Quality of Dental Implants

Asbjørn Jokstad
University of Toronto

Situation, end of 90'ies

The number of implants and implant systems increase continuously

FDI is concerned about the quality of all the new implants being marketed

FDI Science Committee commissioned a project to investigate the issue

What characterizes a good quality implant? When..

- there are clinical data over 3 ... 5 ...10yrs?
- implant is made from cpTi grade 1 ...3 ...4?
- implant is rough ..etched ..groovy ...rounded ...connects internally ...sandblasted ...?
- the producer follows an ISO9001 standard?
- a well known researcher tells you so?
- a well known clinician tells you so?
- your sales rep tells you so?
- scientific clinical studies provide an answer?

Scientific studies with similar aims:

Eckert et al. Validation of dental implant systems through a review of literature supplied by system manufacturers. J Prosthet Dent 1997;77: 271-9.

Esposito et al. Interventions for replacing missing teeth: different types of dental implants. Cochrane Database Syst Rev 2002;(4). (version 1)

Jokstad et al. Quality of dental implants. Int Dent J 2003;53 (6 Suppl 2): 409-43.

Eckert et al. Comparison of dental implant systems: quality of clinical evidence and prediction of 5-year survival. Int J Oral Maxillofac Impl 2005; 20: 406-15.

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Interventions for replacing missing teeth with or without osseointegrated implants [protocol]

Reviewer(s)	Esposito M, Coulthard P, Worthington HV, Thomsen P
Contribution of Reviewer(s)	Paul Coulthard - data collection, assessment and analysis and final review Marco Esposito - data collection, assessment and analysis and final review Asbjorn Jokstad - data collection, assessment and analysis and final review Helen Worthington - statistical analysis and final review Peter Thomson - final review
Issue protocol first published	2000 Issue 3
Date of most recent amendment	30 August 2000

This protocol should
teeth with or without

or replacing missing
ary, Issue 1, 2001.

Background

Missing teeth and supp
masticatory, phonetic f
showing that bone will
concept, termed osseo
past 20 years. A multit
implant retained prosth

g restoration of
over 10 years
ell-accepted
s in dentistry over the
osseointegrated

Cochrane Oral Health Group

Since 2000: 10 systematic reviews completed on osseointegrated dental implants

Esposito M, Coulthard P, Worthington H, Thomson P / (Jokstad A)

Problem: Selection of studies to include

Cochrane systematic reviews:

(Coulthard / Esposito & Worthington)

1. Zygomatic implants	0 RCT
2. Hyperbaric oxygen therapy	0 RCT
3. Use of prophylactic antibiotics	0 RCT
4. Perimplantitis	1 RCT
5. Preprosthetic surgery vs implants	1 RCT
6. Bone augmentation techniques	4 RCTs
7. Surgical techniques	4 RCTs
8. Immediate or conventional loading	5 RCT
9. Maintenance	5 RCTs
10. Characteristics of implants	12 RCTs

Quality Assessment of Randomized Controlled Trials of Oral Implants

Marco Esposito, DDS, PhD[1]/Paul Coulthard, BDS, MFGDP, MDS, FDSRCS, PhD[2]/
Helen V. Worthington, BSc, MSc, PhD, FIS[3]/Asbjørn Jokstad, DDS, PhD[4]

The aim of this study was to assess the quality of randomized controlled trials (RCTs) concerned with the effectiveness of oral implants and to create a trial register. A multilayered search strategy was used to identify all RCTs published by the end of 1999 in any language. The Cochrane Oral Health Group specialist register, PubMed, and personal libraries were searched. Seventy-four RCTs were identified. Forty-three articles, not presenting the same patient material, were independently assessed by 3 researchers using a specially designed form. A statistician assessed all trials for the appropriateness of statistics. The quality of each study was assessed on 7 items, including 3 key domains. Randomization and concealment allocation procedures were not described in 30 articles (70%). Reasons for withdrawals were not given in 10 reports (23%). No attempt at blinding was reported in 31 studies (72%). The quality of RCTs of oral implants is generally poor and needs to be improved.

INT J ORAL MAXILLOFAC IMPLANTS 2001;16:783–792

IJOMI 2001; 16: 783-92

The quality of RCTs of oral implants is generally poor and needs to be improved

Jokstad, Brägger, Brunski, Carr, Naert, Wennerberg. *Int Dent J 2003; 53 Sup 2: 409-33*

Asbjørn Jokstad, Oslo, Norway
Urs Braegger, Bern, Switzerland
John B. Brunski, Troy, USA
Alan B. Carr, Rochester, USA
Ignace Naert, Leuven, Belgium
Ann Wennerberg, Gothenburg, Sweden

Materials and methods

1. PICO:

Problem:	Intervention	Comparison	Outcomes
Claims of superiority	Implant characteristic (material, geometry, surface topography)	Implant without characteristic	Clinical relevant & Clinical significant

Materials and methods

1. PICO:

Problem:	Intervention	Comparison	Outcomes
Claims of superiority	Implant characteristic (material, geometry, surface topography)	Implant without characteristic	Clinical relevant & Clinical significant

All types of information sources:

Scientific & quasi-scientific literature, WWW, promotional brochures and leaflets, CD/DVDs, trade exhibitions, etc.

Materials and methods

All information sources:

Brochures, trade exhibitions, WWW, leaflets, presentations, etc.

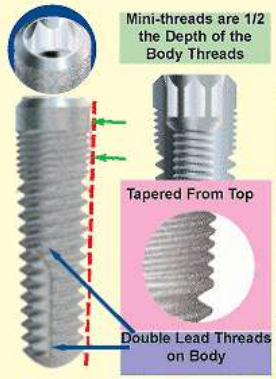
PICO:

Problem:	Intervention	Comparison	Outcomes
Claims of superiority	**Implant characteristic** (material, geometry, surface topography)	**Implant** without characteristic	**Clinical relevant & Clinical significant**

Compare ScrewPlant to Zimmer's *Screw-Vent®

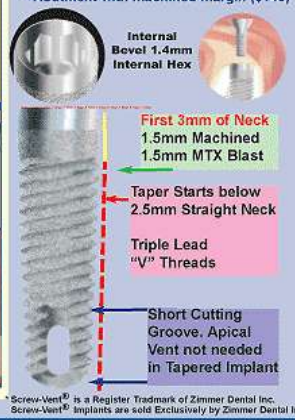
ScrewPlant Implant
1. SBM Blasted Surface to Top
2. Mini-Threads + Double-lead Threads
3. Body Taper starts at Top for Expansion
4. Long Cutting Groove - No Vent
5. Fixture-Mount is Transfer & can be Shorten for *Final Abutment*

US List Price: $150 Complete
Healing Collar (2mm) + Abutment with machined margin & Comfort Cap



Screw-Vent Implant
1. Machined Surface 1.5mm from Top
2. Triple Lead Threads overall
3. Body Taper starts 2.5mm from Top
4. Short Cutting Groove & Vent
5. Fixture-Mount is Transfer & can be Shorten for *Temporary Abutment*

US List Price: $512 Complete
Implant ($325) + Healing Collar($42) +Abutment with machined margin ($145)

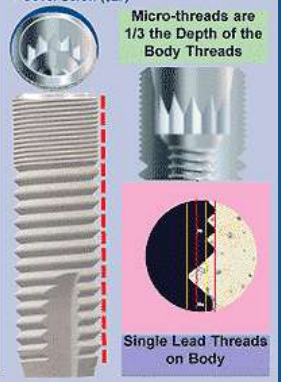


*Screw-Vent® is a Register Tradmark of Zimmer Dental Inc. Screw-Vent® Implants are sold Exclusively by Zimmer Dental Inc.

icro-Thread Implant

Astra Implant
1. TiO_2 Blasted Surface to Top
2. Micro-threads + Single-lead Threads
3. Straight Body. Optional Implant only provides taper in Micro-Thread area.
4. Fixture-Mount fictional engagement Counter-torque needed to remove.
5. Fixture Mount serves single purpose

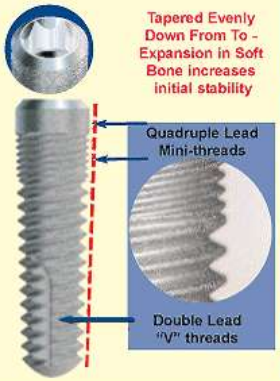
US List Price $537.50 Complete:
Implant($295) + Healing Collar ($50) +Abutment /Cap ($140.75) + Transfer ($24.75) + Cover Screw ($27)



Compare ScrewPlant to 3i's™ Certain* Implant

ScrewPlant Implant
1. SBM Blasted Surface 20u pits
2. Mini-Threads & Double-lead Threads
3. Body Taper starts at Top
4. Internal Hex 2mm Deap x 2.5mmD
5. Angled Abutments Indexed to Hex

US List Price: $150 Complete
Includes Healing Collar, Straight Abutment, Snap-on Cap and Transfer



3i Certain™ Implant
1. Acid Etched Osseotite 1-2u Pits
2. Minimal Thread Surface
3. Body Tapers from mid-point.
4. Internal Hexes 3mmD & 2.5mmD
5. No Indexing - need Encode™ Collars

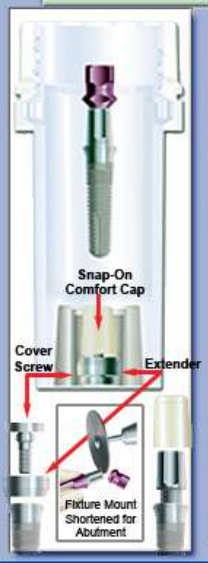
US List Price: $536 Complete
Implant ($319) +Healing Collar ($45) +Abutment ($147) +Cap ($13) +Transfer (12

ScrewPlus Implant vs Straumann's ITI Tapered Implant

ScrewPlus Implant Packaging Includes Fixture Mount (Transfer and Final Abutment) Cover Screw, 2mm Extender and Snap-on Comfort Cap

Straumann ITI Tapered Implant Includes Cover Screw Only

COMPARE US PRICES



Compare US List Price	ITI Tapered Implant	Screw Plus Implant
Implant	$305.00	$150
Cover Screw	$34.50	Included
Healing Cap	$48.00	2mm Included
Straight Abutment	$129.00	Included
Protective Cap	$7.50	Included
Transfer	$7.50	Included
TOTAL US List Price	$521	$150
SAVINGS	3.5X	71%

ITI is a Registered Trademark of Straumann Company

Implant Direct's Replant™ VS Nobel's *Replace Select

SURGICAL AND PROSTHETIC COMPATIBILITY
RePlant Implant is inserted with Nobel *Replace Surgical Instruments
RePlant Platform is Compatible with Nobel *Replace Abutments

PRICE COMPARISON - SAVE 60% FOR STRONGER, BETTER DESIGN

4mm Deep Tri-lobe Internal Connection

Implant Direct RePlant Implant
US PRICES Incl. COVER SCREW
3.5, 4.5, 5.0 & 6.0mmD = $150
Straight Snap-On Abutment = $75

Nobel *Replace Select Implant
US PRICES Incl. COVER SCREW
3.5, 5.0 & 6.0mmD = $384; 4.3mmD = $365
Straight Snap-On Abutment = $182

1.5mm Deep Tri-lobe Internal Connection

RePlant Design Advantages

TITANIUM ALLOY FOR STRENGTH (SBM SURFACE)

CP TITANIUM WITH *TIUNITE SURFACE (Alloy on HA)

*RePlace Select and TiUnite are Trademarks of Nobel Biocare Inc.

www.implantdirect.com

Materials and methods

All information sources:

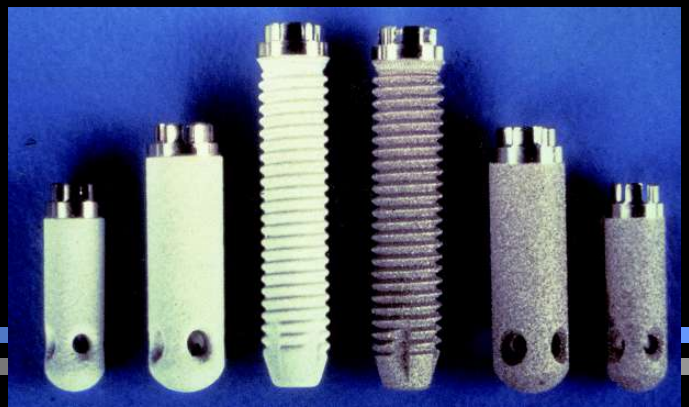
Brochures, trade exhibitions, WWW, leaflets, presentations, etc.

PICO:

Problem:	**Intervention**	**Comparison**	**Outcomes**
Claims of superiority	**Implant characteristic (material, geometry, surface topography)**	**Implant** without characteristic	**Clinical relevant & Clinical significant**

Differences in implant material:

- C.p.1 Titanium (e.g. Nobel Biopharma)
- C.p.2 Titanium
- C.p.3 Titanium (e.g. Straumann)
- C.p.4 Titanium (e.g. AstraTech)
- Titanium-alloys (e.g. C.p.5: Ti-6Al-4V)
- Hydroxyapatite
- ....



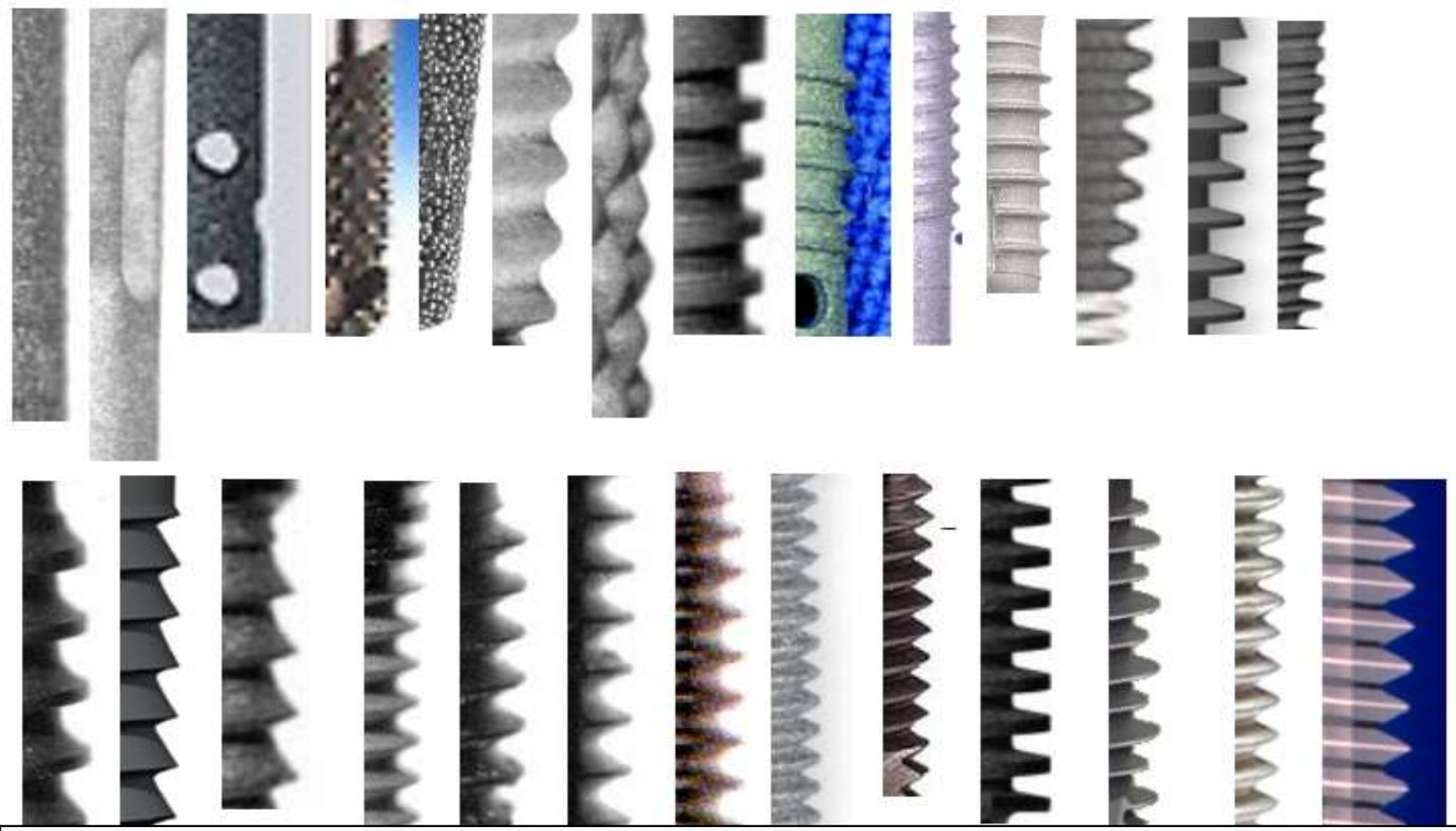
Differences in implant body geometry:

- Major morphological form
- Flange design
- Main body w/ wo/ threads
- Apex form, grooves & vents
- Interface geometry
- Surface topography

Straight, Tapered, Conical, Ovoid, Trapezoidal, Stepped & combinations …

Flange design

- Flange vs. no flange
- Straight vs. flared vs. widening
- Height
- Polished vs. threads
- Added features
- Surface topography



- Threads vs. non-threads
- Shape: V- vs. square- vs. reverse buttress- vs. combinations
- Number and size of “lead threads”
- Number and location of grooves, groove forms and groove sizes
- Surface micro-topography
- Thread angle

Apex

- Threaded vs non-threaded
- V-shape vs flat vs curved apex
- Holes, round, oblong
- Apical chamber
- Grooves and groove size
- Flared apex
- Surface topography

Interface geometry

- External vs Internal
- Hexagonal vs. Octagonal vs cone
- Morse taper
- Rotational vs non-rotational
- Added non-rotational features
- Heights & widths
- Butt vs bevel joints
- Slip-fit vs friction-fit joints
- Resilience vs nonresilience ….

Surface topography	Machining process	Example
Anisotropic with oriented cutting marks	Turned	Brånemark System® MKIII (Nobel Biocare)
Isotropic	Blasted	TiO2 particles (Tioblast®, AstraTech)
Isotropic	Blasted + acid etched	1. Large size Al2O3 particles & HCl & H2SO4 (SLA®, Straumann) - 2. Tricalcium phosphate & HF & NO3 (MTX®, Centerpulse)
Isotropic with high frequency irregularities	Acid etched	HCl / H2SO4 (Osseotite®, 3i)
Isotropic and rough	Hydroxyapatite coated	Sustain® (Lifecore)
Isotropic and rough	Titanium Plasma Sprayed	ITI® TPS (Straumann)
Isotropic with craterous structure	Oxidized	TiUnite® (Nobel Biocare)

Materials and methods

All information sources:

Brochures, trade exhibitions, WWW, leaflets, presentations, etc.

PICO:

Problem:	Intervention	Comparison	**Outcomes**
Claims of superiority	Implant characteristic (material, geometry, surface topography)	Implant without feature	**Clinical relevant & Clinical significant**

Claims of improved clinical outcomes

1. Ease of placement
2. Osseointegration
3. Esthetics
4. Peri-implant mucositis
5. Marginal bone loss
6. Mechanical problems of the implant-abutment-superstructure connections
7. Mechanical failing of dental implants

Materials and methods

1. *PICO: Comparative elements*
2. *Information presented by manufacturers*
3. *Evidence in the scientific literature*

- *Category A1, clinically controlled trial with patient randomization (RCT)*
- *Category A2, clinically controlled trial with split-mouth randomization, (Split-mouth RCT)*
- *Category B, (prospective) clinically controlled trial without randomization (CCT)*
- *Category C, clinical study applying any other study design than A or B (e.g. retrospective cohort, case-series, case-controls, etc.).*

Cochrane, ISI, Medline, Embase, IADR abst.,etc

Results

N=1270

Commercially available implant and implant systems in October 2003:

225 implant brands
78 manufacturers – from all continents
~70 implant brands no longer marketed
Clinical documentation:
from none to extensive

126 clinical studies related outcome to implant characteristics (material, geometry, surface topography)

	RCTs	CCTs	Other	
1. Ease of placement	4	3	0	7
2. Osseointegration	25	3	21	49
3. Esthetics	1	1	0	2
4. Peri-implant mucositis	21	0	3	24
5. Marginal bone loss	19	6	2	27
6. Mechanical problems of the implant- abutment-superstructure connection	6	1	6	13
7. Mechanical failing of dental implant	1	1	2	4
	77	15	34	126

126 clinical studies related outcome to implant characteristics (material, geometry, surface topography)

	RCTs	CCTs	Other	
1. Ease of placement	4	3	0	7
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5. Marginal bone loss	19	6	2	27
6. Mechanical problems of the implant- abutment-superstructure connection	6	1	6	13
7. Mechanical failing of dental implant	1	1	2	4
	77	15	34	126

49 clinical studies related a specific implant characteristic to the outcome: osseointegration

	RCTs	CCTs	Other	
Implant geometry	**4**	**-**	**8**	**12**
Implant material	**3**	**-**	**2**	**5**
Implant surface	**5**	**-**	**1**	**6**
Complex study design	**13**	**3**	**10**	**26**
	25	**3**	**21**	**49**

Has this report led to anything?

Quality of Dental Implants

Background

More than 220 implant brands produced by about 80 manufacturers are commercially available worldwide. These are made from different materials, undergo different surface treatments and manifest in different shapes, lengths, widths and forms. The clinician can in theory choose among more than 2000 implants.

FDI recognizes that:

- Implants made from titanium and titanium alloys appear to perform well clinically in properly surgically prepared bone, regardless of small variations in design.
- The scientific evidence of the influence of dental implant material, geometry and surface topography on their clinical performance is limited and the study methodology is not strong. Hence there is inconclusive evidence for promoting specific implants or implant systems over others.
- Implants are manufactured and sold in some parts of the world without compliance to international standards. It would seem prudent to only use dental implants supported by sound clinical research documentation and which conform to the general principles of good manufacturing practice in compliance with the ISO Standards or FDA (Food and Drug Administration) and other regulatory bodies.
- Most clinical trials on dental implants focus on criteria relative to peri-implant aspects over relatively short observation periods. Such criteria are only surrogate measures for treatment outcome from the patient and general public perspectives.

Submitted by: FDI Science Committee

Reference: FDI Science Committee Project 5-98: Jokstad A, Brägger U, Brunski JB, Carr AB, Naert I, Wennerberg A. Quality of Dental Implants. *International Dental Journal*, 2003; 53: Suppl 3:409-443.

Adopted by the FDI General Assembly
12th September 2004 – New Delhi

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Latest News from the World Dental Federation

FDI supports World Health Day 2005

Oral health is important to mother and child health...read the full text and

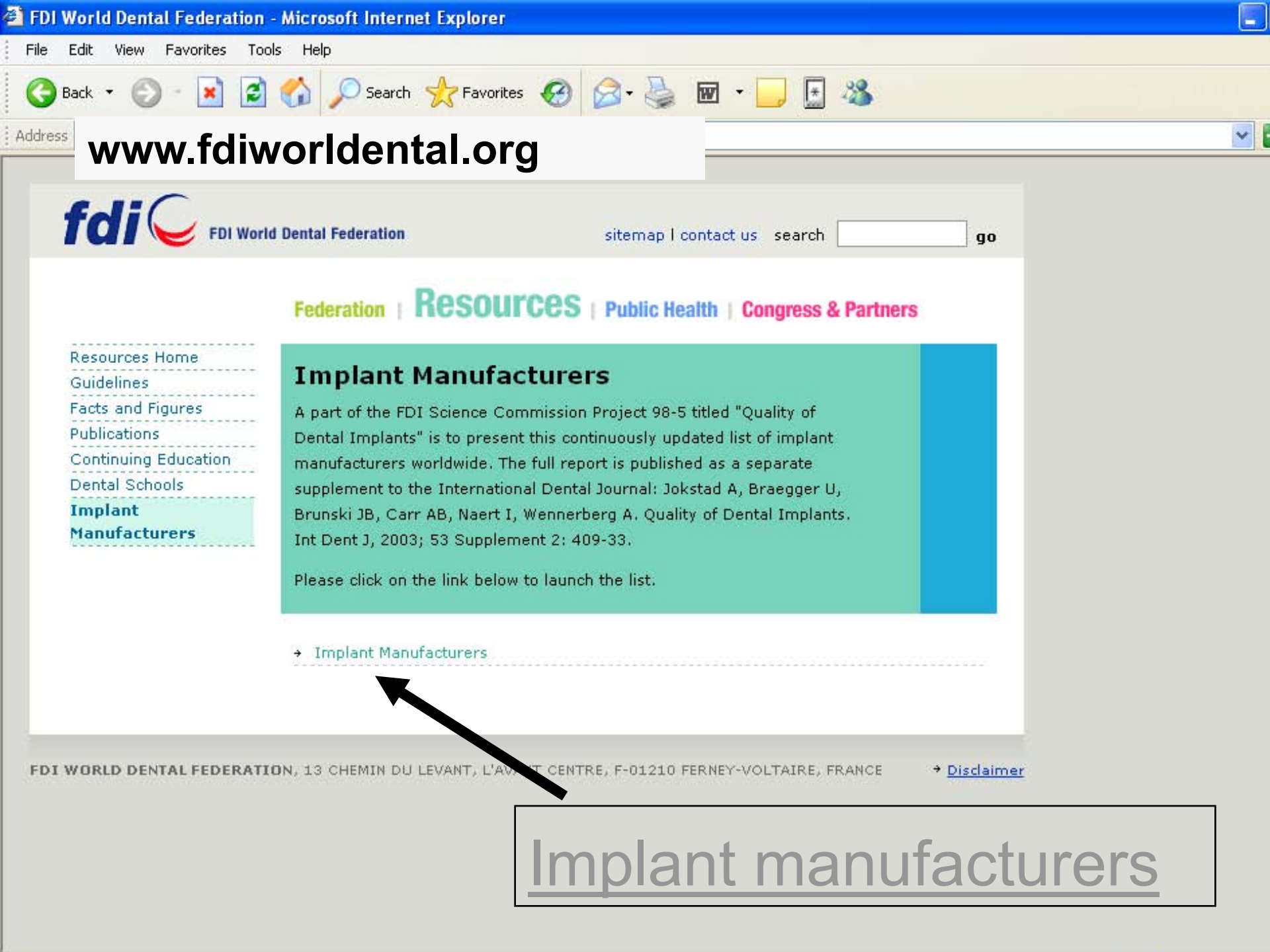
2006 Annual World Dental Congress

The Congress will take place in Shenzhen, China.
Le Congrès se déroulera à

2005 Montréal Congress

Dates: 24th -27th August
Venue: Palais des Congrès

ON-LINE REGISTRATION!!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Dental Schools
Implant Manufacturers
Implant Manufacturers
A part of the FDI Science Commission Project 98-5 titled "Quality of Dental Implants" is to present this continuously updated list of implant manufacturers worldwide. The full report is published as a separate supplement to the International Dental Journal: Jokstad A, Braegger U, Brunski JB, Carr AB, Naert I, Wennerberg A. Quality of Dental Implants. Int Dent J, 2003; 53 Supplement 2: 409-33.
Please click on the link below to launch the list.
Implant Manufacturers
FDI WORLD DENTAL FEDERATION, 13 CHEMIN DU LEVANT, L'AVANT CENTRE, F-01210 FERNEY-VOLTAIRE, FRANCE
Disclaimer
Implant manufacturers

Jokstad, Brägger, Brunski, Carr, Naert, Wennerberg.

Int Dent J 2003; 53 Sup 2: 409-33

&

Int J Prosthodont 2004; 17: 607-41

The "Groovy implant"

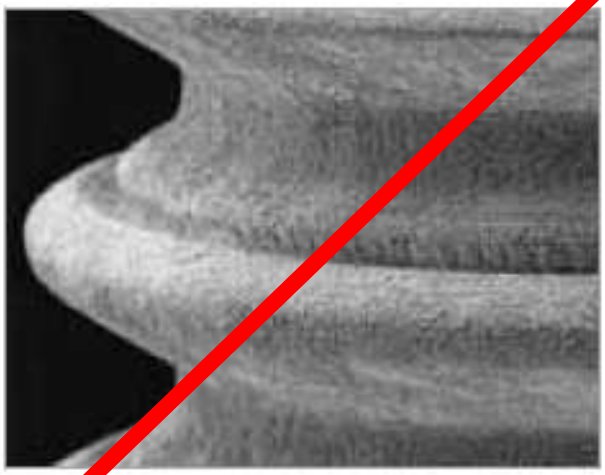
Benefits of Grooves Incorporated onto the Thread of the Implant:

- Up to 30 percent higher stability
- Enhanced osseoconductive properties leading to higher biomechanical stability
- Bone forms more rapidly along the grooves compared to the rest of the implant
- Particularly effective in soft bone

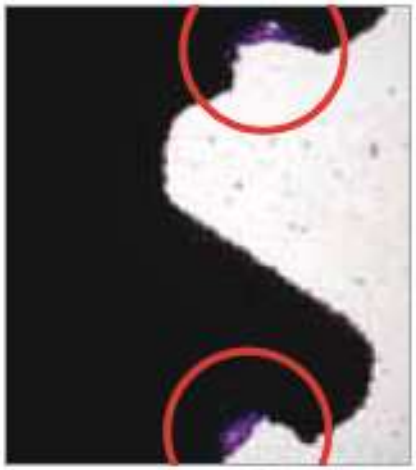
30%

Feeling Groovy

In 2005, Nobel Biocare took the complete range of TiUnite® implants to a new level of effectiveness with the introduction of the Groovy™ technology. As a further step towards shorter healing times and safer implant treatment, Nobel Biocare added a groove of optimal dimensions to the thread of the implants. The combined effect of TiUnite® and the groove is a favorable environment that stimulates faster bone growth within and along the groove. The result is not only further enhancement of the rate of osseointegration, but also up to 30 percent higher implant stability due to increased mechanical interlock between the bone and the implant.



> GROOVY IMPLANT
The groove at the thread takes the TiUnite® implants to a new level of effectiveness.



> GROOVY BONE FORMATION
Faster bone growth within the groove results in enhanced rate of osseointegration and biomechanical stability.

Page 33. In: Nobel Biocare. *Annual report* 2005

APR 19 2005

K050258

1.4 510(k) Summary of Safety and Effectiveness

Submitted by:	Herbert Crane Manager, Regulatory Affairs
Address:	Nobel Biocare USA LLC 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Telephone:	(714) 282-4800, ext. 7830
Facsimile:	(714) 282-9023
Date of Submission:	February 2, 2005
Classification Name:	Endosseous Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	Groovy Implants
Legally Marketed Device(s):	Nobel Biocare Endosseous Implants (K041661)

2.Feb 2005:

510K Application

Indications for Use:
Nobel Biocare's Groovy Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's Groovy Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare Groovy Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied.

Groovy implants are indicated for use in soft bone in posterior regions or whenever immediate or early

…bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants.

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Hall J, Miranda-Burgos P, Sennerby L.

Nobel Biocare AB, Goteborg, Sweden. jan.hall@nobelbiocare.com

Purpose: *Study if bone formation and implant stability were influenced by 110 μm and 200 μm and 70 μm deep grooves positioned at a thread flank*

M&M: 18 rabbits – 6 x 7 mm implants

9: 3 control impl. + 3 test impl. (110 μm wide & 70μm deep)

9: 3 control impl. + 3 test impl. (200 μm wide & 70μm deep)

6 weeks → Removal torque (RTQ) (2 control impl. vs 2 test impl.)

→ Histology (1 control impl. vs 1 test impl.) "bone-fill"

Results:	RTQ	% bonefill	
110x70 μm grooves	+30% p< 0.05 (36)	p< 0.05 (18)	vs. control
200x70 μm grooves	+ 8% p< 0.05 (36)	p< 0.05 (18)	vs. control

Conclusion: *"The 110 micron-wide groove was shown to increase the resistance to shear forces significantly. It is suggested that implants with such a groove may be one way to optimize implant stability in suboptimal clinical conditions."*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nobel Biocare AB
C/O Mr. Herbert Crane
Manager, Regulatory Affairs
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

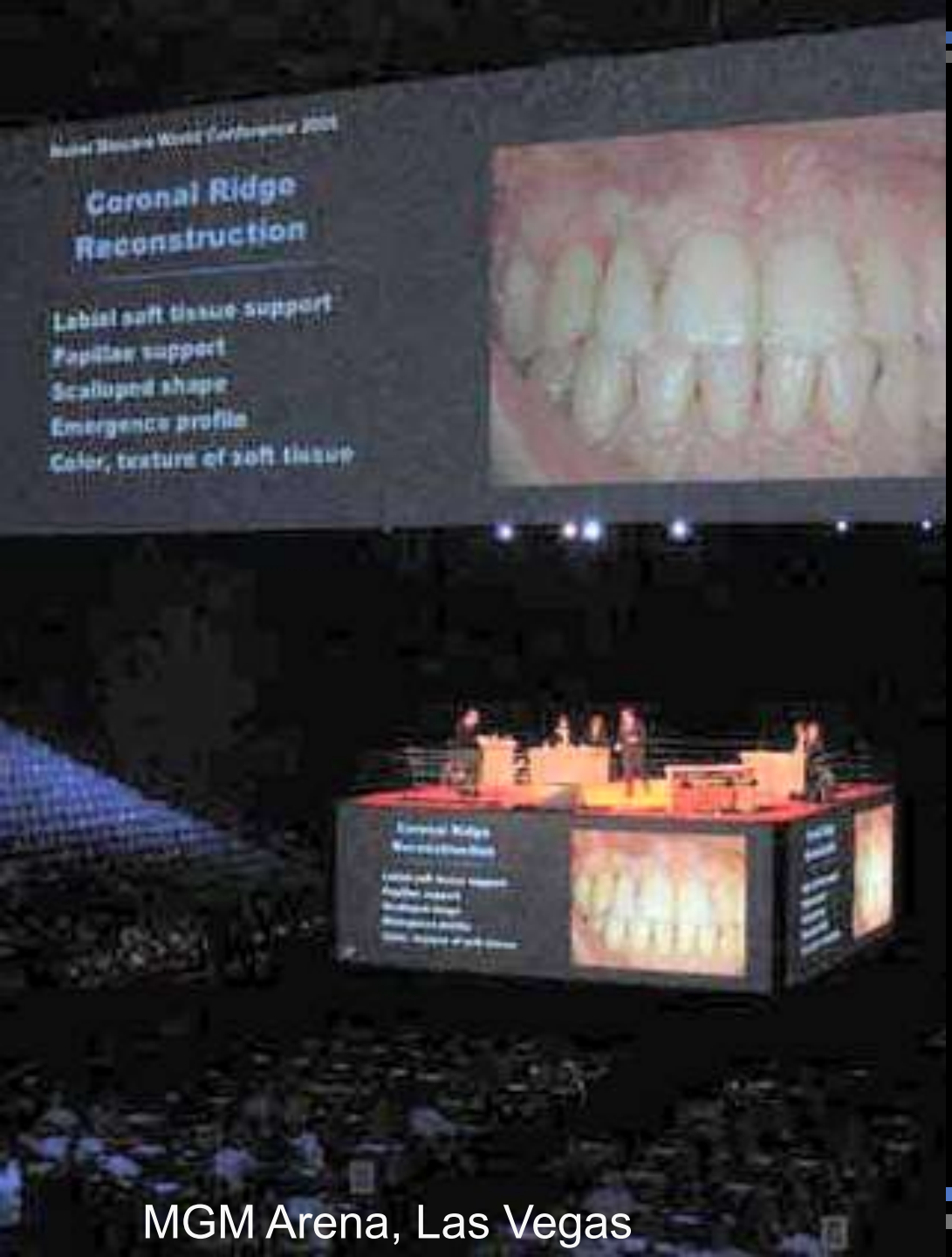
APR 19 2005

Re: K050258
Trade/Device Name: Groovy Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: February 2, 2005
Received: February 3, 2005

19. April 2005:
510K Approval

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.



MGM Arena, Las Vegas

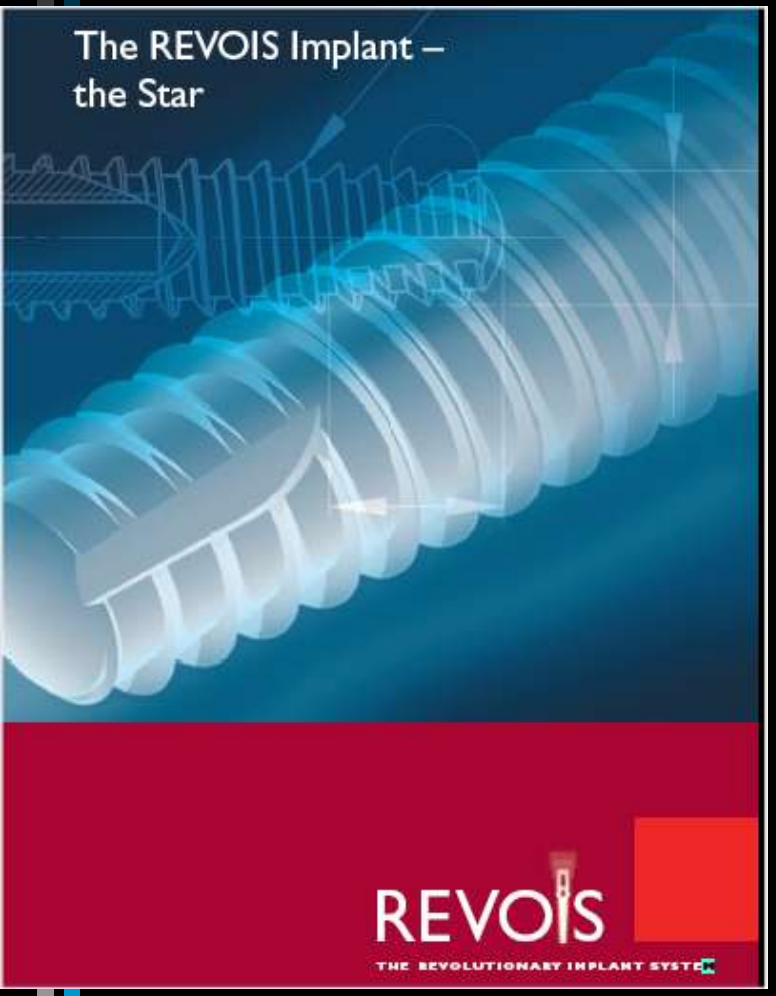
2 Feb 2005:
Application

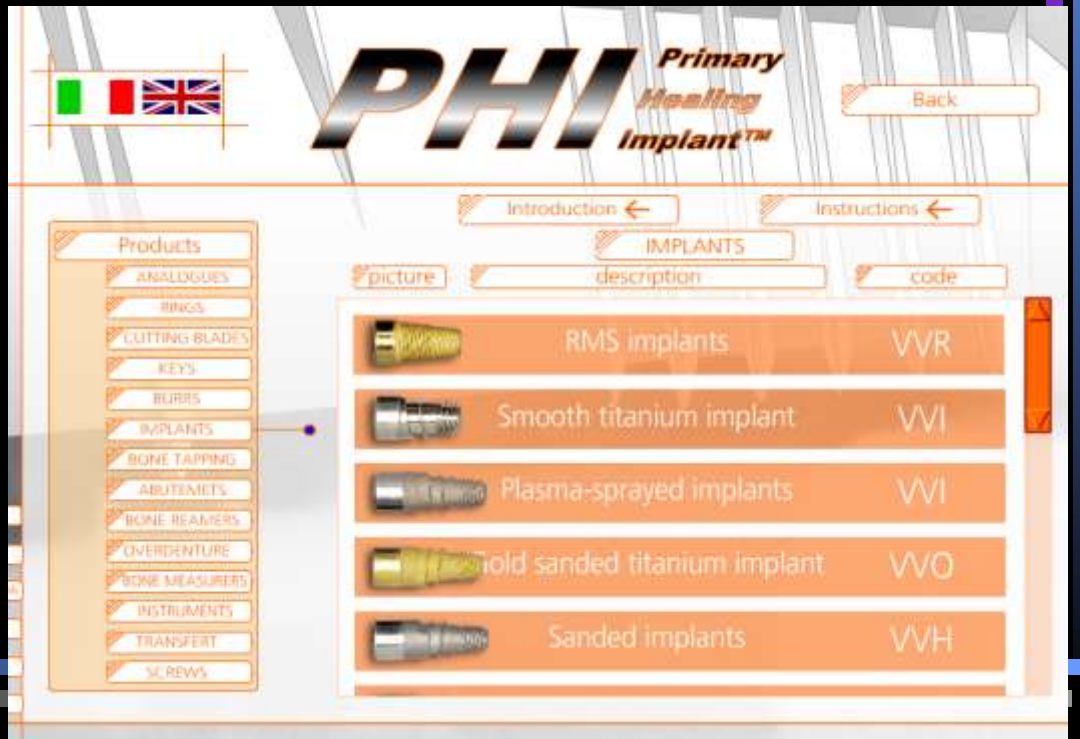
19 April 2005:
Approval

6 June 2005:
World Premiere!

*“ Welcome to **Dentium Dental Implant System**: Since the establishment of Dentium in the USA in 2004, we have been manufacturing high quality dental implant products. Our extensive clinical documentation and research have lead to the development of an innovative, simple, and versatile dental implant system…”*

New implants since Oct 2003:





Thank you for your kind attention