Prodent Italia

PRIMECONOMET

Clinical Protocol

Prodent Italia has implemented a Quality Management System in compliance with UNI CEI EN ISO 13485. Within the scope of the Quality Management System, numerous controls are envisaged and conducted with the aim of assuring an extremely high-quality level for all Prodent Italia products. Before placing each Medical Device on the market, all the necessary tests are carried out to assure that every device is conformed to the relative Safety and Performance Requirements established by current Legislations.

The first System and Product certifications issued to Prodent Italia date back to 1998. Over the years, Prodent Italia has continued to innovate its Medical Devices, which are currently CE marked according to Regulation (EU) 2017/745 and subsequent amendments (also known as MDR – Medical Devices Regulation). In addition, Prodent Italia will continue to place CE marked Medical Devices on the market in compliance with Directive 93/42 EEC and subsequent amendments, in accordance with Article 120 of the MDR and according to the schedule indicated therein.

For all Medical Devices, post-market surveillance, market surveillance and vigilance are carried out as required by MDR.

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.

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 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.

This Clinical Protocol can be consulted and it is available in the latest revision on the website: https://www.prodentitalia.eu/enpro/useful-resources/, replacing all previous versions and it is valid and effective from the date 2023-10-31, together with the code and the revision index as shown on its back cover.

For further requests on previous versions of this Clinical Protocol, contact PRODENT ITALIA S.r.l.

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

PRODENT ITALIA S.r.l. Via Pitagora, 9 - 20016 Pero (MI) - Italy
www.prodentitalia.eu

GENERAL CHARACTERISTICS

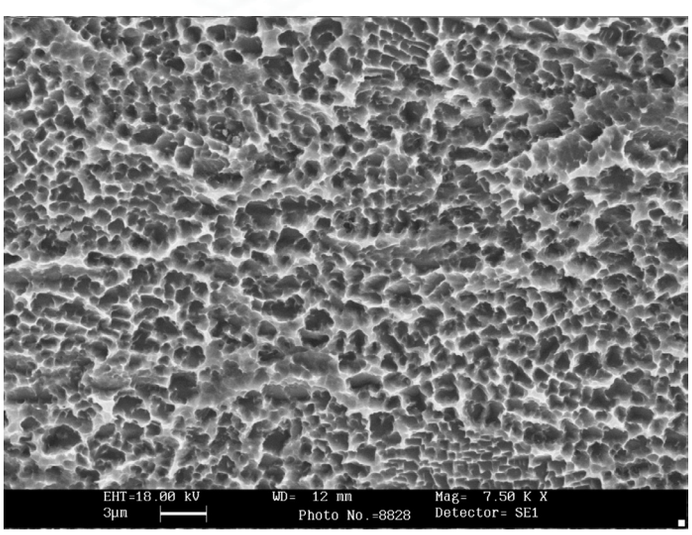
The PRIME CONOMET RANGE implants are made of pure titanium and have been designed and manufactured to assure high performance even in situations where the bone quality is poor. In this case an excellent primary stability is essential.

The PRIME CONOMET RANGE implants allow, as a whole, the treatment of all esthetic and functional rehabilitation cases to be implemented using endosseous dental implants. They can be used in the upper and/or lower arch for patients, that suffer from partial or total edentulism and when it is possible to prosthesize with single crowns, partial or total fixed or removable prostheses.

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.



SEM 7.500x

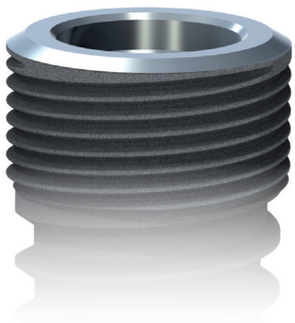
MPS Micro Profile Surface

(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 370.000 fixtures.

GENERAL CHARACTERISTICS



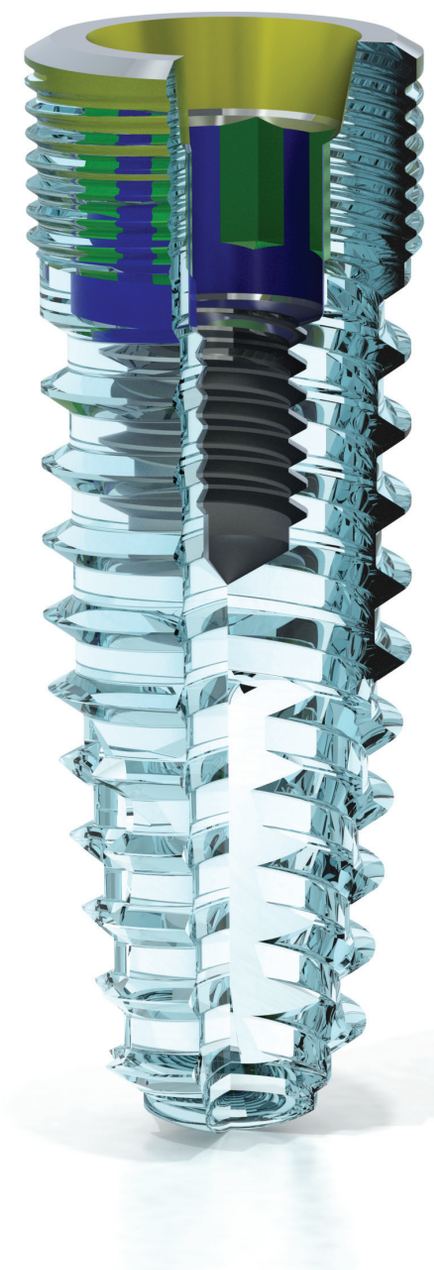
The PRIME CONOMET implants with the MPS (Micro Profile Surface) treatment on the entire body are mainly suitable in the clinical cases where the practitioner deems it possible to position the implant at crestal bone level or slightly at a subcrestal bone level.

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.

PRIME CONOMET implants have a deep internal tapered connection with a hexagonal engaging element that creates a seal in the coupling with the abutment and optimises masticatory load distribution. 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.

PRIMECONOMET



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 **TS TAPERED 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.

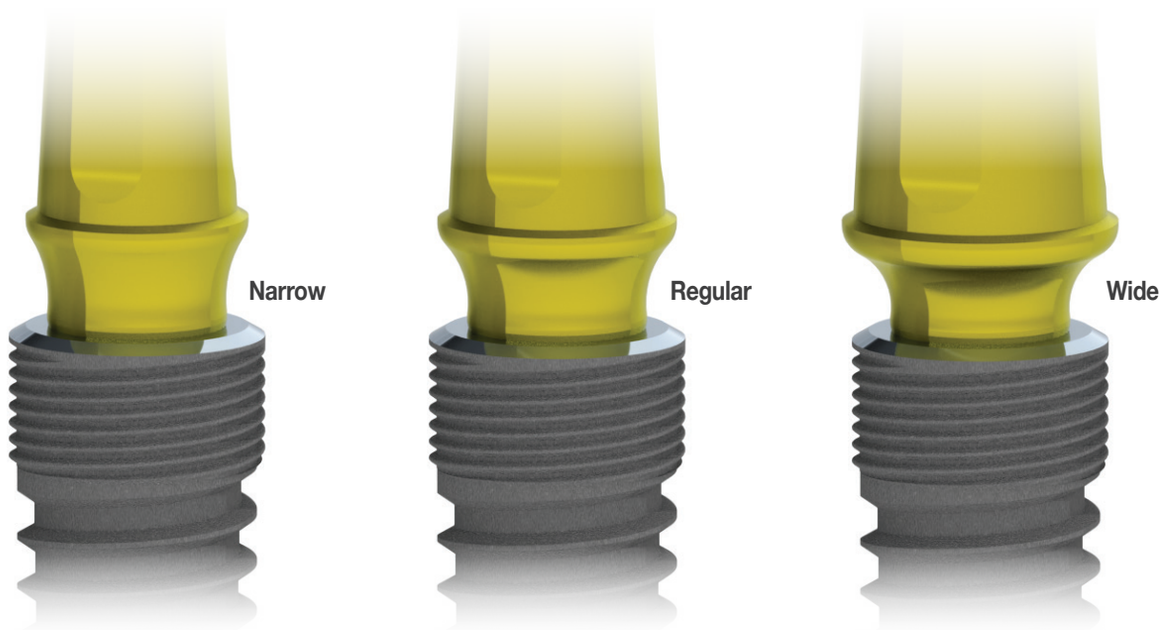
The devices intended for use with the TS connection restoration range are **colour-coded** golden yellow.

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.

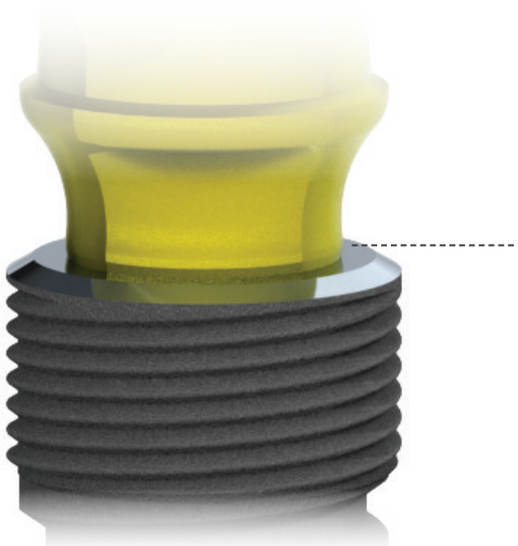
Certain restoration parts are available with three different emergence profiles: NARROW, REGULAR and WIDE.

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.

IMPLANTS RANGE

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

PRIMECONOMET IMPLANTS

THE ONLY
RESTORATION RANGE
COLOUR-CODED
GOLDEN YELLOW

		implant height	codes
Ø 3.8		h 8.5 h 10 h 11.5 h 13 h 15	2401700 2401702 2401704 2401706 2401708
Ø 4.2		h 8.5 h 10 h 11.5 h 13 h 15	2401710 2401712 2401714 2401716 2401718
Ø 4.6		h 8.5 h 10 h 11.5 h 13 h 15	2401720 2401722 2401724 2401726 2401728
Ø 5.1		h 8.5 h 10 h 11.5 h 13 h 15	2401730 2401732 2401734 2401736 2401738

PACK

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.

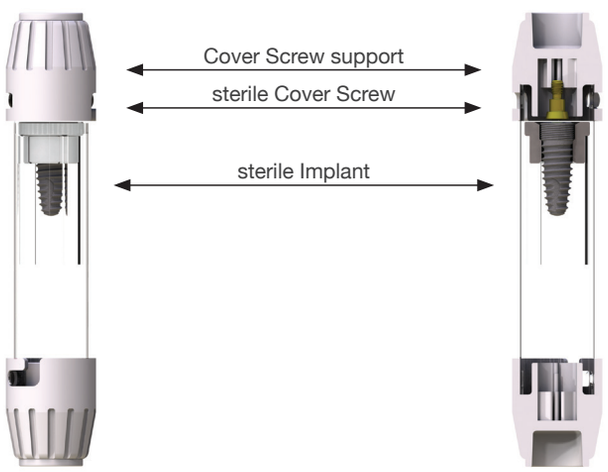
The implant housing and its extraction instruments make it possible to avoid contact between the surface of the implant and other components and surfaces other than titanium before placement in the site.

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

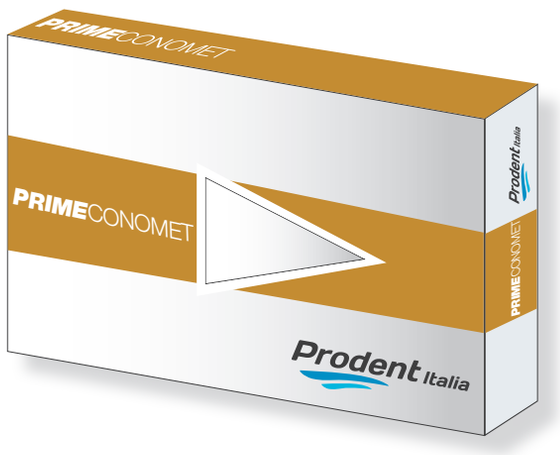
STORING AND HANDLING THE PACK

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.



Ampoule that contains the Implant



PRIME CONOMET implants pack

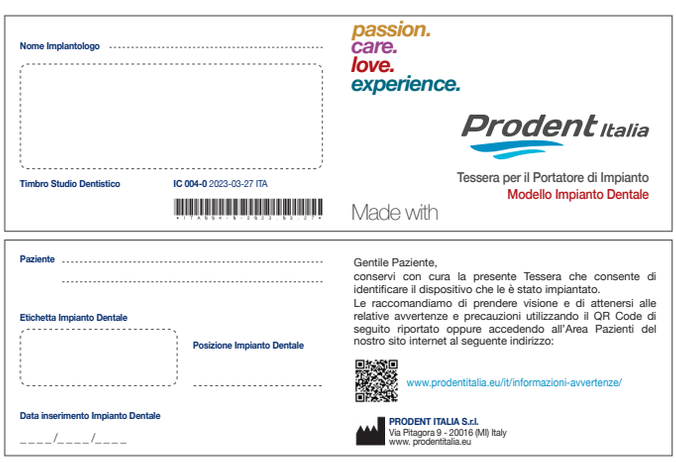
DOCUMENTATION AND IMPLANT IDENTIFICATION

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

The implant and the prosthetic components identifications are 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) and the prosthetic component data (restoration component type, diameter and batch number) are transcribed on the patient record or otherwise filed.

The operator should complete the Implant Card (Implant Model/ Prosthetic Component Model) contained in the device 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.



Implant Card– Dental Implant Model

Implant Card – Prosthetic Component Model

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 (see CONTRAINDICATIONS paragraph in the Instructions for Use of the Implants), 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.

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.

SURGICAL PLANNING

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 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.

	PRIME CONOMET			
Ø Implant	Ø 3.8	Ø 4.2	Ø 4.6	Ø 5.1
UPPER missing parts				
CENTRAL INCISORS	■	△	●	●
LATERAL INCISORS	●	●	●	△
CANINES	■	△	●	●
PREMOLARS	■	△	●	●
MOLARS	■	■	△	●
LOWER missing parts				
CENTRAL INCISORS	●	●	△	△
LATERAL INCISORS	●	●	△	△
CANINES	■	●	●	●
PREMOLARS	■	△	●	●
MOLARS	■	■	△	●

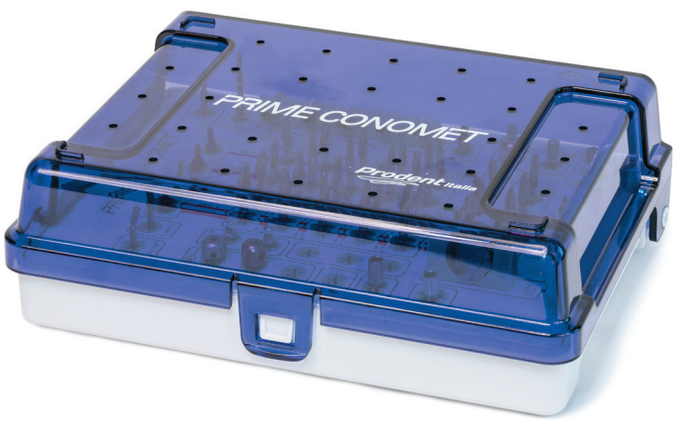
● optimal position △ discretionary position ■ contraindicated position

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

The PRIME CONOMET Surgical Tray 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 Tray is customised with colours and screen-printing that allow it 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 lines 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.



PRIME CONOMET Surgical Tray
2410901

SURGICAL ACCESSORIES

TISSUE PUNCHES

To be used connected at the Contra-angle at low rotation speed (25 RPM), when applying the ***flapless*** surgical technique, to remove the portion of gingival tissue on the cortical bone, creating holes meant for the successive passages of bone burs.

Ø 4.3 and Ø 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. For complete removal of the gingival tissue after the passage of the Tissue Punches, it may be necessary to use manual instruments.

In case of low thickness of keratinized gingival tissue, it is advisable not to not use Tissue Punches, but to make an incision in the flap in correspondence of the implant site. They can also be used to create holes that are useful for the removal of cover screws without opening the flap.

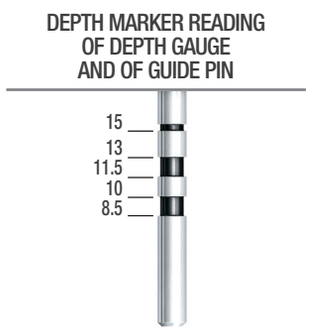
0503070
Ø 4.3

0503071
Ø 5.5

Ø 2.2 DEPTH GAUGE/ GUIDE PIN

To be used after the Slim Pilot Bur passage, to assess the depth of the surgical site also radiographically. In the event that two or more implants are inserted, the pin can be used as reference for parallelism.

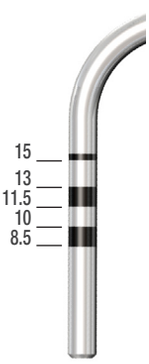
0810100



Ø 2.2 DEPTH GAUGE

This instrument allows you to assess the depth of the surgical site created by means of the Slim Pilot Bur.

0810102



DEPTH MARKER READING OF
DEPTH GAUGE

17° Ø 2.2 GUIDE PIN

To be used after the Slim Pilot Bur passage, in order to assess the implant insertion axis with respect to the prosthetic axis.

0810101

BUR EXTENSION

To be used in order to extend the connection between the Bur and the Contra-angle without exceeding a torque of 45 Ncm.

0510059

DIGITAL WRENCH

To be used connected to the Screw Taps in order to start tapping the surgical site and connected to the Manual Driver for manual implant insertion. To be used connected to the Driver for EQUATOR, the Digital Wrench allows the first screwing of the EQUATOR attachments in the implants.

0510064

SURGICAL ACCESSORIES

SCREWDRIVERS

For tightening and unscrewing all Screws pertaining to all Prodent Italia restoration ranges. Available with three different lengths, they allow 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).

long
2410062

medium
2410061

short
2410060

CONTRA-ANGLE CONNECTION

For mechanical use of Screw Taps and Implants Manual Drivers. Never exceed 25 RPM and a torque of 45 Ncm.

0510062

EXTENSION

To be used when it is deemed necessary to increase the length of the Connection between the Digital Wrench or the Torque Wrench or the Contra-angle connection and dedicated devices.

0510060

TORQUE WRENCH

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 20-30-45-60-70 Ncm. Cleaning, disassembly and assembly operations are described in the instructions for use.

0510120

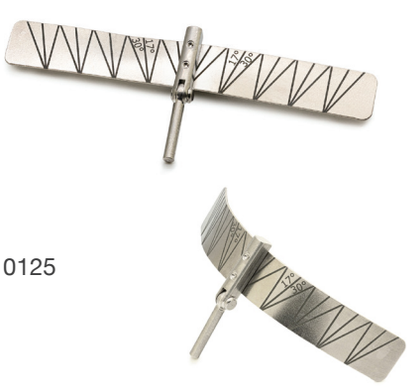
DIRECTION GUIDE

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°.

Thanks to the indicators on the guide, it allows the practitioner to have an indication of the implant insertion axis, both when it is perpendicular to the bone crest (0°) and when it has 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 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.



0510125

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, that have to be used connected to the Contra-Angle, are made of surgical stainless steel and feature an 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 make incisions in the cortex.

The **Slim Pilot Bur** is used after the Corticotomy Bur to reach the final depth of the implant receptor site. It can be used with or without the corresponding Drill Stops and it has an O-ring for connecting to those devices.

The **Conical Burs** must be used after the Slim Pilot Bur. According to a specific sequence, they are used to obtain the final shape and size of the implant site for the implant body.

Before using the Bur dedicated to the implant to be inserted, gradually widen the site respecting the surgical sequence indicated in the Clinical Protocol, paying attention to the depth to be reached.

The **Drill Stops** can be connected to the Slim Pilot Bur. They must be inserted from the cutting-edge side, up to the stop and complete coverage of the cylinder placed in the center of the bur. They ensure that the required depth is observed during milling. Their use is recommended to have a better perception of the depth reached by the bur. On reaching the required depth, they rest directly on the bone, preventing further drilling. Before cutting, check always that the lower face of the drill stops is aligned with the depth mark corresponding to the height of the implant.

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.

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

BURS AND DRILL STOPS

Ø 2
CORTICOTOMY
1003001

Ø 2.2
SLIM PILOT
0803700

Ø 2.2
DRILL STOP
SLIM PILOT

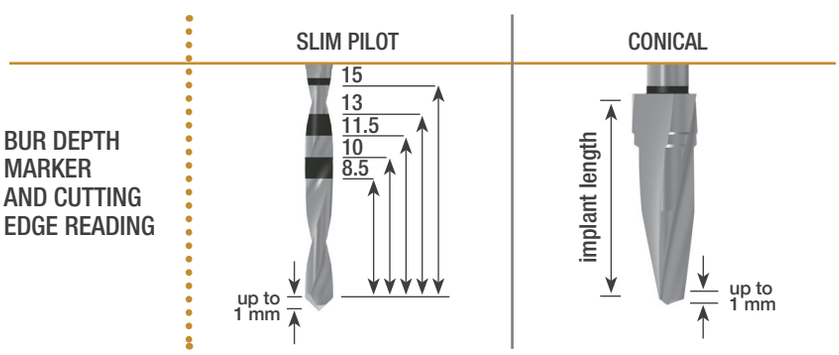
h 8.5	0810855
h 10	0810856
h 11.5	0810857
h 13	0810858
h 15	0810859

direction of
drill stop insertion
on the bur

CONICAL BURS

	Ø 3.8	Ø 4.2	Ø 4.6	Ø 5.1
h 8.5	0803180	0803150	0803160	0803170
h 10	0803181	0803151	0803161	0803171
h 11.5	0803182	0803152	0803162	0803172
h 13	0803183	0803153	0803163	0803173
h 15	0803184	0803154	0803164	0803174

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. All the Neck Diameter Indicators are also marked with the relative item code and colour coded.

NECK DIAMETER INDICATORS

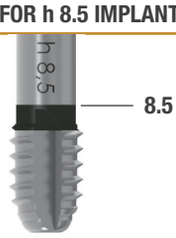
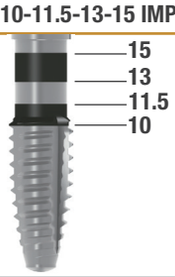
After using the Slim Pilot Bur, the Neck Diameter Indicators allow you to assess the neck diameter of the implant to be inserted.

SCREW TAPS

In the event of compact bones - after producing the surgical site, using the burs - the Screw Taps allow you to screw the bone, reducing the implants insertion torque. It is possible to screw manually the tap with the Digital Wrench and/or with the Torque Wrench. If you proceed mechanically, use the Contra-angle Connection and do not exceed 25 RPM and a torque of 45 Ncm.

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

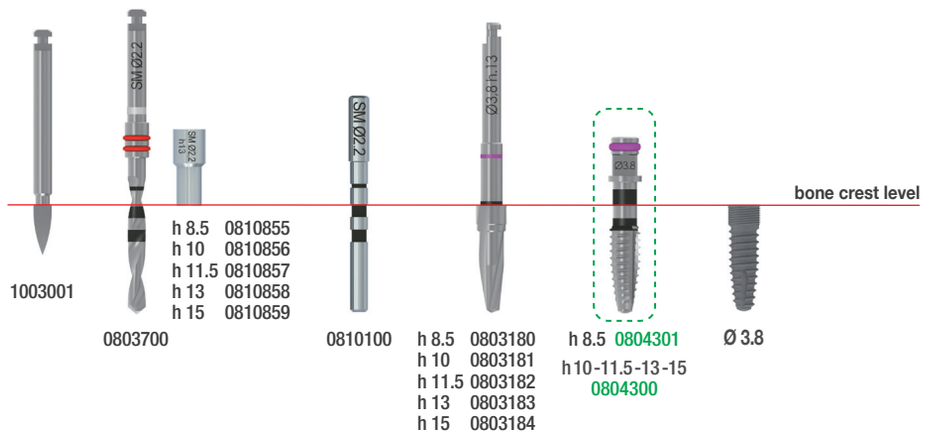
	FOR h 8.5 IMPLANTS	FOR h 10-11.5-13-15 IMPLANTS
DEPTH MARKER READING		

SURGICAL SEQUENCE

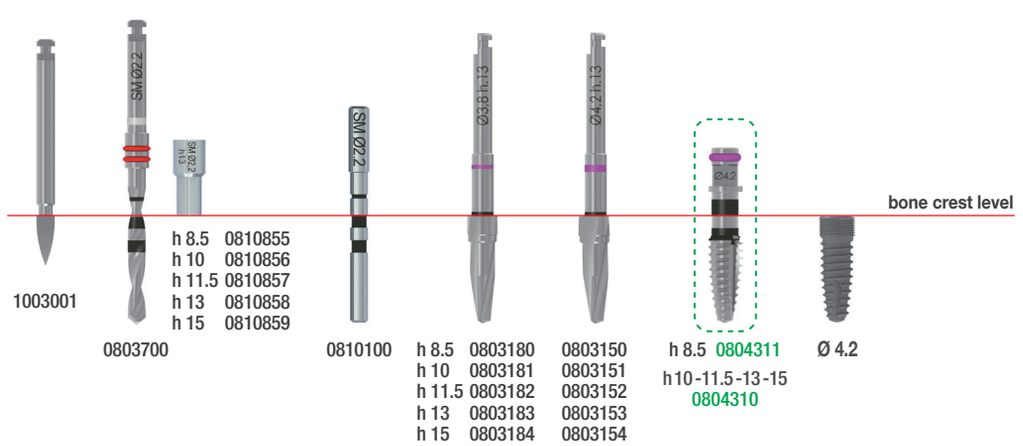
SEQUENCE BASED ON IMPLANT DIAMETER AND HEIGHT

The devices with green code (in the dotted box) are optional and they must be used **only** in a compact bone.

Ø 3.8



Ø 4.2

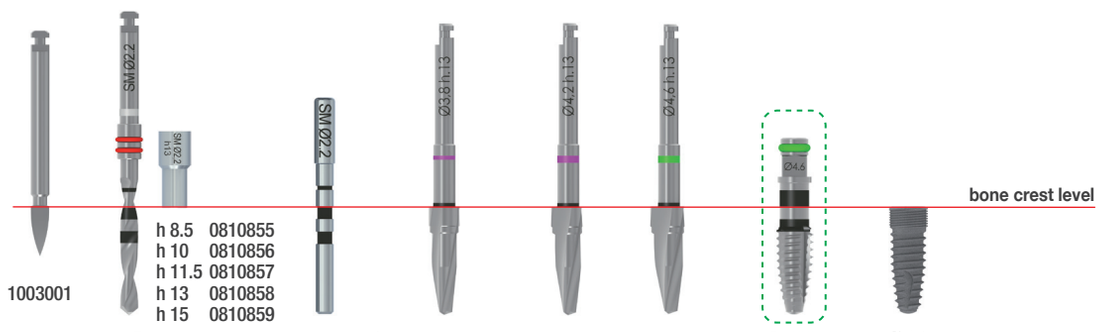


SURGICAL SEQUENCE

SEQUENCE BASED ON IMPLANT DIAMETER AND HEIGHT

The devices with **green code (in the dotted box)** are optional and they must be used **only** in a compact bone.

Ø 4.6



1003001

0803700

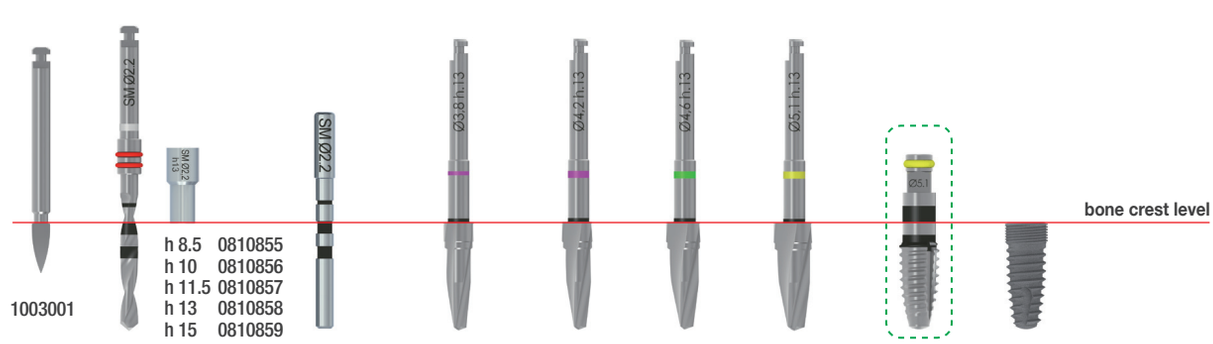
h 8.5 0810855
h 10 0810856
h 11.5 0810857
h 13 0810858
h 15 0810859

0810100

h 8.5	0803180	0803150	0803160	h 8.5 0804321
h 10	0803181	0803151	0803161	h 10-11.5-13-15
h 11.5	0803182	0803152	0803162	0804320
h 13	0803183	0803153	0803163	
h 15	0803184	0803154	0803164	

Ø 4.6

Ø 5.1



1003001

0803700

h 8.5 0810855
h 10 0810856
h 11.5 0810857
h 13 0810858
h 15 0810859

0810100

h 8.5	0803180	0803150	0803160	0803170	h 8.5 0804331
h 10	0803181	0803151	0803161	0803171	h 10-11.5-13-15
h 11.5	0803182	0803152	0803162	0803172	0804330
h 13	0803183	0803153	0803163	0803173	
h 15	0803184	0803154	0803164	0803174	

Ø 5.1

DRIVERS

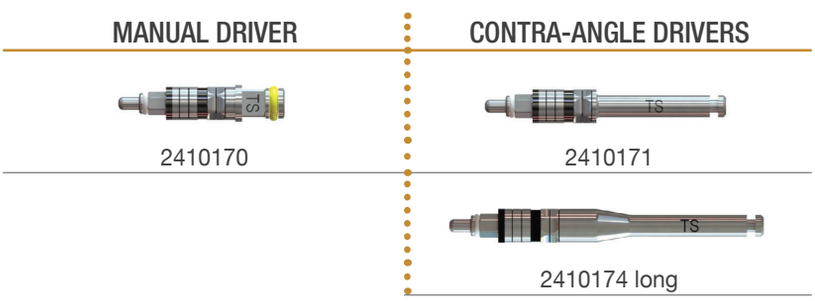
MANUAL DRIVER

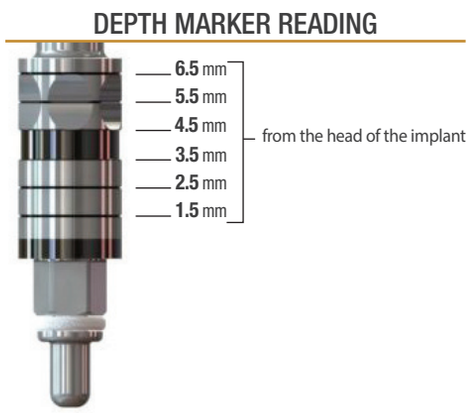
To be used connected to the Digital Wrench, to take the implant from the ampoule and to place it in the implant site to then proceed with its manual or mechanical insertion.

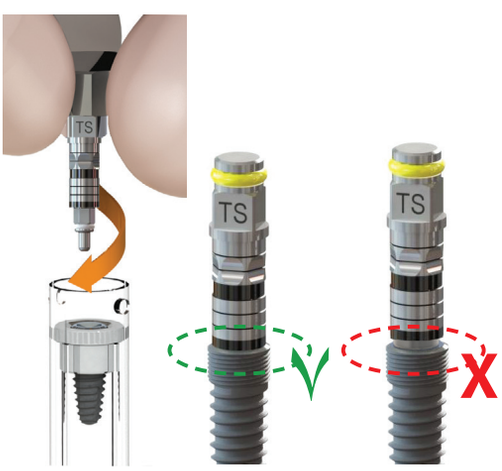
CONTRA-ANGLE DRIVERS

To be used connected to the Contra-angle, to take the implant from the ampoule and to place it 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.

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.





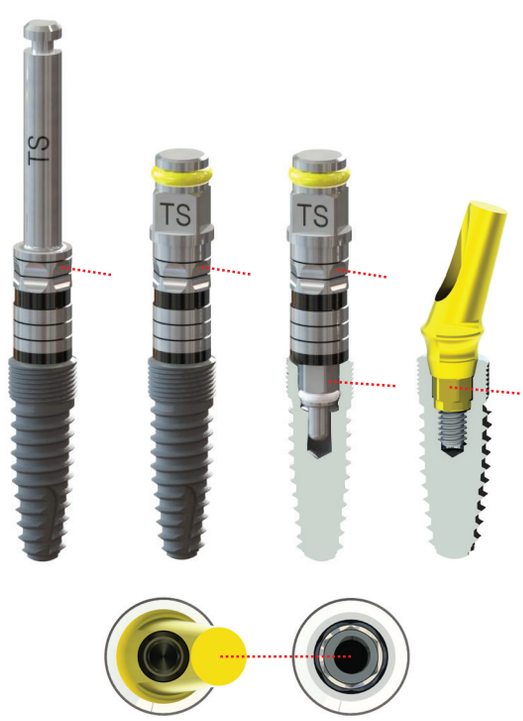


Place the Driver into the implant connection, checking that it has completely engaged the implant connection. During the procedures for extracting the implant from the ampoule, we recommend that you **gently press the Driver and at the same time rotate it clockwise to perfectly connect the Driver and the implant.**

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

The Drivers have six indents, which, when the Driver is inserted in the implant, indicate the position of the hex faces of the connection.

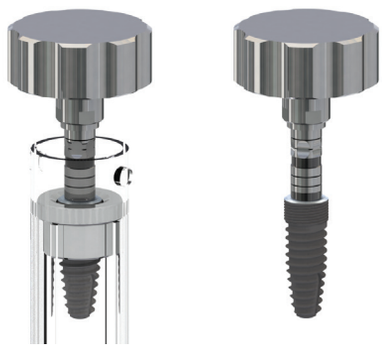
If the implant is prosthesized with an Angled Abutment, during the insertion of the implant it is important to match one of the Driver's indents with the implant axis, so that once inserted, the Angled Abutment has an optimal angle.



IMPLANT INSERTION

Primary stability of the implants is essential to ensure success: it is advisable to solve any unfavorable situations before surgery. During and after the surgery, it is advisable to follow all the instructions provided by this Protocol.

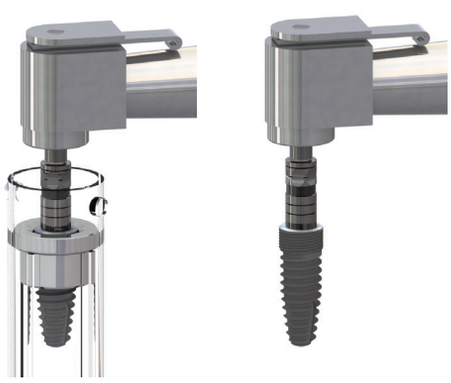
MANUAL INSERTION



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.

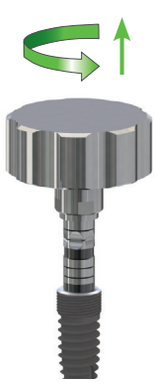
Insertion of the implant completed with the Torque Wrench and the Manual Driver.
It is recommended **not to exceed a Torque of 60 Ncm.**

MECHANICAL INSERTION



The implant is extracted from the sterile ampoule with the Contra-angle and with the Contra-angle Driver for the screwing phase of the implant into the implant site.
It is recommended **not to exceed 25 RPM and a Torque of 45 Ncm**.

DRIVER REMOVAL AFTER THE IMPLANT INSERTION



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.

PREOPERATIVE AND STERILE DEVICE PREPARATION

IMPORTANT RECOMMENDATIONS FOR DEVICE CLEANING AND STERILIZATION

Cleaning and sterilization procedures must be carried out under the practitioner's responsibility by qualified personnel using regularly maintained, calibrated and validated instruments. It is recommended to use validated and continually monitored cleaning and sterilization processes under the practitioner's responsibility and according to the information provided by the manufacturer of the detergent and of the eventual washing machine. It is recommended to refer to UNI EN ISO 17665 for the development, validation and routine control of the moist heat sterilization process and to UNI EN 13060 to determine the test methods of steam sterilizers and define the sterilization cycles.

Both single-use and reusable devices **MUST** be cleaned, disinfected and sterilized through validated method and under the practitioner's responsibility immediately before using them on the patient.
To clean, disinfect and sterilize the devices to be used by the practitioner, it is recommended to follow the following Protocol validated by Prodent Italia.

Cleaning and sterilization Protocol

Cleaning and disinfection phase:

- Immerse the samples in demineralized water at 45°C and brush them manually with a toothbrush. Thereafter brush them with a hard bristle toothbrush for at least 30 seconds.
- Immerse the devices in an ultrasonic tank using a suitable neutral detergent and following the Instructions for Use of the manufacturer thereof.
- Rinse the device well with demineralized water for at least 4 minutes in an ultrasonic tank.

Drying phase: dry in a cool, dry place away from contamination.

Sterilization phase: once the drying phase is completed, the devices must be packaged in sterilization bags and steam sterilized at 134°C for at least 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

Prodent Italia designs, manufactures, does the post-market surveillance and vigilance of all its devices in compliance with the regulations for medical devices in force.

DISPOSAL PROCEDURES

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

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.

HEALING SCREWS

Intended to be screwed directly into the connection of the implant to condition the soft tissues healing until the subsequent assembly of the final prosthetic handwork.

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.

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

LINK HEALING SCREWS

Intended to condition the soft tissue when it is planned to do a restoration with Link Base on a PRIME CONOMET implant.

The Link Healing Screws condition the healing of soft tissues with the correct transmucosal anatomical configuration in order to permit a non-traumatic application of Link Bases.

The screw head is laser-marked with coronal height (hc), with transmucosal height (ht) and with the abbreviation "LK" for Link, based on their specific intended use.

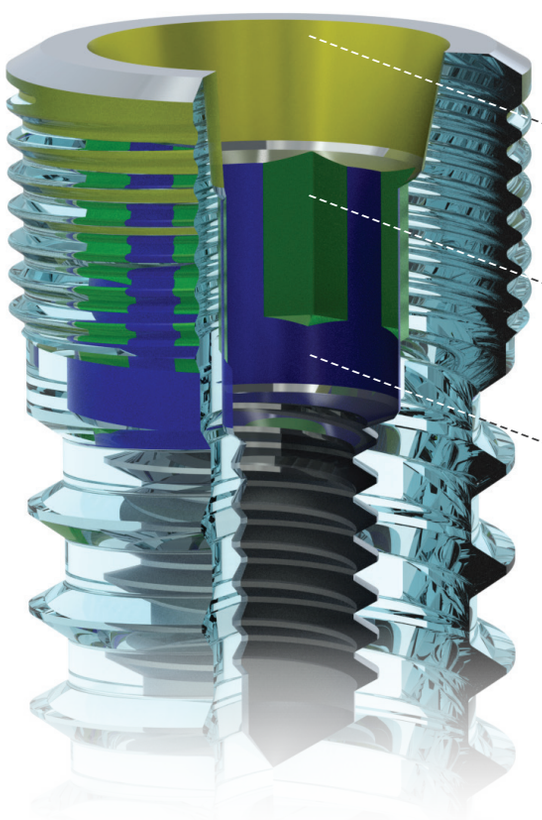
		hc 2	hc 4
LINK HEALING SCREWS	ht 2	 2406040	 2406042
	ht 4	 2406041	 2406043

PROSTHETIC PLATFORM

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, Link Bases, Equator 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.

MATERIALS

- **Grade 5 titanium**: Healing Screws, metal Prosthetic Components, Direction Guide (marked sheet in grade 2 Titanium), Drill Stops, Neck diameter indicators, metal devices for Impression Taking, Fastening Screws
- **Surgical stainless steel**: Surgical Accessories, Burs, Screw Taps, Drivers, Restoration Accessories
- **Peek**: Easytransfer, Transfer for Ball Attachments, non-titanium parts of Scanmarkers, Carrier for 0° FAST Bases, Guides for FAST Countersink Bur
- **Polycarbonate**: all castable parts of Prosthetic Components
- **Polyphenylsulphone**: Easycap

IMPRESSION TAKING AND MODEL

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.

There are various kind of Transfers, allowing the practitioner to choose the most suitable option for the restoration work to be performed.

PRECISION IMPRESSION TRANSFERS

Designed for use connected to implants with their Screws, they are suitable for taking precision dental impressions by means of a custom perforated impression tray, even in the case of implants with non-parallel axes. They come in three designs (NR=Narrow, RG=Regular, WD=Wide) and two transmucosal heights (ht), 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, that is purchasable singularly.

EASYCAP AND TEAR-OFF IMPRESSION TRANSFER

Designed for use connected to implants with its Screws, it is used to 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 an high level of precision. When used without Easycap, it is suitable for taking standard dental impressions.

EASYCAP

Designed for use connected to Easycap and Tear-off Impression Transfers, on which it is to be pressure-fitted.

EASYTRANSFER FOR LINK BASES

Used to take conventional impressions with unperforated impression tray on single implant.
Designed for use connected to Link Base, on which it is to be pressure-fitted.

IMPLANT ANALOGUE

Taking the impression with Transfer, it is used to create the working model on which the dental technician builds the prosthetic handwork.

DIGITAL ANALOGUE

Taking the impression with Scanmarker, it is used to create the prototyped and 3D printed working model on which the dental technician builds the prosthetic handwork.

		Design		
		NR=Narrow	RG=Regular	WD=Wide
PRECISION IMPRESSION TRANSFERS	ht 2	 2407000	 2407002	 2407004
	ht 4	 2407001	 2407003	 2407005
EASYCAP AND TEAR-OFF IMPRESSION TRANSFER			 2407020	
EASYCAP			 0807000	
EASYTRANSFER FOR LINK BASES			 0807006	
IMPLANT ANALOGUE		 2409000		
DIGITAL ANALOGUE				 2409002

SCANMARKER AND SCANMARKER FOR LINK BASES

SCANMARKER

Designed for use connected to implants with its Screws, 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 conventional impressions, using laboratory dental scanners to allow the user to acquire the position of the implant connection.

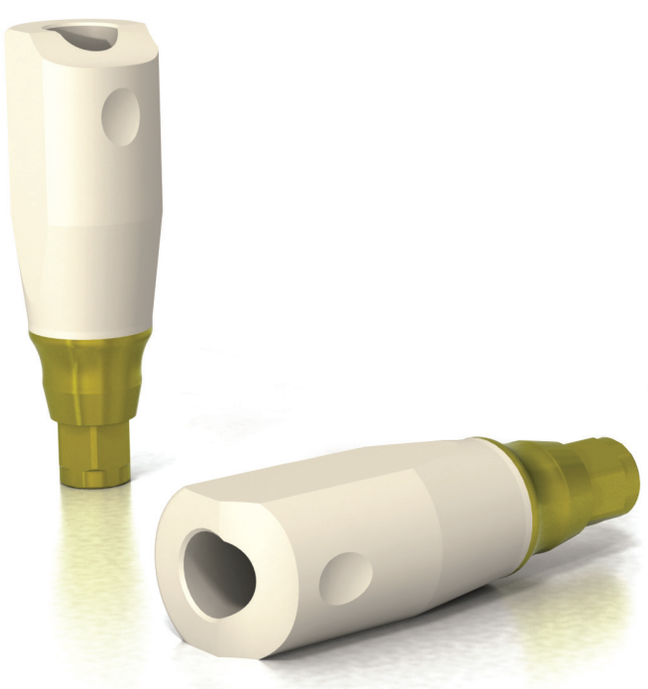
SCANMARKER FOR LINK BASES

Designed for use connected to Link Bases with its Screws, it is suitable for recording intraoral digital impressions using intraoral dental scanners. Positioned directly on Link Bases and screwed together in the implant, it allows you to acquire the position of the implant connection. It is also suitable for scanning models obtained from conventional impressions, using laboratory dental scanners to allow the user to acquire the position of the implant connection.

In order to use the Scanmarkers for Link Bases correctly, connect the Scanmarker to the Link Base without its screws, then connect the Base, together with the Scanmarker, to the implant or to the analogue for laboratory use and finally screw the assembly, using the dedicated Scanmarker screw.

If used combined with **Link Bases ht 2**, it must be screwed using the **Screw for Scanmarker Link Base ht 2** (not colour-coded, code 2407015), already provided in the Scanmarker pack. If used combined with **Link Bases ht 4**, it must be screwed using the **Screw for Scanmarker Link Base ht 4** (golden-coloured, code 2407016).

SCANMARKER	 2407100
SCANMARKER FOR LINK BASES	 2407200



LINK BASES AND CONNECT BASES

LINK BASES

To be used with CAD-CAM systems to create customized restorations with adhesive bonding technique. These bases make it possible to create permanent cemented or screwed-retained prostheses with outstanding esthetic characteristics whilst guaranteeing a titanium coupling with the implants. In order to obtain a good restoration result, the Link Bases, of which the coronal height is 6 mm, can be cut in the coronal portion to obtain the suited height to the clinical case to deal with. Cutting at the first marker, the Link Base will be 4 mm coronal high; cutting at the second marker, the Link Base will be 3 mm coronal high.

Available in the ENGAGING 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 two transmucosal heights (ht), to be chosen according to the restoration planned. Do not use Link Bases in the non-engaging version to prosthesize individual implants.

Link bases can be connected either to a Scanmarker for Link Bases, to be retained using a dedicated screw, in order to take an impression digitally or to an Easytransfer device in order to take an impression on a single tooth using a tear-off technique with a unperforated impression tray.

Do NOT modify Link bases before using them to take impressions with EasyTransfer.

	ht 2	ht 4
LINK BASES engaging	 2405310	 2405311
LINK BASES non-engaging	 2405320	 2405321

CONNECT BASES

To be used with CAD-CAM systems to make customized restorations with adhesive bonding technique. These bases make it possible to create permanent cemented or screw-retained prosthesis with outstanding esthetic characteristics whilst guaranteeing a titanium coupling with the implant. In order to obtain a good restoration result, the Connect Bases 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 two transmucosal heights (ht) to be chosen according to the restoration planned. Do not use Connect Bases in the non-engaging version to prosthesize individual implants.

The transmucosal section that can be obtained using the Connect bases is not the same as the one obtained using the healing screws. In order to obtain a valid prosthetic solution with outstanding esthetic characteristics, condition the gum with a temporary restoration using a Connect base, before fitting the final restoration.

	ht 0	ht 2	ht 4
CONNECT BASES engaging	 2405850	 2405851	 2405852
CONNECT BASES non-engaging	 2405855	 2405856	 2405857

MULTI ABUTMENTS

MULTI ABUTMENTS

The Multi Abutments are multifunctional components to be used with CAD-CAM systems. They are 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 ABUTMENT engaging version	ht 2	 2405301
MULTI ABUTMENT non-engaging version	ht 2	 2405300
MULTI ABUTMENT CASTABLE SLEEVES		 2405302

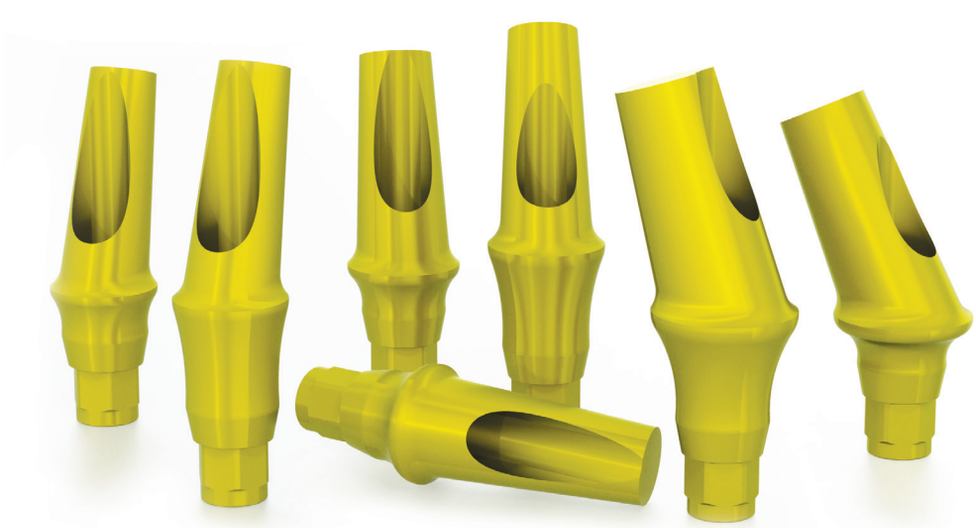
0° ABUTMENTS

Indicated for cemented restorations on individual implants or bridges. They are 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.

17° and 25° ABUTMENTS

Indicated for cemented restorations on individual implants or bridges in case of disparallelism. They are 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 abutments is shoulderless and is therefore indicated for vertical preparations.

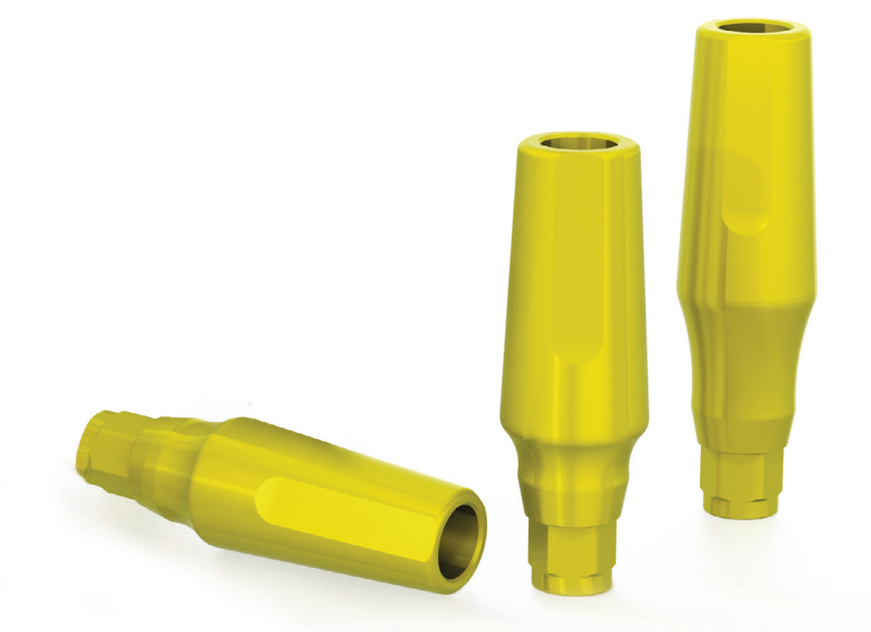
SHOULDERLESS 0° ABUTMENTS

Indicated for cemented restorations on individual implants or bridges. They are available with one emergence design (RG=Regular) and two different transmucosal heights (ht), to be chosen according to the restoration planned.

SHOULDERLESS 20° ABUTMENTS

Indicated for cemented restorations on individual implants or bridges in case of disparallelism. They are 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



PREMILLED ABUTMENTS

Designed to be worked to make customized abutments, with CAD-CAM systems, using automatic milling machines. Premilled Abutments are made with Medentika® attachment. They are indicated to make abutment with maximum working height of 16 mm and with an angulation up to 17° and up to 25°, in the versions with Ø 11.5 mm and 15.8 mm, respectively. Use only the dedicated Premilled Screwdriver to tighten and loosen the intact abutment.

PREMILLED ABUTMENT Ø 11.5	 2405721
PREMILLED ABUTMENT Ø 15.8	 2405722

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 Wrench but only manually with the 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
CASTABLE ABUTMENT engaging	**ht 2**	 2405401
CASTABLE ABUTMENT non-engaging	**ht 2**	 2405400

ROD ABUTMENT

ROD ABUTMENT

Designed to be worked in the castable part to make 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

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.
The OT EQUATOR Driver for Torque Wrench must be used connected to the Digital Wrench for the first screwing of the EQUATOR attachment to the implant and it must be used connected to the Torque Wrench to tighten the EQUATOR attachment at 30 Ncm.

	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:

TITANIUM + TiN ATTACHMENT	STAINLESS STEEL CAP CONTAINER	PROTECTIVE DISK	CAPS KIT, VARIOUS TYPES (4 pcs.) (purple: strong, white: standard, pink: soft, yellow: extra soft)
			

Spare parts

	PURPLE STRONG retention 2.7 Kg	WHITE STANDARD retention 1.8 Kg	PINK SOFT retention 1.2 Kg	YELLOW EXTRA SOFT retention 0.6 Kg	BLACK only for LABORATORY USE
CAPS	 1108057 (4 pack)	 1108058 (4 pack)	 1108059 (4 pack)	 1108060 (4 pack)	 1108061 (4 pack)

	STAINLESS STEEL CAP CONTAINER	TITANIUM CAP CONTAINER
CAP CONTAINERS	 1108062 (2 pack)	 1108064 (2 pack)

	STAINLESS STEEL CAP CONTAINER	PROTECTIVE DISK	BLACK CAP for laboratory use	CAPS KIT, VARIOUS TYPES (4 pcs.) (purple: strong, white: standard, pink: soft, yellow: extra soft)
SPARE PARTS KIT				
	1108063			

OT EQUATOR CASTABLE MALES	 1108065 (2 pack)

OT EQUATOR

Rods

THREADED OT EQUATOR KIT WITH BONDING SLEEVE

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.	STEEL SPACERS - 2 pcs. for threaded sleeve	CAPS KIT, VARIOUS TYPES - 8 pcs. (2 white: standard, 2 pink: soft, 2 yellow: extra-soft, 2 black: processing)
				

1108066

THREADED OT EQUATOR

FOR CAD/CAM BAR (2 mm thread)	FOR TITANIUM SLEEVE (1.6 mm thread)
	
1108067	1108070

CASTABLE OT EQUATOR KIT

CASTABLE "SEMI-SPHERICAL" MALES 2 pcs.	STAINLESS STEEL CAP CONTAINERS 2 pcs.	CAPS KIT, VARIOUS TYPES - 4 pcs (2 white: standard, 2 pink: soft)
		

1108069

OT EQUATOR SLEEVE

TITANIUM SLEEVE (1.6 mm thread)	SPACER FOR OT EQUATOR SLEEVE
	
1108071	1108072

THREADED COVER SCREW

1108073

PASSIVE BAR CONNECTION SYSTEM "ELASTIC SEEGER"

CASTABLE ABUTMENTS FOR SEEGER CONTAINERS 2 pcs.	RED PLASTIC SEEGER for laboratory use 3 pcs.	ELASTIC RETENTION SEEGER for prosthesis locking 3 pcs.	THREADED COVER SCREWS 2 pcs.
			

1108068

SEEGER

RED (for laboratory use)	WHITE (for bar locking)
	
1108074 (6 pack)	1108075 (6 pack)

CASTABLE CYLINDERS FOR SEEGER

h. 2.5	h. 3.5
	
1108076 (6 pack)	1108077 (6 pack)

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)

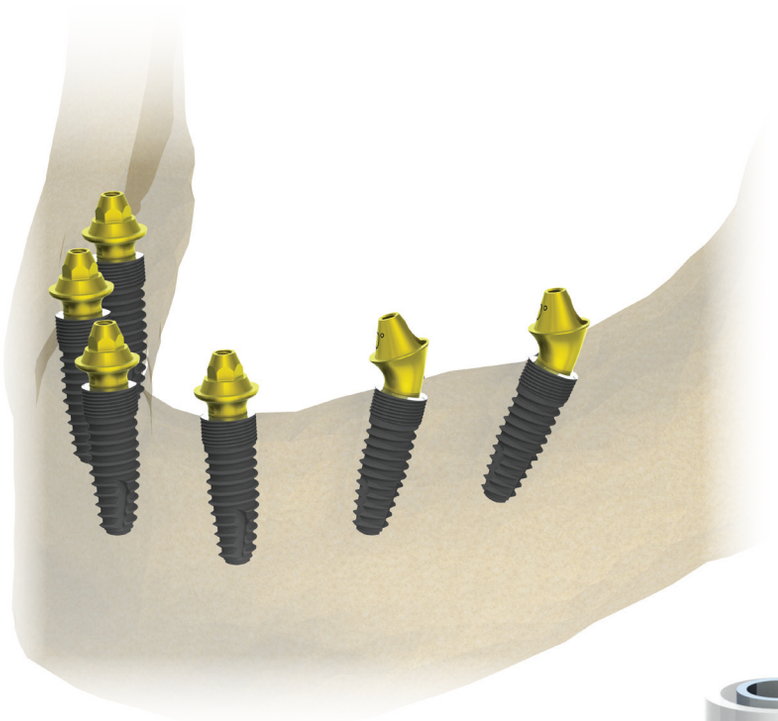
Instruments

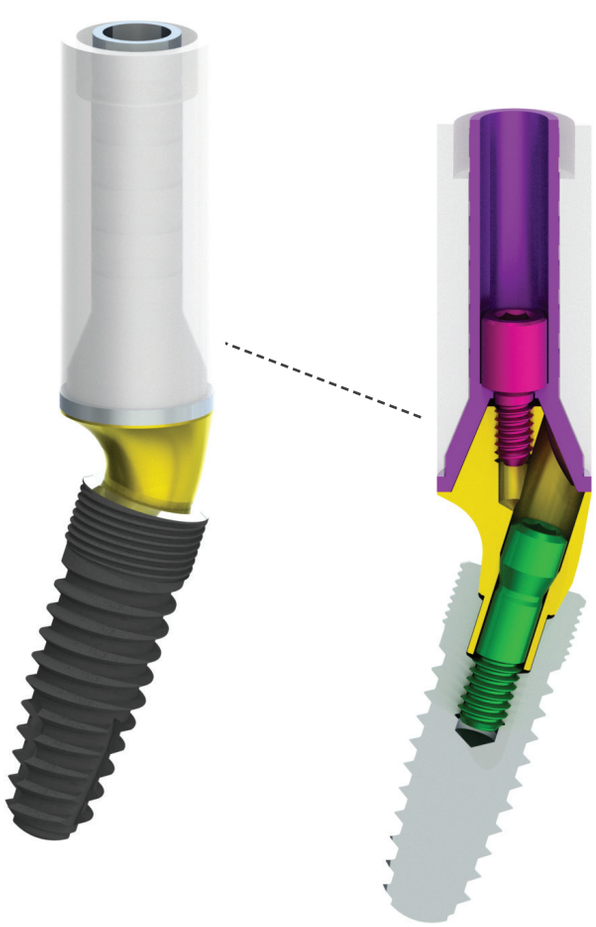
OT EQUATOR DRIVER FOR TORQUE WRENCH	 1110000
WRENCH FOR PARALLELOMETER NORMO	 1108081
SQUARE WRENCH + HOLDER (for OT EQUATOR screwing) 1.25 mm square	 1108082
INTERCHANGEABLE HOLDER	 1108083
CONNECTOR FOR TORQUE CONTROLLER 1.25 mm square	 1108084
CAP INSERTION TOOL EQUATOR - NORMO - MICRO	 1108085
CURVED TOOL FOR SEEGER INSERTION (to use with universal handle)	 1108086
CAP EXTRACTOR	 1108087
BLUE UNIVERSAL HANDLE, TOOL HOLDER AND SEEGER INSERTION TOOL	 1108088

FAST RESTORATION RANGE

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.

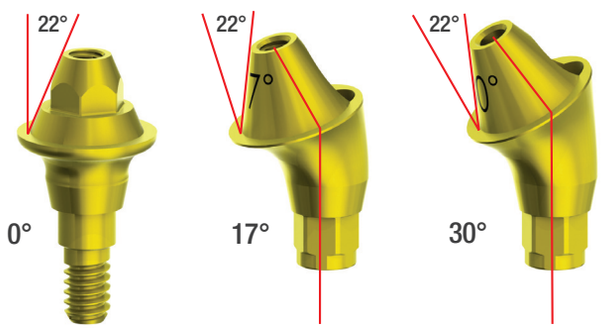
The **FAST restoration range** described in the following pages allows you to make this type of full prosthesis with any kind of surgical-prosthetic techniques, thanks to the components available with three different angulations and equipped with upper tapered connection.



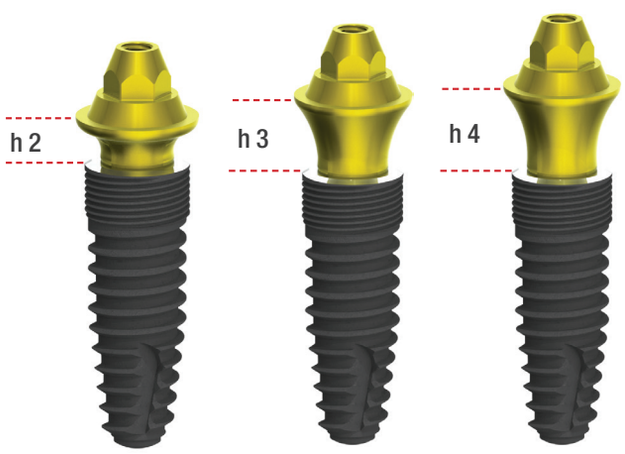


The FAST restoration range has been designed to simplify the construction of immediate loading full threaded prostheses, parallelizing implants with significant divergences (a usual condition in the distal region) in complex restoration projects, such as treatment of toothless patients. The immediate 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".

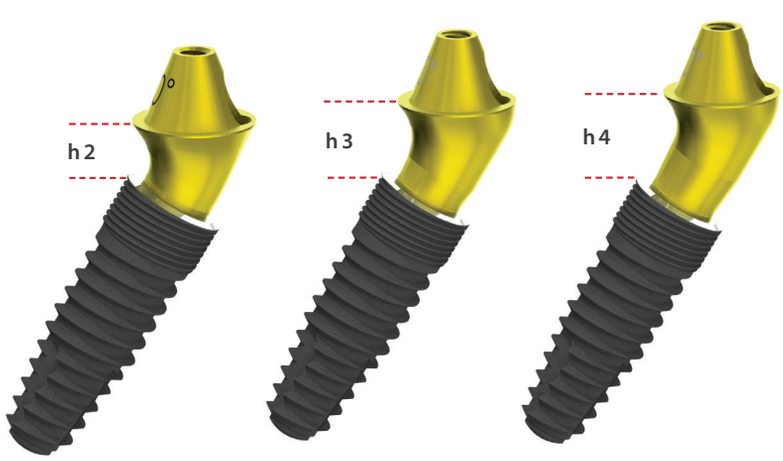
FAST bases are available with three different angles (0° - 17° - 30°), to be chosen according to the inclination of the PRIME CONOMET implants inserted, in order to parallelise the prosthetic axis of insertion of the screw-retained crown.



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.
Do not use the FAST Bases to make prostheses on individual implants or bridges.
Do not use the straight FAST Bases in the presence of disparallelism.



FAST 0° BASES



FAST 17° - 30° BASES

FAST SURGICAL PLANNING

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 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	■	△	●	●
LOWER missing parts				
CENTRAL INCISORS	●	●	●	●
LATERAL INCISORS	●	●	●	△
CANINES	■	●	●	●
PREMOLARS	■	●	●	●
MOLARS	■	△	●	●

● optimal position △ discretionary position ■ contraindicated position

SURGICAL ACCESSORIES

FAST COUNTERSINK BUR

To be used connected to the Contra-angle, in combination with the dedicated Guide, once the implant has been inserted, to obtain the seat suitable for inserting the FAST angled bases in the cortical bone.

0803300

GUIDE FOR FAST COUNTERSINK BUR

To be used connected to the implant, that has been inserted in the site, for correct use of the FAST Countersink Bur, to protect the head of the implants during the bone crest grinding procedure. **Do not use the Guide for Fast Countersink Burs, that is intended for use only with implants with an SM connection (code 0807302 and 0807303).**

2410300 (4 pcs.)

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.

0810141

FAST HEALING CAP

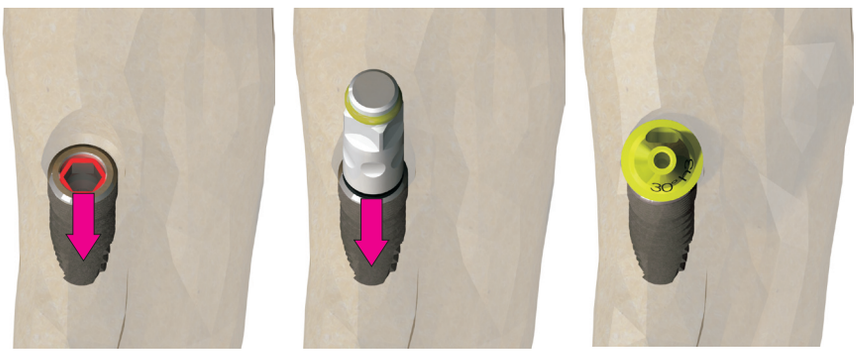
A useful component to protect the FAST connection pending prosthesization of immediate loading threaded implants.

0806300

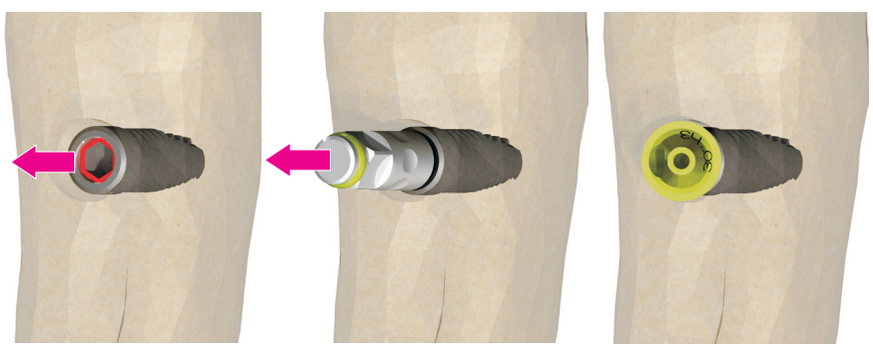
IMPLANT POSITIONING

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.

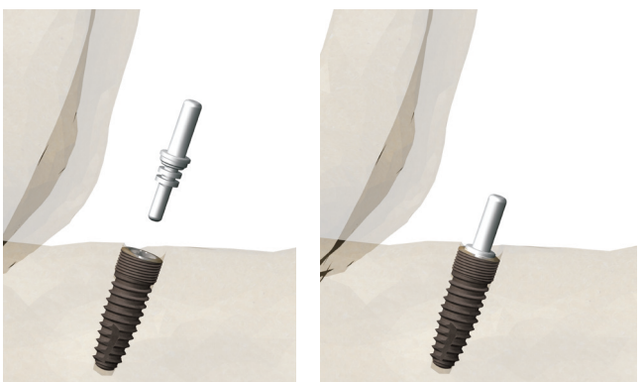
The Surgical Sequence for inserting the PRIME CONOMET implants is described in detail in the dedicated section.



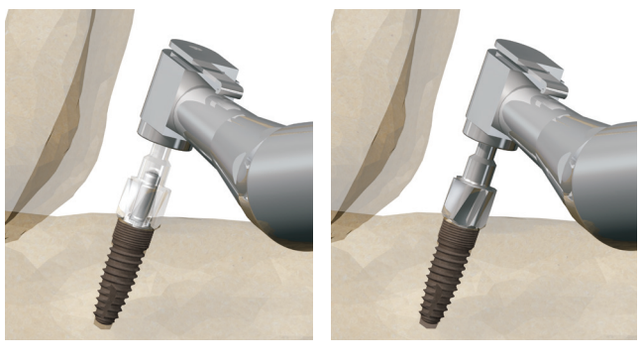
In the case of mesiodistal disparallelism (or vice versa), the implant shall be positioned leaving one side of the internal hex in mesial or distal direction - using the six oval indents on the Drivers corresponding to the six sides of the hex - to optimise recovery of the implant axis through the 17°/30°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

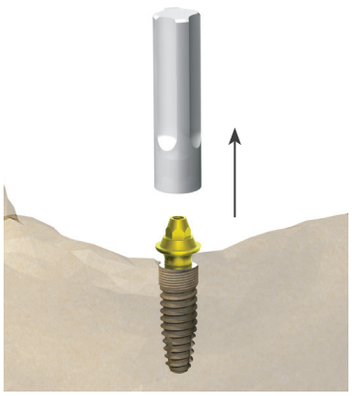


Before inserting the FAST 17°-30° angled Bases in the implants, use the FAST Countersink Bur over the head of the implants. To protect the implant head while passing with the Bur, use the Guide for FAST Countersink inserting it in the implant.



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.

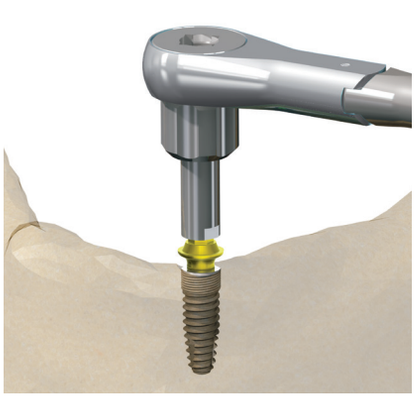
FAST 0° BASES



Use the 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 Carrier by slightly levering upward.

Screw on the FAST 0° Base using the CH 2.6 Hex Wrench.



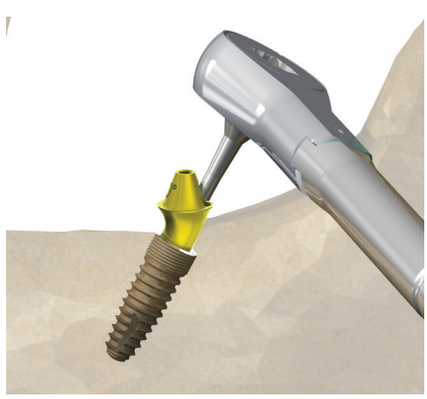
Finally tighten using the Torque Wrench adjusted to 30 Ncm on the wrench square.

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° or 30° Base into the implant, parallelising the implant axis.

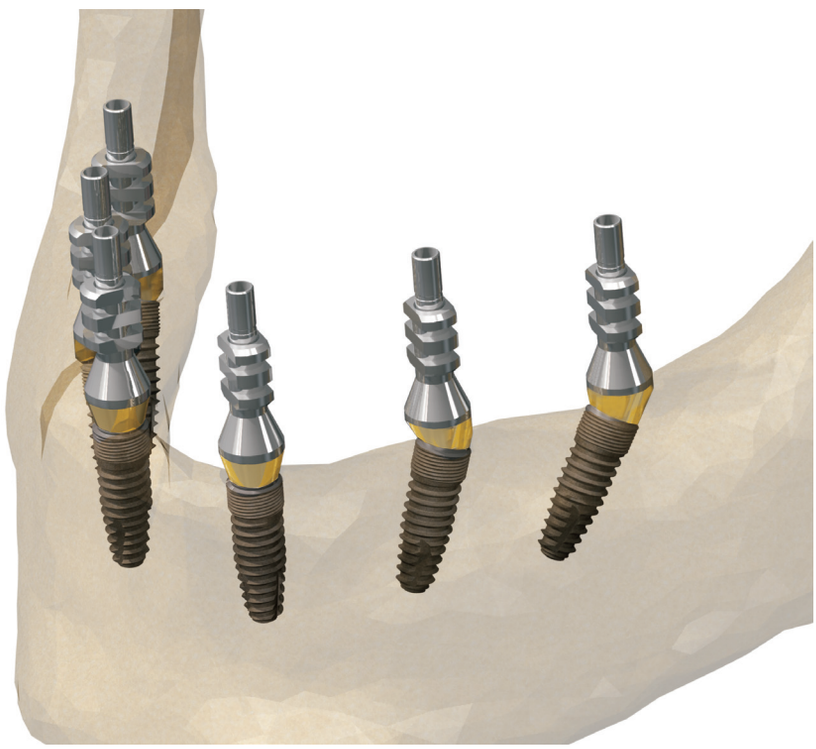
Manually screw in the Fastening Screw of the FAST 17° or 30° Base using the Screwdriver, or mechanically using the Contra-angle Screwdriver (max. 30 Ncm).



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

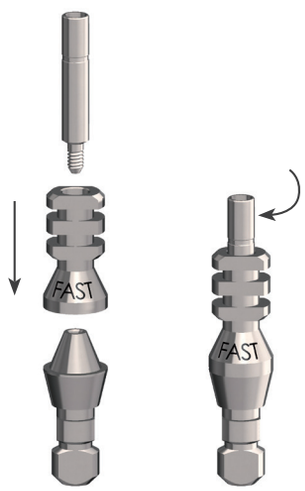
After inserting all the FAST Bases (straight and angled), it is advisable to take an intraoral X-ray to check that the implants and the FAST Bases are correctly coupled.

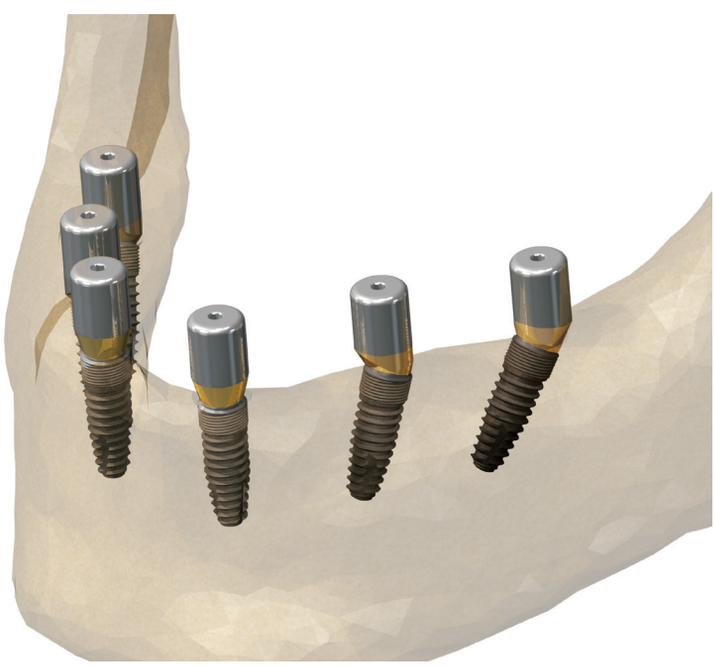
At this point, you can proceed with impression taking using the FAST Precision Impression Transfers or the FAST Scanmarkers for impressions with Digital Intraoral Scanmarkers.



Only screw manually the FAST Transfers or the FAST Scanmarkers onto the FAST Bases using the Screwdriver and take an impression using a custom perforated impression tray in case of FAST Transfer or using the Intraoral Digital Scanner in case of FAST Scanmarker.

The dental laboratory can reproduce the model using the FAST Analogues for analog impressions or the FAST Digital Analogues for digital impressions, that perfectly reproduce the tapered head of both straight and angled FAST Bases.



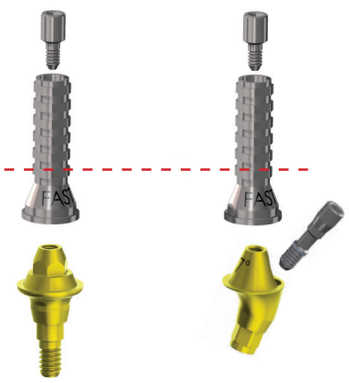


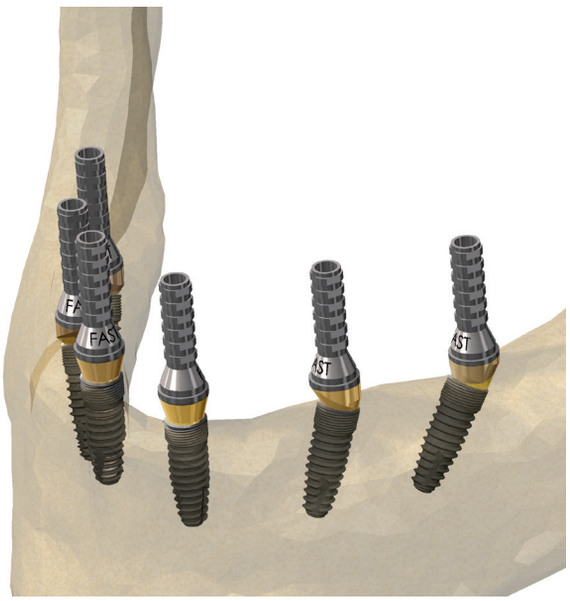
During the temporary laboratory phases, the FAST Healing Caps can be placed to consolidate the soft tissues.

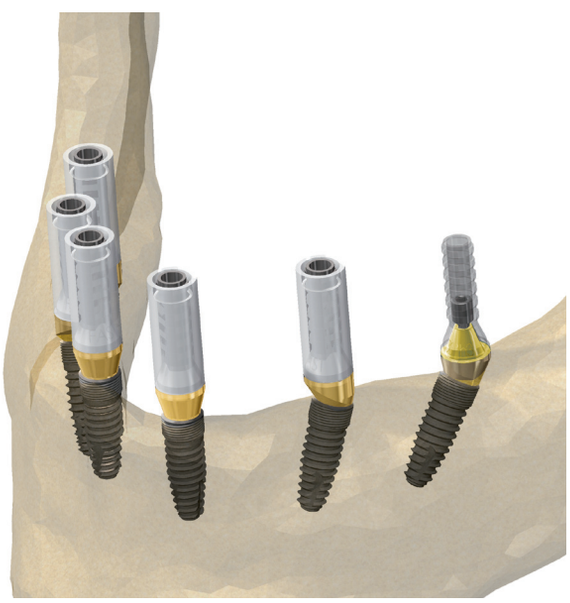
After removing the Healing Caps from the FAST Bases, make sure that they are correctly and completely connected to the implants by tightening them to a torque of 30 Ncm using the Torque Wrench.

FAST CLINICAL PROCEDURES

The temporary prosthesis can be constructed using the FAST 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 FAST Abutments.
The FAST Abutments must not be cut below the first ring starting from the bottom. Tighten only with the surgical/prosthetic torque wrench (20 Ncm).

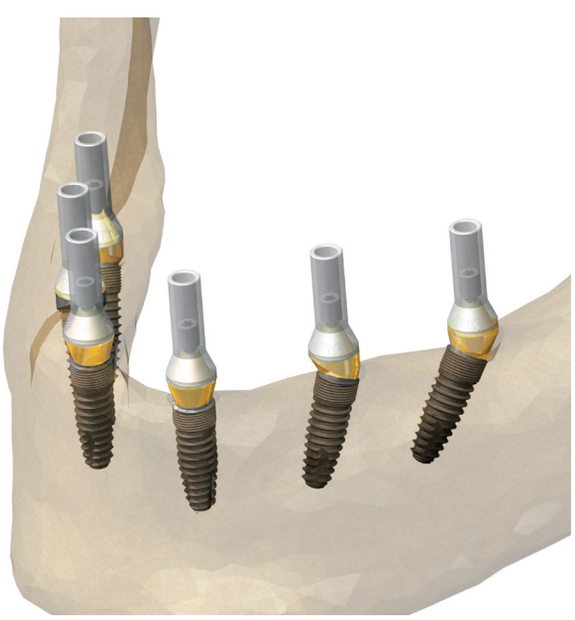






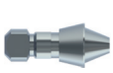
To construct the final prosthesis through passivation, use the Castable Sleeve connected to the FAST Abutment for the construction and gluing of the final device. Do not exceed a torque of 20 Ncm to tighten the final prosthesis.

To construct the final prosthesis, use the FAST Castable Abutment connected to the FAST Bases, 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.



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

All the 0° (straight) FAST Bases are provided already packaged with a peek carrier pre-assembled on the FAST Base, for the first placing into the oral cavity and for the first screwing onto the implant.

	Unique device
FAST ABUTMENT	 0805930
CASTABLE SLEEVE FOR FAST ABUTMENT	 0805932
FAST CASTABLE ABUTMENT	 0805931
FAST ANALOGUE	 0809200
FAST DIGITAL ANALOGUE	 0809405
FAST PRECISION IMPRESSION TRANSFER	 0807300
FAST SCANMARKER	 0807420

RESTORATION ACCESSORIES

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).

long 2410062 | medium 2410061 | short 2410060

CONTRA-ANGLE SCREWDRIVERS

To be used connected to the Contra-angle, to mechanically tighten and loosen the devices with a hexagonal recess, except for screws that are used on intact Premilled Abutments, without exceeding 30 Ncm.

Available in two different sizes.

For those prosthetic components that require it, subsequently perform final tightening manually with the hex bit for the torque wrench.

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).

2410070 | long 2410072

SCREWDRIVER FOR PREMILLED

It is suitable for tightening and loosening all Screws of intact and customized Premilled Abutments with maximum height of 16 mm.

2410065

TORQUE WRENCH

With torque function to complete the final tightening of Fastening Screws. The device can be used either in ratchet mode or torque wrench mode. In torque wrench mode preset values are 20-30-45-60-70 Ncm. Cleaning, disassembly and assembly operations are described in the Instructions for Use.

0510120

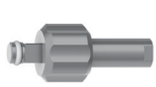
HEX BIT FOR TORQUE WRENCH

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

long 0510076 | short 0510075

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 Wrench (final tightening).



0510019

FASTENING SCREWS

The Fastening Screws are provided in the packs of all the components with which they are used. They can also be purchased individually quoting the item codes detailed on the following page.

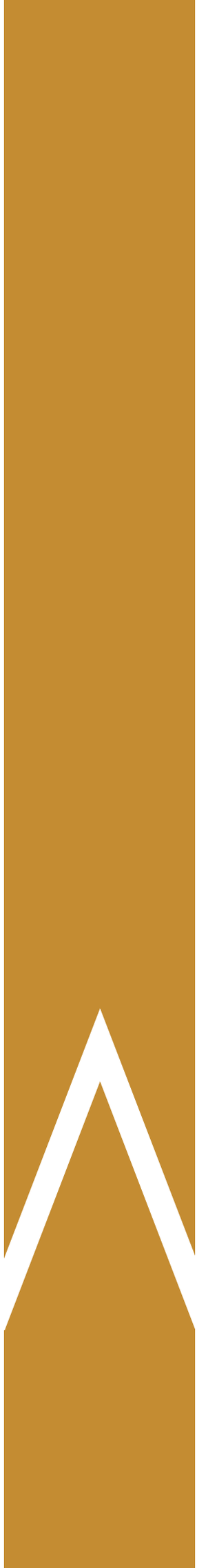
The Fastening Screws must be tightened to 30 Ncm, except for the FAST Abutments which must be tightened to 20 Ncm and for the ones which must be tightened manually.

The Fastening Screws for the following items must only be tightened manually with Screwdriver:

- Castable Abutments
- Rod Abutments
- Scanmarkers
- Transfers

FASTENING SCREWS

Components	Fastening screw
PRECISION IMPRESSION TRANSFER	 2407010  2407014
EASYCAP AND TEAR-OFF IMPRESSION TRANSFER	 2407013
SCANMARKER	 2407012
SCANMARKER FOR LINK BASES ht 2	 2407015
SCANMARKER FOR LINK BASES ht 4	 2407016
LINK BASES CONNECT BASES MULTI ABUTMENT 0° ABUTMENTS 17° e 25° ABUTMENTS SHOULDERLESS 0°- 20° ABUTMENTS PREMILLED ABUTMENTS CASTABLE ABUTMENTS FAST BASES	 2405001
ROD ABUTMENT	 0805651
FAST COMPONENTS: ABUTMENT, CASTABLE ABUTMENT, SCANMARKER	 0805935
FAST PRECISION IMPRESSION TRANSFER	 0807301
DIGITAL ANALOGUE FAST DIGITAL ANALOGUE	 0809410



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