

# CLINICAL PROTOCOL PRIME CONOMET

Prodent Italia has implemented a Quality Management System in compliance with UNI CEI EN ISO 13485. The first certifications issued by Certiquality to Prodent Italia date back to 1998.

Within the scope of the Quality Management System, systematic controls are envisaged and conducted both during production, and upon receipt of raw materials or of products processed by subcontractors, with the aim of assuring a high quality level for all the items manufactured.

Before putting each individual device on the market, all the necessary tests are carried out to verify compliance with the relative product specifications, that are defined so as to assure that every device is conform to the applicable Essential Requirements of Directive 93/42/EEC and subsequent amendements.

Additional tests and trials are periodically conducted and documented. They concern both the product and the environmental characteristics. In addition, we closely collaborate with Italian universities with the aim of continually improving our products.

Prodent Italia's main objective is to satisfy its customers in the best possible way, by continually improving the quality of the products and the service provided.

This policy is implemented and sustained at all corporate levels.





UNI CEI EN ISO 13485:2016

# **WARNINGS**

Before using each device, read thoroughly the up-to-date Information for the User, consisting in the Instructions for Use, in which the main warnings are also described, and the Clinical Protocol. Prodent Italia declines all responsibility for failure to comply with the Information for the User, updated versions of which are available from the company website.

This Clinical Protocol provides users with guidance in order to optimise implant site preparation and the insertion of PRIME CONOMET TS implants: it must not, however, be considered a substitute for the practitioner's professional experience and training. For all other implants in the PRIME range, see Clinical Protocol CL 008. See Clinical Protocol CL 009 for Guided Implantology procedures.

The Clinical Protocol complements, without being a replacement for, the Instructions for Use provided with each Prodent Italia device.

**PRIME RANGE** implants are available in a number of different types, namely: PRIME SM, PRIME SM FREE, PRIME SM COLLAR, PRIME CONOMET TS, PRIME TWINNER SM and TWINNER SM COLLAR. PRIME CONOMET TS implants are referred to in the Information for the User as **CONOMET IMPLANTS**; PRIME SM, PRIME SM FREE and PRIME SM COLLAR implants are referred to as **PRIME IMPLANTS**; and PRIME TWINNER SM and TWINNER SM COLLAR implants are referred to as **TWINNER IMPLANTS**.

The symbol TS is used to identify devices pertaining to the restoration range with a TS Tapered Seal connection. CONOMET implants have this type of connection and some of the devices intended exclusively for use with them are marked with the symbol 'TS'. This symbol has been omitted from the names used in this Clinical Protocol, in the interests of readability.

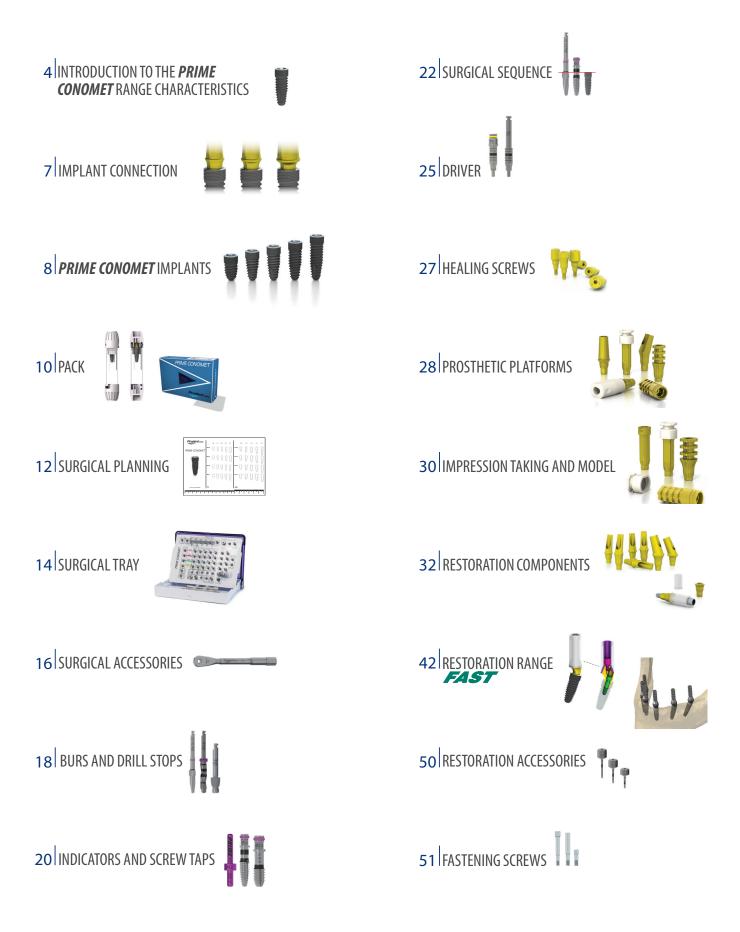
The symbol SM is used to identify certain surgical devices intended for use with CONOMET implants as these devices were initially intended exclusively for implants with a PERFORM SM connection (for which Clinical Protocol CL 008 applies). This symbol has been omitted from the names used in this Clinical Protocol, in the interests of readability.

All the measurements indicated in the Information for the User are expressed in millimetres.

Each device is identified and can be ordered using the item code given below the corresponding image in this Protocol.

For further information or clarification, contact your local dealer or the manufacturer.

# CONTENTS



# GENERAL CHARACTERISTICS - SURFACE TREATMENT

The PRIME CONOMET RANGE implants are made of pure titanium and have been designed and manufactured to assure high performance even in situations where the bone quality is poor. In this case an excellent primary stability is essential.

All the PRIME CONOMET RANGE implants are available in a number of different diameters and heights, to meet any and all anatomical requirements.



The **PRIME CONOMET** implants with "root-form" design are available in the following version:

 MPS treatment on the entire implant body and fully micro-threaded collar, combined with the main spiral, to always provide optimal primary stability in the cortical area.

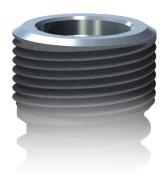


# MPS Micro Profile Surface (Double Acid-Etched)

The MPS surface treatment, where envisaged, is carried out by means of a double etching process, which results in controlled and homogeneous roughness of the treated surface and provides an excellent clot retention, an essential requirement for osteointegration.

The excellent performance of the MPS surface treatment is backed by the high percentages of success in clinical use of over 200.000 fixtures.

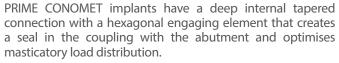
# GENERAL CHARACTERISTICS - INDICATIONS FOR USE, CONNECTION



The PRIME CONOMET implants are suitable in all the clinical cases where the practitioner deems it possible to position the implant at crestal bone level or, in biotypes with thin gingival tissues, at a subcrestal bone level.



The implant-restoration connection of PRIME CONOMET RANGE implants creates a substantial platform switching condition that optimises preservation of the gingival tissues and reduces bone resorption events.

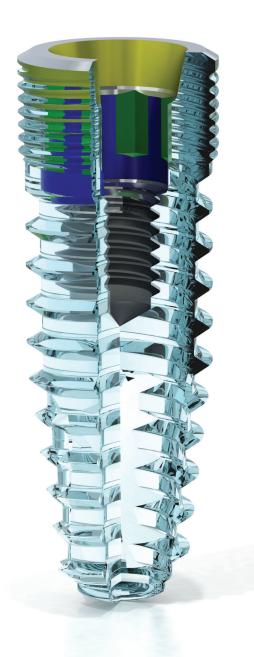


If used appropriately, these implants have an estimated useful life of at least 10 years; this time period has been validated by means of mechanical fatigue tests conducted with at least 5 million load cycles.

The PRIME CONOMET RANGE implant restoration range has been designed and developed to allow practitioners to construct all types of modern prostheses, both in terms of aesthetics and immediate-loading.



# PRIME CONOMET



**Triple micro-thread** combined with the main spiral which - during insertion -activates with the same pitch as the largest spiral, resulting in excellent primary stability in the cortical area.

**Root-form** morphology, characterised by a first cylindrical section and a second more apical/conical section; this will allow you to always get a reliable grip even if the bone quality is poor.

**Semispherical-bottomed conical apex,** ideal to place in sites regenerated contextually with a large maxillary sinus lift.

# RESTORATION CONNECTION - PLATFORM SWITCHING

PRIME CONOMET implants have a **TSTAPERED SEAL** connection, characterised by a hexagonal internal element that guarantees engagement of the structures and is located below the tapered element that creates a seal in the coupling with the abutment to prevent the infiltration of bacteria.

The **implant diameter** corresponds to its maximum dimensions at the level of the neck section.

The diameter of the connection is the same for all implant diameters.

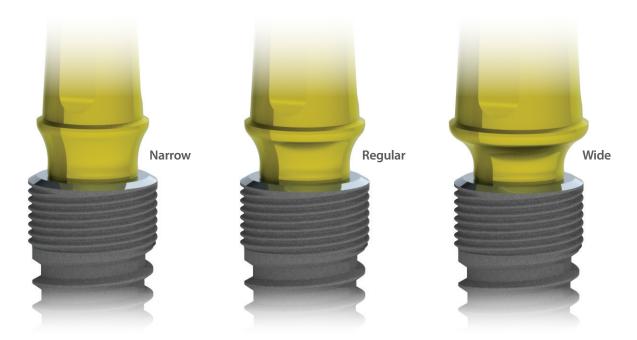
The devices intended for use with the TS connection restoration range are colour-coded golden yellow.

Certain devices are also labelled with a **marking** that identifies their size; further details are provided on the pages describing the procedures to be followed for the use of each device.

All devices are also labelled with their code, batch number, device characteristics and other pertinent indications by means of standard symbols.

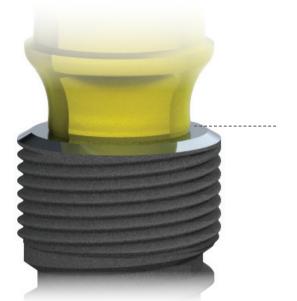
Certain restoration parts are available with three different emergence profiles: NARROW, REGULAR and WIDE.

WIDE profile abutments should not be used with Ø 3.8 and 4.2 implants.



All implants have a Platform Switching system, which assures the preservation of the gingival tissues and, consequently, the crestal bone level.

The abutment-implant joint is thus transferred from a vertical to a horizontal plane, moving it away from the bone-implant interface point; this condition preserves the peri-implant tissues reducing any triggering of inflammatory phenomena and safeguarding the crestal bone level.



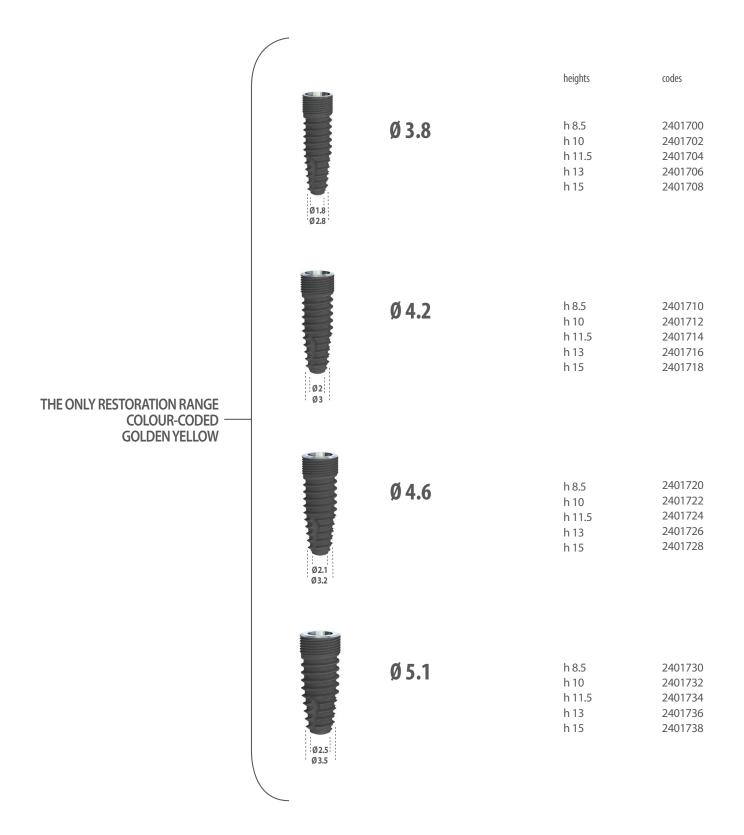
"Platform Switching" Horizontal biological space to maintain the peri-implant soft tissues.

# IMPLANT RANGE

PRIME CONOMET implants are available with four different diamaters and five different heights. The pack includes the Cover Screw.



# PRIME CONOMET



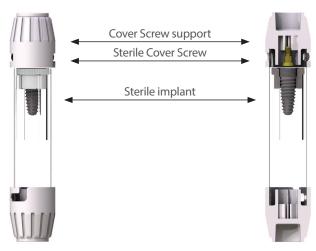
### **PACK AND STERILITY**

The PRIME CONOMET Implants are delivered in a sterile plastic ampoule, housed on a ring in pure titanium. The Cover Screw is fitted into the cap which closes the implant housing.

The ampoule is contained in a sealed plastic blister pack to preserve sterility and the blister pack comes in a sealed cardboard box suitable for storage.

The implant housing and its extraction instruments make it possible to avoid contact between the surface of the implant and other components and surfaces other than titanium before placement in the site.

The implant label is found on the box. The box also contains the Instructions for Use, the patient's Dental Implant Passport and the extra peel-off label with the device identification details, to be attached to the patient's clinical records.



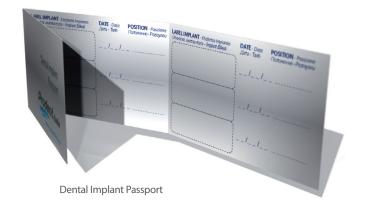
Primary pack for PRIME CONOMET implants

# **DOCUMENTATION AND IMPLANT IDENTIFICATION**

PRODENT ITALIA S.r.l. recommends that you keep the complete clinical/radiological and statistical documentation.

Implant identification is assured if the label contained in the pack is applied on the patient record, or if the implant data (implant type, diameter, height and batch number) is transcribed on the patient record or otherwise filed.

The operator should complete the patient's Identicard (Dental Implant Passport) contained in the pack, filling in all the required data and applying the peel-off labels in the spaces provided. The card should then be handed to the patient providing him or her with all the instructions to follow after the operation.



# STORING AND HANDLING THE PACK

Implant sterility is guaranteed if the original pack is unopened, intact and stored in a dry place at ambient temperature until the expiry date indicated on the label (5 years from the date of sterilization - shelf-life). Before using the implant, always check that the pack is undamaged and shows no visible signs of damage that could compromise its sterility.

The pack must not be opened until the implant is to be used. The blister must be opened and the implant taken out in asepsis conditions.

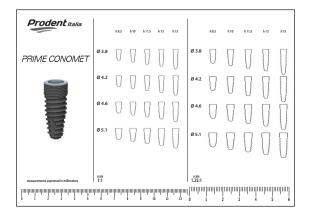


# SURGICAL PLANNING

Before surgery, it is of fundamental importance to perform a careful preoperative anamnesis of the patient in order to verify the suitability of the implantation treatment. After excluding any contraindication to the implant-restoration treatment, it is essential that the practitioner carries out careful clinical planning taking various aspects into account, such as the position and optimal orientation of the chosen implants in relation to the occlusal plane and correct stress distribution. At this stage, it may be helpful to prepare a surgical template to guide correct positioning of the implants during surgery. Depending on the case, you can decide whether to use a one- or two-phase surgical procedure.

As well as a clinical and radiographic evaluation, the specialist can do a CAT scan of the area involved and, once obtained the radiographic and tomographic plates, he can identify the most suitable implant using the transparency viewers.

The transparencies show the two-dimensional profiles of the implants in 1:1 and 1.25:1 scale. This will allow the operators to superimpose the transparencies both on the endoral radiographies and on the CAT (scale 1:1), as well as on the orthopantomographies (scale 1.25:1), thus directly evaluating the type of implant to insert and the related diameter. The transparency viewers should not be used to make measurements; they only provide an indication of the shape/size of the implants.



Clinical planning should also take into account the minimum distance to be respected between implants or between the implant and the natural tooth. That way you can prevent possible clinical complications that might compromise success of the surgical treatment.

Implant integration is a necessary prerequisite for the subsequent final prosthesization. Following implant insertion, the following timeframes are possible:

- The prosthetic component (in its various versions) is connected to the implant during surgery by immediately applying a temporary prosthesis that will be replaced with the final prosthesis when osteointegration is complete.
- The Healing Screw is applied contextually with implant insertion, or after a variable period of time required for the mucosa to heal, which will depend on the screw morphology, so as to create a suitable site for the prosthetic component.
- Once the osteointegration process has been completed, the Healing Screw will be connected and followed directly by the prosthetic component, according to a procedure that may be defined "conventional".

The choice of the correct procedure to use in the phases following implant insertion is up to the practitioner, based on his or her evaluation of the surgical treatment suited to the clinical case. Prodent Italia merely provides indications and warnings on the correct sequence and on the procedures for using the components that may be employed in the surgical and prosthetic phases. As conventional procedures have always been considered more conservative, in case of doubt on which phase to choose, it would be preferable to use a conventional procedure as a precautionary measure.



In implant-restoration treatments, it is always preferable to use implants of a diameter suited to the size of the missing part, thus optimising the quality of the prosthesis from both the aesthetic and the biomechanical point of view.

The table below shows the dental positions where the PRIME CONOMET RANGE implants perform best. By "discretionary position" we mean a position selected by the practitioner only after careful evaluation of the implant size in relation to the prosthetic load.

Ø Implant	PRIME CONOMET				
	Ø 3.8	Ø 4.2	Ø 4.6	Ø 5.1	
<b>UPPER</b> missing parts					
CENTRAL INCISORS		$\triangle$		•	
LATERAL INCISORS	•		•	$\triangle$	
CANINES		$\triangle$		•	
PREMOLARS		$\triangle$	•	•	
MOLARS			$\triangle$	•	
LOWER missing parts					
CENTRAL INCISORS	•		$\triangle$	$\triangle$	
LATERAL INCISORS	•	•	$\triangle$	$\triangle$	
CANINES				•	
PREMOLARS					
MOLARS			$\triangle$	•	
optimal position	discretionary position	contraindicated	l position		

If used in DISCRETIONARY position, do not prosthesize Ø 4.2 PRIME CONOMET implants with abutments having an angulation greater than 17°.

In the case of implant-restoration treatments with immediate loading threaded implants, we recommend that you refer to the dedicated section "FAST surgical planning".

# SURGICAL TRAY

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The Surgical Tray PRIME CONOMET contains all the cutting instruments and surgical accessories needed for the surgical site preparation and for the subsequent implant insertion.

Made of sterilizable plastic, the Surgical Trays are customised with colours and screen-printing that allow them to be practically and intuitively used by both the operator during surgery, and by the assisting staff when washing and placing the devices back into the Surgical Tray. The position of each instrument is indicated by the corresponding screen-printed image, and where devices are available in different variants, their size is indicated too, so to identify the correct instrument to use.

The coloured lines - that follow the identification colour code - guide the operator, facilitating the use of the surgical instruments in the correct sequence.

The silicon instrument holders are customised based on the instrument they are intended to house; they also help to hold the instruments in place during handling and sterilization of the Surgical Tray.







# SURGICAL ACCESSORIES

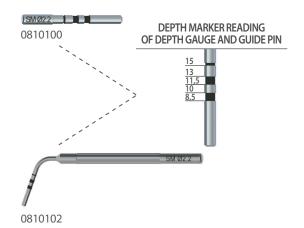
# **TISSUE PUNCHES**

Circular scalpels to be used in the flapless surgical technique before passing bone burs, connected to the contra-angle and at low rotation speed (25 RPM), to remove gingival tissue, creating holes meant for the successive passages of burs. They can also be used to create holes that are useful to remove cover screws without opening the flap.  $\emptyset$  4.3 and  $\emptyset$  5.5 tissue punches create a hole with a diameter 3.3 and 4 respectively. The diameter marked on the device refers to its maximum outer dimensions.



#### **GUIDE PIN**

It is used to assess the depth of the surgical channel (also by using radiography) after drilling with the Slim Pilot Bur. In the event that two or more implants are inserted, the pin can be used as reference for parallelism.



#### **DEPTH GAUGE**

This instrument is equipped with an extra-oral handle to assess the depth of the surgical site after using the Slim Pilot Bur.



In the event of disparallelism, after using the Slim Pilot Bur, it is useful to assess the possibility of recovering the implant axis by means of angled restoration components.



# **BUR EXTENSION**

To use when it is necessary to extend the connection between the Bur and the Contra-angle without exceeding a max. torque of 45 Ncm.



### **DIGITAL WRENCH**

To start tapping the surgical site or for manual implant insertion. When the implant is inserted, it can be used to remove Drivers.



# SURGICAL ACCESSORIES

### **HEX SCREWDRIVERS**

For tightening and unscrewing all screws pertaining to all Prodent Italia restoration ranges. Available with three different lengths, it allows comfortable use, even with customised restorations.

Screwdrivers with a double ring laser marked on the shaft **alone** can be used for TS Screws, **do not** use Screwdrivers without a double ring (codes 0510066 - 0510067 - 0510065).



### **CONTRA-ANGLE CONNECTION**

For mechanical use of Drivers and Screw Taps without exceeding 25 RPM and a maximum torque of 45Ncm.



### **EXTENSION**

For increasing the length of the connection to the dedicated screwing instruments.



## **TOROUE RATCHET**

With fixed function to complete the manual insertion of the implant and the tapping operations of the surgical site. The device also has a torque function with adjustment markers at 20-30-45-70 Ncm. Cleaning, disassembly and assembly operations are described in the instructions for use.



#### **DIRECTION GUIDE**

Manufactured in titanium, it is indicated in clinical cases involving the prosthetic restoration of an entire arch in which implants are inserted into the bone at angles of up to 30°.

The indicators on the guide allow the practitioner to consider implant insertion both perpendicular to the bone crest (0°) and with an offset of 17° to 30°.

It must be bent by hand, following the shape of the arch, and secured to the bone crest by inserting its 11 mm mobile shaft into a site prepared for the purpose using a  $\emptyset$  2.2 pilot bur. The receiving site should be made in the centre of the frontal area mesially to the sites in which the implants are to be inserted.



# BURS AND DRILL STOPS

The same Corticotomy Bur and Slim Pilot Bur with corresponding Drill Stops are used for all PRIME CONOMET implant diameters. The specific intermediate and Final Tapered Burs to be used depend on the diameter of the implant to be inserted.

All the burs are made of surgical stainless steel and guarantee excellent cutting performance. To prevent the bone from overheating, use the burs under abundant sterile saline solution and do not exceed 800 RPM.

The Corticotomy Bur is used to cut the cortex.

The Slim Pilot Bur is used to determine the final depth of the surgical implant site.

When used as a final bur, the Tapered Burs make it possible to obtain a site whose morphology and size are suited to housing the implant; when used as an intermediate bur, they allow a gradual widening of the site.

For the exact sequence of the burs to be used according to the implant to be inserted, consult the "Surgical sequence" section.

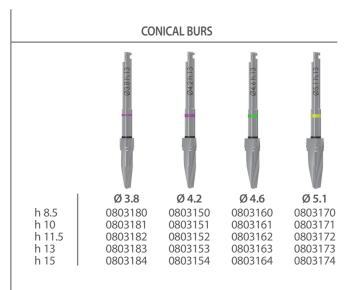
The Drill Stops assure, by means of a mechanical stop, that the required depth is observed during milling: their use is optional depending on the clinical spaces and the morphology of the bone crest. They are made of grade 5 titanium and they are available only for the Slim Pilot Bur.

The sole purpose of the double red O-ring on the Slim Pilot Bur is to guarantee a correct coupling between the Bur and the corresponding Drill Stops.

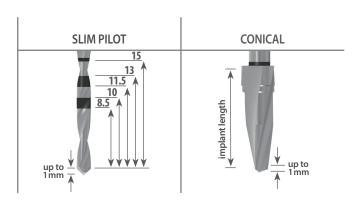


# BURS AND DRILL STOPS





BUR DEPTH MARKER AND CUTTING EDGE READING



# INDICATORS AND SCREW TAPS

The specific Screw Tap and Neck Diameter Indicator to be used depend on the diameter of the PRIME CONOMET implant. All devices are marked with the diameter of the implant they are intended for. All Screw Taps are also marked with depth indicators.

# **NECK DIAMETER INDICATORS**

After using the Slim Pilot Bur, the Neck Diameter Indicators allow you to check the diameter at the crest of the implant neck; the side of the instrument to be inserted is marked Ø 2.2.

#### **SCRFW TAPS**

In the event of compact bones - after using the Final Bur - the Screw Taps allow you to create a calibrated surgical site for the insertion of the implants they have been designed for. It is preferable to screw manually the tap with the Digital Wrench or Ratchet. If you proceed mechanically, use the Contra-angle Connection and do not exceed 25 RPM.



# INDICATORS AND SCREW TAPS

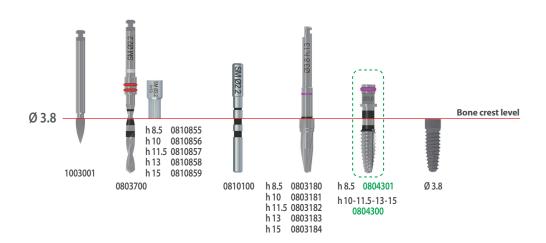
Implant diameter	Ø 3.8	Ø 4.2	Ø 4.6	Ø 5.1
NECK DIAMETER INDICATORS	0810150	0810151	0810152	0810153
SCREW TAPS FOR IMPLANTS h 8.5	0804301	0804311	0804321	0804331
SCREW TAPS FOR IMPLANTS h 10-11.5-13-15	0804300	0804310	0804320	0804330

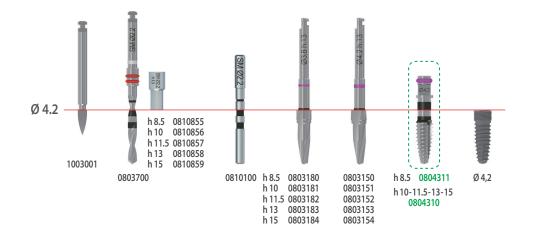
	FOR h 8.5 IMPLANTS	FOR h 10-11.5-13-15 IMPLANTS
DEPTH MARKER READING	8.5	——15 ——13 ——11.5 ——10

# SURGICAL SEQUENCE

# SEQUENCE BASED ON IMPLANT DIAMETER AND HEIGHT

The devices with green code are optional and they must be used in a compact bone.

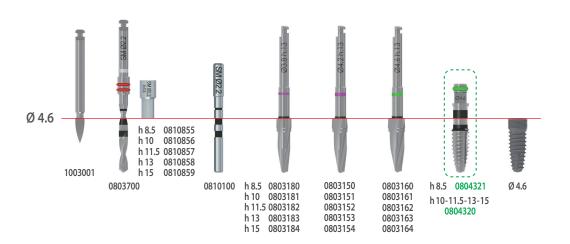


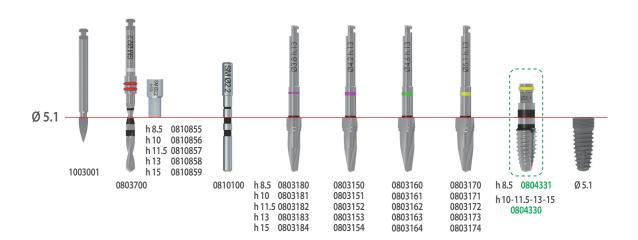


# SURGICAL SEQUENCE

# SEQUENCE BASED ON IMPLANT DIAMETER AND HEIGHT

The devices with green code are optional and they must be used in a compact bone.





# PREOPERATIVE AND STERILE DEVICE PREPARATION

### PREOPERATIVE PREPARATION

Preparing the surgical room to assure proper environmental conditions for surgery, providing appropriate clothing for the patient and for the surgery staff, checking that appropriate instruments and a sufficient stock of implants are available: these are all activities to be carried out according to good dental practice, under the practitioner's responsibility.

### STERILE DEVICE PREPARATION

The surgical instruments may be housed in a sterilizable surgical tray which can be used to easily set down and pick up all the instruments required for appropriately preparing the surgical site and for subsequent insertion of the implants.

# IMPORTANT RECOMMENDATIONS FOR DEVICE CLEANING AND STERILIZATION

Cleaning and sterilisation procedures must be carried out under the practitioner's responsibility by qualified personnel using validated procedures and regularly maintained, calibrated and validated instruments. It is recommended to use validated and continually monitored cleaning and sterilization processes. Decontaminate each device by immersing it in a disinfectant solution suitable for the type of material - specified in the Instructions for Use - the device is made of. Wash all parts of the devices; disassemble the devices only if required and only as indicated in the Instructions for the specific device; use neutral detergents suitable for the material the parts of the devices are made of; the brushes and picks used must be previously decontaminated, washed and sterilised; do not use abrasive products or brushes and sponges with metal parts. Rinse all devices under running water, preferably demineralised, to eliminate any trace of detergent. Wear personal protection equipment when washing and rinsing the devices. In order not to compromise the sterilization process, dry the device with a clean, soft cloth or with filtered compressed air.

The devices must be packed in suitable material immediately prior to sterilising. To determine the suitability of the packing material with the sterilisation method, consult the reference standards and the information provided by the manufacturer of the material. Do not reuse the packaging material.

Prodent Italia advises you to refer to EN ISO 17665-1 for the development, validation and routine control of the steam sterilization process in autoclaves, and recommends using autoclaves with a type B sterilization cycle according to the EN 13060 classification.

**Single-use** devices must be cleaned and sterilized just before using them on the patient.

**Reusable** devices must be cleaned and sterilized just before using them on the patient. **Reusable** devices must be rinsed immediately after use to remove any residue, brushing them with a plastic, non-metallic, stiff bristle.

**Ultrasonic cleaning** is recommended according to the instructions provided by the washing machine and detergent manufacturers. Do not use products that contain substances that may cause alteration of the surfaces; do not place devices made of different metals in the same container, and observe the validated washing times. It is unadvisable to use chemical agents such as oxygenated water, glutaraldehydes and oxidising acids (oxalic acid, sulphuric acid, nitric acid) for titanium instruments. It is unadvisable to use detergents containing high concentrations of oxalic acid and chlorine for stainless steel instruments.

**Sterilization in saturated steam autoclaves**: the cleaned and thoroughly dried devices should be packed appropriately and sterilized in an autoclave according to the validated sterilization process and referring to the instructions provided by the autoclave manufacturer. It is important to remember that the presence of contaminants (organic residues, oxidation, etc.) released in the autoclave water cycle by previous sterilizations may adhere to the instruments, even if they are new, during the subsequent sterilization cycles.

PRODENT ITALIA S.r.l. has tested the efficacy, on devices of its own manufacture, of the sterilisation process in a saturated steam autoclave at 134°C for 5 minutes.

#### Storage

After sterilization, the devices must be kept in the bags used for sterilization. The bags are to be opened just before use. Items sterilized in bags may not be stored for longer than recommended by the bag manufacturer.

The devices must be stored in a cool and dry place away from direct sunlight, water and heat sources.

## **REGULATORY REFERENCES**

All the devices are designed and manufactured in compliance with the latest directives and harmonised standards as regards the materials used, the production processes, the information provided and the packaging.

## **DISPOSAL PROCEDURES**

After use, the devices must be disposed of as biological waste in accordance with the local regulations in force.

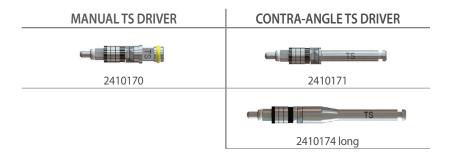
### **MANUAL TS DRIVER**

Connected to the Digital Wrench, they allow the implants to be taken from the ampoule and to be placed in the implant site to then proceed with manual insertion. If necessary, complete insertion using the Driver connected to the Torque Ratchet.

#### **CONTRA-ANGLETS DRIVER**

Connected to the Contra-angle, they allow the implants to be taken from the ampoule and to be placed in the implant site to then proceed with mechanical insertion. Complete insertion by screwing in. Never exceed 25 RPM and a maximum torque of 45 Ncm. Available in two variants: standard and long.

Primary stability of the implants is essential to ensure success; it is advisable to solve any unfavourable situations before surgery. The Drivers feature laser-marked depth indicators to facilitate implant insertion, especially when a flapless technique is used, as they indicate the distance between the individual indicator and the head of the implant.







During the procedures for extracting the implant from the ampoule, we recommend that you **gently press** the Driver and at the same time rotate it to perfectly connect the Driver and the implant.

Incorrect procedures would prevent proper use of the device: in these events, <u>it is recommended to repeat</u> <u>the connection procedure.</u>

After the Driver use and **before extracting it upwards**, if the insertion torque is close to its maximum limit (60 Ncm), **it can be useful to gently press the Driver rotating it anticlockwise** to more easily detach it from the implant.

In order to extract the Driver, it can be useful to use the Digital Wrench.

The Drivers have six indents, which, when the driver is inserted in the implant, indicate the position of the hex faces of the connection. If the implant is prosthesized with an Angled Abutment, during the insertion of the implant it is important to match one of the driver's indents with the implant axis, so that once inserted, the Angled Abutment has an optimal angle.



# IMPLANT INSERTION

# MANUAL INSERTION



The implant is extracted from the sterile ampoule with the Digital Wrench and the Manual Driver for the first screwing phase of the implant into the implant site.



# **MECHANICAL INSERTION**



The implant is extracted from the sterile ampoule with the Contra-angle and the Contra-angle Driver for the first screwing phase of the implant into the implant site. Insertion of the implant completed with the Ratchet and the Manual Driver.

It is recommended **not to exceed** a **Torque of 60 Ncm.** 

The Healing Screws feature a transmucosal portion with three different emergence designs, to be chosen according to the implant's position inside the oral cavity, and that permit an ideal conditioning of the soft tissues.

The head of the Screws is marked to identify the device according to its emergence design (NR=Narrow, RG=Regular, WD=Wide), coronal height (hc) and transmucosal height (ht).

The aim is to condition the soft tissues during the healing phase with the correct anatomical configuration to permit a non-traumatic application of subsequent components such as impression transfers and abutments.

			De	sign		
	NR=Narrow		RG=Regular		WD=Wide	
	hc 2	hc 4	hc 2	hc 4	hc 2	hc 4
ht 2	2406000	2406002	2406010	2406012	2406020	2406022
ht 4	2406001	2406003	2406011	2406013	2406021	2406023

hc = coronal heightht = transmucosal height

The configuration of the devices used for impression-taking and subsequent restoration work should be chosen to match the design and size of the healing screw used for soft tissue conditioning, in order to avoid any dimensional interferences that might irritate the soft tissues surrounding the implants.

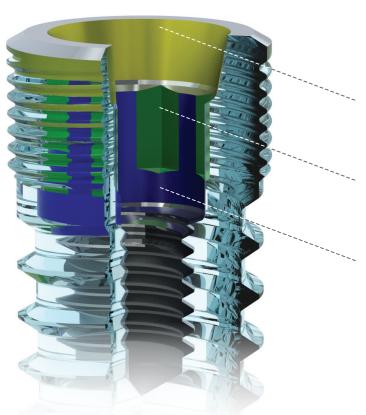




All PRIME CONOMET range implants have the same **TS TAPERED SEAL** implant-restoration connection, which is indicated, on the secondary components, with golden yellow colour-coding and, where appropriate, the symbol 'TS'.

Different restoration solutions are available: as well as the classic preformed components, other solutions can be chosen, such as Multi Abutments, Temporary Aesthetic Abutments, Locator, and the FAST range dedicated to Immediate Loading Threaded Implants.

	PRIME CONOMET					
	Ø 3.8 - Ø 4.2 - Ø 4.6 - Ø 5.1					
HEX	2.3					
SCREW	1.8					



**Tapered connection:** guarantees a seal to prevent the infiltration of bacteria and provides implant/restoration interface stability.

**Engaging hex:** withstands torsional stresses preventing restoration component rotation and micromovements of the interface that contribute to loosening of the through screw.

**Cylindrical surface:** avoids transverse and flexural stresses, preventing them from overloading the hex or the connection screw.

## **MATERIAL**

- Grade 5 titanium: All the metal components.
- Polycarbonate: all the Castable components.
- Peek: Temporary abutment peek sleeve, Scanmarker.
- Polyphenylsulphone: Easycap.



The components intended for impression-taking and model development are of fundamental importance to reproducing the position of the implants in the patient's oral cavity with absolute precision. For this reason, these components too are manufactured with the same construction tolerances as the implants and the restoration components.

Impressions can be taken using two different methods - the precision technique and the tear-off technique - allowing the practitioner to choose the most suitable option for the restoration work to be performed.

### PRECISION IMPRESSION TRANSFER

Indicated for precision impression-taking using individual impression trays, even in the case of implants with disparallel axes; they come in three designs (NR=Narrow, RG=Regular, WD=Wide) and two transmucosal heights, to match the previously-chosen conditioning using Healing Screws. They can be used with their standard fastening screw, that is included in their pack, or with the long fastening screw for Transfer TS, that is purchasable singularly.

### **EASYCAP AND TEAR-OFF IMPRESSION TRANSFER**

Used to take impressions with an unperforated impression tray by means of tear-off technique for a maximum number of three implants with disparallelism of less than 8°. When connected to Easycap, it is suitable for taking dental impressions with a high level of precision. When used without Easycap, it is suitable for taking standard dental impressions.

## **EASYCAP**

Sterilisable and resistant to high temperatures (up to 207°C). Designed for use connected to Easycap and Tear-off Impression Transfers, on which it is to be pressure-fitted.

#### **IMPLANT ANALOGUE**

Used to create the working model on which the orthodontic technician builds the restoration.

			Design			
		NR=Narrow	RG=Regular	WD=Wide		
PRECISION IMPRESSION TRANSFER	ht 2	2407000	2407002	2407004		
	ht 4	2407001	2407003	2407005		
EASYCAP AND TEAR-OFF IMPRESSION TRANSFER		2407020				
EASYCAP			0807000			
IMPLANT ANALOGUE			2409000			

**ht** = transmucosal height

# SCANMARKER

# **SCANMARKER**

It is suitable for recording intraoral digital impressions using intraoral dental scanners; it will allow you to acquire the position of the implant connection. It is also suitable for scanning models obtained from traditional impressions, using laboratory dental scanners. Allows the user to acquire the position of the implant connection.





# CONNECT BASE AND PREMILLED ABUTMENT

# **CONNECT BASE**

To be used with CAD-CAM systems to make personalised prostheses, this base makes it possible to create permanent cemented or screw-retained restorations with outstanding cosmetic characteristics whilst guaranteeing a titanium coupling with the implant. In order to obtain a good restoration result, the Connect Base must not be modified and postoperative soft tissue healing must take place using the same base combined with a personalised temporary restoration.

Available in the ENGAGING version and in the NON-ENGAGING version, free from anti-rotational constraints, to ease insertion even in the presence of disparallelism. Both versions are available with three transmucosal heights (ht) to be chosen according to the restoration planned.

Do not use non-engaging Connect Bases for single-implant restorations.

#### PREMILLED ABUTMENT

Made of grade 5 titanium, it is indicated to make customized abutments, with maximum working height of 16 mm, to make cemented or screwed prostheses with CAD-CAM technique, using automatic milling machines. It is available in two different cylindrical sections: 11.5 mm (for angulation to 17°) and 15.8 mm (for angulation to 25°). Premilled Abutments are made with Medentika® attachment.



	ht 0	ht 2	ht 4
CONNECT BASE engaging	2405850	2405851	2405852
CONNECT BASE non-engaging	2405855	2405856	2405857
PREMILLED ABUTMENT Ø 11.5		<b>₽</b> 2405721	
PREMILLED ABUTMENT Ø 15.8		2405722	

# MULTI ABUTMENTS

# **MULTI ABUTMENTS**

Multifunctional component suitable for temporary or permanent prostheses, according to the method that is most suited to the clinical case. Available in the ENGAGING version or in the NON-ENGAGING version, which is free from engagement constraints so as to ease insertion even in the event of disparallelism.

Do not use Multi abutments in the non-engaging version to prosthesize individual implants.

# **MULTI ABUTMENT CASTABLE SLEEVES**

They are designed to be combined with the Multi Abutments to make permanent prostheses with adhesive bonding system, in order to obtain total passivation of the secondary structures.



		Design NR=Narrow
MULTI ABUTMENTS engaging version	ht 2	2405301
MULTI ABUTMENTS non-engaging version	ht 2	2405300
MULTI ABUTMENTS castable version		2405302

# **ABUTMENTS**

# 0° ABUTMENTS

Indicated for cemented restorations and available with three different emergence designs (NR=Narrow, RG=Regular, WD=Wide) and two different transmucosal heights (ht).

# 17° and 25° ABUTMENTS

Indicated for cemented restorations and available with three different emergence designs (NR=Narrow, RG=Regular, WD=Wide) and two different transmucosal heights (ht) to be chosen according to the restoration planned, in order to correct disparallelisms of up to 17° and 25°, respectively.



		Design		
		NR=Narrow	RG=Regular	WD=Wide
0° ABUTMENTS	ht 2	2405100	2405103	2405106
	ht 4	2405101	2405104	2405107
17° ABUTMENTS	ht 2	2405110	2405113	2405116
	ht 4	2405111	2405114	2405117
25° ABUTMENTS	ht 2	2405120	2405123	2405126
	ht 4	2405121	2405124	2405127

# SHOULDERLESS ABUTMENTS

This type of abutment is shoulderless and is therefore indicated for vertical preparations.

# **SHOULDERLESS 0° ABUTMENTS**

Indicated for cemented restorations and available with one emergence design (RG=Regular) and two different transmucosal heights (ht).

# **SHOULDERLESS 20° ABUTMENTS**

Indicated for cemented restorations and available with one emergence design (RG=Regular) and two different transmucosal heights (ht), to be chosen according to the restoration planned, in order to correct disparallelisms of up to 20°.



		Design
		RG=Regular
SHOULDERLESS 0° ABUTMENTS	ht 2	2405200
	ht 4	2405201
SHOULDERLESS 20° ABUTMENTS	ht 2	2405210
	ht 4	2405211

### **CASTABLE ABUTMENTS**

Suitable for constructing cemented or screw-retained prostheses only in cases where preformed components cannot be used; they may be modified by the dental technician up to the limit indicated on the screw head. Do not tighten with the Torque Ratchet but use only the Hex Screwdriver. Available also in the non-engaging version. Do not use Castable Abutments in the non-engaging version to prosthesize individual implants.



	Design
	NR=Narrow
ht 2	2405401
	2405401
ht 2	2405400

## ROD ABUTMENT

### **ROD ABUTMENT**

Suitable for constructing overdenture bars. Composed of a titanium base and a customisable coronal portion. The base features an engaging system that connects with the implant and a sloping surface that supports the customised portion.



		Design
		NR=Narrow
ROD ABUTMENT	ht 2	2405500

### OT EQUATOR

CAPS KIT, VARIOUS TYPES (4 pcs.)

(purple: strong, white: standard, pink: soft, yellow: extra soft)

OT EQUATOR low-profile removable restoration attachments are amongst the smallest on the market; this system offers a number of options, allowing various overdenture solutions, depending on the space available.

The caps come with 4 retention levels that vary according to their colour and they must always be used with the metal housings provided, in order to guarantee their duration over time and to facilitate replacement.

The total vertical height (male + female and housing) is just 2.1 mm. The maximum width is Ø 4.4 mm.

TITANIUM + TiN

**ATTACHMENT** 



**EQUATOR CASTABLE MALES** 

	ht 2	ht 3	ht 4	ht 5	ht 6
EQUATOR	1108100	1108101	1108102	1108103	1108104

### CONTENT OF THE OT EQUATOR PACK

each of the EQUATOR item codes mentioned in the table above contains the following devices: PROTECTIVE DISK

1108065 (2 pack)

			9			
Coove weather	I					
Spare parts						
CAPS	PURPLE STRONG retention 2.7 Kg	WHITE STANDARD retention 1.8 Kg	PIN SO reter 1.2	FT ntion	YELLOW EXTRA SOFT retention 0.6 Kg	BLACK only for LABORATORY USE
	1108057 (4 pack)	1108058 (4 pack)	1108059	(4 pack)	1108060 (4 pack)	1108061 (4 pack)
	STAINLESS STEEL CAP CONTAINER			TITANIUM CAP CONTAINER		
CAP CONTAINERS						
	11	1108064 (2 pack)				
SPARE	STAINLESS STEEL CAP CONTAINER	PROTECTIVE DISK	BLACE for labora		(purple: strong, white	US TYPES (4 pcs.) e: standard, pink: soft, extra soft)
PARTS KIT						
	1108063					
OT						

STAINLESS STEEL

**CAP CONTAINER** 

## OT EQUATOR

Rods						
THREADED OT EQUATOR KIT	THREADED OT EQUATOR - 2 pcs. for titanium sleeve (1.6 mm thread)	THREADED SLEEVES - 2 pcs. (1.6 mm thread)	STAINLESS STEEL CAP CONTAINERS - 2 pcs.		CAPS KIT, VARIOUS TYPES - 8 pcs. (2 white: standard, 2 pink: soft, 2 yellow: extra-soft, 2 black: processing)	
WITH BONDING SLEEVE						
			11080	66		
	FOR CAD/CAM BAR (2 mm thread)			FOR TITANIUM SLEEVE (1.6 mm thread)		
THREADED OT EQUATOR				<u>~</u>		
•						
		1108067			1108070	
CASTABLE OT EQUATOR	CASTABLE "SEN MAL 2 pc	ES	STAINLESS STEEL CAP CONTAINERS 2 pcs.		CAPS KIT, VARIOUS TYPES - 4 pcs (2 white: standard, 2 pink: soft)	
KIT				3		
			11080	69		
	TITANIUM SLEEVE			SPACER FOR OT EQUATOR SLEEVE		
OT EQUATOR	(1.6 mm thread)					
SLEEVE						
	1108071				1108072	
THREADED COVER SCREW				)		
	1108073					
	CACTABLE ABUTA	AFNITC DE	D. DI. ACTIC	FLACTIC	TUREARER	
	FOR SEEGER		D PLASTIC ELASTI SEEGER RETENTION		THREADED ER COVER SCREWS	
PASSIVE BAR CONNECTION SYSTEM "ELASTIC SEEGER"	CONTAINERS for l		aboratory use for prosthesis lo 3 pcs. 3 pcs.		ng 2 pcs	
	o pesi.			2  - 22.		
			11080	068		
	RED			WHITE		
SEEGER	(for laboratory use)			(for bar locking)		
		1108074 (6 pack)		1108075 (6 pack)		
CASTABLE CYLINDERS		h. 2.5		h. 3.5		
FOR SEEGER						
	1108076 (6 pack)			1108077 (6 pack)		

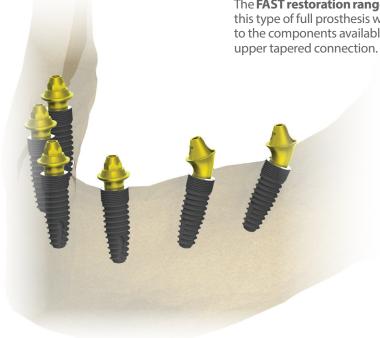
# OT EQUATOR

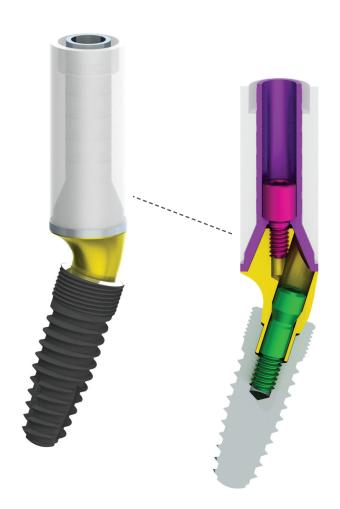
Accessories	
OT EQUATOR TRANSFER (for custom tray)	1108078 (2 pack)
IMPLANT ANALOGUES FOR LABORATORY USE	1108079 (2 pack)
TEAR-OFF IMPRESSION TRANSFER	1108080 (2 pack)
Instruments	
OT EQUATOR DRIVER FOR TORQUE RATCHET	1110000
WRENCH FOR PARALLELOMETER - NORMO	1108081
SQUARE WRENCH + HOLDER (for OT EQUATOR screwing) 1.25 mm square	1108082
INTERCHANGEABLE HOLDER	1108083
CONNECTOR FOR TORQUE CONTROLLER 1.25 mm square	1108084
CAP INSERTION TOOL - EQUATOR - NORMO - MICRO	1108085
CURVED TOOL FOR SEEGER INSERTION (to use with universal handle)	1108086
CAP EXTRACTOR	1108087
BLUE UNIVERSAL HANDLE, TOOL HOLDER AND SEEGER INSERTION TOOL	1108088

### RESTORATION RANGE FAST

In the case of immediate loading of screw-retained prostheses used in multiple implants, restoration components are required to convert - simultaneously with insertion of the fixtures - the engagement of the implants and their disparallelism into a non-engaging transmucosal connection. These shall also result in a restoration parallelism between the abutments.

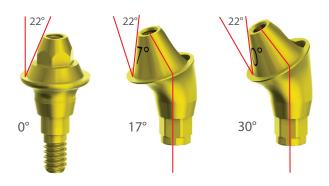
The **FAST restoration range** described in the following pages allows you to make this type of full prosthesis with any kind of surgical-prosthetic techniques, thanks to the components available with three different angulations and equipped with upper tapered connection



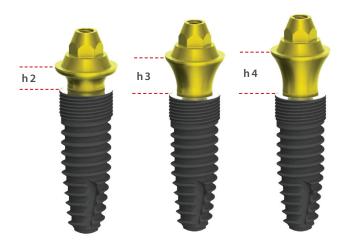


### RESTORATION RANGE FAST

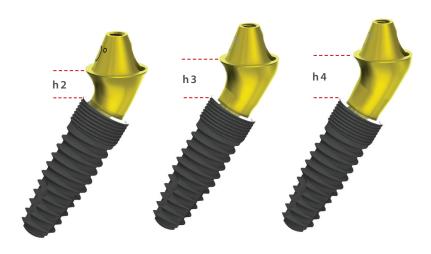
The FAST restoration range has been designed to simplify the construction of immediate loading full threaded prostheses, parallelizing implants with significant divergences (a usual condition in the distal region) in complex restoration projects, such as treatment of toothless patients. The immediate loading of full temporary prostheses brings significant benefits to patients in terms of extremely short realisation times and contained costs. Thanks to the FAST range, practitioners can plan to carry out both the insertion of the implants and the temporary restoration (until such time as the permanent restoration is ready) in day surgery. FAST bases are available with three different angles (0° - 17° - 30°), to be chosen according to the inclination of the PRIME CONNECT implants inserted, in order to parallelise the prosthetic axis of insertion of the screw-retained crown.



The tapered section of the FAST Bases allows the screw-retained prostheses to be connected in the case of disparallelisms of up to 22°. This feature, in combination with FAST 17° or 30° Angled Bases allows prosthesization also of implants angled at 45° with respect to the implant axis.



FAST 0° BASES



FAST 17° - 30° BASES

### SURGICAL PLANNING FAST

In implant-restoration treatments with Immediate Loading Threaded Implants, it is recommended to plan implants with a diameter suited to the size of the missing part, thus optimising the quality of the final result both in terms of aesthetics and biomechanics. The table below indicates the dental position where the PRIME CONOMET RANGE implants perform best in Immediate Loading Threaded Implants. By "discretionary position" we mean a position selected by the practitioner only after careful evaluation of the implant size in relation to the prosthetic load.

#### IMPLANT SIZE INDICATIONS FOR IMMEDIATE LOADING THREADED IMPLANTS

	PRIME CONOMET					
Ø Implants	Ø 3.8	Ø 4.2	Ø 4.6	Ø 5.1		
UPPER missing parts						
CENTRAL INCISORS			•			
LATERAL INCISORS						
CANINES	•		•			
PREMOLARS		•	•			
MOLARS		$\triangle$	•			
LOWER missing parts						
CENTRAL INCISORS						
LATERAL INCISORS			•			
CANINES	•		•			
PREMOLARS			•			
MOLARS		$\wedge$				

### **SURGICAL ACCESSORIES**

### **FAST COUNTERSINK BUR**

Cutting instrument useful for milling the bone crest to grind the cortical section of angled implants prosthesized with FAST 17°-30° Bases.



### **GUIDE FOR FAST COUNTERSINK BUR**

Useful accessory for correct use of the FAST Countersink Bur, that protects the head of the implants during the bone crest grinding procedure. Do not use the Guide for Fast Countersink Burs intended for use with implants with an SM connection only (code 0807302 and 0807303).



### **CARRIER FOR FAST BASES**

Instrument to place the 17°-30° FAST bases in the oral cavity, also useful for correcting orientation when connecting the Bases to the implants.



#### **FAST HEALING CAP**

A useful component to protect the FAST connection pending prosthesization of Immediate Loading Threaded Implants.



### **IMPLANT POSITIONING**

Total rehabilitation of toothless patients through an Immediate Loading Threaded Implant, a removable screw-on prosthesis, is normally carried out on at least 6 fixtures with an implant insertion torque of not less than 35 Ncm. In these rehabilitation cases, it is advisable not to exceed an angulation of 45° for the implants placed in the distal regions.

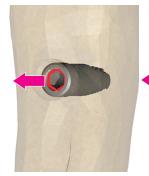
The Surgical Sequence for inserting the PRIME CONOMET RANGE implants is described in detail in the dedicated section.







In the case of mesiodistal disparallelism (or vice versa), the implant shall be positioned leaving one side of the internal hex in mesial or distal direction using the six oval indents on the Drivers corresponding to the six sides of the hex - to optimise recovery of the implant axis through the 17°/30° FAST Bases.







In the case of vestibular-lingual (or vice versa) disparallelism or vestibular-palatal (or vice versa) disparallelism, the implant shall be positioned leaving one side of the internal hex in vestibular or lingual-palatal direction - using the six oval indents on the Drivers corresponding to the six sides of the hex. Also in this case, this is done to optimise recovery of the implant axis through the 17°/ 30° FAST Bases.





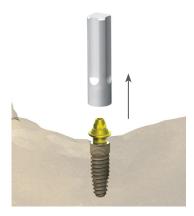
Before inserting the FAST 17°-30° Angled Bases in the implants, use the FAST Countersink Bur over the head of the implants. To protect the implant head while passing with the Bur, use the Guide for FAST Countersink inserting it in the implant.





Pass the FAST Countersink Bur (do not exceed 800 RPM and a torque of 55 Ncm) -flushing with abundant sterile saline solution- over the implant head so as to countersink the bone crest creating the correct housing for the FAST Bases.

### FAST 0° BASES



Use the plastic carrier provided in each pack to place the FAST 0° Base (straight single component usable in case of implants parallel to the implant axis) in the oral cavity and to do the first screwing into the implant.

Remove the plastic Carrier by slightly levering upward.

# FAST 17° - 30° BASES



To place the FAST 17° or 30° Base (angled component with Fastening Screw usable in case of implants not parallel to the implant axis) in the oral cavity, while outside of the mouth screw the titanium Carrier for FAST 17°/30° Bases onto the threaded head of the Base.

Insert the FAST  $17^{\circ}$  or  $30^{\circ}$  Base into the implant, parallelising the implant axis.



Screw on the FAST 0° Base using the CH 2.6 hex wrench.



Manually screw in the Fastening Screw of the FAST 17° or 30° Base using the Hex Screwdriver, or mechanically using the Contra-angle Hex Screwdriver (max. 30 Ncm).



Finally tighten using the torque ratchet adjusted to 30 Ncm on the wrench square.

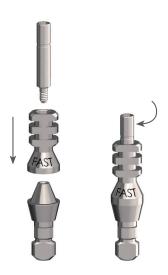


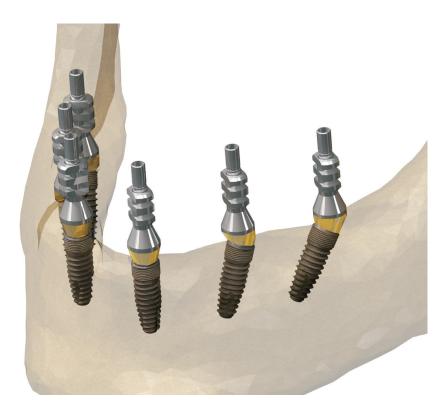
Unscrew the Carrier from the Base head and tighten definitively the device using the surgical/prosthetic Torque Ratchet adjusted to 30 Ncm connected to the Hex Bit for Torque Ratchet.

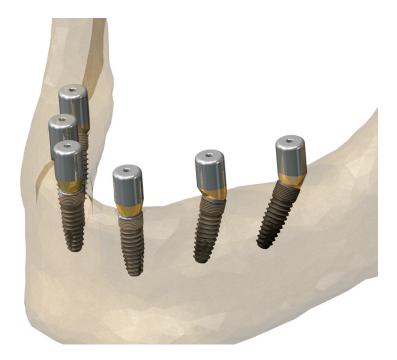
After inserting all the FAST Bases (straight and angled), it is advisable to take an intraoral X-ray to check that the implants and the FAST Bases are correctly coupled.

At this point, you can proceed with impression taking using the FAST Precision Impression Transfers.

Only use the Prodent Hex Screwdriver to screw the FAST Transfers onto the FAST Bases and take an impression using an open individual scoop. The dental laboratory can reproduce the model using the FAST Analogues that perfectly reproduce the tapered head of both straight and angled FAST Bases.







During the temporary laboratory phases, the FAST Healing Caps can be placed to consolidate the soft tissues.

After removing the Healing Caps from the FAST 0° Bases, make sure that they are correctly and completely connected to the implants by tightening them to a torque of 30 Ncm using the Torque Ratchet.



The temporary prosthesis can be constructed using the FAST Temporary Abutments. In case of a preventive construction of the prosthesis - opened in correspondence of the FAST Bases - the prosthesis may be directly attached to the FASTTemporary Abutments. The FAST Temporary Abutments must not be cut below the first ring starting from the bottom. Tighten only with the surgical/prosthetic torque ratchet (20 Ncm).



To construct the final prosthesis through passivation, use the FAST Castable Temporary Abutments connected to the FAST Temporary Abutment for the construction and gluing of the final device. Do not exceed a torque of 20 Ncm to tighten the final prosthesis.





To construct the final prosthesis, use the FAST Castable Abutment, with which it is possible to create a stronger structure through fusion. Do not exceed a torque of 20 Ncm to tighten the final prosthesis.

## RESTORATION RANGE **FAST**

	ht 2	ht 3	ht 4
FAST 0° BASES	2405900	2405902	2405901
FAST 17° BASES	2405910	2405912	2405911
FAST 30° BASES	2405920	2405922	2405921

	Unique device
FAST TEMPORARY ABUTMENT	0805930
FAST CASTABLE TEMPORARY ABUTMENT	0805932
FAST CASTABLE ABUTMENT	0805931
FAST ANALOGUE	0809200
FAST TRANSFER	0807300
FAST INTRAORAL SCANMARKER	0807420
FAST SCANMARKER	0805855

### RESTORATION ACCESSORIES

### **HEX SCREWDRIVERS**

For tightening and unscrewing all screws pertaining to all Prodent Italia restoration ranges.

Available in three different lengths, it is also suitable for use in the case of customised restoration components.

Screwdrivers with a double ring laser marked on the shaft **alone** can be used for TS Screws, **do not** use Screwdrivers without a double ring (codes 0510066 - 0510067 - 0510065).



#### **CONTRA-ANGLE SCREWDRIVER**

To be connected to the contra-angle, for tightening and unscrewing all Screws pertaining to all Prodent Italia restoration ranges.

Available in two different sizes.

Contra-angle Screwdrivers with a double ring laser marked on the shaft **alone** can be used for TS Screws, **do not** use Contra-angle Screwdrivers without a double ring (codes 0510070 and 0510077).



### PREMILLED SCREWDRIVER

Made of surgical stainless steel, it is suitable for tightening and loosening intact and customized Premilled Abutments.



#### 2410065

### **TOROUE RATCHET**

With torque function to complete the final tightening of Fastening Screws and Restoration Screws. The device can be used either in ratchet mode or torque wrench mode. In torque wrench mode preset values are 20-30-45-70 Ncm. Cleaning, disassembly and assembly operations are described in the Instructions for Use.



0510120

### **HEX BIT FOR RATCHET**

Connected to the Ratchet, it is used for final tightening of Fastening Screws and Restoration Screws. Available in two different sizes.



### **HEX WRENCH CH 2.6**

Screwing instrument for FAST 0° Bases and Ball Attachments; it is equipped with a digital section for manual use (first screwing) and a connection square to use in combination with the Torque Ratchet (final tightening).



### **FASTENING SCREWS**

All the Fastening Screws are made of grade 5 titanium and are provided in the packs of all the components with which they are used (with the exception of: Castable Multi Abutments and FAST Castable Temporary Abutments).

They can also be purchased individually quoting the item codes detailed on the following page.

The screws for the Restoration Components must be tightened to 30 Ncm, except for the FAST Temporary Abutments which must be tightened to 20 Ncm.

The screws for the following items must be tightened with the Hex Screwdriver only:

- Castable Abutments.
- Rod Abutments.
- Scanmarker.

components	fastening screw
PRECISION IMPRESSION TRANSFER	2407010 2407014
EASYCAP AND TEAR-OFF IMPRESSION TRANSFER	2407013
SCANMARKER	2407012
CONNECT BASES MULTI ABUTMENTS 0° ABUTMENTS 17° - 25° ABUTMENTS CASTABLE ABUTMENTS FAST BASES SHOULDERLESS 0° - 20° ABUTMENTS	2405001
ROD ABUTMENT	0805651
FAST COMPONENTS: TEMPORARY ABUTMENT, CASTABLES ABUTMENT , SCANMARKER AND INTRAORAL SCANMARKER	0805935
FAST TRANSFER	0807301



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