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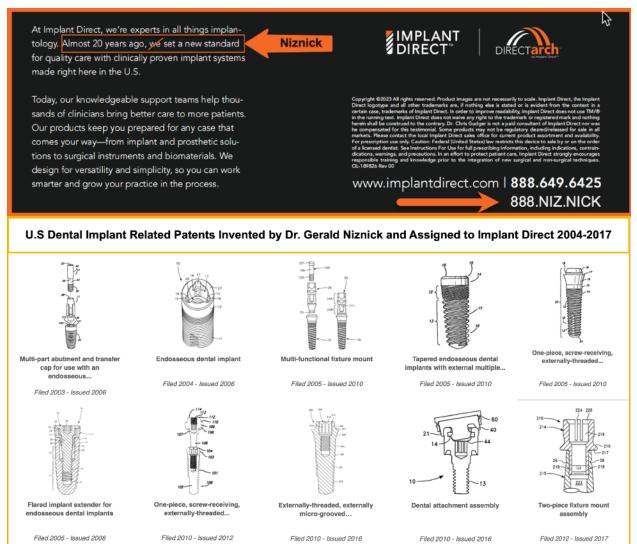
THE EVOLUTION OF IMPLANT DIRECT'S "ICONICtm" IMPLANT SYSTEM Gerald Niznick DMD, MSD, a prosthodontist, started his career as an implant manufacturer in 1982 with the launch of Core-Vent Implant System. In 1986, Core-Vent introduced the Screw-Vent implant with an internal hex and 45deg. lead-in bevel, the first conical connection (Niznick U.S. Pat. #4,960,381). In 1999, Dr. Niznick's company, then called Paragon, launched the Tapered Screw-Vent (TSV) with the same conical connection. This implant became the cornerstone for most modern day implant designs. In 2001, Dr. Niznick sold his company and patents to what became Zimmer Dental and eventually ZimVie. Through 2022, the TSV was ZimVie's flagship product. In 2004 Dr. Niznick formed Implant Direct ("ID") and in 2007, shortly following the expiration of the conical connection patent in October 2007, ID launched the Legacy implant with the TSV's 45deg. lead-in bevel and NobelBiocare introduced the NobelActive with its 78deg. conical connection. The 45deg. lead-in bevel internal hex connection has been copied by so many companies that it is often called the "Standard" connection. The first version of the Legacy implant differed from the TSV in that it included microthreads on the neck (Niznick U.S. Patent #7,677,891). Legacy 2, 3 and 4 were added with progressively deeper threads and with different packaging options. The Legacy 4 is supplied on a carrier that also serves as a transfer and straight abutment (Niznick Pat. 9,697, 748). To offer a cost effective, prosthetically compatible alternative to the NobelActive, Dr. Niznick developed the InterActive with a NobelActive compatible 78deg. conical connection and launched it in 2013. The InterActive has the body of the Legacy 2 & 4 implants with micro-grooves added above the microthreads (Niznick U.S. Patent #7,677,891). Dr. Niznick sold 75% of Implant Direct to Sybron, a division of Danaher, at the end of 2010 and remained president through 2013 when Sybron bought his remaining 25%. Danaher acquired NobelBiocare the end of 2014. Danaher spun off all its dental divisions around 2020 under the name Envista, and today, Implant Direct is operated as a division of NobelBiocare, sharing management, shipping facilities, sales meetings and symposiums. A decade after Dr. Niznick retired as president, Implant Direct launched what it calls the "Iconic"TM Implant with the NobelActive 78 degree lead-in bevel, claiming that connection is now the "industry standard." Rather than "Iconic," this implant could be called the "Ironic" implant. The mismatch between the Legacy implant diameters ranging from 3.2mmD to 5.7mmD and NobelActive 3.0mmD and 3.4mmD conical connections creates limitations in strength with its smaller diameter implants and compromises in emergence profile with its larger diameter implants. Implant Direct's US list price for the Iconic implant is \$220 including a cover-screw and healing collar in contrast to the NobelActive at \$538 plus \$66 for Cover Screw and \$76 for a Healing Collar (\$538 + \$66 + \$76 = \$680 - \$220 = \$460, a 68% savings). NobelBiocare customers should ask the question posted on Implant Direct's Website: **"WHY ARE YOU STILL OVERPAYING FOR IMPLANTS?"**



There is nothing simple or iconic about the Simply Iconic Implant from Implant Direct:

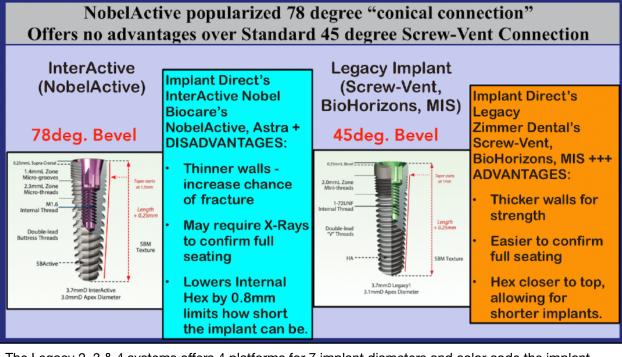
- CLAIM: "designed for optimal primary stability and aesthetics." FACT: Implant Direct acknowledges that the body of the Iconic implant is the same as the Legacy2 & 4 implants so they offer no unique advantage for primary stability vs Legacy.
- CLAIM: "designed for.... aesthetics"
 FACT: Iconic combines the Legacy body with the InterActive/NobelActive connection offers no unique advantage for
 aesthetics over the Legacy, InterActive or NobelActive implants.
- CLAIM: "Treat most cases with just one platform."
 FACT: The Implant system includes a 3.0mmD and 3.4mmD platform options. The 4.7mmD implant if offered with both platform options creating a compromised emergence profile for the 4.7mmD, 5.2mmD and 5.7mmD implants with the 3.4mmD platform.
- CLAIM: "4.7/3.4mm with access to wider emergence profiles when needed." FACT: The loonic abutments do come in two diameters but the profile from the implant to the abutment creates a deep undercut regardless of the diameter of the abutment.

To validate its Iconic System, Implant Direct claims "we're experts in all things implantology. Almost 20 years ago we set a new standard for quality care with clinically proven implant systems made right here in the U. S." While this may be true, it has nothing to do with the current product development and engineering team at Implant Direct today. All the "clinically proven implant systems" sold by Implant Direct prior to 2023 were developed by Dr. Gerald Niznick and were covered by 10 patents issued to him, as shown below. Even Implant Direct's Toll Free phone number 888.649.6425 spells out Dr. Niznick's name. Dr. Niznick started Paragon Implant Co. April 2022 in his Calabasas factory that he rented to Zimmer Dental from 2001-2004 and to Implant Direct from 2004-2014. Since Paragon Implant Company about 28 employees left Implant Direct to join Paragon, confident that Dr. Niznick's ability to innovate new products and his commitment to both quality and value, assured the success of his new company.



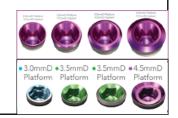
- 24. Filed 2003: 7,014,464 Multi-part abutment and transfer cap for use with an endosseous dental implant with noncircular, beveled implant/abutment interface
- 25. Filed 2003:7,108,510 Endosseous dental implant
- 26. Filed 2005: 7,785,107 Multi-functional fixture mount
- 27. Filed 2005: 7,677,891 Tapered endosseous dental implants with external multiple lead threads
- 28. Filed 2005: 7,699,613 One-piece, screw-receiving, externally threaded endosseous dental implants and related transfer components, comfort caps and abutments
- 29. Filed 2005: 7,396,231 Flared implant extender for endosseous dental implants
- 30. Filed 2010: 8,118,596 One-piece, screw-receiving, externally threaded endosseous dental implants and related transfer components, comfort caps and abutments
- 31. Filed 2010: 9,452,028 External microthreaded and micro-grooved, endosseous dental implants
- 32. Filed 2010: 9,456,881Dental attachment assembly
- 33. Filed 2012: 9,697,748 Two-piece fixture mount assembly

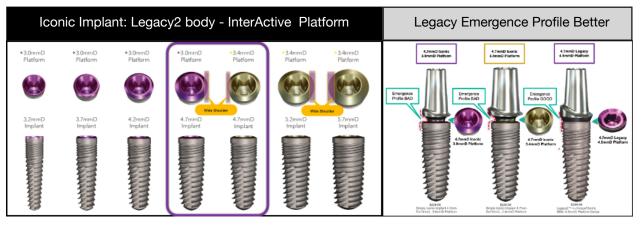
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The Legacy 2, 3 & 4 systems offers 4 platforms for 7 implant diameters and color code the implant platforms and the prosthetic components for simplicity. Reducing the number of platforms does simplify inventory control. Deep undercuts created by using a single narrow implant platform on wide implants compromises esthetics and oral hygiene. The 3.2mmD, 3.7mmD, 4.2mmD and 4.7mmD lconic implants have the same 3.0mmD NobelActive/InterActive connection in contrast to the Legacy System with 3 platforms (3.2, 3.5 and 4.5mmD) for these 4 diameters. The NobelActive System includes 3 platform diameters, 3.0, 3.4 and 5.0mmD but lconic only uses the 3.0mmD and 3.4mmD NobelActive platforms. The 4.7mmD lconic implant is provided with both the 3.0mmD and 3.4mmD platforms. This allows all 4 of the smaller diameter implants to have the same 3.0mmD platform. In all likelihood, these 4 diameters provide a great enough range to meet the needs of full arch restorations with the same multi-unit abutment under the misconception that the emergence profile discrepancy

created by using the same abutment for a 3.2mmD implant as a 4.7mmD implant would be acceptable when using multi-unit abutments for a screw-retained full arch restoration. Offering the same 4.7mmD lconic implant with the 3.4mmD platform recognizes that while this may not be significant with MUAs or OverDenture abutments, it compromises the emergence profile for cemented and screw-retained crowns, thereby effecting both hygiene and esthetics.





Using the NobelActive 3.4mmD connection with a 4.7mmD Legacy body leaves a 0.65mm wide ledge compared to using the Legacy 4.5mmD connection with a 4.7mmD body which leaves only a 0.1mm ledge. The lconic catalog claims that the system offers "a selection of emergence profiles within each interface...for... aesthetics and biomechanics." Attaching an abutment with a wider profile to an implant with a narrow connection provides neither optimal emergence

The claims about the " Iconic" are:

1. "Proven implant body with aggressive threading." FACT: True....I designed the implant body with progressively deeper threads and micro-threads in 2009 for the Legacy implant. (Niznick 2010 Patent on Micro-Threads).

2. The Iconic implant offers a "modern conical connection for enhanced clinical outcomes".

The conical connection was developed in 1986 with a 45 degree lead-in bevel. The patent covered any degree of lead-in bevel, including the original Screw-Vent 45deg. and the NobelActive 78 degrees introduced in 2008, 22 years later. Neither the NobelActive nor Legacy implants were



launched until after the Niznick internal conical connection patent expired in October 2007. Today there are a wide range of implants with different degrees of lead-in bevels. The secret to the stability of any conical connection is making the mating angle of the abutment 1 degree less, as measured from the vertical, than the lead-in bevel of the implant. This assures engagement primarily at the opening to the internal shaft. A study entitled Abutment Connections: Evaluation of 3-Year Postloading Outcomes showed "no significant difference between-group differences in RMBL [P = .74], gingival bleeding on probing.

3. Iconic's connection is called "SimplePlatform(tm)" by Implant Direct

The Iconic claims simplicity by using the NobelActive 3.0mmD platform, with its 78 degree lead-in bevel, on the 3.2, 3.7, 4.2 and 4.7mmD Legacy bodies, claiming that these implants with the same platform can be used for most cases. This is in contrast to the 3.2mmD Legacy implant which uses a 2mmD internal hex connection and the 3.7mmD Legacy uses a 2.5mmD connection. Using these narrower connections makes the relatively narrow Iconic implants more prone to fracture than Legacy implants of the same diameter.



The Nobelization of Implant Direct

Danaher completed the purchase of Implant Direct from Dr. Gerald Niznick in January 2014 and December of the same year bought NobelBiocare ("Nobel"). In 2019, Danaher's dental related companies were spun off as a separate public company under the name Envista. While NobelBiocare and Implant Direct have different presidents, the two implant companies coordinate their operations with Implant Direct shipping its products out of Nobel's Yorba

Linda facility and the two companies share trade show booths, symposiums and national sales meetings. Implant Direct salespeople are discouraged from trying to convert Nobel customers even though Implant Direct's RePlant Tri-lobe implant as well as InterActive and Iconic implants offer compatible prosthetic platform with Nobel implants. Nobel customers should pay attention to Implant Direct's marketing slogan "SAVVY CLINICIANS ARE CHOOSING IMPLANT DIRECT...WHY ARE YOU STILL OVERPAYING FOR IMPLANTS?"



Considering that Implant Direct's implants with All-in-1 packaging are about 65-70% less expensive than Nobel's implants plus the added components provided free with Implant Direct's implants, it sounds like Implant Direct is saying Nobel customers are not "SAVVY". To close the price gap between the two companies' products, Implant Direct introduced "DIRECTarch" MUAs that mimics Nobel's abutments, effectively at a price increase of about 50% when you consider the components provided free with the Legacy and InterActive abutments. These Nobel MUAs use a fixation screw for the prosthesis that is 1.4mmD vs the Legacy/InterActive at 1.72mmD. The result is that strength and stability of the narrow screw is reduced, with only 15Ncm. vs 30Ncm.

recommended. In order to sell "new" abutments, Implant Direct makes a number of unsubstantiated claims. Truly savvy clinicians will not be fooled and will stick with Legacy.



Questionable claims in the DIRECTarch brochure

CLAIM 1: "Control the complexity of parts and pieces"

FACT: Changing the MUA platform to match the NobelActive abutments and eliminating the snap-on transfer and comfort cap that is included with the Legacy and InterActive MUAs, increases "the complexity of parts and pieces."

CLAIM 2: "Universal multi-unit abutment (MUA) prosthesis connection enables easy use with any workflow."

FACT: Since both types of straight MUAs have retentive grooves but only the Legacy and InterActive angled MUAs have retentive grooves on the , the workflow does not become easier.

CLAIM 3. "SimplePlatform[™] for simpler inventory management of restorative components matching implant diameter"



Dr. Mehrdad Favagehi is guoted in this advertisement touting the advantages of Implant Direct's Iconic™ Implant. The same marketing piece is featured on Implant Direct's Website. Dr Favagehi has years of experience and success with Implant Direct's Legacy System. After he has experience with the Iconic system, he will realize that a more appropriate name would be the "Ironic" System.

surgeon in Falls Church, VA. He went on to explain: "For example, in a case involving immediate implant placement in an extraction socket, I must choose an implant diameter that is wide enough to engage or go beyond the walls of the extraction socket to give me primary stability. But I still want my restorative colleague to choose the best restorative components for the ideal restoration. That's where the lconic Implant system comes in."

FACT: The diameter of a crown on a tooth flares out from the CEJ in what is a smooth emergence profile. If teeth drift to reduce the width of the space, the diameter of the implant, the abutment and the crown will also have to be reduced in diameter. There is no reason not to maintain a smooth emergence profile for both esthetic and hygienic reasons. The Iconic implants from 3.2mm to 4.7mm all have the same 3.0mmD platform. The 4.7mmD implant also has an option of a 3.4mmD platform in an effort to improve the emergence profile, but the difference is only 0.2mm on each side, about twice the thickness of a human hair. The greater problem exists with the 4.7mmD, 5.2mmD and 5.7mmD lconic implants with its 3.4mmD platform, compared to Legacy for the same diameter implants of 4.5mmD and 5.7mmD platforms.

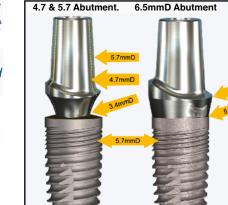
"The Simply Iconic implant is unique because it allows me to separate restorative platform choices from

implant surgical options. I can choose a wider implant diameter based on surgical reasons without limiting the restorative dentist to using only wider implant restorative components," said Dr. Favagehi.

FACT: Just like natural teeth, the diameter of the abutment (and crown) will increase proportionately with the diameter of the implant. Choosing a narrow abutment with a wide implant is the definition of poor emergence profile. Iconic straight abutments come in two diameter options BUT since the base on the wider implants is only 3.4mmD, an undercut is created regardless which diameter abutment is used. Legacy System only offers 1 diameter of straight, contoured abutment for each implant platform diameter with each abutment flaring slightly wider than the platform to create an ideal emergence profile and to provide material for the dentist to prepare the margins on the abutment. Having only one abutment option adds to the simplicity for the restorative dentist.

"This means that restorative components can be an industry standard 3.4-mm conical connection, allowing for the ideal implant emergence profile and esthetics, even for wider body 4.7-or 5.7-mm diameter implants. "This makes Simply Iconic perfect for immediate implant placement," he added."

This shows unacceptable emergence profile with 5.7mmD Iconic with its 3.4mmD connection, regardless if the 4.7mmD or 5.7mmD Abutment is used.



5.7mmD Iconic 5.7mmD Legacy

FACT: NobelBiocare's 3.4mmD conical connection with its 78 degree lead in bevel is not "industry standard". More implant companies use the Screw-Vent's/Legacy's 45 degree conical connection first introduced in 1986, 22 years before NobelActive was launched. This claim that the NobelActive connection is "the industry standard" is probably the reason behind the launch of the Iconic by Implant Direct, operating as a division of NobelBiocare. In 2021, Straumann introduced its Neodent Nuvo



plant Direct's Simply Iconic implant system is a win fo both implant surgeons and restorative dentists-them to create the ideal restoration with no limit

implant system and the connection it chose was the 45deg. Internal hex Screw-Vent connection.

Unique Design

"An implant designed for biomechanical stability and optimum esthetics, Simply Iconic has an expansive range of implant diameters and two prosthetic platforms."

FACT: The Iconic's "expansive range of implant diameters" matches 6 of the 7 implant diameters offered with the Legacy System. By using the very narrow range of platform diameters (only 3.0mmD and 3.4mmD) from the InterActive (and NobelActive) implants, a mismatch is created that weakens the smaller diameter implants and compromises emergence profile of the 4.7mmD, 5.2mmD and 5.7mmD lconic implants. Legacy includes a 7mmD implant for immediate insertion in molar extraction sockets.

"It has all the modern features of a next-generation implant, including a stable conical connection, platform switching, and a proven implant surface," said Dr. Favagehi, adding "wider platform switch options allow for better bone level maintenance that prevents dentists from removing too much tissue around the implant to fit restorative components."

FACT: The conical connection on the Legacy from Implant Direct and TSV/TSX from Zimvie, have a long history of providing a stable conical connection. All conical connections inherently have a platform switching interface because the abutment is emerging from the internal shaft of the implant. <u>Research shows no clincial benefit to platform switching interfaces</u>. This quote, attributed to Dr. Favagehi, tries to justify the "wider platform switch" inherent in the mismatch of using Legacy implant diameters with NobelActive platform diameters. A "wider platform switch" is the definition of a poor emergence profile.

"I can't think of a site or situation that the Simply Iconic implant is not advantageous," he said.

FACT: I can think of a number of situations where the lconic implant is at a disadvantage to the Legacy implant. One (see picture on Page 3) is in the unfavorable emergence profile with stock and cad milled abutments that is unavoidable using the 4.7, 5.2 and 5.7 Iconic implants with only a 3.4mmD connection. Another is the risk of fracture with the 3.2mmD Iconic implant with its 3.0mmD platform and 2mm deep 78 degree hevel vs Legacv's 3.2mmD Success Rooted in Simplicity



"Unlike other implant manufacturers that offer a variety of implant systems with various surface treatments, tissue and bone levels, and hybrid implant designs, Implant Direct systems are primarily based on just 2 proven restorative connections: the internal hex and conical connection," Dr. Favagehi said.

Fact: The internal hex connection of the Legacy implants is the original conical connection. Both the Legacy and lconic implants have internal hexes. The differences are in the angle (45deg. Vs 78deg.) and depth (0.5mm vs 2mm) of the lead-in bevels and the diameter of the internal shaft that receives the abutment. Implant Direct does offer a variety of implant systems with various surfaces (HA and SBM), tissue and bone level (SwishPlant, GoDirect and ScrewIndirect tissue level implants). As the developer of both the Legacy and InterActive implant systems, I would never have considered using the connection of one with the body dimensions of the other. The only purpose in the first place for developing the InterActive was to offer a low priced alternative to NobelActive customers. Implant Direct is now operated as a division of NobelBiocare. The only business rational I can figure for Implant Direct's promotion of the Iconic implant over its flagship Legacy product line is that NobelBiocare wants Implant Direct to also be advocating its 78 degree conical connection as the "industry standard." Of course, the introduction and promotion of the Iconic allows Implant Direct to charge an additional \$50 for every Legacy1 implant and \$20 for every Legacy2 implant sale it converts to the Iconic at \$220.

"This simplicity is ideal for busy clinicians who must rely on their team members to order components and maintain an inventory in their clinics," he said.

Fact: Implant Direct, under Niznick's management (2004-2013) created the value segment in the implant industry with fair pricing and All-in-1 implant packaging that simplified ordering and inventory control.







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 implantabutment 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



Peri-implantitis in independent study Odds ratios of peri-implantitis at 9 years after implant placement.

> Nobel Biscar Astra Tech



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 supercreatal position, and (b) test group patients had implants placed in a sub-

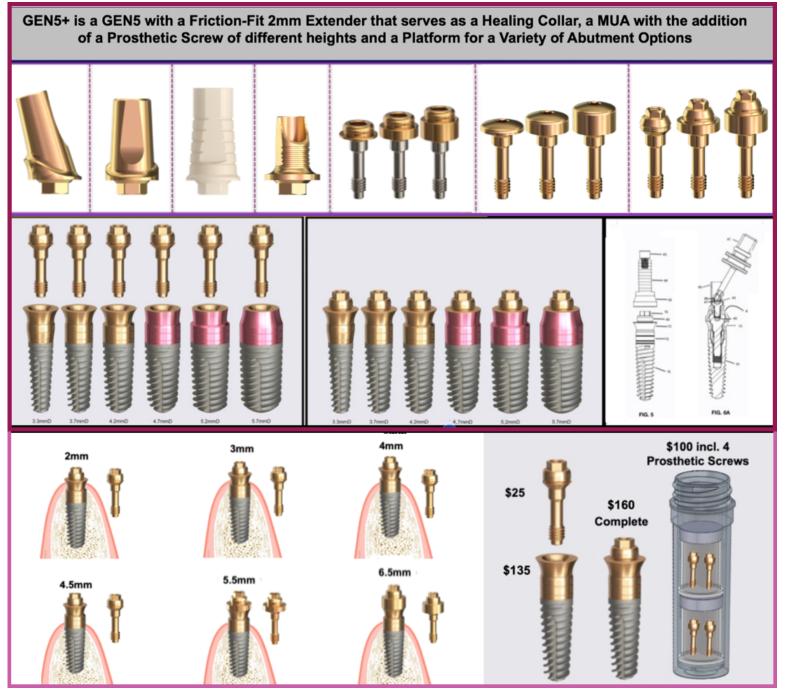
Paragon's GEN5[™], GEN5+ and NizPlant[™] implants have the same implant body with a 2.5 mm machined, anodized neck. Depth gauge lines at 1 mm, 2 mm and 2.5 mm from the top (Pat. Pend.), along with 2 depths of drill stops, facilitate placement level with or 1mm above the crest of the ridge. The insertion 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.



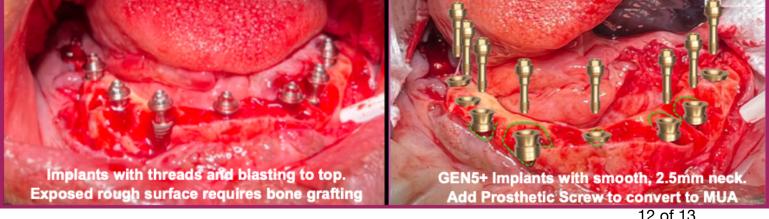
Each Paragon implant is 1 mm longer than the standard lengths of the respective Screw-Vent and Legacy implants. Paragon's surgical system includes two options of drill stops. One is for placement 1mm supra-crestal, which moves the implant-abutment junction away from the bone and and creates a 1mm supra-crestal 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.



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

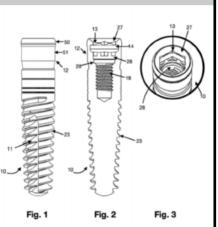


NIZPLANT 1-PIECE IMPLANT WITH DUAL FUNCTION PLATFORM FUNCTION AS OVERDENTURE AND MULTI-UNIT ABUTMENT

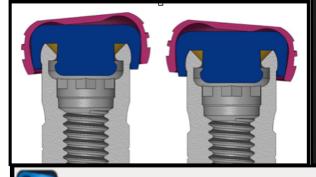
NizPlant 1-Piece Locator Compatible Implant with Internal Threads

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 undercut/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.





Zest LODI 2-Piece Implant with Over-denture Attachment @\$220, Includes Cap Attachment Components

NizPlant 1-Piece Implant with Dual Function Platform @ \$150, Includes Cap Attachment Components

