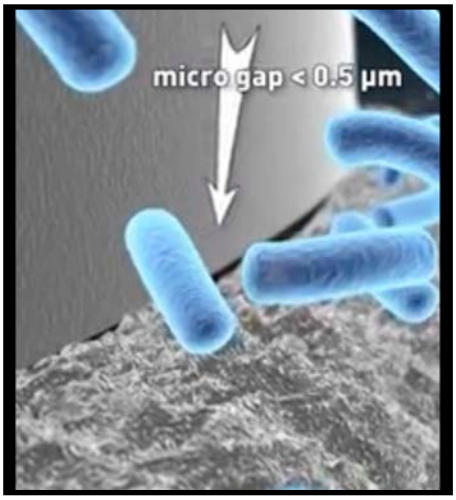
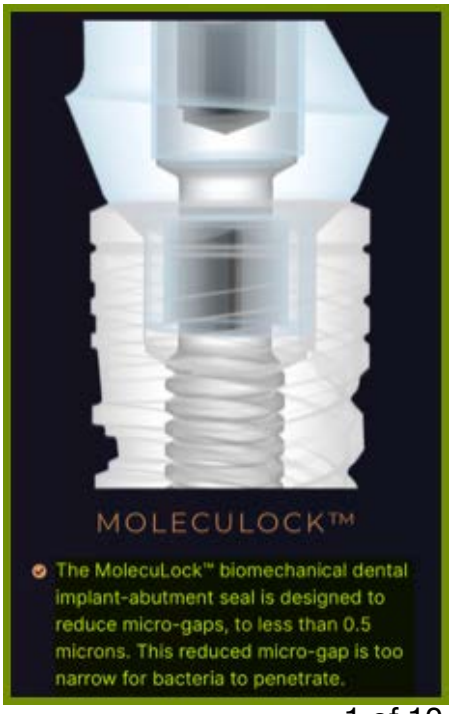
Ditron's claim that it "reduces micro-gaps to less than 0.5 micron" is physically impossible.
Ditron as a 50 year old Israeli automotive parts company that, for the last 12 years, has also been making dental implants. Its "Ultimate" Implant with a concave, micro-grooved neck has been on the market for at least 7 years in Europe and Israel. Today, there are 25 such Israeli companies making and selling dental implant products with the two most prominent ones being Alpha Bio Tec, acquired by NobelBiocare in 2008 and MIS, acquired by Dentsply in 2016. Both of these companies started in the 1990's cloning Core-Vent Corporation's 1986 Screw-Vent implant with its internal hex/bevel connection patented in the US, but not in Israel. Dr. Ole Jensen is listed as the "Founder and Chairman of the Board," of Ditron's US subsidiary which launched in September 2020. Ditron US is selling the Molecular Precision MPItm and Ultimate Precision ULTtmDental Implant Systems. The main marketing claim or ***Unique Selling Proposition*** 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 2.45 mm internal hex/45 deg. bevel connection first introduced in 1986 on the Screw-Vent for which a US patent issued to Niznick 1990 (Expired 2007).





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.

MOLECULAR PRECISION IMPLANT (MPI) CHARACTERISTICS

MPI *(Molecular Precision Implants, Ditron Dental, Israel)*:
The characteristics of this new implant are: MolecuLock™ *(seal between implant and abutment; biomechanical design and l_μ level production to reduce micro gaps and micro movement risks)*

Former Director of Engineering, Implant Direct

Tightest Tolerances on Screw Machines +/- 0.0005"
Tightest Tolerances on Broaching the Hex =/- 0.00025
Gages for inspecting broaching +/- 0.0001"

WELCOME TO THE ULTIMATE IN PRECISION

The ULT™ Precision implant is a 3rd generation implant design which incorporates many progressive design features such as the MolecuLock™ biomechanical implant-abutment seal, a patented Reverse Concave Neck (**RCN** with micro threads) and one universal abutment platform (2.45mm internal hex connection) shared across ALL implant diameters.

The ULT implants are the clinician's choice for those who demand Ultra-precision, Progressive Design, and Premium Quality, Not a Premium Price.

NOT TRUE

< 0.5 microns

NOT TRUE

MolecuLock™ Implant Abutment Connection

NOT TRUE

MolecuLock bioseal is designed to reduce micro-gaps to **LESS** than 0.5 microns. This seal, minimizes micromovement and microleakage preventing the ingress of bacteria.

"What Ditron does...they make the most accurate machined parts in the world, for aerospace, for high performance cars such as Tesla, Maserati or BMW. ***AND*** they make the most accurate, well-fitting dental implant."

NOT TRUE

Ole T. Jensen, DDS, MS
Founder, Ditron Dental USA

Call 844-434-8766 to place your order or contact your sales representative below.

Please Contact: _____

Email: _____

Phone: _____

To learn more, please visit our website:

www.ditrondentalusa.com or Call 844-4DITRON (434-8766)

DITRON DENTAL USA

“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

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.

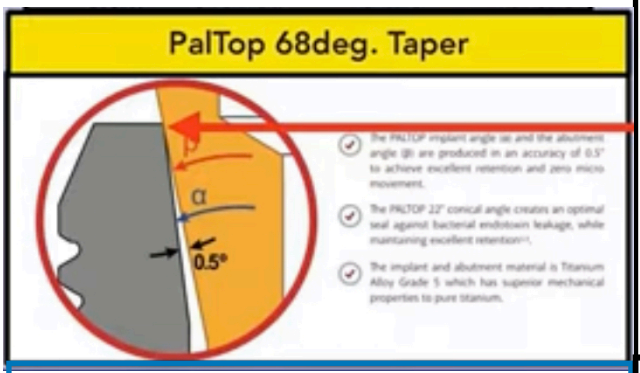
Results: In all the tested implants, bacteria were found in the inner side with a median percentage of 1.35%. The analysis revealed that, in untreated implants, bacteria grew *(internally and externally)* for the first forty-eight hours, but subsequently, they started to die. Moreover, the difference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

The optimum seal with an internal conical connection is created by making the abutment’s bevel 1/2 deg. less, regardless if the lead-in bevel is 45 deg. (Standard), 64 deg. (Neodent) or 78 deg. (NobelActive).



MolecuLock™

- Seal between implant and abutment.
- Biomechanical design and 1 micron level production to reduce micro gaps and micro movement risks.

Restorative platform

- Subcrestal placement including a beveled collar shifting the implant-abutment junction inward, in order to achieve platform-switching configuration.
- Platform switching generates a perfect environment for the soft-tissue growth and helps prevent bone resorption.

Core-Vent Corporation’s patented Internal Hex Conical Connection and its Friction-Fit Patent were sold in 2001 to Zimmer Dental. Zimmer Biomet recently celebrated the 20th anniversay of selling the Tapered Screw-Vent and its Friction Fit Abutments. These products are recognized by many as the “Third Generation” osseointegrated Implant System, popularizing innovative thread design, tapered body and Selective Surface

Published Research on Leakage Compares Different Connections, Materials & Torques.

Studies confirm a minimum of a 12 microns gap exists with screw-retained abutments. Conical connections had significantly less leakage than flat-to-flat Trilobe Connections

Bacterial leakage in implants with different implant–abutment connections: an in vitro study

Bartolomeo Assenza et al. J Periodontol. 2012 Apr.

The present study confirms …very low (1 in 10) permeability to bacteria of the conical implant-abutment connection, and the high prevalence of bacterial penetration of trilobed (flat to flat) implant-abutment assemblies.

Abstract

Methods: A total of 30 implants (10 implants per group) were used. The implants presented a screwed trilobed connection (group 1), a cemented connection (group 2), and an internal conical connection (group 3). The inner parts of five implants, per group, were inoculated with Pseudomonas aeruginosa suspension and the remaining five implants, per group, with Aggregatibacter actinomycetemcomitans. The penetration of bacteria into the surrounding solution was determined by the observation of turbidity of the broth.

Results: In group 1, bacterial contamination was found in six of 10 implants. In group 2, no contaminated samples were found. In group 3, bacterial contamination was found in one implant of 10. Statistically significant differences were detected between group 1 versus group 3 ($P < 0.05$) and between group 1 versus group 2 ($P < 0.01$), whereas no significant differences were found when comparing group 2 versus group 3 ($P > 0.05$).

Conclusion: The present study confirms previous results about the hermeticity of the cement-retained implant-abutment assembly, the very low permeability to bacteria of the conical implant-abutment connection, and the high prevalence of bacterial penetration of screw-retained implant-abutment assemblies.

Connection Systems

Mohammad Reza Talebi Ardakani et al. J Oral Implantol. 2019 Oct.

Tested 4 Different Implant/Abutment connections of 1-piece Healing Collars at 10 and 20 Ncm of Torque. All Leaked at 10Ncm
Tapered Screw-Vent (internal bevel + internal hexagon) faired better than Morse Taper and External Bevel interfaces
3 of the 4 Interfaces showed better seal at 20Ncm than at 10Ncm

Abstract

This study sought to assess microbial leakage through the implant-healing abutment interface in 4 dental implant connection systems. Ten implants of each of the 3i (double hexagon + flat to flat; group 1), IDI (internal hexagon + Morse taper; group 2), Swiss Plus (external bevel + internal octagon; group 3), and Tapered Screw-Vent (internal bevel + internal hexagon; group 4) systems were used in this in vitro, experimental study. Healing abutments were screwed to the implants with 10 Ncm torque. Implants were immersed in *Escherichia coli* suspension for 24 hours. Samples were taken of the internal surface of implants and cultured. The number of grown colonies was counted after 24 hours of culture and after 7 and 14 days of immersion in microbial suspension. The same was repeated with healing abutments torqued to 10 and 20 Ncm. With 10 Ncm torque, all specimens in all groups showed microleakage at one day with the highest microleakage in one sample in group 3. At 7 days, the highest microleakage was noted in one specimen in group 2. With 20 Ncm torque, group 3 showed significantly higher microleakage than other groups at 1 and 7 days ($P < .05$). Increasing the torque decreased microleakage in all groups except for group 3. Microbial leakage occurred in almost all implant systems in our study. In one-stage implant placement, healing abutments should be preferably torqued to 20 Ncm to minimize microleakage. Optimal torque for healing abutment insertion should be analyzed individually for each system.

Bacterial leakage in implants with different implant–abutment connections: an in vitro study

CONCLUSIONS: Over time, bacterial will leak through the implant-abutment microgap. The titanium-abutment interface was 12.38 =/- 3.73 microns which was smaller than the interface microgap with Zirconia Abutments. Changing the screw-torque from 20 to 35 Ncm reduced leakage with zirconia abutments but had no effect on titanium abutments.

Bartolomeo Assenza et al. J Periodontol. 2012 Apr.

Abstract

Purpose: The purpose of this study was to evaluate sealing at 2 different implant-abutment interfaces under different screw torque values.

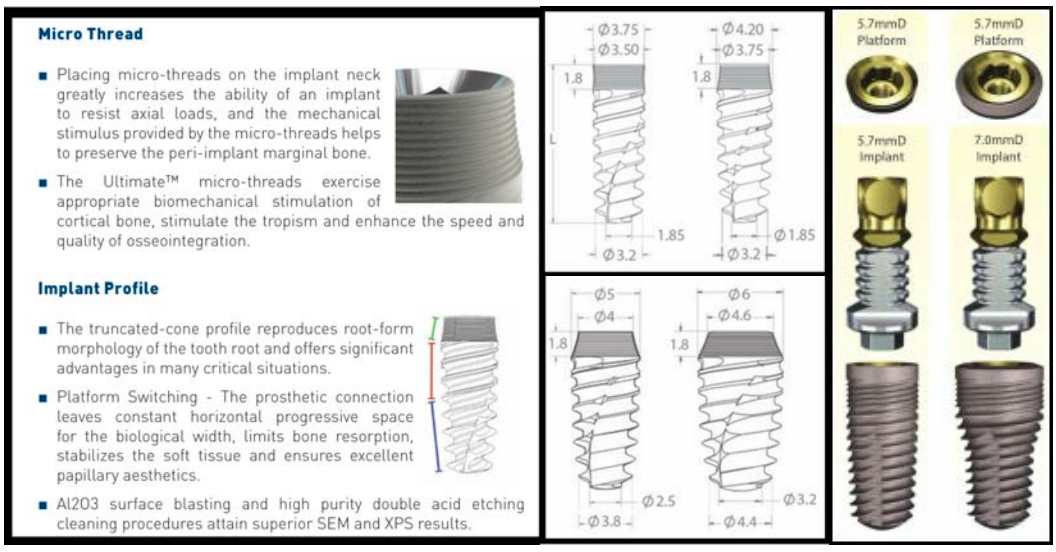
Material and methods: Twenty sterile zirconia abutments and 20 sterile titanium abutments were screwed into 40 sterile implants and placed in test tubes. The ability of a bacterial mixture of Prevotella intermedia, Porphyromonas gingivalis, and Fusobacterium nucleatum to leak through an implant-titanium abutment seal under 20 and 35 Ncm torque values and an implant-zirconia abutment seal under 20 and 35 Ncm torque values was evaluated daily until leakage was noted. Once a unit demonstrated leakage, a specimen was plated. After 4 days, the number of colonies on each plate was counted with an electronic colony counter. Plating was used to verify whether or not bacterial leakage occurred and when leakage first occurred. The implant-abutment units were removed and rinsed with phosphate buffered saline solution and evaluated with a stereomicroscope. The marginal gap between the implant and the abutment was measured and correlated with the amount of bacterial leakage. The data were analyzed with ANOVA.

Results: Bacterial leakage was noted in all specimens, regardless of material or screw torque value. With titanium abutments, changing the screw torque value from 20 to 35 Ncm did not significantly affect the amount of bacterial leakage. However, with zirconia abutments, changing the screw torque value from 20 to 35 Ncm was statistically significant ($P < .017$). Overall, the marginal gap noted was larger at the zirconia-abutment interface (5.25 ±1.99 μm) than the titanium-abutment interface (12.38 ±3.73 μm), irrespective of the screw torque value. Stereomicroscopy revealed a nonuniform marginal gap in all specimens.

Conclusion: The results of this study showed that, over time, bacteria will leak through the implant-abutment microgap at the implant-abutment interface. Implants with a titanium abutment demonstrate a smaller microgap than implants with a zirconia abutment. Tightening the zirconia abutment screw from 20 to 35 Ncm decreases the size of the microgap, which suggests a more intimate fit between the implant and the abutment.

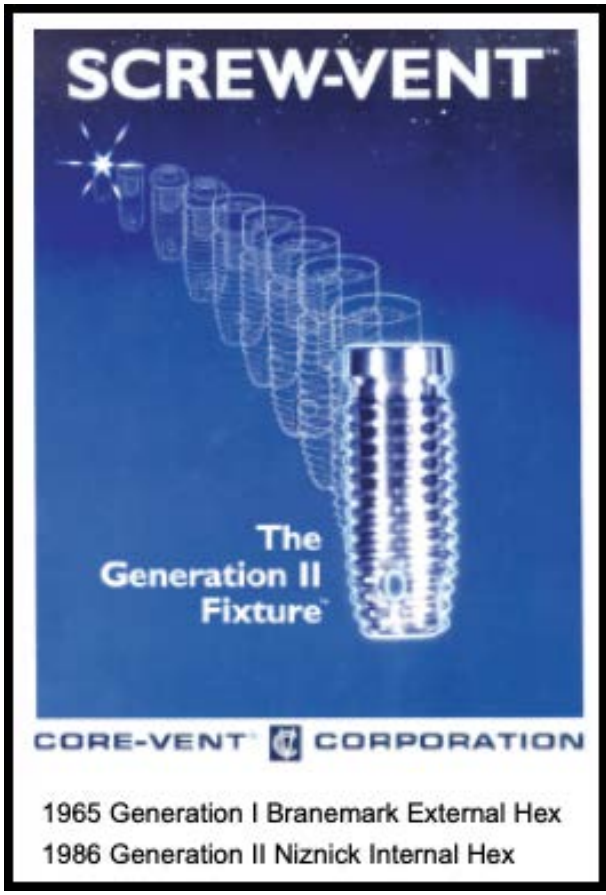
Dr. Ole Jensen, President of Ditron US Gives Bias and Inaccurate Testimonial

Ditron posted on LinkedIn a prepared testimonial by Dr. Jensen in which he claims that he and several colleagues have ***"decided to develop a new and innovative technology…that has a chance to change dentistry as we know it today.".*** There is nothing new about Ditron's implant designs. They have been available for at least the last 7 years in Europe and Israel. Dr. Jensen states in his testimonial that ***"Ditron now is the foundation for what we are looking for in an implant".*** This implies that Ditron's current implant designs will need ***"new and innovative technology"*** if it hopes to ***"change dentistry."*** Dr. Jensen has recruited an impressive list of members for Ditron's Advisory Board but neither Dr. Jensen nor his fellow board members have any significant accomplishments in designing or manufacturing dental implants. Dr. Jensen makes the unsubstantiated claim that ***"the Ditron implant, when compared to leading brands, is much more innovative and easier to use."*** This clearly shows that he lacks the knowledge to differentiate innovative features that provide true clinical benefits from inconsequential design variations made for marketing purposes. NobelActive in 2008 introduced the back-tapered neck with micro-grooves like Ditron's "Ultimate" (ULT) implant, after it had been available in Israel for several years. The fact that Ditron, to differentiate from the NobelActive, made the ULT's neck concave, adds nothing to initial stability and further thins the walls of the implant increasing the risk of fracture. Furthermore, it precludes making a narrow 3.2-3.3mmD implant found in many systems today. 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 that will require grafting. The two wider diameters of the Legacy System (below Rt) have wider necks designed to minimize the gap following immediate molar replacement and add to initial stability. Unlike all of Ditron's implants with only the original Screw-Vent 3.5mmD platform, the Legacy System offers 4 platform diameters for improved emergence profile. The Legacy1 implant includes a cover screw, 2mm healing collar and a carrier that is a transfer. At $155, this Made-in-America implant is $14 less than Ditron's "Ultimate" implant with a US price for its implant and cover screw of $169.

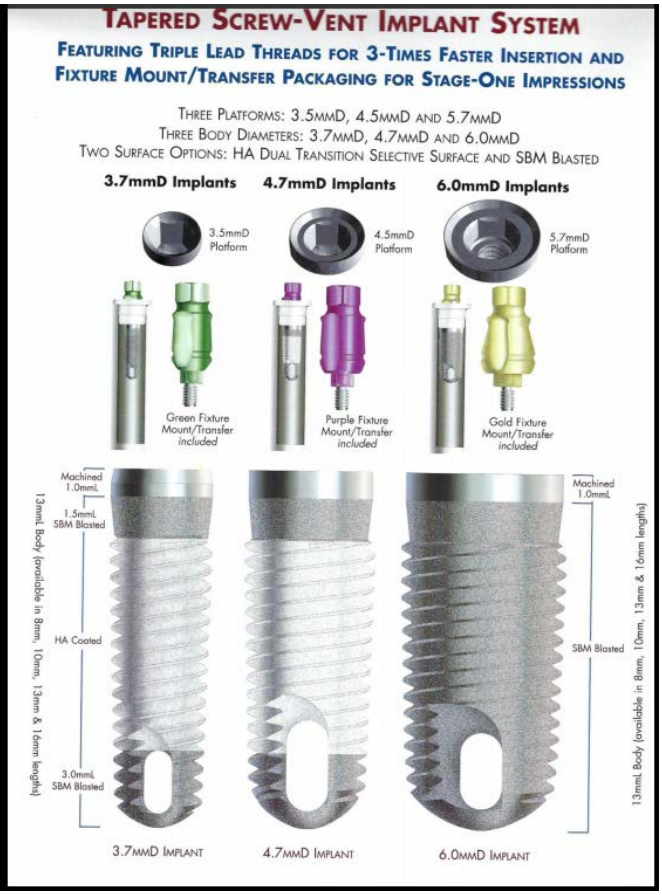


What does “new and innovative technology” in dental implants look like?

Dr. Jensen and Ditron’s marketing refers to the Ditron “Ultimate” implant as Third Generation Implant Technology, indicating their ignorance to the evolution of screw implants after the Branemark External Hex Implant launched in 1983. The Screw-Vent implant, introduced in 1986 with an internal hex and 45deg. lead-in bevel (now called a conical connection), is the exact connection used by Ditron and many other companies today. This was the cornerstone of modern implant designs and was clearly the Second Generation following the Branemark implant. The 1999 tapered, self-tapping Screw-Vent implant with Selective Surfaces and triple lead threads was the next leap forward in implant technology and should be considered the start of the Third Generation of osseointegrated implants. If any system on the market today is to be credited with being the Forth Generation including ***“new and innovative technology”*** that have ***“changed dentistry”***, it would be Implant Direct’s Application Specific 1 and 2-piece implants with All-in-1 packaging that created the Value Segment of the market in 2006. First came the patented 1-Piece ScrewIndirect implant with a multi-unit platform and All-in-1 packaging that included a comfort cap, transfer and 2mm extender, all for $150. Then came the GoDirect 1-piece implant with a Zest compatible platform. When the Screw-Vent patent expired in 2007, Implant Direct made the Legacy implant which evolved into the Legacy 1,2,3 & 4, each with different threads and packaging options. The Legacy2-4 implants expanded dimensional options by including 6 lengths (6mmL-16mmL) and 7 diameters (3.2mmD-7.0mmD). All these new generation 1 & 2-Piece implants from Implant Direct have the patented double-lead body threads and quadruple-lead micro-threads. The Legacy implants included a healing collar retained by the cover screw and the Legacy4 includes a patented 3-piece implant carrier that also functions as a transfer and straight abutment. The 7 diameter options of the Legacy 2-4 Systems include 4 different diameters of internal hex/bevel connections for optimized emergence profiles whereas the Ditron implants only have the one original Screw-Vent connection. Below (left) is a 1986 brochure showing the evolution from the Branemark to the Screw-Vent. Below (right) is the 1999 catalog of the Tapered Screw-Vent.

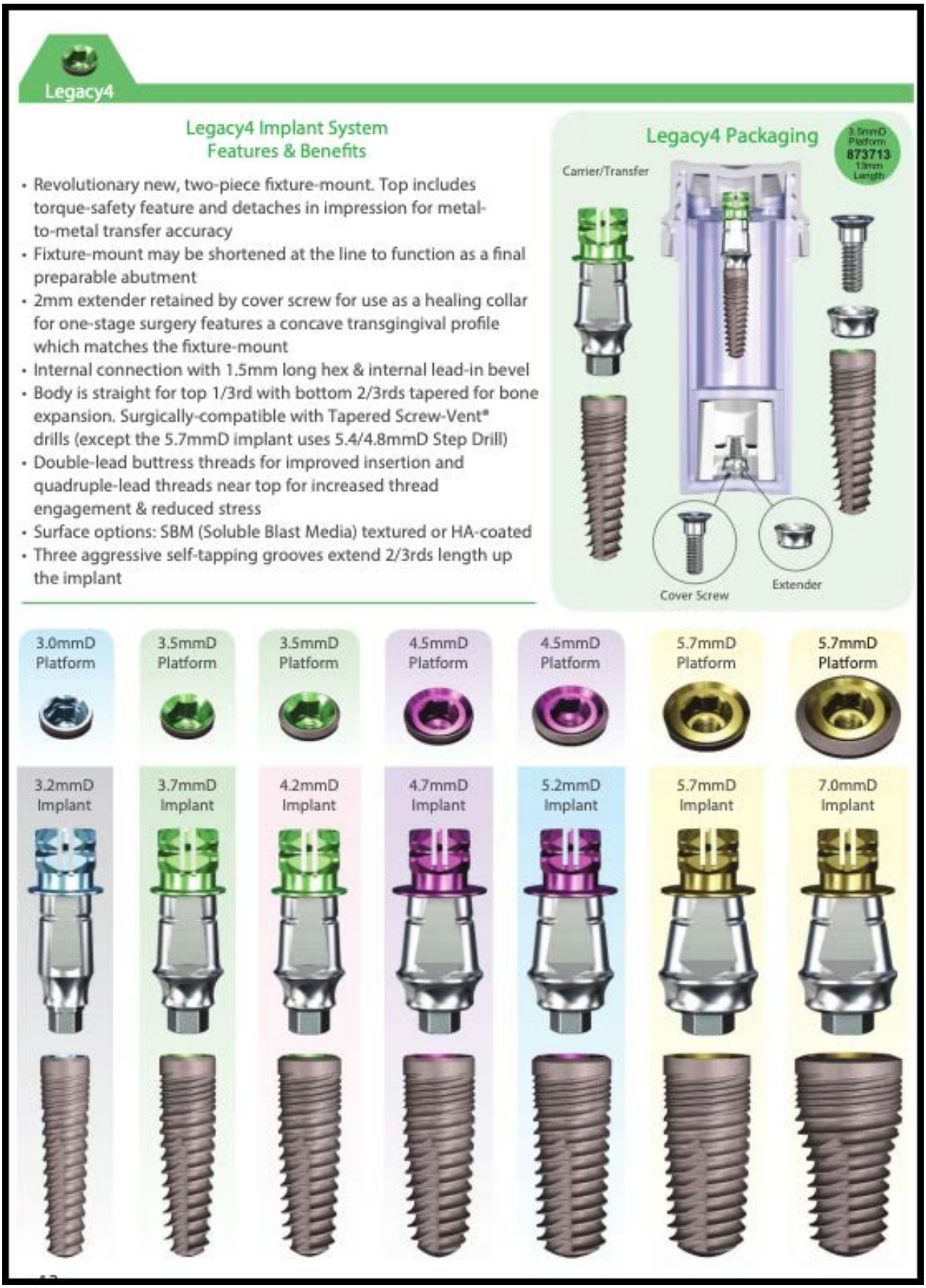


GENERATION 2 INTERNAL HEX SCREW IMPLANT

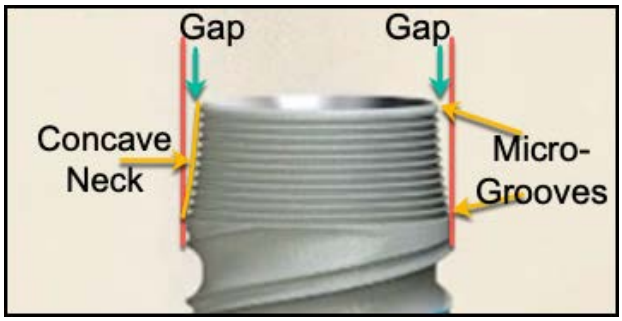


GENERATION 3 TAPERED INTERNAL HEX SCREW IMPLANT

Below is the catalog page of the Legacy4 implant with its All-in-1 Packaging



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



Dr. Jensen claims that ***"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 drill, thus preserving the labial plate of bone.

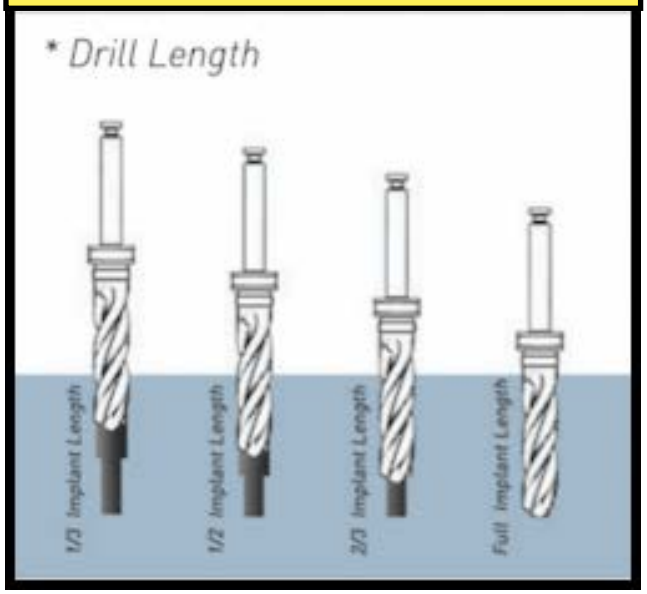
EASE OF USE:

When I introduced the Tapered Screw-Vent in 1999, its surgical protocol, like Ditron's today, required using some of the straight drills only to partial depths to create a socket that was narrower in its apical region so that the threads of the apical end of the tapered implants would engage bone. Implant Direct and others use Step-down Spade drills for apical thread engagement

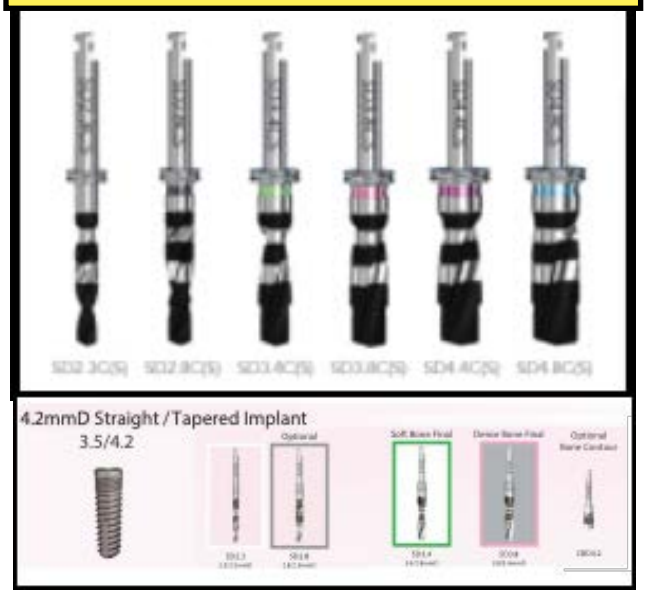
Drill sequence

Bone type	drill length*	I,II	RPM	Bone type	drill length*	III,IV	RPM
● Ø 3.75 mm		Ø1.9 mm	Full 1200-1500			Ø1.9 mm	Full 1200-1500
		Ø2.0 mm	Full 900-1200			Ø2.0 mm	Full 900-1200
		Ø2.8 mm	2/3 500- 700			Ø2.8 mm	1/2 500- 700
		Ø3.2 mm	1/3 200- 400				

Ditron's Protocol to create narrower apex



Implant Direct's Protocol using Step Drills

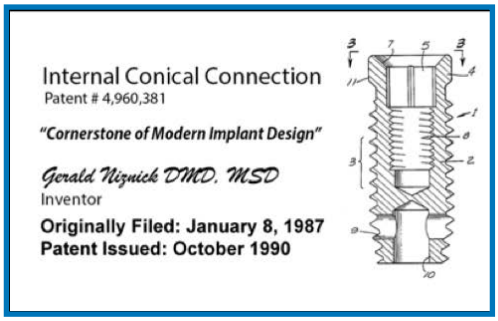


Differentiating Marketing Rhetoric from Clinically Significant Innovations.

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 decade that have been sold in EU and Israel.

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. 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.* ***(nothing original in the Ditron System)***

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 $169)***



DR. JENSEN FAILED TO MENTION THAT THE DITRON IMPLANTS , AS SHOWN IN THIS PICTURE FROM THE ZOOM INTERVIEW, USE THE SAME INTERNAL HEX/BEVEL CONNECTION DEVELOPED FOR THE SCREW-VENT IMPLANT IN 1986. THAT WAS THE TRUE SECOND GENERATION IMPLANT AND IS THE CORNERSTONE OF ALL MODERN IMPLANTS, INCLUDING DITRON'S.

In Dr. Jenson's Dental IQ interview he explains why he is now getting involved with the commercial side of dental implants. He states that "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 experiences gained over years in the implant industry. This is not the case for Dr. Jenson or his distinguished board of dentist advisors. I launched Core-Vent Corporation in 1982 after a decade of placing with mixed results, the implants available in the 1970's. In the next 35+ years, I gained the manufacturing, design and engineering experiences to earn 33 US Patents related to dental implants which makes me uniquely qualified to differentiate marketing rhetoric from real design advantages.

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 is something that I am also familiar with as I own Acromil Aerospace. Its two factories total about 200,000sq. ft., and make parts for many of the prime aerospace companies including Boeing, Lockheed, Northrop, Gulfstream and Bell Helicopters. According to my VP of Manufacturing, tolerances of 0.0005" (12 microns) are required on some bore holes but structural parts usually only require 0.003" to 0.010". Holding positional tolerances of 0.03" (1000 microns) of one hole in relationship to another is very demanding considering that a 180" long aluminum part can change by 0.03" with a 5deg. change in temperature, which is why Acromil has air conditioning.