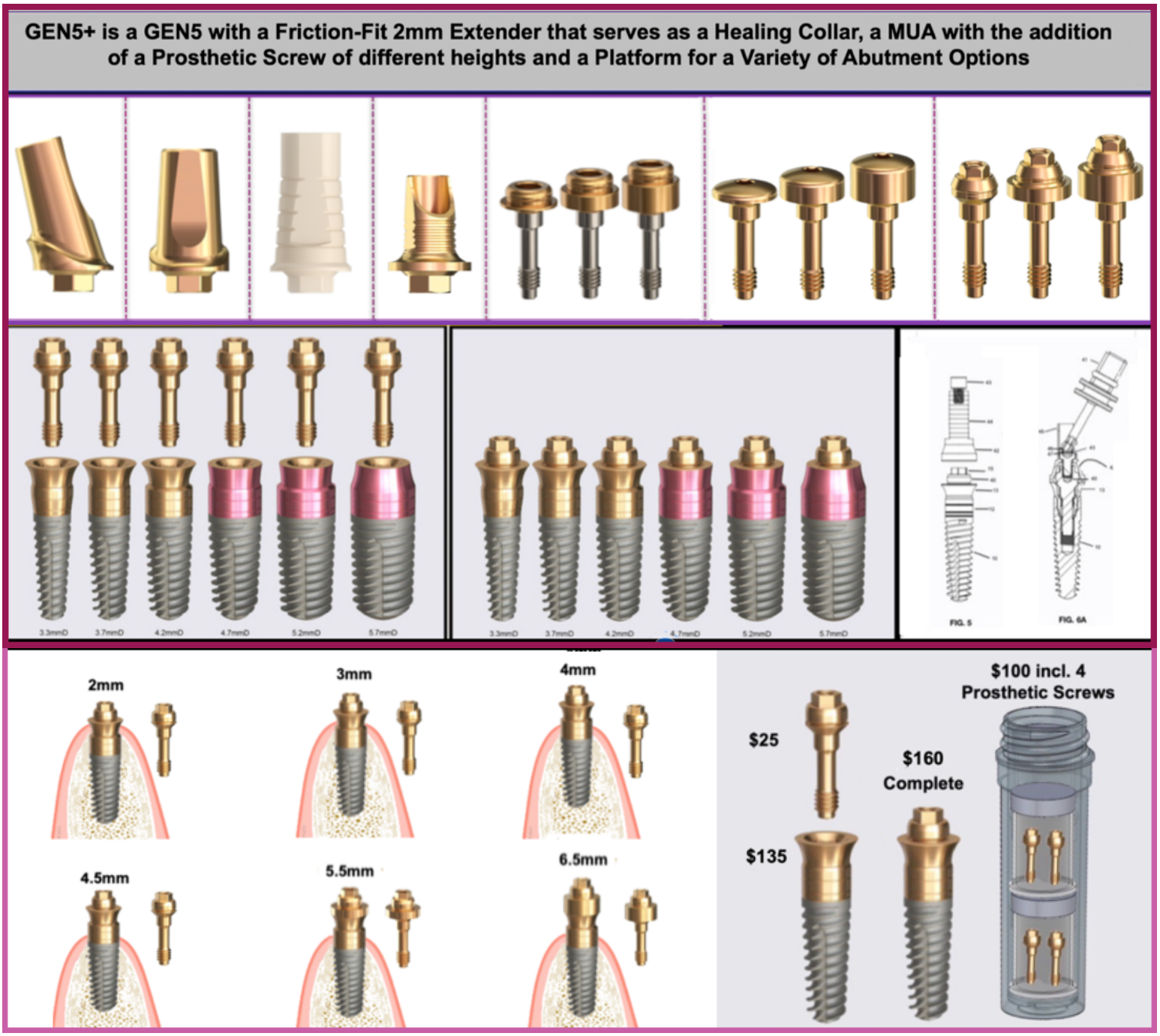


Fig 2 (a) Control group patients had implants placed in a supercrestal position, and (b) test group patients had implants placed in a sub-crestal position.

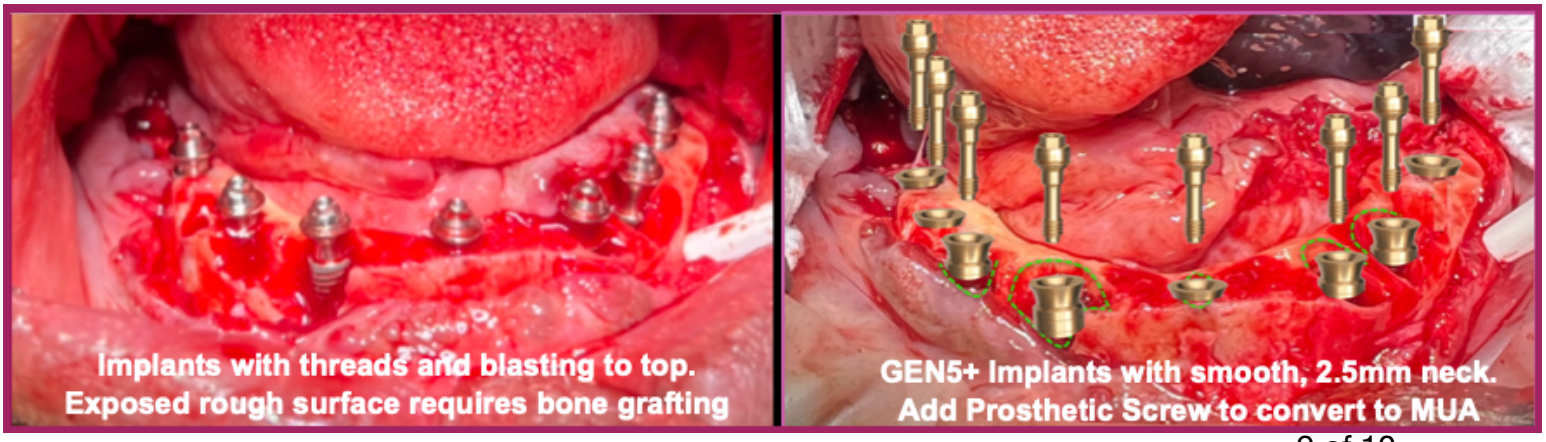
Paragon's GEN5™ , GEN5+ and NizPlant™ implants have the same implant body with a 2.5 mm machined, anodized neck. Depth gauge lines at 1 mm, 2 mm and 2.5 mm from the top (Pat. Pend.), along with 2 depths of drill stops, facilitate placement level with or 1mm above the crest of the ridge. The insertion depth control, in conjunction with the ability to varying the height of the prosthetic screw, minimizes the need and cost of maintaining an inventory of abutment heights. The GEN5+ offers the additional flexibility of a 2 mm friction-fit collar that can serve as the trans-mucosal collar of an abutment or be removed for abutment connection directly to the top of the implant for unprecedented vertical flexibility.

Each Paragon implant is 1 mm longer than the standard lengths of the respective Screw-Vent and Legacy implants. Paragon's surgical system includes two options of drill stops. One is for placement 1mm supra-crestal, which moves the implant-abutment junction away from the bone and and creates a 1mm supra-crestal zone of titanium for undisturbed soft tissue attachment when prosthetic components are attached and removed from the implant. The other drill stop positions the implant level with the highest point on the the ridge, usually on the lingual, leaving the smooth neck exposed if there is bone recession on the labial/buccal. The diameters of the drill stops and the freedom of rotation of the drills within the drill stops allow there use through surgical guide without the need for keys.





Simulated case (right) shows 8 GEN5+ implants replacing exposed implants (left). Little or no bone grafting needed because only smooth surfaces exposed. Attaching a Prosthetic Screw converts platform to standard MUA.

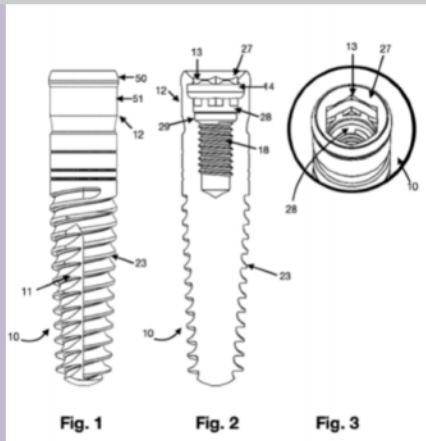


Patented Features of the 1-Piece NizPlant Implant with its Dual-Function Platform

NIZPLANT 1-PIECE IMPLANT WITH DUAL FUNCTION PLATFORM FUNCTION AS OVERDENTURE AND MULTI-UNIT ABUTMENT

NizPlant 1-Piece Locator Compatible Implant with Internal Threads

ABSTRACT:
A screw-type endosseous dental implant includes, near the top on the implant's external surface, a ridge projecting laterally, and an internally-threaded shaft with a lead-in, beveled opening, an internal wrench-engaging surface located below said lead-in, beveled opening, and, below said internal wrench-engaging surface and above said internal threads, an internal under-cut/groove forming a chamber configured to receive a snap attachment for retention of an over-denture.



NizLoc Attachments Engage both outside and inside of the NizPlant implant. The male projection can be removed to reduce the degree of retention.