



PIVOT IMPLANTS

Creating Brighter Smiles



MAKE IN INDIA



TABLE OF CONTENT

About Us	1-2
Pinnacle Highlight	3
Ultra-Clean Surface Technology	4
Pinnacle Mores Design	5
Pinnacle Internal Connection	6
Prosthetics	7-12
Pinnacle NP	13
Prosthetics Pinnacle NP	14-16
Surgical Instruments	17-19
Surgical Procedure Regular	20
Surgical Procedure NP	21
Surgical Instrument Kit	22
Note	23-24

CERTIFICATION



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/2019/000093

1. M/s PIVOT FABRIQUE, B-28, INDL. AREA, PHASE-III, SAS NAGAR, MOHALIMOHALI, --, Punjab (India) - 160055 Telephone No.: 9815525100, 9357754772 FAX: 0172-4014000-05 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Pivot Fabrique, Plot No. B-28, Industrial Area, Phase-III, SAS Nagar, Punjab (India) - 160055 Telephone No.: 0172-4014000 FAX: 0172-4014000

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	<p>Generic Name:Dental Implants</p> <p>Model No.:Dental Implants - L-8.0 mm Dia 3.70/4.20/4.60/5.10 mm ,Dental Implants - L-10.0 mm Dia 3.70/4.20/4.60/5.10 mm ,Dental Implants - L-11.50 mm Dia 3.70/4.20/4.60/5.10 mm ,Dental Implants - L-13.0 mm Dia 3.70/4.20/4.60/5.10 mm</p> <p>Intended Use:Dental implants are tiny titanium screws that are surgically placed in the jawbone. These implants are meant to act as replacement tooth roots</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium Grade 4</p> <p>Dimension(if any):The medical device is made up of various dimensions.</p> <p>Shelflife:5 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Pivot Fabrique</p>

Place:

Date:11-Jun-19

Central Licensing Authority

CERTIFICATION

QUALITY CERTIFICATION



Certificate of Registration

This is to certify that The Quality Management System of Medical Devices

PIVOT FABRIQUE

B-28, Industrial Area, Phase Iii, Mohali-160055,
Punjab, India

has been assessed and found to be in compliance with the requirements of the standard

ISO 13485:2016

for the following scope :

Manufacturing of Dental Implants

CERTIFICATE No. : 21ZQAZ8467M

ISSUED DATE : 10/09/2021
EXPIRY DATE : 09/09/2024

1ST SURVEILLANCE : 09/09/2022
2ND SURVEILLANCE : 09/09/2023



Authorised Signatory

INTERNATIONAL QUALITY CERTIFICATION SERVICES UK LTD
272, Bath Street, Glasgow, G2 4JR, U.K.

This Certificate is Intellectual Property of IQCS and can be maintained through surveillance and renewal audits.
Certificate should be returned to IQCS in case of non compliance of certification procedure.
Authenticity of this certificate can be verified at www.ukacert.co.uk / www.iqacert.co.uk
The Registration is not a Product Quality Certificate.



CERTIFICATION



CERTIFICATE of Compliance

We hereby declare that the technical file of product complied with the requirement of directives **Class -I Medical Devices Directive 93/42/EEC**

Manufacturer

Name : PIVOT FABRIQUE

Address : B-28, Industrial, Area Phase-3, SAS Nagar, Mohali-160055, Punjab, India

**Product : Manufacturer of Dental Implants, Dental Bur, Dental Abutment,
Implant Surgical Kit & Orthopedic Implant**

The technical documentation / inspection / test results comply with the requirements of **Class -I Medical Devices Directive 93/42/EEC**. Hence the manufacturer has issued a Declaration of Conformity according to test report and places the CE marking with his own Responsibility. The quality system has been assessed, approved and is subject to continuous surveillance according to the directives.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.

The certificate remains valid until the manufacturing conditions or the quality systems are changed.

The certificate validity is conditioned by positive results or surveillance audits.

After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Certificate Number: CE21090220

The validity of this certificate can be verified at www.ukicl.org.uk

Date of Certification: 16/09/2021

1st Surveillance Due: 15/09/2022

2nd Surveillance Due: 15/09/2023

Expire/Re-Certificate Due: 15/09/2024



Samuel
Authorise Signatory

This certificate is the property of UK International Certification Limited and shall be returned immediately on request. The validity of certificate is subjected to regular surveillance audit on or before above mention date. UK International Certification Limited is an independent system, products and personal assessment certification body registered with the registrar of companies for England and wales under section 1115 of the company's act, 2006. UK Office:- 27, Old Gloucester Street, London, United Kingdom, WC1N 3AX, Company Number: 12810906, Website:- www.ukicl.org.uk ; E-mail:- info@ukicl.org.uk

ABOUT US

Pivot Fabrique an IATF 16949:2016, a family owned company specializing in Precision Turned and Press Components since 1973. Our Customers have relied upon our consistent quality, JIT standard & viable solutions. We procured Swiss plant & equipment after having training in Switzerland. Our buyers are OEM from Wrist Watch, Meters, Automotive Instruments, Medical, Dental, Defence & Weighing Scale etc. Pivot Fabrique manufacture precision components based on client's requirements. Pivot Fabrique has fully equipped state of art manufacturing unit capable of delivering large quantity orders.

PIVOT IMPLANTS CREATING BRIGHTER SMILES!

WE DELIVER TOP-QUALITY, SIMPLE-TO-USE PRODUCTS

We have mastered the art of simplifying implant technology by developing a surgical kit that fits all our products - implants, abutments and surgical tools. Our surgical kit includes basic surgical instrumentation to advanced therapy tools, and is compatible with all product systems. This means that fewer tools are needed to achieve successful results. It also simplifies work and minimize customer learning curves. With an overall implant clinical success rate of 99.6%*, our top-quality implant systems are based on two platforms and three connections, each has its own perfectly-fit restoration line.

WE LEVERAGE EXPERIENCE AND TECHNOLOGIES

We leverage our experience and technologies to ensure that our products offer the best value-for-money. For three decades, we have been focusing on the development and manufacturing of dental implants and their byproducts. Our cutting-edge, in-house manufacturing facility, which is operational 24/7, includes a dedicated QA department to ensure the highest possible standards and quality of our products and the provision of a lifetime warranty for our dental implants.

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WE UTILIZE RESEARCH AND EXPERTS

Our R&D teams has extensive clinical and academic knowledge. We also invest in preclinical in vivo research, clinical trials, histological studies and in vitro laboratory studies. We are also active in all research fields, including basic research, preclinical studies and clinical trials.

WE ENABLE THE DIGITALIZATION OF THE DENTAL WORLD

We embrace the technological changes involved in the digitalization of the dental world in order to support the present and future needs of our customers. Consequently, our digital CAD/CAM line offers a wide range of restoration products for our three implant connections. Additionally, our Guided Surgery Tool Kit supports surgery methods and enables dentists to plan surgeries, making their work simpler, more precise and minimally invasive.

IMPLANT SYSTEMS

From Internal Hex implants to Conical Hex implants, we offer an entire range of implants, so that each physician can find the precise and most convenient implant to work with in any given moment.

PROSTHETICS & CAD/CAM

For each of our implant connections we offer a wide range of options for any clinical need, including fixed and removable restorations, screw based, cemented prosthesis and a wide range of digital CAD/CAM parts. The diameters for each prosthetic part are interchangeable according to preference and need. All parts are designed for ease of use and high esthetic appearance.

SURGICAL INSTRUMENTATION

Our universal surgical kit is another demonstration of Alpha-Bio Tec's commitment to simplicity. This one kit provides surgeons all the tools needed to perform most of the procedures from marking the drilling point to inserting the implant into its final position. Implant orientation tools for the final restoration are also included. Each kit can be customized to meet the dental professional needs. In addition, as digital enablers, Alpha-Bio Tec's Guided Surgery Tool Kit enables accurate and predictable implant procedures using the planning software of the dentist's choice.

PINNACLE HIGHLIGHTS



SURFACE

ADVANCE SURFACE TREATMENT

Pivot Implant surface treatment achieves the desirable outcome of a highly cleaned and safe implant surface with ideal morphology for accelerated integration, initial Stability, long term bone healing and solid biological fixation of the implant

ROUGH SURFACES (S.L.A)

Sand blasted, large Grit, acid-etched implant surface, (SLA) is a type of surface treatment that creates surface roughness with The Goal of Enhancing osseointegration through greater bone to implant Contact(BIC).

The SLA Process increases The rate at which osseointegration occurs by using a combination of Grit & Acid etching to give The surface increased roughness on Multiple Levels.

This allows osteoblasts to Proliferate and adhere to The implant surface. Through osseointegration, SLA can help provide increased stability of The implant which will ultimately Lengthen its longevity.

We also do The Extra Treatment for cell adhesion, which reduces The amount of treatment Time required while also increasing The treatment Predictability.



CLEAN SURFACES

extensive multi-stage cleaning removes undesired residues derived from manufacturing, yielding a contamination-free surface.

SUPERIOR RAW MATERIAL

Dental Implants:

- Made of biocompatible Grade 4 Pure titanium with mechanical properties.
- Purchased from leading Swiss suppliers.

ULTRA-CLEAN SURFACE TECHNOLOGY

The Ultra High Purity Cleaning Process is a comprehensive approach to producing a high purity surface for dental implants.

Pivot decided to consistently clean their products with ultra-pure water (UPVV), which is rather expensive to produce compared to regular demineralized water and is otherwise mostly employed by the semiconductor industry.

Sterile packaging bedchamber of implants: from simple and non-sterile to elaborately protected.

The illustration shows a complex packaging design where the implant is inserted in a two sleeves made of plastic of medical grade to reduce the influence of other materials to a minimum.

PACKAGED TO STAY CLEAN

Dental implants are delivered in uniquely designed protective packaging. In this superior quality packaging, of medical grade polyethylene.

- Grade 4 Titanium for Implant
- Grade 5 Titanium for prosthetics

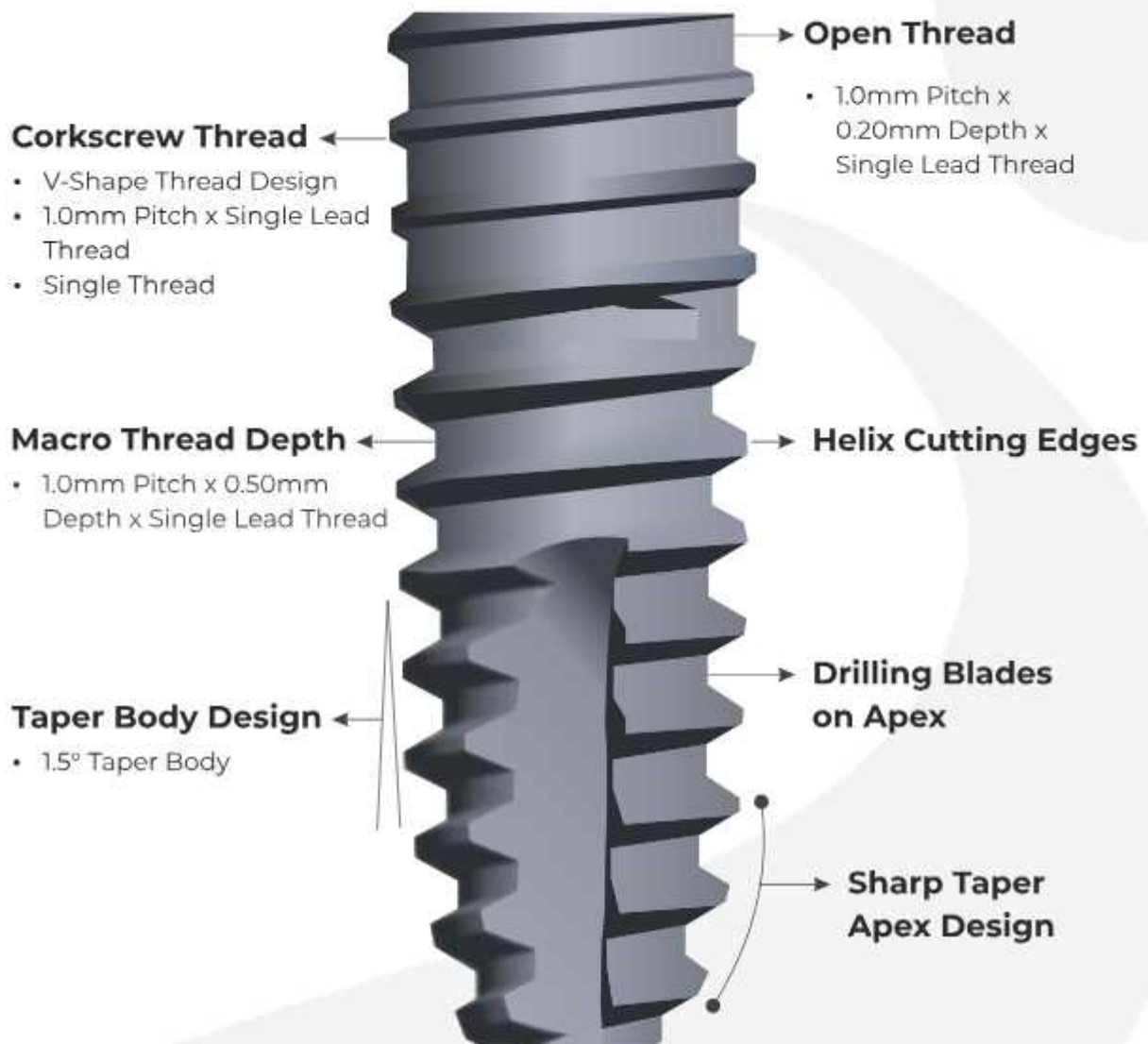
PACKAGED FOR CONVENIENCE

- Delivered sterile and ready for use. (Gamma Rays)
- Compact for easy of storage in dental clinic.
- Effective performance for ease of handling and use.

Components
are Delivered
Sterile

Prosthetic
Components
Packaging

PINNACLE MORSE DESIGN



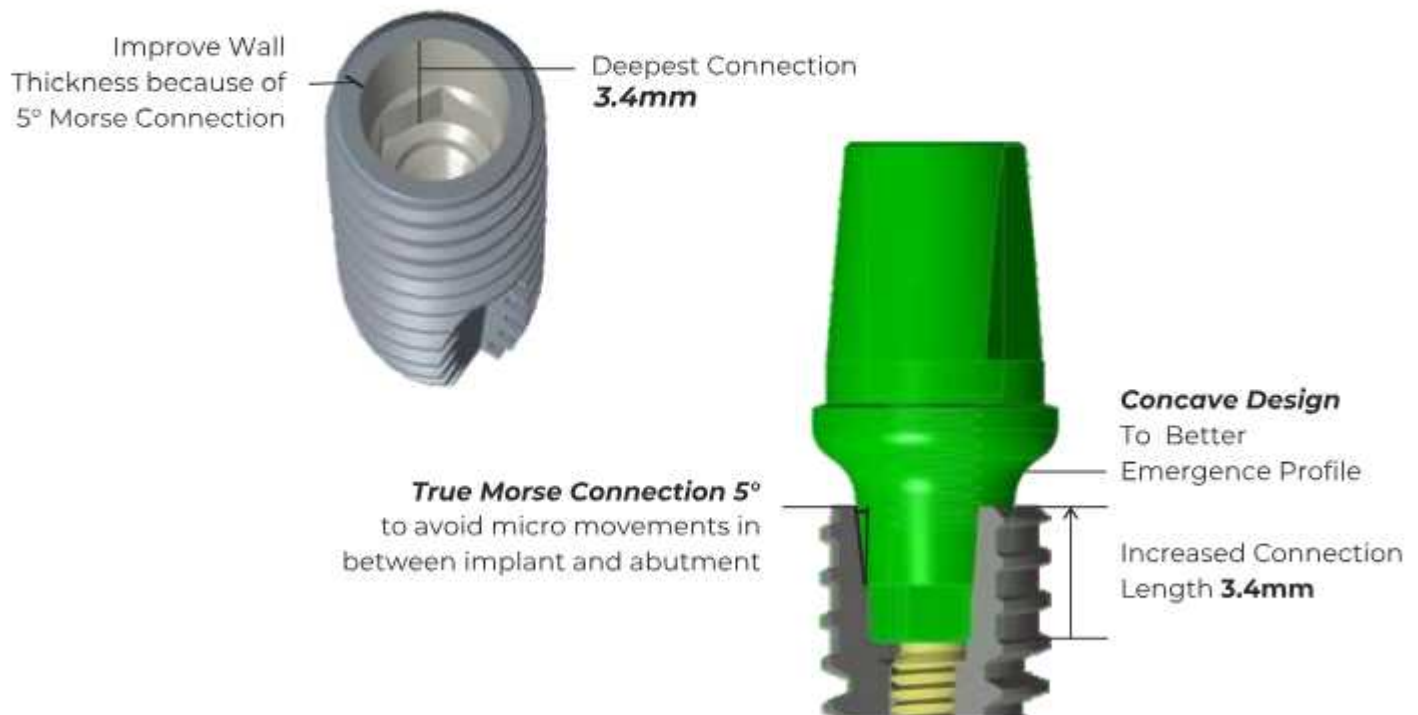
IMMEDIATE THE EVOLUTION OF IMPLANT DESIGN

A new generation implant combining a traditional passive approach with a modern aggressive approach was designed by Pivot to generate optimized bone properties.

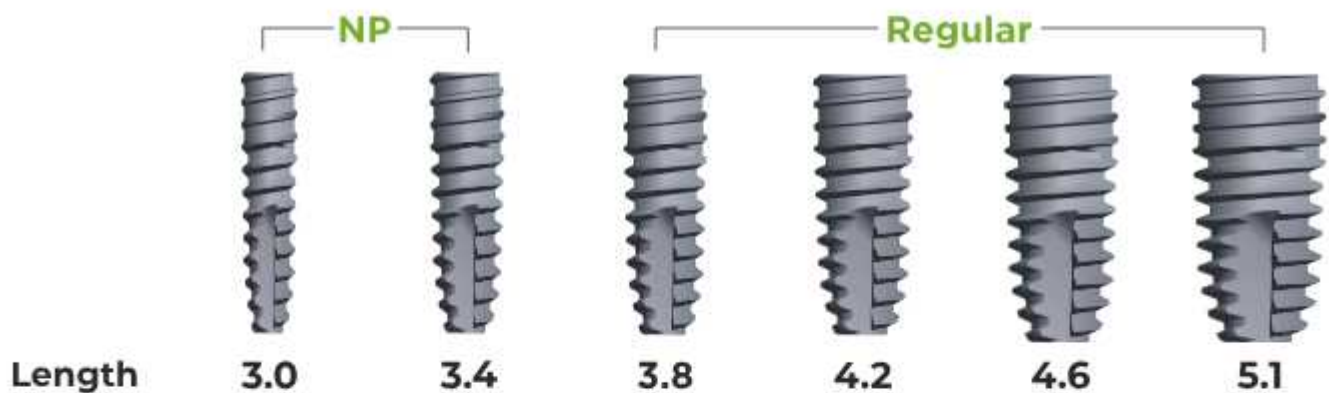
Great Primary Stability & Osseointegration

- Tapered progressive thread for enhanced initial stability
- Accurate osteotomy that meets the implant design.
- Carefully tested drilling protocol that enables insertion torque of 30-50 Ncm and for tightening the abutment screw we need torque 25 Ncm maximum.

5° SEMI ACTIVE PINNACLE INTERNAL CONNECTION



Available Sizes



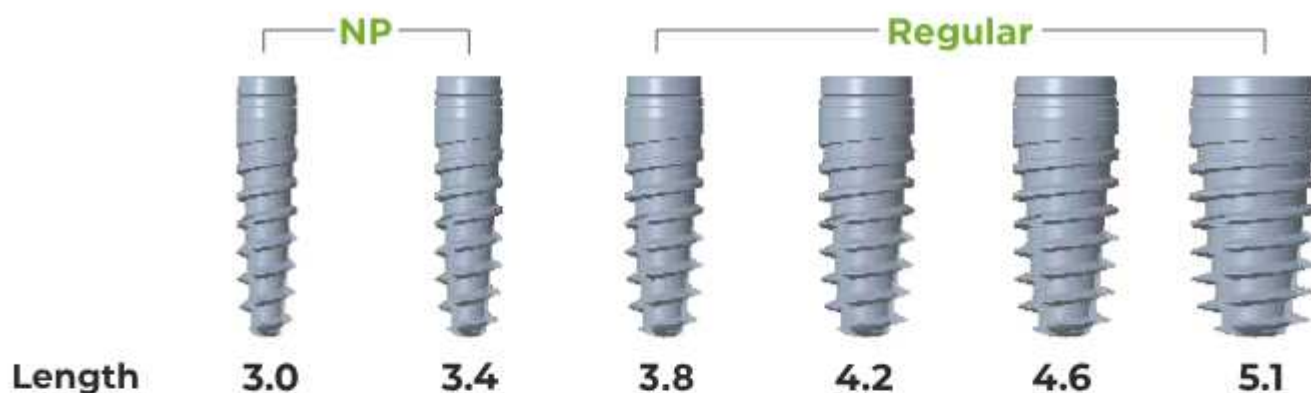
8.0 mm	—	—	PIM3808R	PIM4208R	PIM4608R	PIM5108R
10.0 mm	PIM3010NP	PIM3410NP	PIM3810R	PIM4210R	PIM4610R	PIM5110R
11.50 mm	PIM3011NP	PIM3411NP	PIM3811R	PIM4211R	PIM4611R	PIM5111R
13.0 mm	PIM3013NP	PIM3413NP	PIM3813R	PIM4213R	PIM4613R	PIM5113R
16.0 mm	PIM3016NP	PIM3416NP	PIM3816R	PIM4216R	PIM4616R	PIM5116R

Note: 1) To prevent damage to the Implant driver or fixture, do not over torque during fixture insertion

5° ACTIVE PINNACLE INTERNAL CONNECTION



Available Sizes



8.0 mm	—	—	PIMA3808R	PIMA4208R	PIMA4608R	PIMA5108R
10.0 mm	PIMA3010NP	PIMA3410NP	PIMA3810R	PIMA4210R	PIMA4610R	PIMA5110R
11.50 mm	PIMA3011NP	PIMA3411NP	PIMA3811R	PIMA4211R	PIMA4611R	PIMA5111R
13.0 mm	PIMA3013NP	PIMA3413NP	PIMA3813R	PIMA4213R	PIMA4613R	PIMA5113R
16.0 mm	PIMA3016NP	PIMA3416NP	PIMA3816R	PIMA4216R	PIMA4616R	PIMA5116R

Note: 1) To prevent damage to the Implant driver or fixture, do not over torque during fixture insertion

PROSTHETICS

Straight Abutment 4.5

Recommended Torque Max 25 NCM



AB 4510HR	AB 4520HR	AB 4530HR	AB 4540HR	AB 4550HR
-----------	-----------	-----------	-----------	-----------

Castable Abutment Hex 4.5

Recommended Torque Max 25 NCM



CABR4510H	CABR4520H	CABR4530H	CABR4540H	CABR4550H
-----------	-----------	-----------	-----------	-----------

Castable Abutment Non Hex 4.5

Recommended Torque Max 25 NCM



CABR4510NH	CABR4520NH	CABR4530NH	CABR4540NH	CABR4550NH
------------	------------	------------	------------	------------

Note: 1) To prevent damage to the Prosthetics Screw of Abutments, do not over torque during tightening the abutment

PROSTHETICS

Ball Abutment Regular 4.0

Recommended Torque Max 25 NCM



BA4010R	BA4020R	BA4030R	BA4040R	BA4050R	BA4060R
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Locator Abutment Regular 4.0

Recommended Torque Max 25 NCM



LOCAB4010R	LOCAB4020R	LOCAB4030R	LOCAB4040R	LOCAB4050R	LOCAB4060R
------------	------------	------------	------------	------------	------------

Metal cap

Nylon cap

Metal cap

Nylon cap



BAMC 46 31

BANC4126W

LOCMC 46 31

LOCNC4126W

Note: 1) To prevent damage to the Prosthetics Screw of Abutments, do not over torque during tightening the abutment.

NOTE: ALL DIMENTIONS IN MILIMETERS

PROSTHETICS

Angle Abutment Hex A 10 ° (4.5)

Recommended Torque Max 25 NCM



AABR1010HA	AABR1020HA	AABR1030HA	AABR1040HA	AABR1050HA
------------	------------	------------	------------	------------

Angle Abutment Hex B 10 ° (4.5)

Recommended Torque Max 25 NCM



AABR1010HB	AABR1020HB	AABR1030HB	AABR1040HB	AABR1050HB
------------	------------	------------	------------	------------

Angle Abutment Non-Hex 10 ° (4.5)

Recommended Torque Max 25 NCM



AABR1010NH	AABR1020NH	AABR1030NH	AABR1040NH	AABR1050NH
------------	------------	------------	------------	------------

Note: 1) To prevent damage to the Prosthetics Screw of Abutments, do not over torque during tightening the abutment

PROSTHETICS

Angle Abutment Hex A 15 ° (4.5)

Recommended Torque Max 25 NCM



AABR1510HA	AABR1520HA	AABR1530HA	AABR1540HA	AABR1550HA
------------	------------	------------	------------	------------

Angle Abutment Hex B 15 ° (4.5)

Recommended Torque Max 25 NCM



AABR1510HB	AABR1520HB	AABR1530HB	AABR1540HB	AABR1550HB
------------	------------	------------	------------	------------

Angle Abutment Non-Hex 15 ° (4.5)

Recommended Torque Max 25 NCM



AABR1510NH	AABR1520NH	AABR1530NH	AABR1540NH	AABR1550NH
------------	------------	------------	------------	------------

Note: 1) To prevent damage to the Prosthetics Screw of Abutments, do not over torque during tightening the abutment

NOTE: ALL DIMENSIONS IN MILLIMETERS

PROSTHETICS

Angle Abutment Hex A 25 ° (4.5)

Recommended Torque Max 25 NCM



AABR2510HA	AABR2520HA	AABR2530HA	AABR2540HA	AABR2550HA
------------	------------	------------	------------	------------

Angle Abutment Hex B 25 ° (4.5)

Recommended Torque Max 25 NCM



AABR2510HB	AABR2520HB	AABR2530HB	AABR2540HB	AABR2550HB
------------	------------	------------	------------	------------

Angle Abutment Non-Hex 25 ° (4.5)

Recommended Torque Max 25 NCM



AABR2510NH	AABR2520NH	AABR2530NH	AABR2540NH	AABR2550NH
------------	------------	------------	------------	------------

Note: 1) To prevent damage to the Prosthetics Screw of Abutments, do not over torque during tightening the abutment

PROSTHETICS

Closed Tray Impression

4.5 REGULAR	ITR114517CL
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Open Tray Impression

4.5 REGULAR	ITR154525OP
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Lab Analog

4.0 REGULAR	LAR4012
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Healing Screw



Regular	HAB5050R	HAB5060R
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NOTE: ALL DIMENSIONS IN MILLIMETERS

PROSTHETICS PINNACLE NP

Straight Abutment NP (4.0)

Recommended Torque Max 20 NCM



AB 4010NP	AB 4020NP	AB 4030NP	AB 4040NP	AB 4050NP
-----------	-----------	-----------	-----------	-----------

Castable Abutment NP HEX (4.0)

Recommended Torque Max 20 NCM



CABH4010NP	CABH4020NP	CABH4030NP	CABH4040NP	CABH4050NP
------------	------------	------------	------------	------------

Castable Abutment NP Non-Hex (4.0)

Recommended Torque Max 20 NCM



CABNH4010NP	CABNH4020NP	CABNH4030NP	CABNH4040NP	CABNH4050NP
-------------	-------------	-------------	-------------	-------------

Note: 1) To prevent damage to the Prosthetics Screw of Abutments, do not over torque during tightening the abutment

PROSTHETICS PINNACLE NP

Angle Abutment Hex A 10 ° (4.0)

Recommended Torque Max 20 NCM



AABM1010HA	AABM1020HA	AABM1030HA	AABM1040HA	AABM1050HA
------------	------------	------------	------------	------------

Angle Abutment Hex B 10 ° (4.0)

Recommended Torque Max 20 NCM



AABM1010HB	AABM1020HB	AABM1030HB	AABM1040HB	AABM1050HB
------------	------------	------------	------------	------------

Angle Abutment Non-Hex 10 ° (4.0)

Recommended Torque Max 20 NCM



AABM1010NH	AABM1020NH	AABM1030NH	AABM1040NH	AABM1050NH
------------	------------	------------	------------	------------

Note: 1) To prevent damage to the Prosthetics Screw of Abutments, do not over torque during tightening the abutment

PROSTHETICS PINNACLE NP

Angle Abutment Hex A 15 ° (4.0)

Recommended Torque Max 20 NCM



AABM1510HA	AABM1520HA	AABM1530HA	AABM1540HA	AABM1550HA
------------	------------	------------	------------	------------

Angle Abutment Hex B 15 ° (4.0)

Recommended Torque Max 20 NCM



AABM1510HB	AABM1520HB	AABM1530HB	AABM1540HB	AABM1550HB
------------	------------	------------	------------	------------

Angle Abutment Non-Hex 15 ° (4.0)

Recommended Torque Max 20 NCM



AABM1510NH	AABM1520NH	AABM1530NH	AABM1540NH	AABM1550NH
------------	------------	------------	------------	------------

Note: 1) To prevent damage to the Prosthetics Screw of Abutments, do not over torque during tightening the abutment

SURGICAL INSTRUMENT

Drill Extension

Art. No.
PDE



Parallel Pin

Art. No.
PP31 20



Torque Hex Drivers | Hex 1.18

Type	Length	Art. No.
Torque-Driver (press-fit)	27	PTD PF 27 118L
	22	PTD PF 22 118S



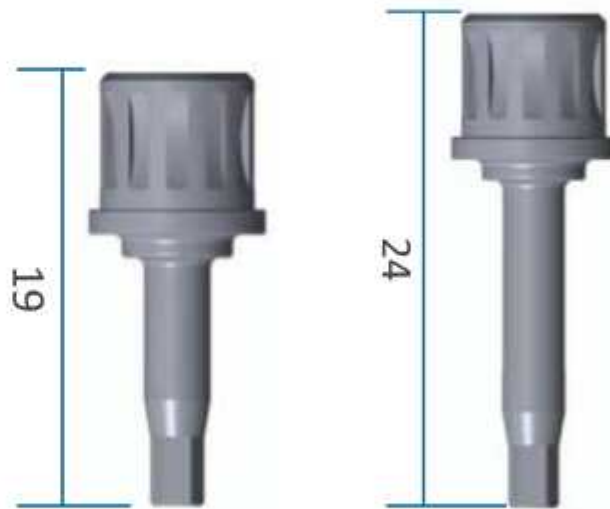
DEPTH GAUGE



PFDG

SURGICAL INSTRUMENT

Implant Driver (Regular)

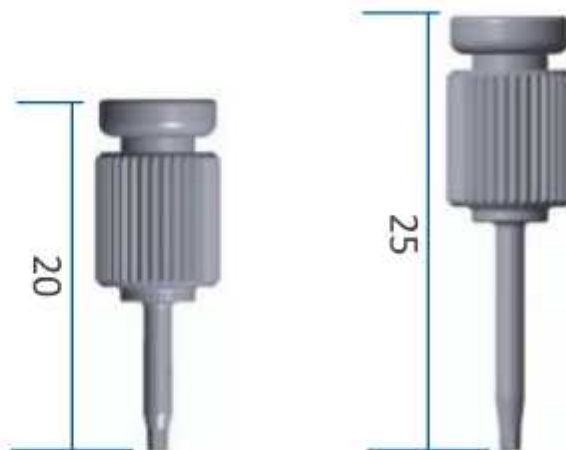


19

24

Torque-Driver	PTD19 217SR	PTD24 217LR
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Hex Driver (1.2)



20

25

Hand Driver	PTHHD 20S	PTHHD 25L
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SURGICAL INSTRUMENT

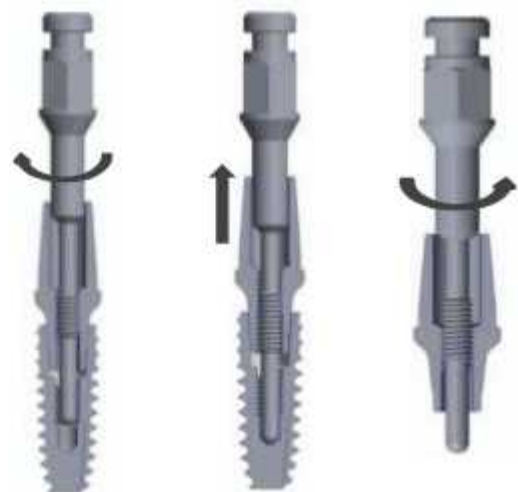
UNLOCKING SYSTEM



Once two conical surfaces get connected, the morse effect is produced and implants and abutment get locked together. This effect can be nullified by inserting the extractor.

EXTRACTOR

- Regular
- Mini



CORTICAL DRILL (COUNTER SINK)

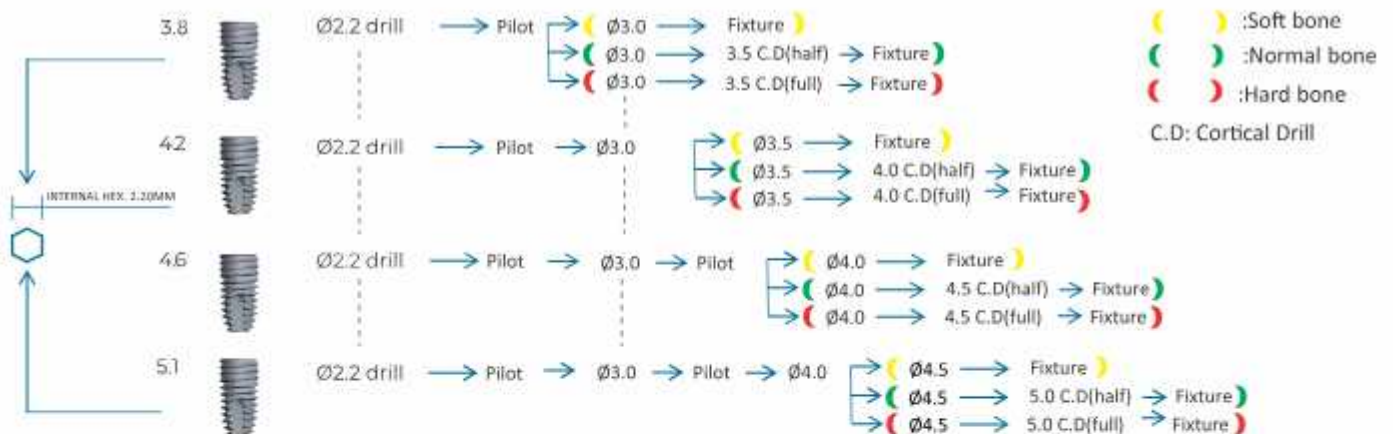
Product	3.70 Drill	4.20 Drill	4.60 Drill	5.10 Drill
Design 	 <div> <div>Ø3.77</div> <div>Ø3.55</div> <div>2.0</div> <div>2.0</div> </div>	 <div> <div>Ø4.18</div> <div>Ø4.10</div> <div>2.5</div> <div>2.4</div> </div>	 <div> <div>Ø4.58</div> <div>Ø4.50</div> <div>2.5</div> <div>2.3</div> </div>	 <div> <div>Ø5.03</div> <div>Ø4.90</div> <div>3.0</div> <div>2.3</div> </div>
Art. No.	PCD40C37	PCD40C42	PCD40C46	PCD40C51

Surgical Procedure Regular

Soft Bone

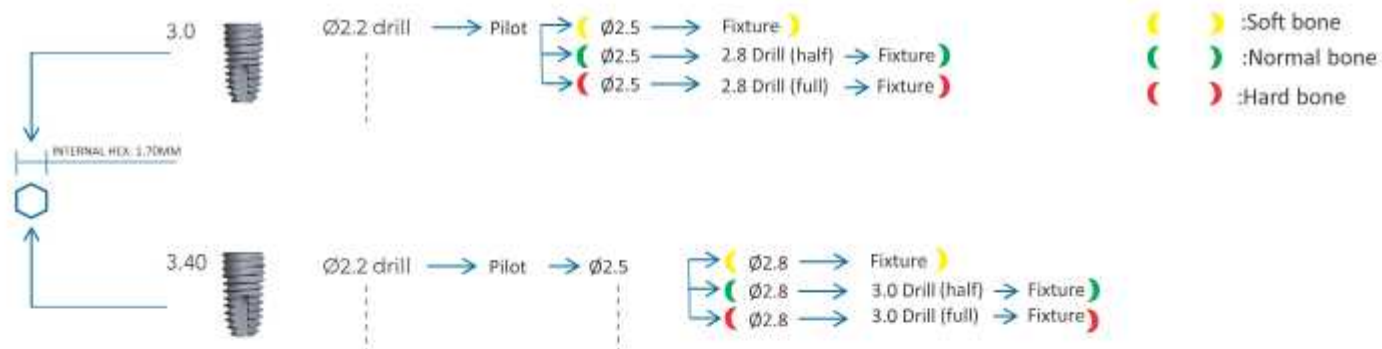


- **Normal bone** ← Additionally drill 1/2 depth with cortical drills.
- **Hard bone** ← Additionally drill full depth with cortical drills.



NOTE: ALL DIMENTIONS IN MILLIMETERS

Surgical Procedure N.P.



NOTE: ALL DIMENTIONS IN MILLIMETERS

SURGICAL INSTRUMENT KIT



Features :

- Enable to maximize total initial contact area between bone and implant
- All-in-one full kit consisting of surgical drills, prosthetic drivers & tools
- Safe to use (stopper for different bone length)
- Easy to use (simply surgery protocol)
- Helps a surgeon reduce surgery time

COMPATIBLE WITH ISRAEL SYSTEM

INTERNAL HEX



ACTIVE IMPLANT

AVAILABLE SIZES



3.50



3.75



4.20



5.0



6.0

LENGTH

8.0 mm	PIMI358R	PIMI3758R	PIMI4208R	PIMI508R	PIMI608R
10.0 mm	PIMI3510R	PIMI37510R	PIMI42010R	PIMI5010R	PIMI6010R
11.50 mm	PIMI35115R	PIMI375115R	PIMI420115R	PIMI50115R	PIMI60115R
13.0 mm	PIMI3513R	PIMI37513R	PIMI42013R	PIMI5013R	PIMI6013R
16.0 mm	PIMI3516R	PIMI37516R	PIMI42016R	PIMI5016R	PIMI6016R
18.0 mm	PIMI3518R	PIMI37518R	PIMI42018R	PIMI5018R	PIMI6018R

Note: 1) To prevent damage to the Implant driver or fixture, do not over torque during fixture insertion

PIVOT IMPLANTS

MULTI UNIT ABUTMENT REGULAR 5° MORSE CONNECTION WITH ACCESSORIES



Straight MUA



18° GH2



30° GH 2.0



45° GH 2.0



Straight MUA Handle



Healing Cap MUA



Handle



Titanium Cylinder MUA



Plastic Sleeve MUA



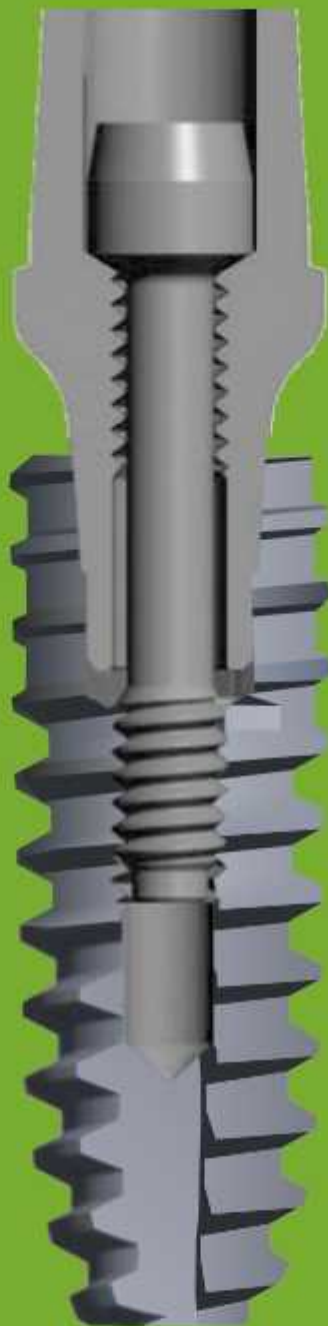
Impression MUA



Lab Analog MUA



Screws



B-28, Indl. Area, Phase- 3, S.A.S, Nagar (Pb) India - 160055
Contact: 81959 81950, 93577 54772



ISO Certified
13485 : 2016

CDSCO Licence Number :
MFG/MD/2019/000093

www.pivotimplants.com

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