i-Fix Implant

“i-Fix implants: Made in India for the World”

Dr Mohammad Shahnawaz

Kamal Medtech
Who we are?

Global Footprint

Unit 1 - Manufacturing Facilities at Yamunanagar -200Km north of Delhi

Unit 2 - Casting & Machining Facilities at Yamunanagar

Unit 3 - New Facility at IMT Faridabad, NCR Delhi

Kamal Medical Devices Brands

kamal

Stenoflex
Sirolimus Eluting Coronary Stent System

Everoshine
Everolimus Eluting Coronary Stent System

i-Fix™
POWERING SMILES

The Beginning……

Research Partners

Indian Institute of Technology, Delhi

iFix Dental Implant has been Conceptualized, Designed & Developed by Indian Institute of Technology (IIT), Delhi in collaboration with Maulana Azad Institute of Dental Sciences (MAIDS), Delhi

Maulana Azad Institute of Dental Sciences
New Delhi

iFix Dental Implant has been Clinically studied at Maulana Azad Institute of Dental Sciences, New Delhi

Council of Scientific and Industrial Research

Under the Patronage of Council of Scientific & Industrial Research (CSIR) - NMITLI Program

kamal

Manufacturers of high quality medical devices of global standards

Certifications: MDR 2017 & ISO 13485

सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2019/000057

1. M/s KAMAL ENCON INDUSTRIES LIMITED, 56 INDUSTRIAL ESTATEYAMUNA NAGAR, –, Haryana (India) - 135001 Telephone No.: 1123351365 FAX: 1123721657 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s KAMAL ENCON INDUSTRIES LIMITED, Plot No. 917, IMT Faridabad, Sector- 68, Faridabad, Haryana (India) - 121001 Telephone No.: 11-23723158, 11-23351369 FAX: 11-23721657
2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer
4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Dental Implants with Abutments & Prosthesis Model No.:NIL Intended Use:Dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. Class of medical device:Class C Material of construction:Titanium Alloy, TI-6Al-4V Dimension(if any):Diameter (mm): 3.00, 3.50, 4.00, 4.50, 5.00 & 5.50 AND Length (mm): 7.50, 8.50, 10.00, 11.50, 13.00 & 15.00 Shelflife:60 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):IFix, MultiFix, SFix, CFix

Place:

Date29-May-19

S ESWARA REDDY
Central Licensing Authority

| evaluate | assess | certify | Zenith assessors of quality

Certificate No. MD-QMS/91/R/2609

This is to certify that

Kamal Encon Industries Ltd.

Plot No. 917, Sector 68, IMT Faridabad – 121 001, Haryana, India

has been found to conform to the requirements of
Medical Devices - Quality Management System Standard

ISO 13485:2016

This certificate is valid for the following scope :

Design, Development, Manufacture and Sales of :
(1) Interventional Cardiology Products :
-Sirolimus Eluting Coronary Stent System
-Everolimus Eluting Coronary Stent System
(2) Dental Implants and Prosthesis
Manufacture and Sales of Surgical Kits

Initial Certification : 27/07/2019
Valid until : 26/07/2022

ZQA

NABCB
QM 062

Authorised Signatory

The authenticity of this document may be established by writing to certification@zenith-worldwide.com. Lack of fulfillment of conditions of assessment as per the Certification Agreement may render this certificate invalid. Any alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of law.

Accreditation Body: National Accreditation Board for Certification Bodies (NABCB)
Quality Council of India (QCI), 3rd Floor, Institution of Engineers Building, Bahadur Shah Zafar Marg, New Delhi – 110 002, India
www.nabcb.qci.org.in

Issuing Authority: Zenith Quality Assessors Pvt. Ltd.
306, 4th Floor, Sai Apex, Viramagal, Pune – 411 014, Maharashtra, India
www.zenith-worldwide.com

CE CERTIFICATION

CERTIFICATE

EC Certificate No. 1434-MDD-344/2021
Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Kamal Encon Industries Limited
Plot No. 917, Sector-68,IMT, Faridabad 121001,
Haryana, INDIA

for the design, manufacture and final inspection of
medical devices, class IIb

Dental Implants & Prosthesis
The list of medical devices covered by this certificate is provided in the Annexes 1-13

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 25.05.2021 to 27.05.2024

The date of issue of the Certificate: 25.05.2021

The date of the first issue of the Certificate: 25.05.2021

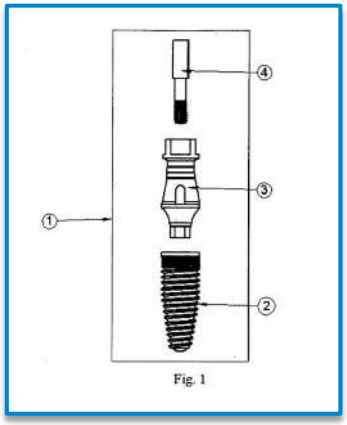
CE 1434

Issued under the Contract No. MD-80/2020
Application No: 138/2020
Certificate bears the qualified signature.
Warsaw, 25/05/2021
Module H2/3/4/5

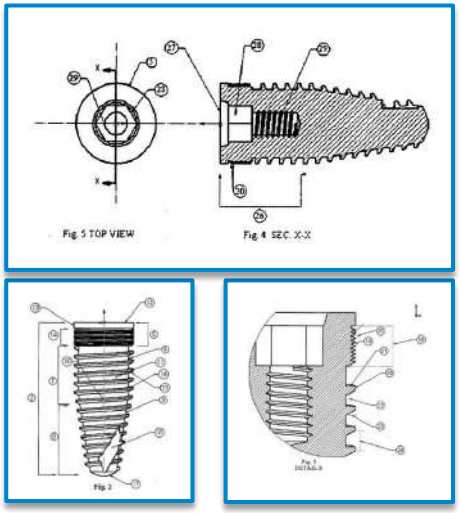
Vice-President

IIT Delhi Conceptual Design - led to Indian and US Patent

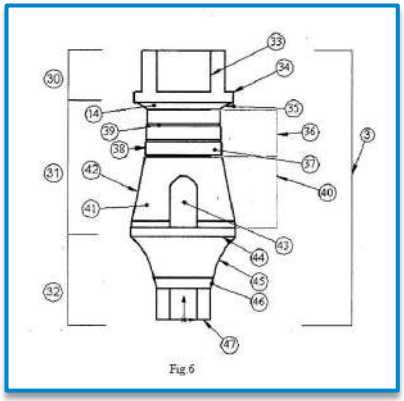
US Patent No. 9,833,300



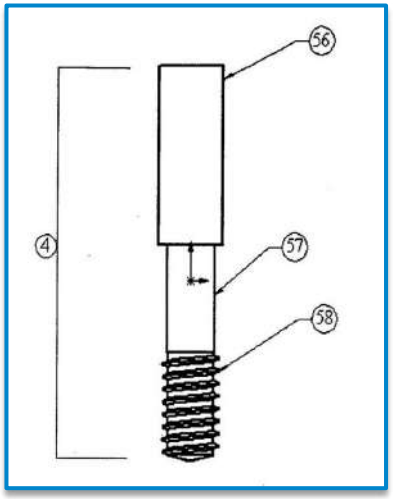
Assembly



Implant



Abutment



Screw

GRADE 5 ELI

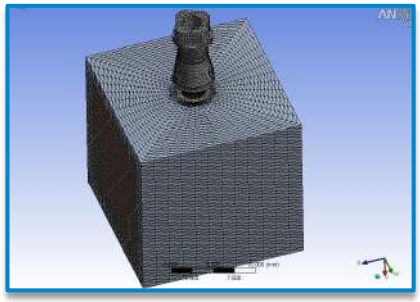
Properties		Advantages
Tensile strength	860 MPa minimum	Extremely high strength/ weight ratio
Elongation	10%	Improved ductility and fracture toughness under static and dynamic loads
Oxygen content	0.13% maximum	
Biocompatibility	Excellent	Direct structural and functional connection between bone and implant surface

Ti Grade 5 ELI

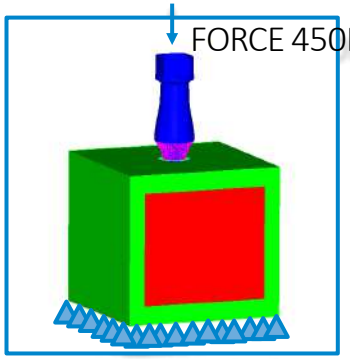
Properties		Advantages
Tensile strength	860 MPa minimum	Extremely high strength/ weight ratio
Elongation	10%	Improved ductility and fracture toughness under static and dynamic loads
Oxygen content	0.13% maximum	
Biocompatibility	Excellent	Direct structural and functional connection between bone and implant surface

- Its properties of biocompatibility, corrosion resistance, high strength, and toughness make it especially suitable for implants and other medical devices.
- ELI is also referred to as Grade 23 Titanium and ASTM F136.
- Ti6Al4V ELI contains reduced levels of oxygen, nitrogen, carbon and iron. ELI is short for “Extra Low Interstitials”, and these lower interstitials provide improved ductility and better fracture toughness for the Ti6Al4V ELI material.

The Design Premise



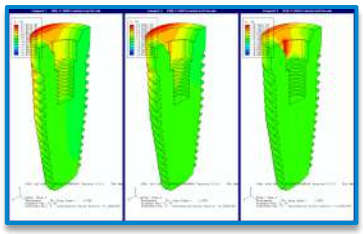
FE Meshing

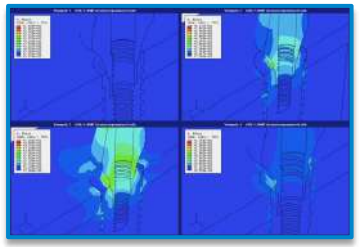


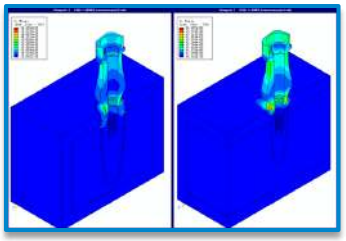
Boundary Condition

Bottom all degree of constrains

Comparison of different thread types under compression, Tension						
S. No.	PARAMETER & LOCATION	Classical V	Reverse Buttress	Buttress	Buttress & Micro threads	Reverse Buttress & Micro threads
I)	COMPRESSION			Units-Mpa		
A)	Implant Abutment interface	41.49	36.51	30.94	38.49	47.08
B)	Crestal bone level	29.71	11.94	20.46	18.48	23.73
C)	Cortico-cancellous interface	30.44	24.39	27.25	18.85	34.88
I)	TENSION					
A)	Implant Abutment interface	40.47	37.57	33.95	38.44	47.08
B)	Crestal bone level	29.73	44.38	20.44	18.48	23.74
C)	Cortico-cancellous interface	30.99	63.34	27.25	22.29	34.88
III)	MOMENT					
A)	Implant Abutment interface	425.34	421.62	278.94	396.09	339.45
B)	Crestal bone level	227.03	120.68	139.97	70.27	49.55
C)	Cortico-cancellous interface	9.59	9.18	30.39	8.57	11.23







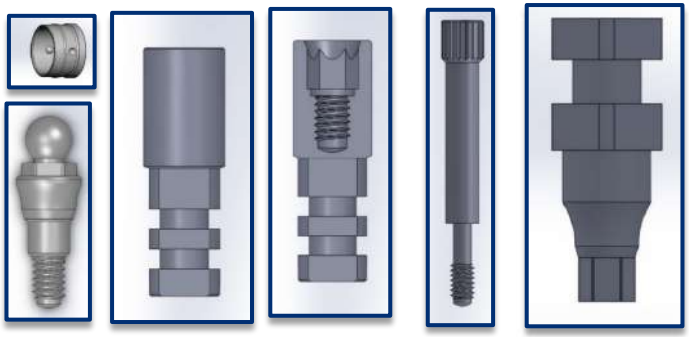
Design of CSIR-NMITLI Dental Implant System


Implant

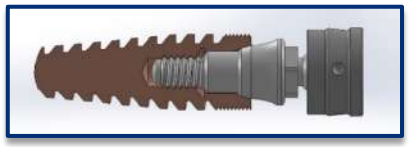

Abutment

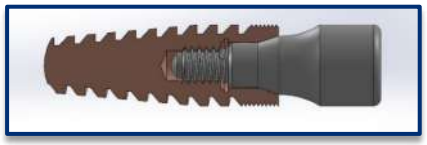

Screw


Ball Abutment


Impression Coping


Implant Abutment Assembly


Implant Ball Abutment Assembly

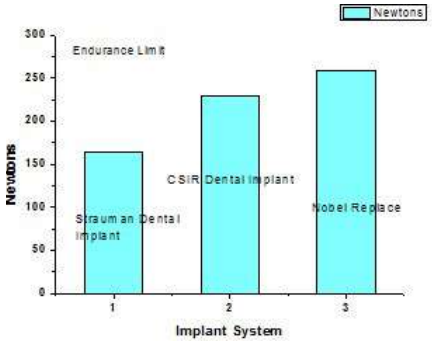

Implant Healing Screw Assembly

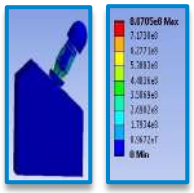
Analysis and Testing as per ISO 14801 & 13498

Loading direction

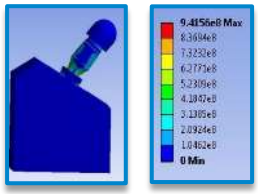
Table 3: Fatigue test results

Serial No.	Load value (in percent of the static load to failure)	Life (No. of cycles)
1.	80 %	3,838
2.	70 %	18,943
3.	60 %	36,726
4.	50 %	89,840
5.	40 %	5,000,000

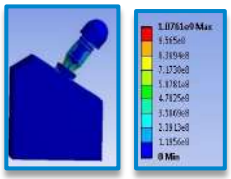




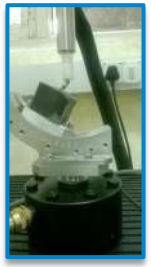
300 N

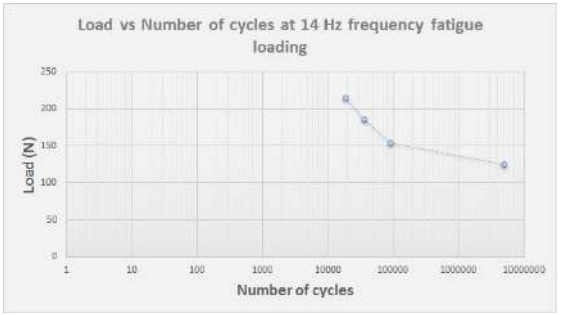


350 N



400 N

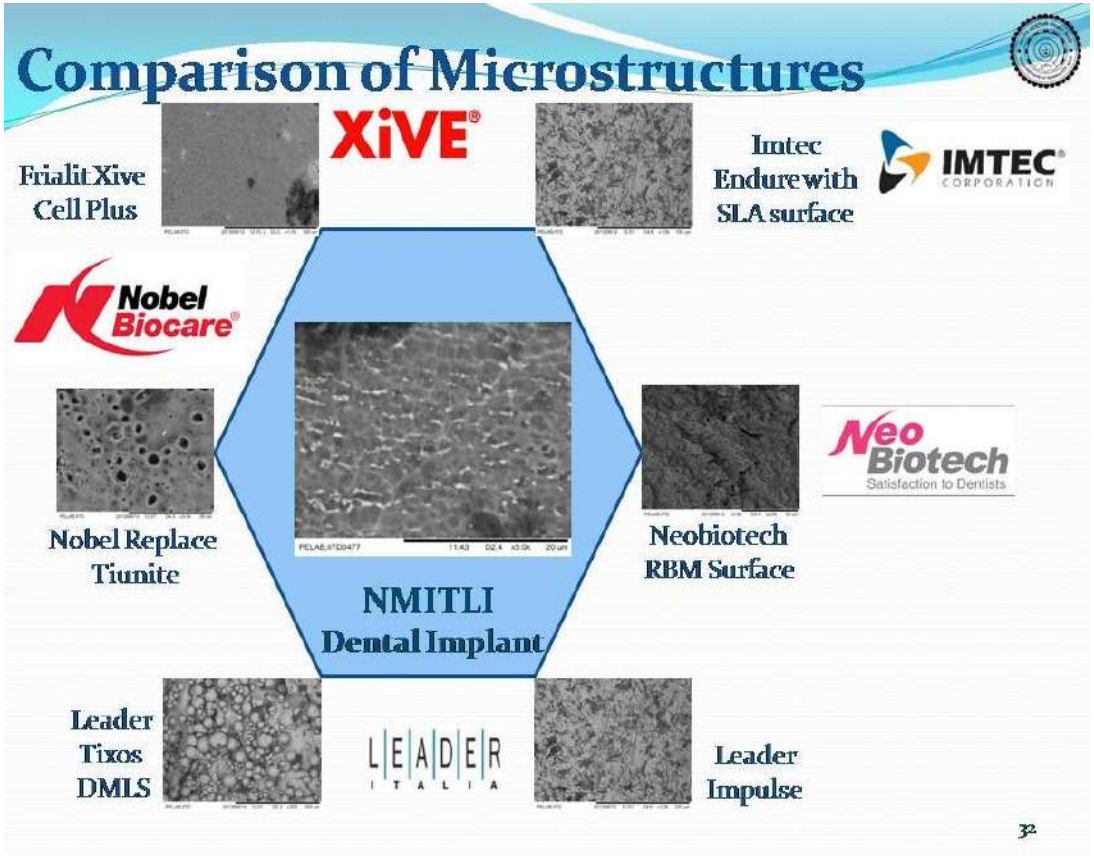




Fatigue Testing ISO 14801

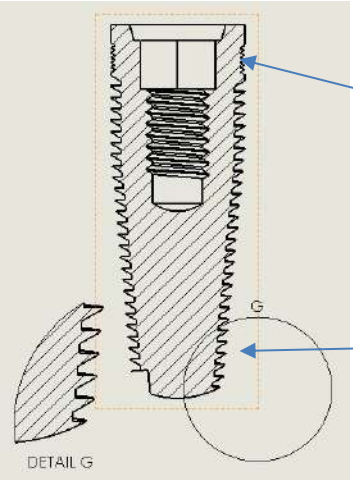
Torsion Testing ISO13498

A comparative study with commercially available Implants



- Animal Trials on rabbit model
- Physical Testing at IIT D
- Micro CT Analysis
- Histomorphometric Study
- Sterility Testing
- Stability testing

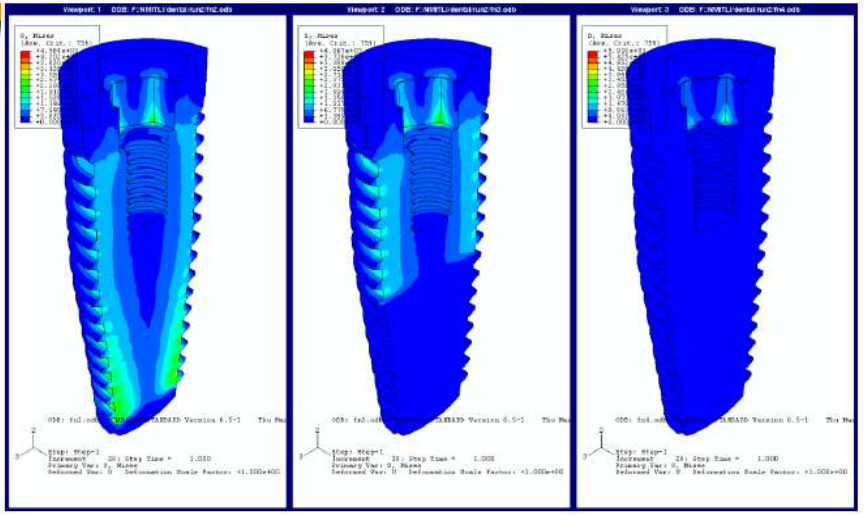
Dental Implant Designing
Evolution &Validation of Designs by FEM



Micro Thread

Buttress Thread

Improved biomechanical performance at bone-implant interface.



Elastic Properties Ascribed to Materials Used In The Models

Materials	Young Modules (GPa)	Poisson`s ratio
Cortical bone	15	0.3
Cancellous bone	1.5	0.3
Titanium	110	0.35

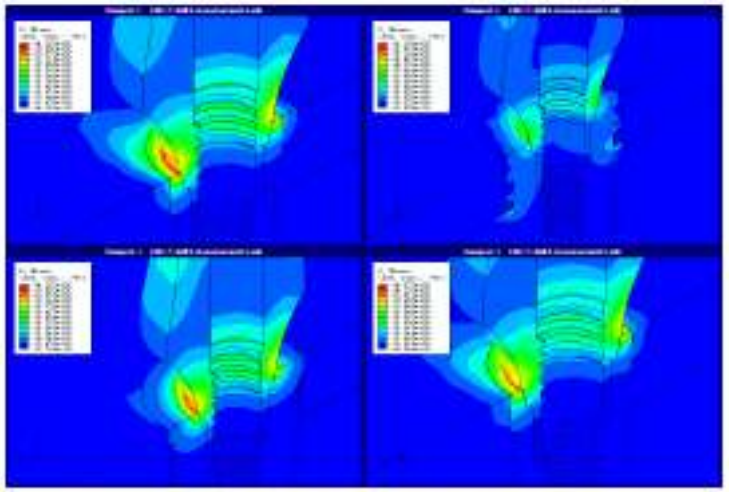
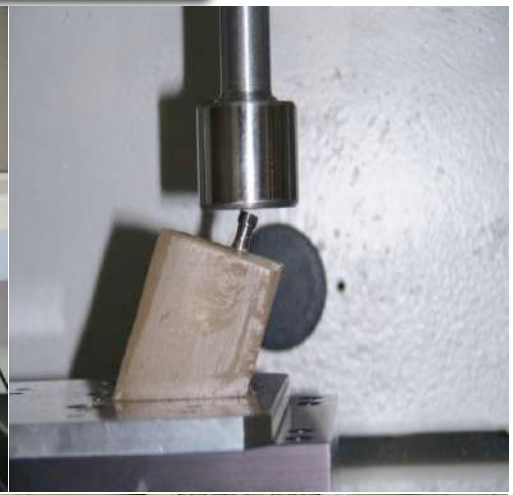


Fig. 3 Comparing different thread types under moment

- DYNAMIC FATIGUE TEST: DONE AT IIT,DELHI ON CETR-UMT-2, BRUKER
- Implant abutment assembly with load applied 30º to vertical for fatigue testing (as per FDA norms)
- • 2 MILLION CYCLES - 1 SAMPLE
- • 5N -800 N COMPRESSION – COMPRESSION TEST



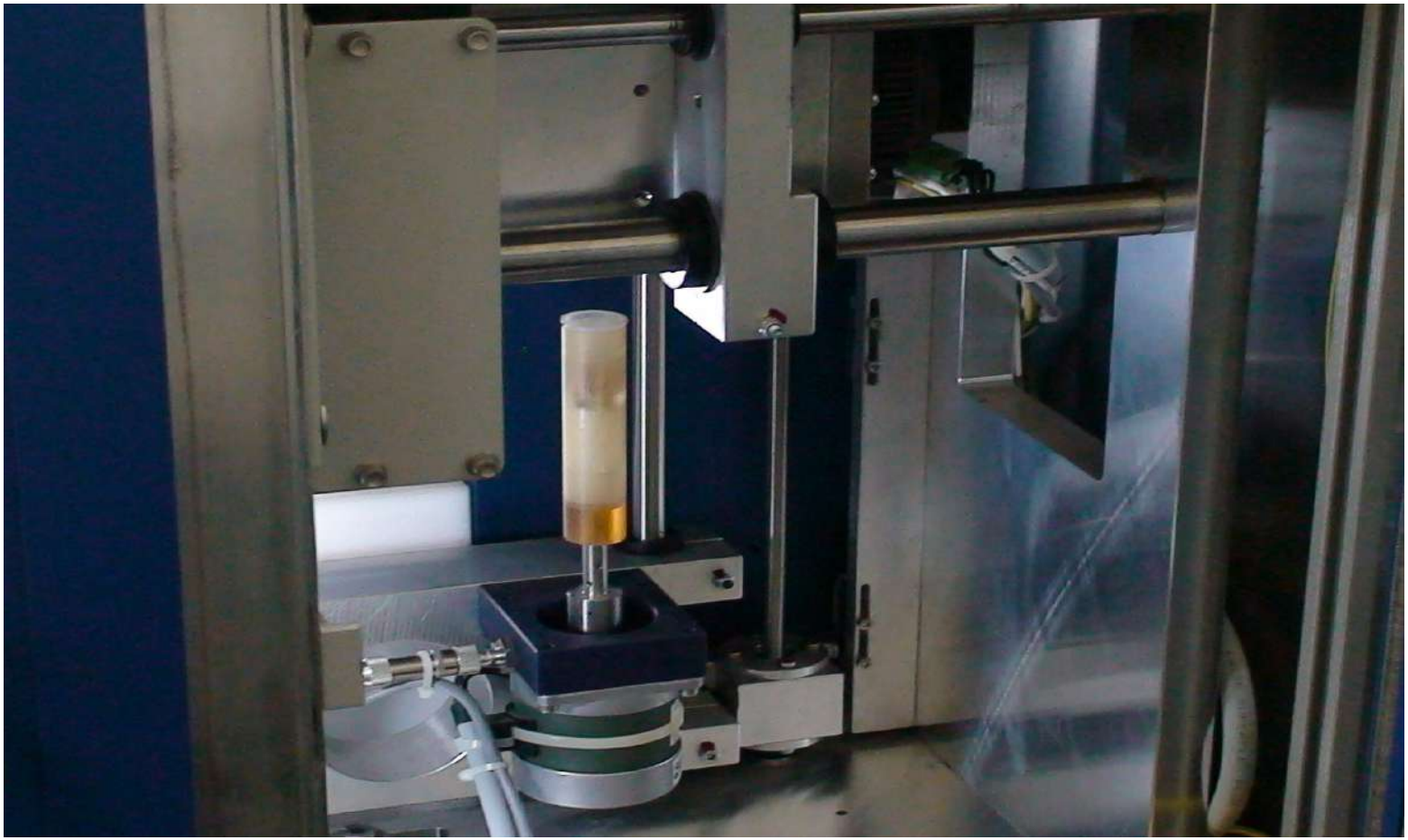
Shri Ram Institute of Industrial Research

In Vivo Implantation study of specially prepared Micro implants were done on femur of White New Zealand rabbits and evaluated after 6 and 12 weeks. After necropsy histological, micro CT and Histomorphometric evaluation was done which revealed no adverse effects and an extremely favourable bone implant contact.

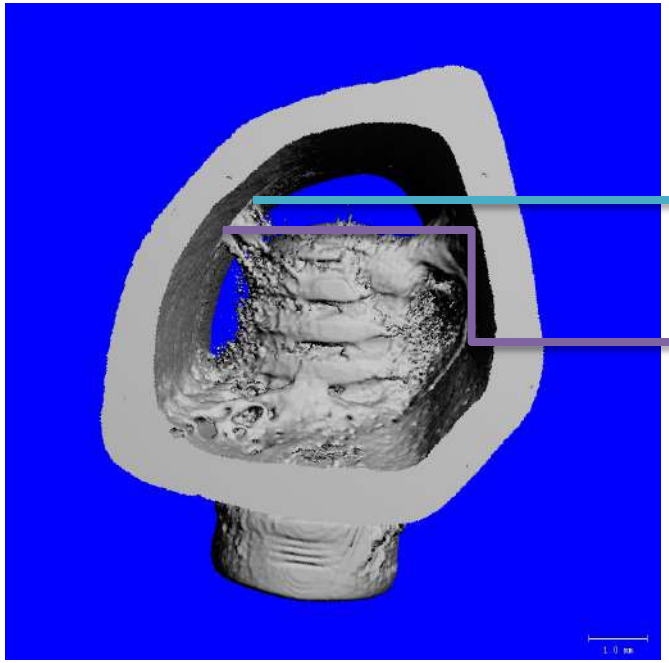
MICRO CT ANALYSIS

Shree Chitra Tirunal Institute for Medical sciences Technology (Bio Medical Technology Wing), Thiruvananthapuram

Sample Holder in Position for Analysis

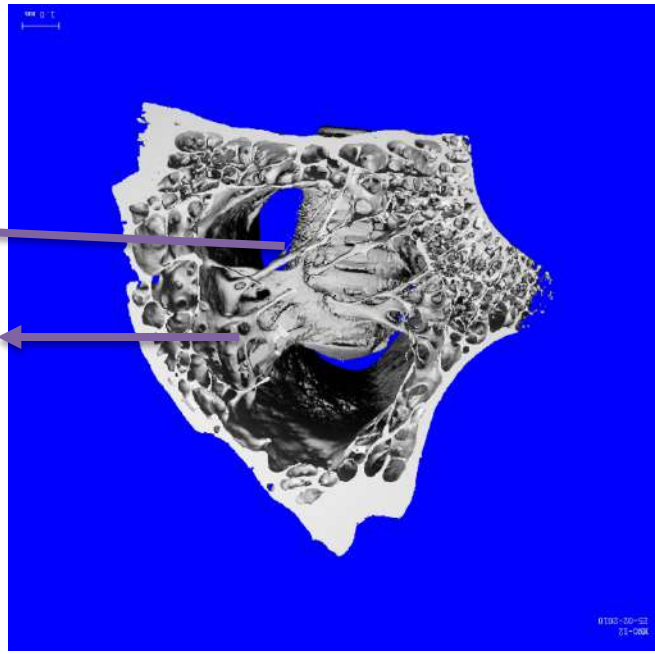


RESULTS OF MICRO CT IMAGING FOR SAMPLE ON DAY 84/ 12 WEEKS (SAMPLE MNC3)



Medullary space

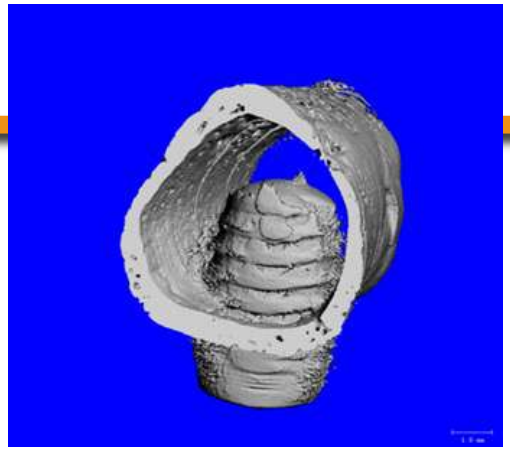
Trabecular projections

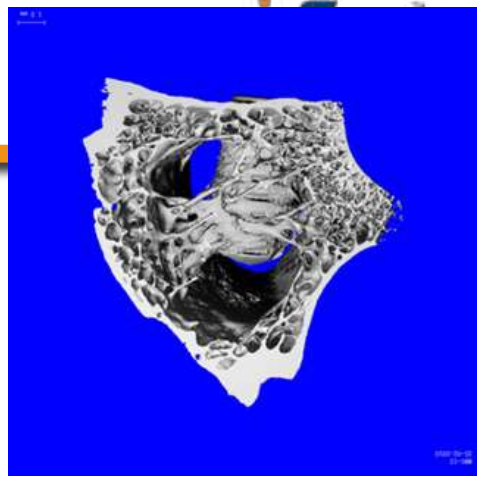


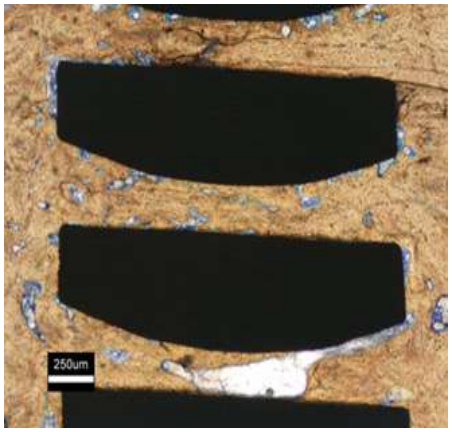
Prominent trabecular projections seen as strands extending from the inner aspect of the surrounding cortical bone towards the implant surface engaging it. High concentration of trabeculae seen near the area where the neck of the implant engages the cortical bone.

6 weeks

12 weeks







S.NO	SPECMEN/ WEEKS	MEAN DISTANCE FROM CRESTS IN RECTANGLE	PERCENTAGE BONE FORMATION
1	12 weeks	415.62 µm	**80.5%**
2	6 weeks	424.63µm.	25.6%

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

(A unit of Shriram Scientific and Industrial Research Foundation)

An ISO - 9001:2008 Certified Institute

TEST CERTIFICATE

000358830

Issued to :
INDIAN INSTITUTE OF TECHNOLOGY, DELHI
DEPT. OF MECHANICAL ENGINEERING
HAUZ KHAS
NEW DELHI - 110016

J.O.No. 502-111-1839
Reg.No. 1370083
Date 21-02-2015
GC-01 (REV-04)
Your Ref.No. -

Kind Attn: DR NARESH BHATNAGAR , PROFESSOR & ASSO. DEAN [R&D]

Sample Particulars : **Date**

One sample of Dental Implant labelled as Lot No. 1 DT 17.01.2015 was received.

"The sampling was not carried out by Shriram Institute for Industrial Research. The sample details provided in test certificate are based on declaration by the party."

TEST RESULTS

S.No	TEST	RESULT	PROTOCOL
1.	Sterility test	Sample complies with the test for sterility	As per guidelines of USP-37

NOTE: Party asked for above test only.

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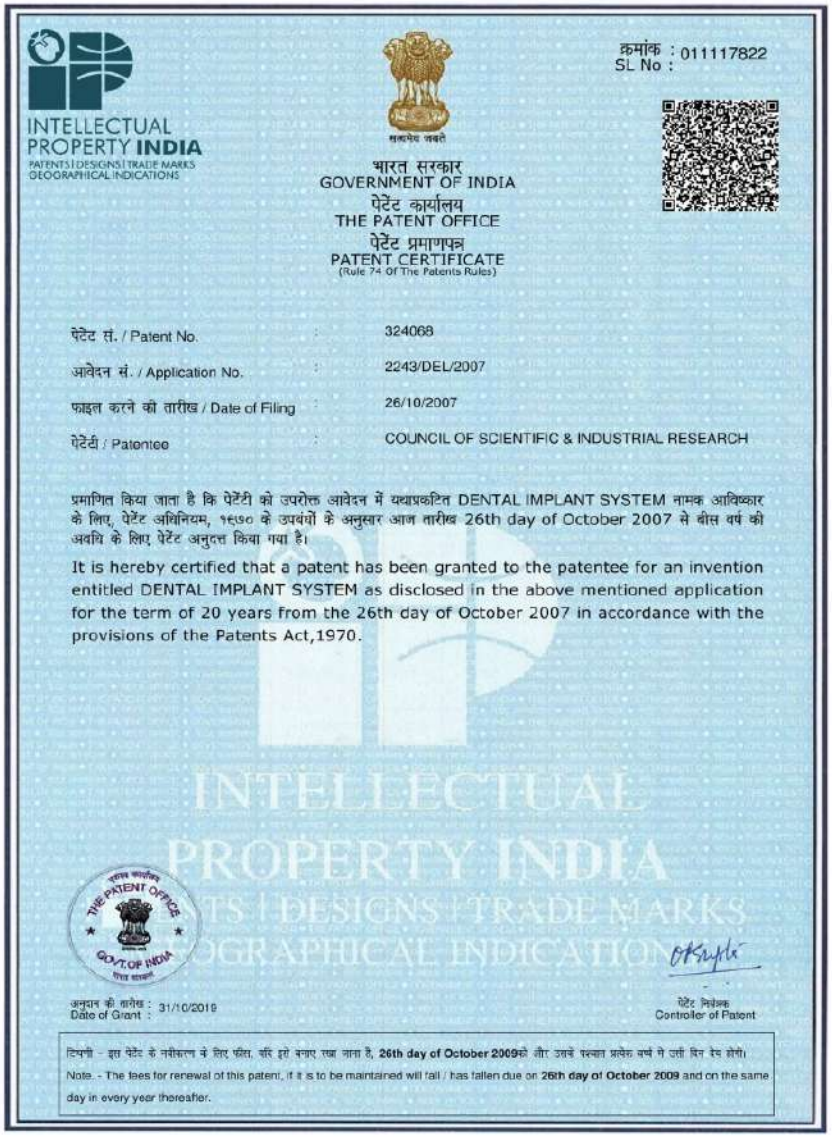
DOR: 06-02-15
DOC: 20-02-15

Indian & US Patent



INTELLECTUAL PROPERTY INDIA
PATENTS | DESIGNS | TRADE MARKS
GEOGRAPHICAL INDICATIONS

क्रमांक : 011117822
SL No :

भारत सरकार
GOVERNMENT OF INDIA
पेटेंट कार्यालय
THE PATENT OFFICE
पेटेंट प्रमाणपत्र
PATENT CERTIFICATE
(Rule 74 Of The Patents Rules)

पेटेंट सं. / Patent No.	:	324068
आवेदन सं. / Application No.	:	2243/DEL/2007
फाइल करने की तारीख / Date of Filing	:	26/10/2007
पेटेंटी / Patentee	:	COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH

प्रमाणित किया जाता है कि पेटेंटी को उपरोक्त आवेदन में यथाप्रकटित DENTAL IMPLANT SYSTEM नामक आविष्कार के लिए, पेटेंट अधिनियम, १९७० के उपबंधों के अनुसार आज तारीख 26th day of October 2007 से बीस वर्ष की अवधि के लिए पेटेंट अनुदत्त किया गया है।

It is hereby certified that a patent has been granted to the patentee for an invention entitled DENTAL IMPLANT SYSTEM as disclosed in the above mentioned application for the term of 20 years from the 26th day of October 2007 in accordance with the provisions of the Patents Act,1970.

अनुदान की तारीख : 31/10/2019
Date of Grant :

पेटेंट नियंत्रक
Controller of Patent

टिप्पणी - इस पेटेंट के नवीकरण के लिए फीस, यदि इसे बनाए रखा जाना है, **26th day of October 2009** को और उसके पश्चात प्रत्येक वर्ष में उसी दिन देय होगी।
Note. - The fees for renewal of this patent, if it is to be maintained will fall / has fallen due on **26th day of October 2009** and on the same day in every year thereafter.

US009833300B2

(12) **United States Patent**
Verma et al.

(10) **Patent No.: US 9,833,300 B2**
(45) **Date of Patent: Dec. 5, 2017**

(54) **DENTAL IMPLANT SYSTEM**

(75) Inventors: **Mahesh Verma**, New Delhi (IN); **Naresh Bhatnagar**, New Delhi (IN); **Abhinav Sood**, New Delhi (IN); **Farukh Faraz**, New Delhi (IN); **Kshitij Sharma**, New Delhi (IN); **Gedela V. Rao**, New Delhi (IN); **Palani S. Kumar**, New Delhi (IN); **Shankar Iyer**, Elizabeth, NJ (US)

(73) Assignee: **Council of Scientific & Industrial Research**, New Delhi (IN)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 188 days.

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§ 371 (c)(1),
(2), (4) Date: **Jan. 28, 2011**

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PCT Pub. Date: **Apr. 30, 2009**

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(30) **Foreign Application Priority Data**

Oct. 26, 2007 (IN) 2243/DEL/2007

(51) **Int. Cl.**
A61C 8/00 (2006.01)

(52) **U.S. Cl.**
CPC ***A61C 8/005*** (2013.01); ***A61C 8/0022*** (2013.01); ***A61C 8/0025*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61C 8/0048–8/0078
(Continued)

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Primary Examiner — Matthew Nelson
(74) *Attorney, Agent, or Firm* — Locke Lord LLP; Daniel J. Fiorello; Joshua L. Jones

(57) **ABSTRACT**

A screw type dental implant system (**1**), having a dental implant fixture (**2**), a multifunctional component (**3**) and an abutment screw (**4**). The screw shape dental implant fixture has an external surface having buttress threads on the body and micro threads at the collar. This combination provides the advantages of: improved biomechanics at the implant abutment interface, self-tapping nature to the implant, and minimizing the stresses at the crest of the bone leading to decrease resorption of crestal bone. The multifunctional component serves the purposes of implant mount, impression analog and final abutment and has a single prosthetic platform so one component is compatible with different implant dimensions, which minimizes the inventory needed for the implant system and allows easy handling of the

(Continued)

Kamal Medtech Facility

Facility Area - 50000 Sqft
State of the Art Clean Rooms 2017 & ISO 13485
High-tech QC Labs Equipments
Well Trained Man Power

Controlled Area – 20000 Sqft
Compliant with MDR

World Class Mfg

Best-in-Class Technologies





Key Features

- Single Prosthetic Platform for all Diameters **hence inventory is minimized**
- Having the benefit of Platform Switch in all connections **hence better soft tissue aesthetics**
- Conical connection 12 degree morse taper which prevents **micro leakage**
- Anatomical tapered design
- Rough Surface – **for better hard and soft tissue integration**
- SLA Surface for **better ossseointegration**
- Smart Surgical Kit – **Comprehensive, Compact and easy to use and caters to most surgical & prosthetic requirement.**

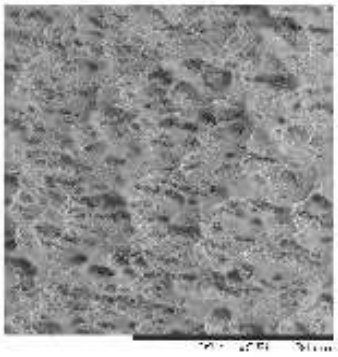
Optimized thread designs

- Buttress thread engineered for superior Primary stability
- Coronal bevel for better soft tissue integration and inbuilt platform shift.
- Reduction of stresses in bone at both Crestal & cancellous level

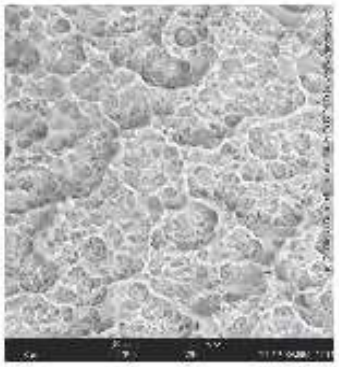
Topography evaluation by SEM of marketed dental implants

- Large grit sand blasted
- 3 Stage acid etching process
- Roughness is 1.2-2.0 Ra value on Buttress Thread
- Extensive multi-stage cleaning removes undesired residues ,yielding a contamination-free surface.

Magnification 2500

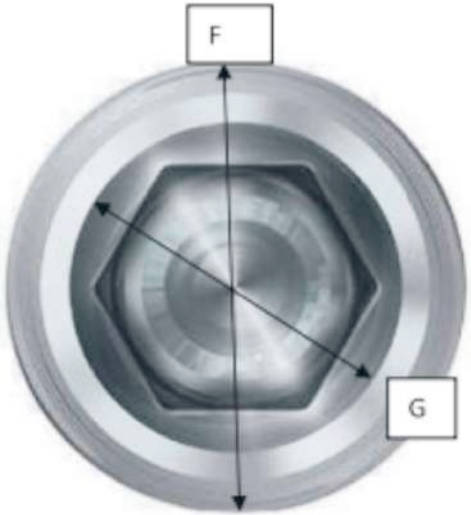


Magnification 5000



Implant Connection - Conical

- Internal Hex design-Rigid connection
- Stable biological seal
- 6 prosthetic positions
- 12^0 Morse taper-Creates an optimal seal against bacterial leakage
- Precise fit
- 2.25mm Hex connection diameter



IMPLANT DIMENSIONS

Implant Dimensions & Drilling Protocol

Size Table

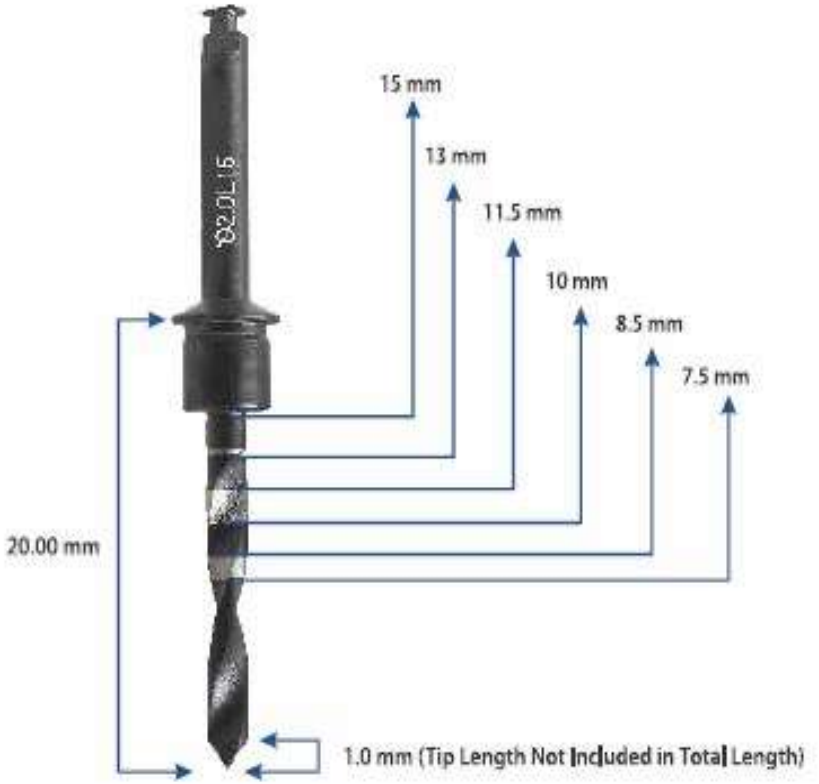
Length (mm)

Diameter (mm)	Dimensions	6.5	7.5	8.5	10	11.5	13	15
	3.5	✗	✗	✓	✓	✓	✓	✓
	4	✓	✓	✓	✓	✓	✓	✓
	4.5	✓	✓	✓	✓	✓	✓	✓
	5	✓	✓	✓	✓	✓	✓	✗

3.5 mm 4 mm 4.5 mm 5 mm

SURGICAL KIT

SURGICAL KIT



Amorphous DLC coated drills for longer shelf life. Length specific laser marking and stoppers for better control while drilling

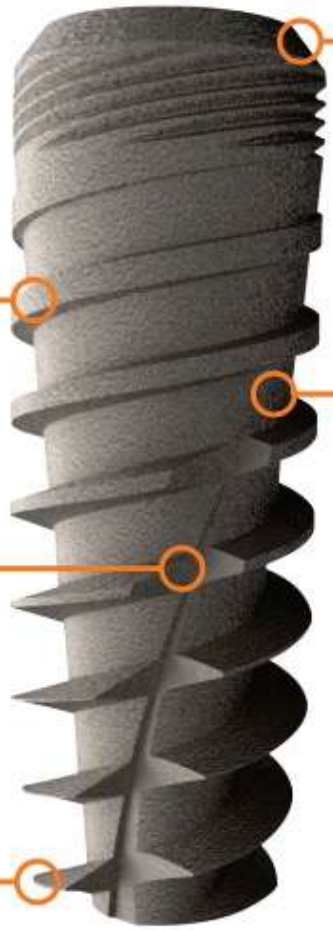
Drilling Sequence as per speed*

Lance Drill	Lindeman Drill	2.0 drill	Tapered Drill	Cortical Drill	Implant Driver
1200 rpm	1000 rpm	1000 rpm	600-800 rpm	600-800 rpm	30-50 Ncm

*WITH COPIOUS IRRIGATION

i-Fix Pro

The unique implant design for high primary stability and better esthetic outcome



The coronal region of the i-Fix PRO 4/4.5&5mm diameter implants are backtapered, a design that allows for maximum bonevolume around the implant platform.

Double lead threads The expanding taper with double lead thread design of i-Fix PRO offers high initial stability, a gradual bonecondensing property, and adjustable implant orientation for optimal prosthetic connection angulation. In detail, the 1.3mm spacing of the double start threads advances the implant 2.6mm with each rotation. In contrast to i-Fix implants advance approximately 0.9mm with each rotation.

Implant body design The expanding tapered body is designed to attain high stability even in compromised bone situations.

Reverse-cutting flutes Running along i-Fix PRO are two reverse-cutting flutes (length of the flutes depends on implant length). Insertion of the implant counterclockwiseengages the cutting capability of these flutes, thereby gradually widening the osteotomy and allowing for continued insertion.

Apical drilling blades facilitate insertion into minimally prepared sites.designThe apical region of i-Fix Pro features twin cutting blades that

i-Fix PRO – For Superior Initial Stability

	7	8.5	10	11.5	13	15	18	20
3.0			✓	✓	✓	✓		
3.5		✓	✓	✓	✓	✓	✓	✓
4.0	✓	✓	✓	✓	✓	✓	✓	✓
4.5	✓	✓	✓	✓	✓	✓		
5.0	✓	✓	✓	✓	✓	✓		
5.5	✓	✓	✓	✓	✓	✓		

PROSTHETIC PORTFOLIO

TEMPORARY ABUTMENTS

- Available in Hex & Non-Hex
- Retentive grooves to engage acrylic temporary materials.
- For Single unit (Hex) and Multiple unit (Non-Hex) temporizations.
- For screw-retained single- and multiple-unit restorations.
- Extended length designed for customization per clinical requirements

Hex

Non-Hex

Temporary Abutment Hex	TAH4001
Temporary Abutment Non-Hex	TANH4001

TEMPORARY ABUTMENTS (IMPLANT LEVEL)

Place the abutments

Fabricate temporary using vacuum formed stent

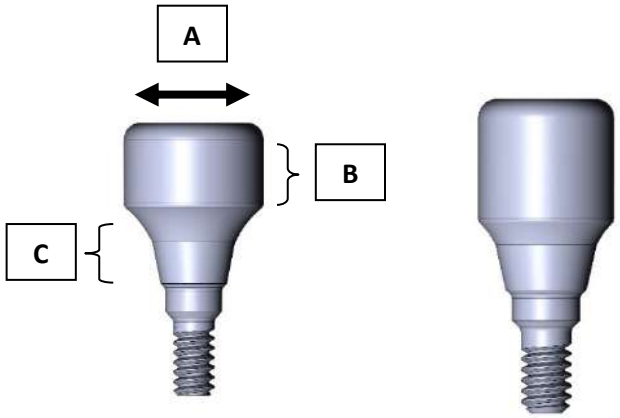
Drill holes in the stent and remove material to access the screws

Remove provisional & finish it

Screw the bridge and seal the access holes with composite

Temporary Abutment
Titanium

HEALING ABUTMENTS



Diameter	Collar	Length	Article code
4.15	1	2	HA4012
4.15	1	4	HA4014
4.15	2	3	HA4023
4.15	2	5	HA4025
4.15	2	6	HA4026
4.15	3	3	HA4033
4.15	3	5	HA4035
4.15	3	6	HA4036
5.2	1.5	3	HA5153
5.2	1.5	4	HA5154
5.2	2.5	3	HA5253
5.2	3.5	3	HA5353

Healing Abutment :

- Use Hex driver
- Tightening torque : 5-8Ncm

IMPRESSION COPING – OPEN/ CLOSED

Open Tray Impression Coping :

- **Custom tray is used for pick up impression taking.**
- **Use 1.2 Hex driver**
- **Packing contents: Impression Coping + Guide Pin**

Collar	4.15	5.2
1mm	OTI4001	-
1.5mm	-	OTI5001
2mm	OTI4002	-
2.5mm	-	OTI5002

Closed Tray Impression Coping

- **Custom tray is used for pick up impression taking.**
- **Use 1.2 Hex driver**
- **Packing contents: Impression Coping + Guide Pin**
- **Available as Long and Short.**

Product Description	Article Code
Closed Tray Impression Coping- Long	CTICL
Closed Tray Impression Coping- Short	CTICS
Closed Tray Impression Screw- Long	CTISL
Closed Tray Impression Screw- Short	CTISS

SHOULDER ABUTMENT

Cement Retained | Single or Multiple

Margin Height Selected based on Soft Tissue Depth

Benefits

- **Packaging unit: Abutment+ Abutment screw**
- **Tightening Torque: 35Ncm**
- **Available in multiple collar heights and 2 diameters.**
- **Available as Hex & Non-Hex.**
- **Versatile features make this abutment indicated in multiple clinical scenario.**

Product Description	Hex	Non-Hex
S Abutment 4.15 x1	SAH4001	SANH4001
S Abutment 4.15 x2	SAH4002	SANH4002
S Abutment 4.15 x3	SAH4003	SANH4003
S Abutment 5.2 x1.5	SAH5001	SANH5001
S Abutment 5.2 x2.5	SAH5002	SANH5002
S Abutment 5.2 x3.5	SAH5003	SANH5003

4.15 Hex

4.15 Non-Hex

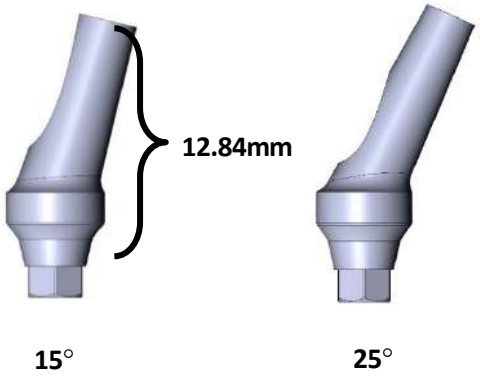
5.2 Hex

5.2 Non-Hex

ANGLED ABUTMENT

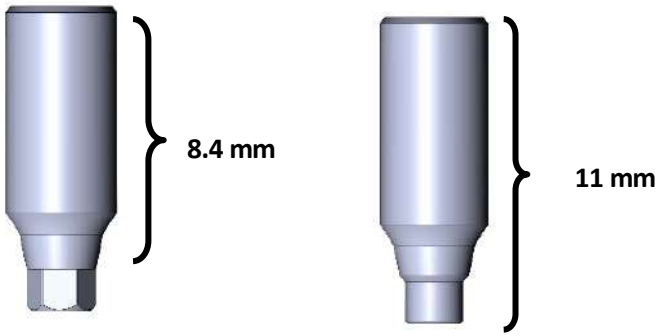
Pre-fabricated Titanium abutment for single retained restorations

- Margin designed to profile natural soft tissue contours
- 15 & 25 degrees angulation
- Indicated in anterior esthetic zone
- Comprehensive selection of varying margins and angulations minimizes chair-side adjustments.
- Use Hex Driver.
- Packaging contents: Abutment + Abutment Screw.
- Tightening torque: 35Ncm
- Length of abutment is 12.84mm



Product Description	15°	25°
Angled Abutment 4.15 x 1	15A4001	25A4001
Angled Abutment 4.15 x 2	15A4002	25A4002
Angled Abutment 5.2 x 1.5	15A5001	-
Angled Abutment 5.2 x 2.5	15A5002	-

UCLA ABUTMENT

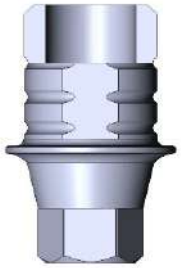


UCLA with Hex 4.15x1mm	UCH4001
UCLA with Hex 5.2x1.5mm	UCH5001
UCLA Nonhex 4.15x1 mm	UCNH4001
UCLA Nonhex 5.2x1.5	UCNH5001
Abutment screw	AS01

Versatile:

- Custom abutment for all indications using the lost wax casting technique which can be used for both cement or screw retained restorations.
- For screw-retained restorations directly to the implant
- Burn-out cylinder for wax application
- For single (hex) or multiple (non-hex) units.
- Used to correct implant angulation and adaptable to limited inter-occlusal dimensions
- Custom abutment for the small labs without the purchase of capital equipment.
- Length of abutment is 11mm (8.4 mm from collar)

CUSTOMIZED SOLUTION : TIBASE ABUTMENT



Ti-Base Hex

Ti-Base Non-Hex

Ti Base abutment Hex	TBH40
Ti Base abutment Non-Hex	TBNH40

Will be available for Digital Prosthetic workflow post April 2022

Ti Base Abutment:

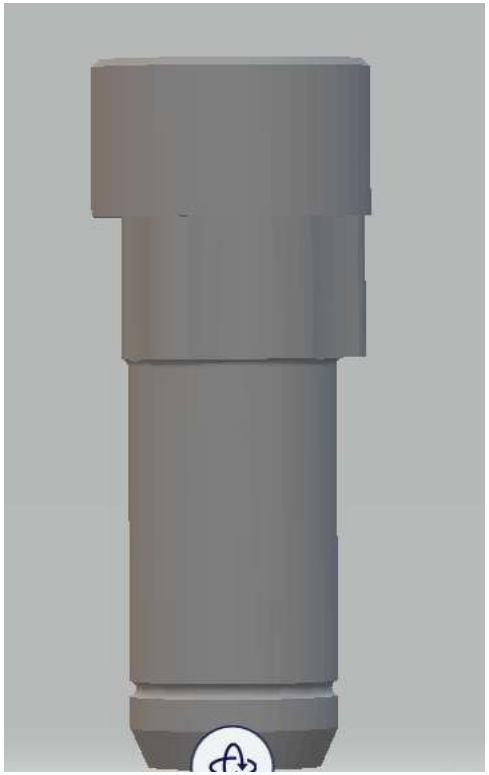
- Titanium bonding base for the production of customized abutments made of zirconia for i-Fix Implants.
- No requirement of sandblasting
- CAD/CAM Zirconia superstructure bonded to titanium base
- Indicated for anterior esthetic zone.
- Screw-retained single tooth restorations: CAD/CAM zirconium dioxide superstructure and directly veneered crown bonded to titanium base
- Cemented single/ bridge tooth restorations: CAD/CAM zirconium dioxide superstructure bonded to titanium base, with full-ceramic crown
- Packaging unit: Tibase abutment + 2 abutment screws
- Tightening Torque: 35 Ncm

CUSTOMIZED SOLUTION :PREMILL BAR

Pre-milled bar 10mm	PB10
Pre-milled bar 14mm	PB14

- These are used to fabricate customized abutments
- Available in 2 diameters 10 & 14mm & total length of 28mm
- Intact internal connection.

Digital Workflow Solution : HScan Body & Digital Analog



Digital Aanlog

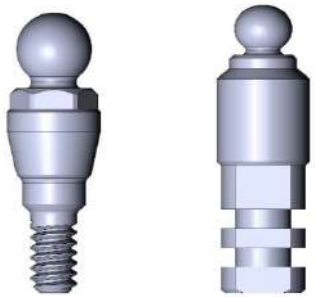
H scan Body

H-Scan Body :

- **Use to take Digital Impressions & enables the digital workflow to be more efficient.**
- **Available in 2 diameters 4.15 & 5.2mm**
- **Available in 3 lengths 4mm, 6mm & 8mm**
- **Titanium-made – autoclavable and visible in X-ray scans**

Full Arch Solutions: Over Denture Solution

Ball Abutment



Versatile:

- Packing unit: Ball Abutment + Abutment Holder
- Ball Abutment Cap package contains: Ball Cap, Spacer and O Rings
- Tightening torque: 25Ncm
- Ball cap insertion and removal tool is available for changing o rings

Ball Abutment 1mm collar	BA01
Ball Abutment 1mm collar	BA03
Ball Abutment 1mm collar	BA05
Ball Abutment Housing Package	BAHP1
Nylon ring Black	NRB
Nylon ring Clear	NRC
Nylon ring Pink	NRP
Spacer	SPA1
Ball Abutment Housing	BAH
Ball Abutment Analog	BAA01
Ball Abut InsertionTool	BAIT

Over Denture Solutions – Locator Abutment

Locator Abutment

Locator Abutment

Pink (soft) 0,9 kg

White (Standard)1,5 kg

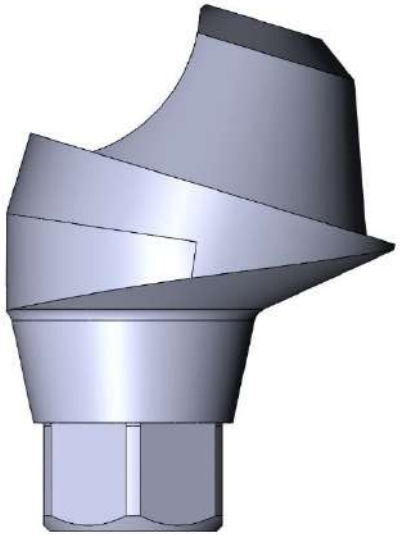
Violet (Strong)1,8 kg

- Simple to use low-profile solution for secure over denture attachment
- Simple nylon “male” attachments color coded for retention, simple maintenance and self aligning
- Allows for diverging angulations up to 40 degrees
- Provided in multiple tissue height orientations designed to facilitate removable implant retained overdenture

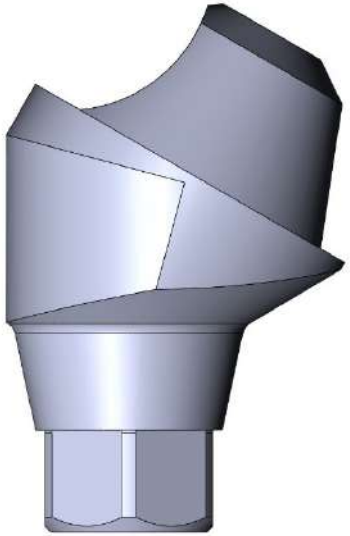
Locator Abutment 0mm collar	**LA00**
Locator Abutment 2mm collar	**LA02**
Locator Abutment 4mm collar	**LA04**
Locator Abutment 6mm collar	**LA06**
Locator Abutment Housing Package	**LAHP1**
Locator Abutment Analog	**LAA01**

Full Arch Solutions: Multi-unit Abutment

St.Multi Unit

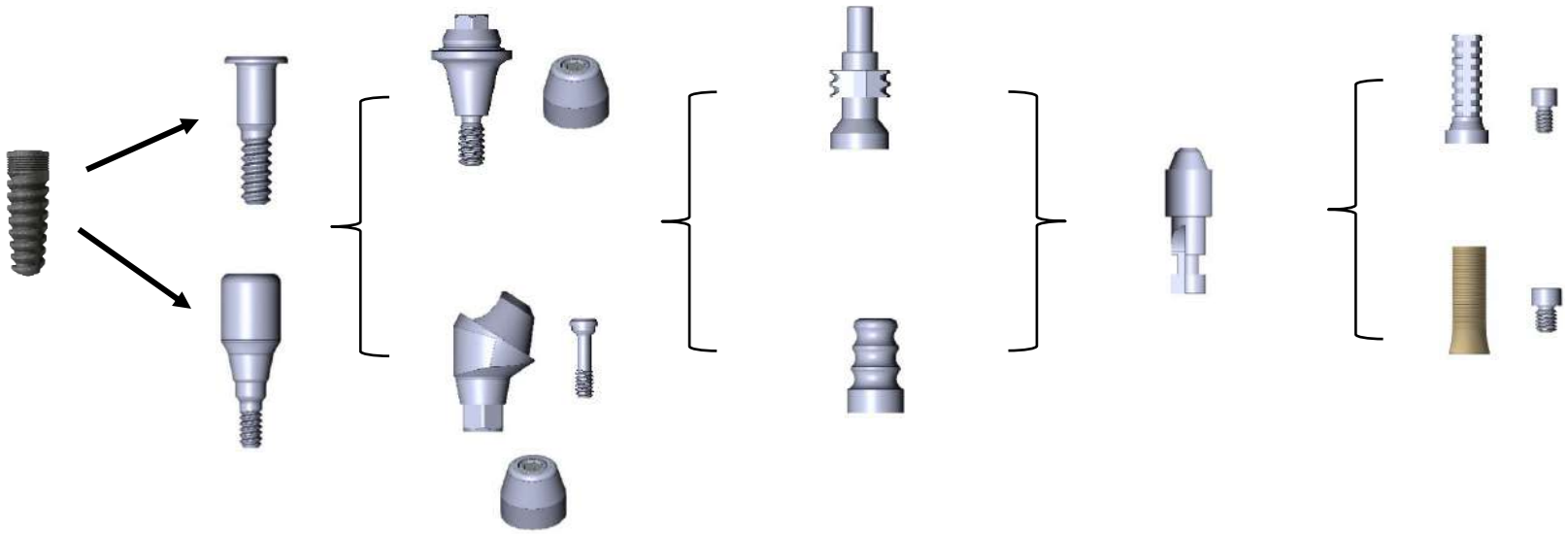


17°



30°

Flowchart – Multi unit



i-Fix-k

Engineered for Durability

KONNECTION

ENGINEERED TO SIMPLIFY

A New Solution for Clinicians
Simplified Design & Connection for long term success

i-Fix-k
Engineered for Durability

Double start threads, where thread advances the implant 1.6mm in 3.6 diameter implant & 2 mm with all other diameters with each rotation. In contrast to i-Fix implants advance approximately 0.9mm with each rotation.

The coronal region of the i-Fix -k 4/4.5/5/6mm diameter implants are back tapered, a design that allows for maximum bone volume around the implant platform.

Implant body design The expanding tapered body is designed to attain high stability even in compromised bone situations.

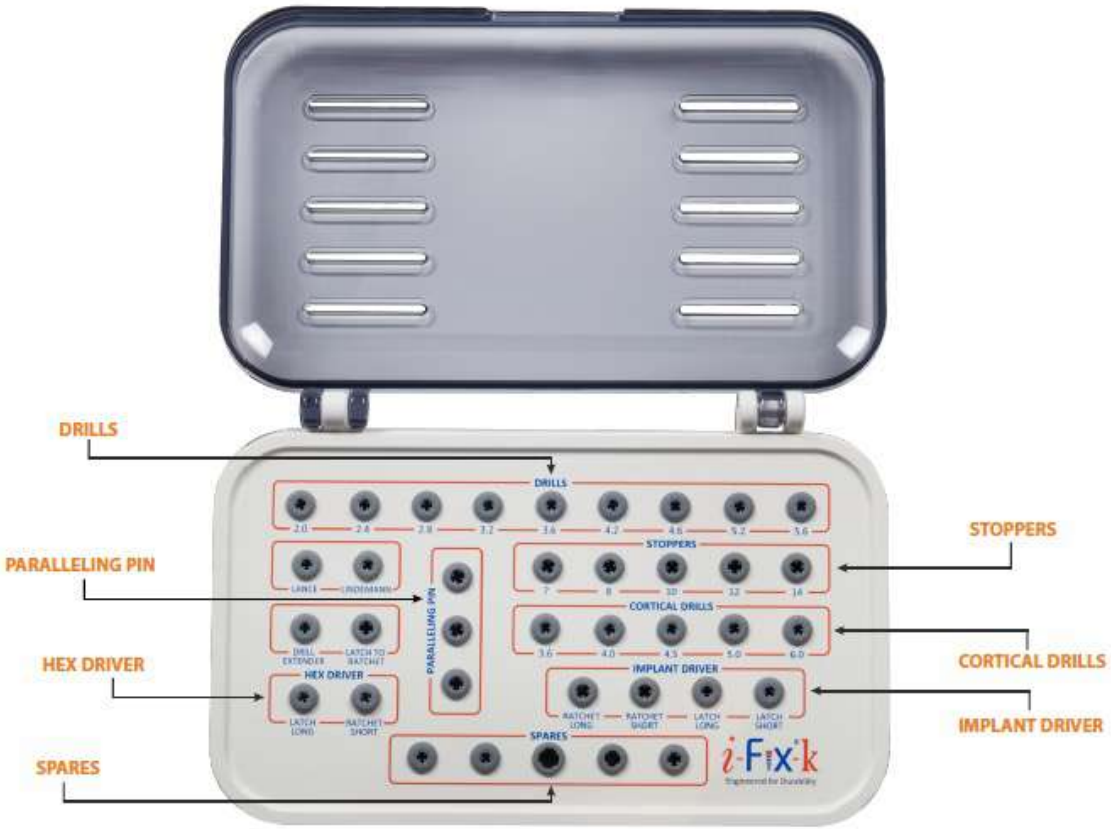
Apical drilling blades facilitate insertion into minimally prepared sites.

i-Fix-k : Konnection Engineered to Simplify

i-Fix-k
Engineered for Durability

	7	8	10	12	14
3.6		✓	✓	✓	✓
4.0	✓	✓	✓	✓	✓
4.5	✓	✓	✓	✓	✓
5.0	✓	✓	✓	✓	
6.0	✓	✓	✓	✓	

i-Fix-k : Master Surgical Kit



Prefabricated Abutment

i-Fix-k
Engineered for Durability

Single Unit Restoration

Screw Retained

St.MUA

CCM Hex

UCLA Hex

Cement Retained

Cemented Abutment

Angled Abutment

TiBase Hex

Multiple Unit

Screw Retained

St.MUA

CCM Non Hex

UCLA Non Hex

Cement Retained

Angled Abutment Non Hex

Tibase Non Hex

Edentulous Solution

Screw Retained

Multiunit Abutment

Removable

Ball Abutment

Locator Abutment

S

Prosthetic Components

i-Fix-k
Engineered for Durability

Cover Screw

KCS01

Implant Analog

Implement the abutment on the working model.
Kind of connection - HEX 2.5

Height	Diameter	Item Code
12 MM	4.5 MM	KIA01

Healing Abutment

Diameter	Collar Height	Article Code
4.0	1	KHA4010
4.0	2	KHA4020
4.0	3	KHA4030
4.0	4	KHA4040
4.5	1	KHA4510
4.5	2	KHA4520
4.5	3	KHA4530
4.5	4	KHA4540
5.5	1	KHA5510
5.5	2	KHA5520
5.5	3	KHA5530
5.5	4	KHA5540

Prosthetic Components

i-Fix-k
Engineered for Durability

Temporary Abutment	
Temporary Abutment Hex	KTAH
Temporary Abutment Non-Hex	KTANH

Open Tray Impression Coping

For Transferring the implant position to the master model.
Available for Pick-Up(open tray) technique.

Open Tray Impression Coping Short

KOTIS

Open Tray Impression Coping Long

KOTIL

Closed Tray Impression Coping:

For Transferring the implant position to the master model.
Available for Pick-Up(close tray) technique

Closed Tray Impression Coping Short

KCTIS

Closed Tray Impression Coping Long

KCTIL

Prefabricated Final Abutments

i-Fix-k
Engineered for Durability

Cement Retained Solutions

Cemented Abutment

Available in a selection of diameters and heights.
Kind of connection -HEX 2.5 ·
Height - 7.0mm
Used for making the general cement type of the prosthetics.
Recommended Tightening Torque : 30Ncm
Use a 1.2 Hex driver

Diameter	Collar Height	Article Code
4.5	1	KCA4510
4.5	1.5	KCA4515
4.5	2.5	KCA4525
4.5	3.5	KCA4535
5.5	1	KCA5510
5.5	1.5	KCA5515
5.5	2.5	KCA5525
5.5	3.5	KCA5535

Angled Abutment

Available in a selection of diameters and heights.
Kind of connection - HEX 2.5
2 kinds of angle - 15º, 25º ·
Used for adjusting the path of the prosthetics
Use a 1.2 Hex driver.
25º G/H 1.0 screw may protrude slightly

15º

Collar Height	1	2	3
Hex	K15AH5001	K15AH5002	K15AH5003
Non Hex	X	K15ANH5002	K15ANH5003

25º

Collar Height	1	2	3
Hex	K25AH5001	K25AH5002	K25AH5003
Non Hex	X	X	X

Prefabricated Final Abutments

Engineered for Durability

UCLA Abutment

The path of abutment can be controlled through the milling process on the patient oral condition.

Material - Red (Hex) / White (Non-Hex)
Use a 1.2 Hex driver

UCLA Hex

KUCH

UCLA Non Hex

KUCNH

CCM Abutment:

Available in a selection of diameters
Material - CCM (Body) Red (Hex) White (Non-Hex)
Kind of connection - HEX 2.5
Use a 1.2 Hex driver

Description	Article Code	
CCM Hex	KCCMH	
CCM Non Hex	KCCMNH	

Ti Base Abutment

Description	Article Code	
Ti Base abutment Hex	KTBH	
Ti Base abutment Non Hex	KTBNH	

Prefabricated Final Abutments

Multiunit Abutment

Description	Article Code	
Straight Multi Unit abut 1.5mm	KMUA15	
Straight Multi Unit abut 3.5mm	KMAU35	
17 Deg Multi Unit abut 2.5mm	K17MUA25	
17 Deg Multi Unit abut 3.5mm	K17MUA35	
30 Deg Multi Unit abut 3.5mm	K30MUA35	
30 Deg Multi Unit abut 4.5mm	K30MUA45	
Healing cap Multi Unit	HCMUA	
Abutment Screw Multi Unit	ASMUA	
Prosthetic Screw Multi Unit	PSMUA	
Temporary Titanium Coping Multi Unit	TCMUA	
Open Tray Imp Coping Multi Unit	OTICMUA	
Closed Tray Imp Coping Multi Unit	CTICMUA	
Abutment Analog Multi Unit	AAMUA	
Castable Sleeves Multi Unit Plastic	CSPMUA	
Protection Analog Multi Unit	PAMUA	

Over Denture Solutions

i-Fix-k
Engineered for Durability

Ball Abutment

Over Denture solution
Use Ball abutment Driver
Maximum Torque 30Ncm.

Description	Article Code
Ball abutment 1mm	KBA01
Ball abutment 3mm	KBA03
Ball abutment 5mm	KBA05
Ball abutment Housing Package	BAHP1
Ball abutment Analog	BAA1
Ball abutment Insertion tool	BAIT01

Locator Abutment

Over Denture solution
Maximum Torque 30Ncm.

Description	Article Code
Locator abutment 0mm	KLA00
Locator abutment 2mm	KLA02
Locator abutment 4mm	KLA04
Locator abutment 6mm	KLA06
Locator abutment Housing Package	LAHP1
Locator abutment Analog	LAA01

BONE GRAFT

BCP

- 25% ß tricalcium phosphate + 75% Hydroxyapatite
- Porosity 60%
- Pore size 300-500µm
- Mechanical resistance- 3 Mpa
- Resorption- 20% in 1.5yrs

adbone® BCP

75% of hydroxyapatite and

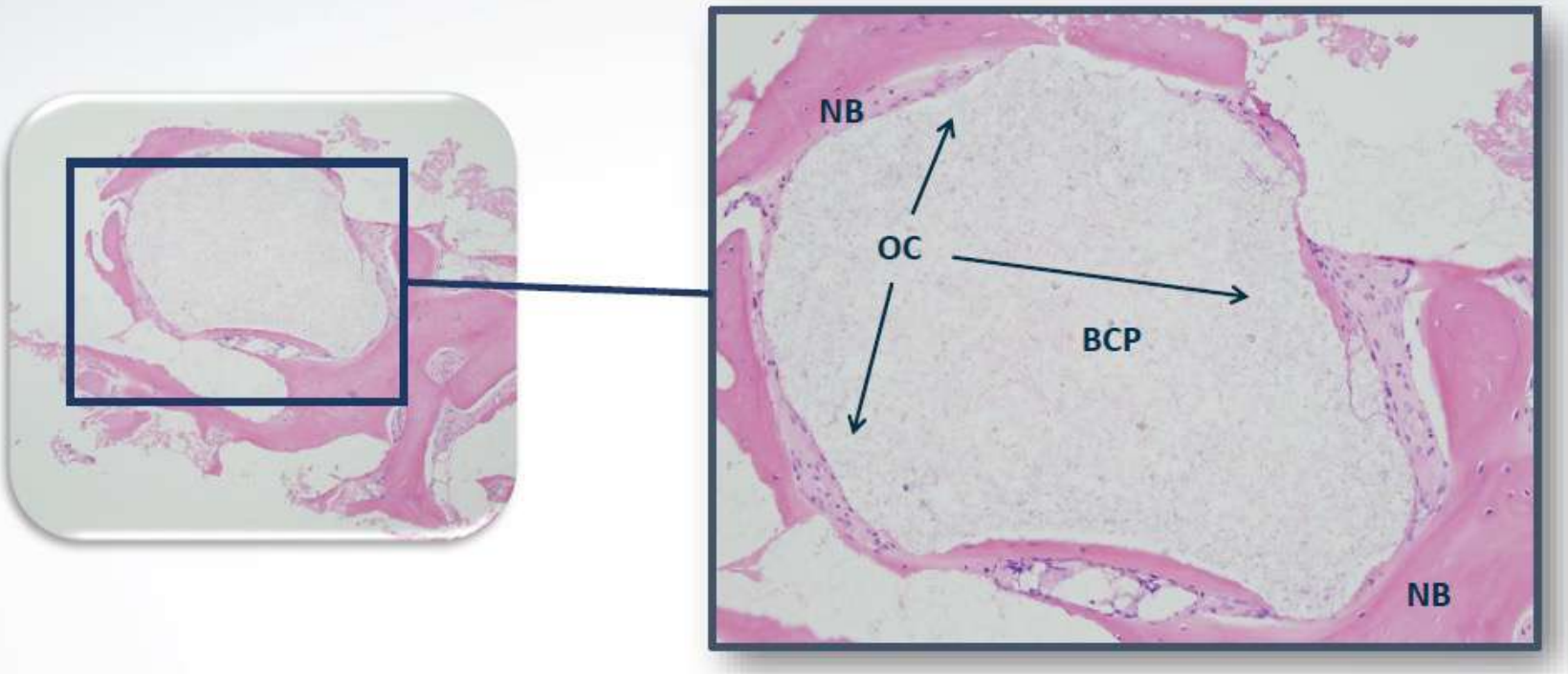
25% of beta-tricalcium phosphate

orthopedic

dental

Available geometries

Granules	Crunch	Cylinder	Wedges	Blocks
				
0,1 – 0,5mm	4 x 7mm	8 x 20mm	6 x 25 x 30mm	4 x 4 x 20mm
0,5 – 1mm			8 x 25 x 30mm	5 x 10 x 15mm
1 – 2mm			10 x 25 x 30 mm	8 x 8 x 20mm
3 – 4 mm			12 x 25 x 30mm	15 x 15 x 20mm
			14 x 25 x 30mm	15 x 20 x 30mm



New vital bone surrounding the granule of adbone®BCP, observable after 12 weeks.
High osteoclastic activity, indicating bone remodeling

TCP

- 100% ß tricalcium phosphate
- Porosity 60%
- Pore size 300-500µm
- Mechanical resistance- 3 Mpa
- Resorption- 20% in 5-6mth

adbone® TCP

100% of beta-tricalcium phosphate

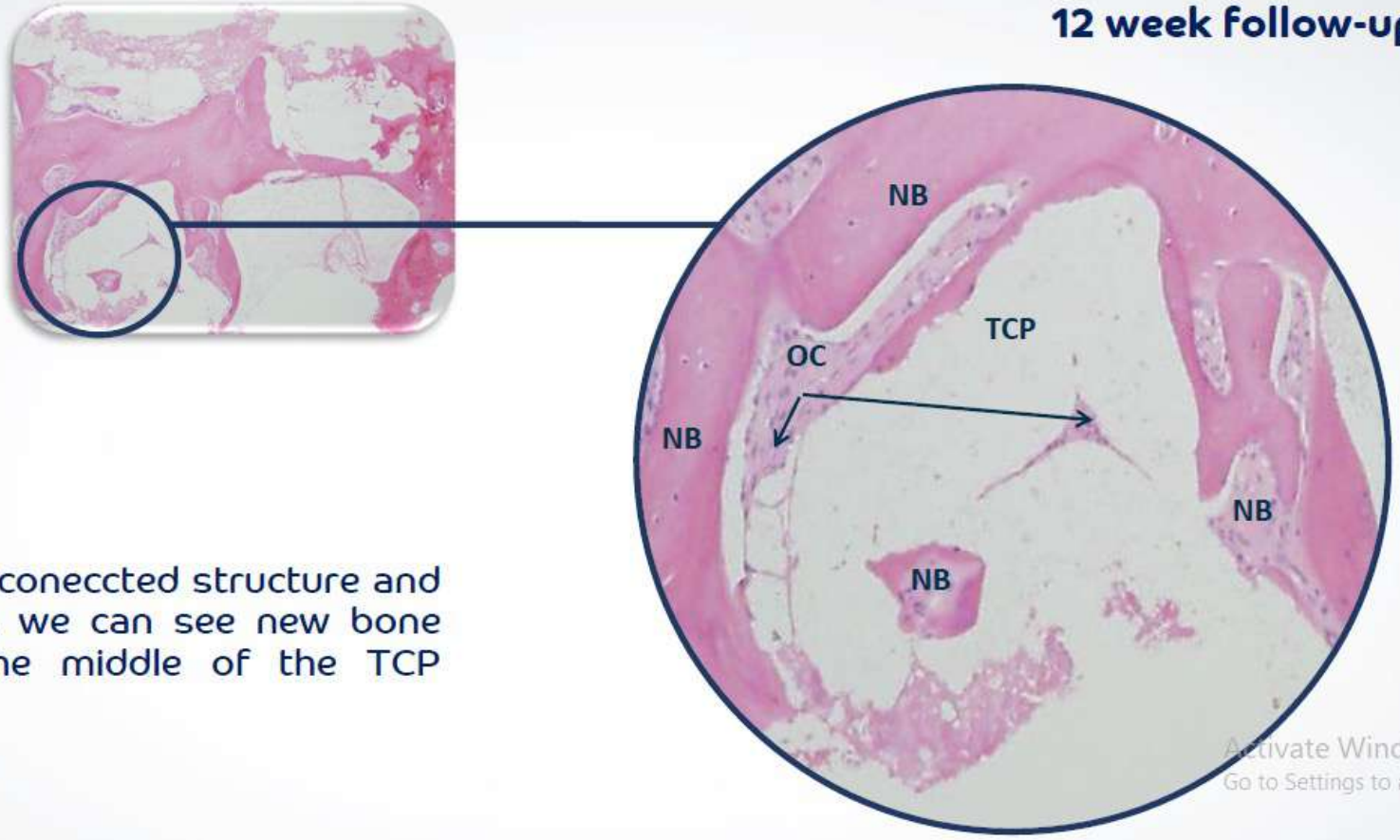
orthopedic

dental

Available geometries

Granules	Crunch	Cylinder	Wedges	Blocks
				
0,1 – 0,5mm	4 x 7mm	8 x 20mm	6 x 25 x 30mm	4 x 4 x 20mm
0,5 – 1mm			8 x 25 x 30mm	5 x 10 x 15mm
1 – 2mm			10 x 25 x 30 mm	8 x 8 x 20mm
3 – 4 mm			12 x 25 x 30mm	15 x 15 x 20mm
			14 x 25 x 30mm	15 x 20 x 30mm

12 week follow-up



Due to our interconeccted structure and large pore size, we can see new bone formation in the middle of the TCP particule

BCX

INDICATIONS

- Full mouth rehabilitation
- Graftless solution
- Thin ridge situation
- Bicortical engagement

	A	B	C	D	E	F	G	H
3.6x8	1	4.5	3.5	1.5	3.1			1.6
3.6x10	1	6	4	1.5	3.1			1.6
3.6x12	1	6	6	1.5	3.1			1.6
3.6x14	1	9	5	1.5	3.1			1.6
3.6x17	1	9	8	1.5	3.1	3	2.5	1.6
3.6x20	1	9	11	1.5	3.1	3	2.5	1.6
3.6x23	1	9	14	1.5	3.1	3	2.5	1.6
3.6x26	1	9	17	1.5	3.1	3	2.5	1.6

A	———	Tip Length
B	———	Thread Length
C	———	Shaft Length
D	———	Apical Core Diameter
E	———	Apical Major Diameter
F	———	Collar Length
G	———	Collar Diameter
H	———	Pitch

PROSTHETIC OPTIONS

Impression Coping

BCX Analog

BurnOut Cap

CIX

INDICATIONS

- Immediate prosthetic loading
- Elimination of screw loosening
- Reduces cost & time

	A	B	C	D	E	F	G	H	I	J
3510	0.65	10	10	2	1.8	0.9	3.5	2.46	1.55	0.5
3512	0.65	12	8	2	1.8	0.8	3.5	2.46	1.55	0.5
3514	0.65	14	7	2	1.8	0.8	3.5	2.46	1.55	0.5
3516	0.65	16	6	2	1.8	0.8	3.5	2.46	1.55	0.5
4008	0.7	8	13.5	2	2.2	1.2	4	2.95	1.55	0.5
4010	0.7	10	13	2	1.8	0.8	4	2.95	1.55	0.5
4012	0.7	12	11	2	1.8	0.8	4	2.95	1.55	0.5
4014	0.7	14	9	2	1.8	0.8	4	2.95	1.55	0.5
4016	0.7	16	8	2	1.8	0.8	4	2.95	1.55	0.5
4508	0.75	8	12.5	2.3	2.8	1.4	4.5	3.05	1.55	0.7
4510	0.75	10	13	2.3	2.3	0.9	4.5	3.05	1.55	0.7
4512	0.75	12	10.5	2.3	2.3	0.9	4.5	3.05	1.55	0.7
4514	0.75	14	9	2.3	2.3	0.9	4.5	3.05	1.55	0.7
5008	0.85	8	14	2.3	3.2	1.8	5	3.55	1.55	0.7
5010	0.85	10	14.5	2.3	2.6	1.2	5	3.55	1.55	0.7
5012	0.85	12	12	2.3	2.6	1.2	5	3.55	1.55	0.7
5014	0.85	14	11	2.3	2.3	0.9	5	3.55	1.55	0.7
5508	0.95	8	18	2.5	3.2	1.8	5.5	4.04	1.55	0.7
5510	0.95	10	18	2.5	2.5	1.1	5.5	4.04	1.55	0.7
5512	0.95	12	15	2.5	2.5	1.1	5.5	4.04	1.55	0.7

A	———	Tip Length
B	———	Thread Length
C	———	Total Angle
D	———	Shaft Diameter
E	———	Apical Diameter
F	———	Apical Core Diameter
G	———	Implant Crestal Diameter
H	———	Implant Crestal Core Diameter
I	———	Pitch
J	———	Thread Depth

PROSTHETIC OPTIONS

Impression Coping

CIX Analog

BurnOut Cap

Thank You