Prodent Italia

PROSHAPE

Clinical Protocol

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.

SISTEMA DI GESTIONE QUALITÀ CERTIFICATO
CERTIQUALITY
UNI CEI EN ISO **13485:2016**

CERTIQUALITY
È MEMBRO DELLA
CONFEDERAZIONE CISQ

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 PROSHAPE TS implants: it must not, however, be considered a substitute for the practitioner's professional experience and training.

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

PROSHAPE TS RANGE implants are available in a number of different types, namely: PROSHAPE TS INTEGRAL and PROSHAPE TS HYBRID. PROSHAPE TS implants are referred to in the Information for the User as **PROSHAPE IMPLANTS**.

The symbol TS is used to identify devices pertaining to the restoration range with a TS Tapered Seal connection. PROSHAPE 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.

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.

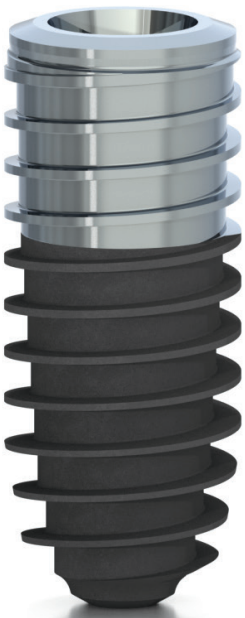
PRODENT ITALIA S.r.l. Via Pitagora, 9 - 20016 Pero (MI) - Italy
www.prodentitalia.eu

GENERAL CHARACTERISTICS

PROSHAPE 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 PROSHAPE RANGE implants are available in two types, both with different diameters and heights, to meet any and all anatomical requirements.

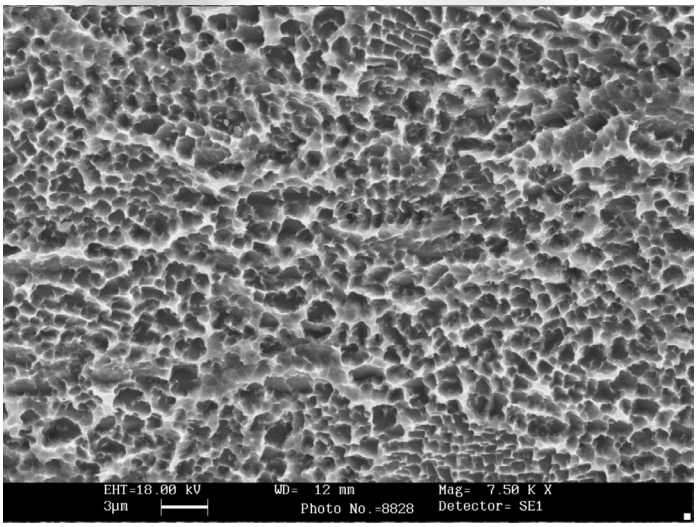
PROSHAPE TS INTEGRAL



PROSHAPE TS HYBRID

PROSHAPE implants are available in the following versions:

- **PROSHAPE TS INTEGRAL: MPS** treatment on the entire implant body.
- **PROSHAPE TS HYBRID:** partial **MPS** treatment in the medio-apical portion and machined coronal area.



SEM 7.500x

MPS Micro Profile Surface

(Double Acid-Etched)

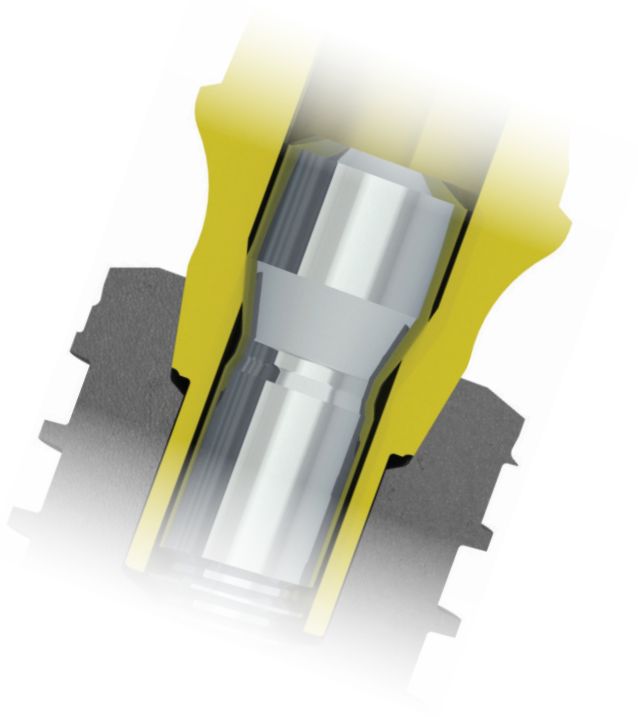
The **MPS** surface treatment, where envisaged, is carried out by means of a double etching process, which results in controlled and homogeneous roughness of the treated surface and provides an excellent clot retention, an essential requirement for osteointegration.

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

GENERAL CHARACTERISTICS

PROSHAPE INTEGRAL implants are suitable in all the clinical cases where the practitioner deems it possible to position the implant at a subcrestal bone level.

PROSHAPE HYBRID implants are mainly suitable in those cases where the practitioner believes, based on his evaluation of the clinical case, that the implant collar will protrude with respect to the bone crest.

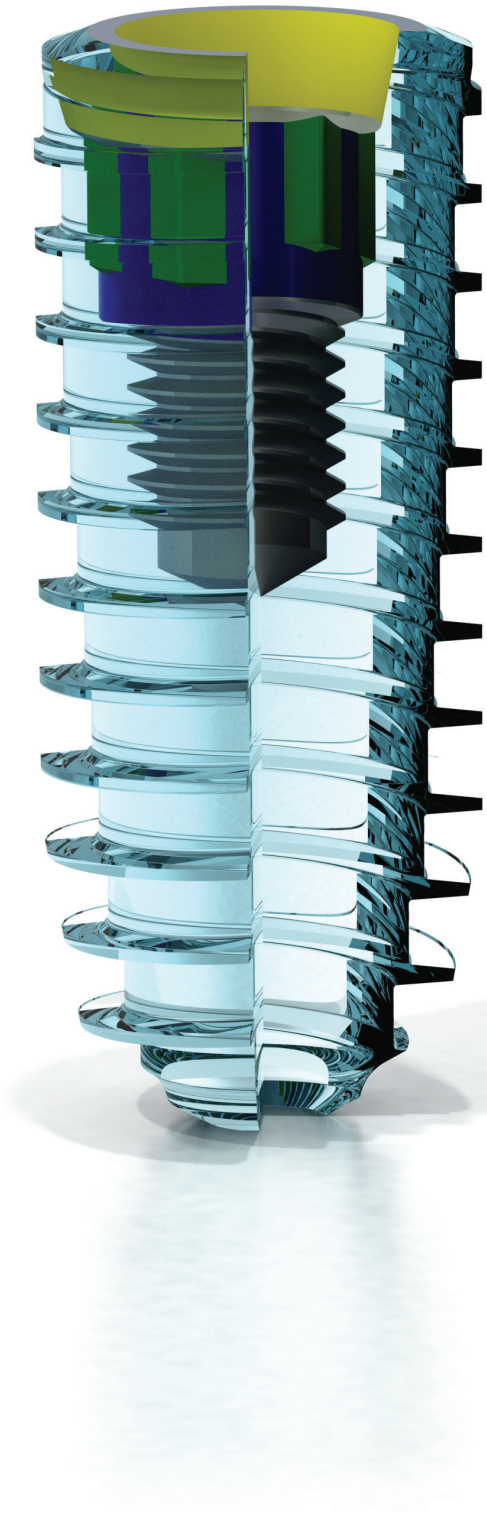


PROSHAPE implants have a deep internal tapered connection with a hexagonal engaging element that creates a seal in the coupling with the abutment and optimises masticatory load distribution.
If used appropriately, these implants have an estimated useful life of at least 10 years; this time period has been validated by means of mechanical fatigue tests conducted with at least 5 million load cycles.

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

The PROSHAPE implants 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.

PROSHAPE



"**Root-form**" implant morphology, characterised by a main cylindrical portion and a tip in which both the shape of the implant body and the arrangement of the threads are conical. This feature allows non-traumatic implant insertion.

The spirals are **flat and penetrating**, in order to reduce any high insertion torques whilst guaranteeing excellent primary stability.

The progressive spirals are **concentrated in the apical portion,** due the variation in their conical arrangement in relation to the implant body. This feature guarantees the implant a reliable grip, even in cancellous bone.

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

RESTORATION CONNECTION - PLATFORM SWITCHING

PROSHAPE 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 in the neck section, included the spirals.

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

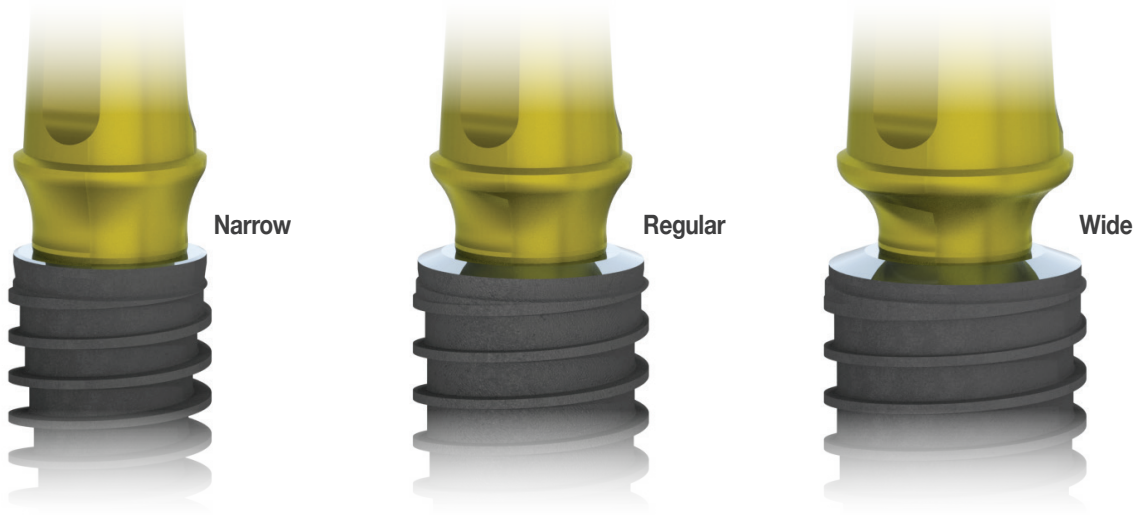
The devices intended for use with the TS connection restoration range are **colour-coded** golden yellow.

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.

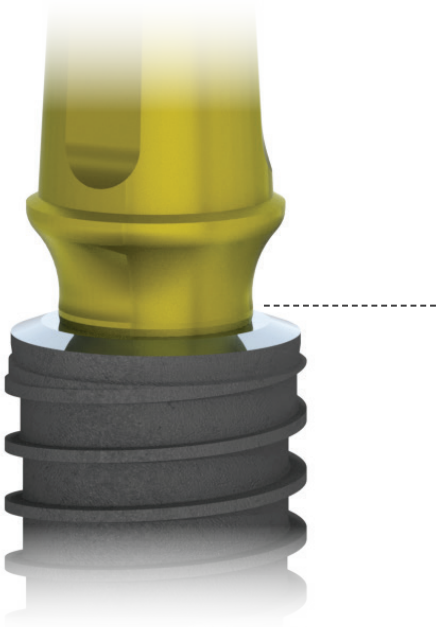
Certain restoration parts are available with three different emergence profiles: NARROW, REGULAR and WIDE.

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

PROSHAPE INTEGRAL implants are available with five diameters; Ø 3.8 and Ø 5.5 implants are available with five heights, while all the other diameters are available with six heights.

PROSHAPE HYBRID implants are available with five diameters; the first four diameters are available with five heights, the widest diameter is available with four heights.

PROSHAPE implants pack include the Cover Screw.

PROSHAPE INTEGRAL

PROSHAPE HYBRID

PROSHAPE IMPLANTS

THE ONLY RESTORATION RANGE COLOUR-CODED GOLDEN YELLOW

Ø 3.8

INTEGRAL Implant height	site depth	codes	HYBRID Implant height	site depth	codes
h 8	h 8.5	2401241I	**h 8**	h 8.5	2401241H
h 9.5	h 10	2401242I	**h 9.5**	h 10	2401242H
h 11	h 11.5	2401243I	**h 11**	h 11.5	2401243H
h 12.5	h 13	2401244I	**h 12.5**	h 13	2401244H
h 14.5	h 15	2401245I	**h 14.5**	h 15	2401245H

Ø 4.2

INTEGRAL Implant height	site depth	codes	HYBRID Implant height	site depth	codes
h 6.5	h 7	2401200I			
h 8	h 8.5	2401201I	**h 8**	h 8.5	2401201H
h 9.5	h 10	2401202I	**h 9.5**	h 10	2401202H
h 11	h 11.5	2401203I	**h 11**	h 11.5	2401203H
h 12.5	h 13	2401204I	**h 12.5**	h 13	2401204H
h 14.5	h 15	2401205I	**h 14.5**	h 15	2401205H

Ø 4.6

INTEGRAL Implant height	site depth	codes	HYBRID Implant height	site depth	codes
h 6.5	h 7	2401210I			
h 8	h 8.5	2401211I	**h 8**	h 8.5	2401211H
h 9.5	h 10	2401212I	**h 9.5**	h 10	2401212H
h 11	h 11.5	2401213I	**h 11**	h 11.5	2401213H
h 12.5	h 13	2401214I	**h 12.5**	h 13	2401214H
h 14.5	h 15	2401215I	**h 14.5**	h 15	2401215H

Ø 5

INTEGRAL Implant height	site depth	codes	HYBRID Implant height	site depth	codes
h 6.5	h 7	2401220I			
h 8	h 8.5	2401221I	**h 8**	h 8.5	2401221H
h 9.5	h 10	2401222I	**h 9.5**	h 10	2401222H
h 11	h 11.5	2401223I	**h 11**	h 11.5	2401223H
h 12.5	h 13	2401224I	**h 12.5**	h 13	2401224H
h 14.5	h 15	2401225I	**h 14.5**	h 15	2401225H

Ø 5.5

INTEGRAL Implant height	site depth	codes	HYBRID Implant height	site depth	codes
h 6.5	h 7	2401230I			
h 8	h 8.5	2401231I	**h 8**	h 8.5	2401231H
h 9.5	h 10	2401232I	**h 9.5**	h 10	2401232H
h 11	h 11.5	2401233I	**h 11**	h 11.5	2401233H
h 12.5	h 13	2401234I	**h 12.5**	h 13	2401234H

The implant must be positioned 0.5 mm below the bone crest and, therefore, the depth of the receptor site is 0.5 mm greater than the implant height.

PACK

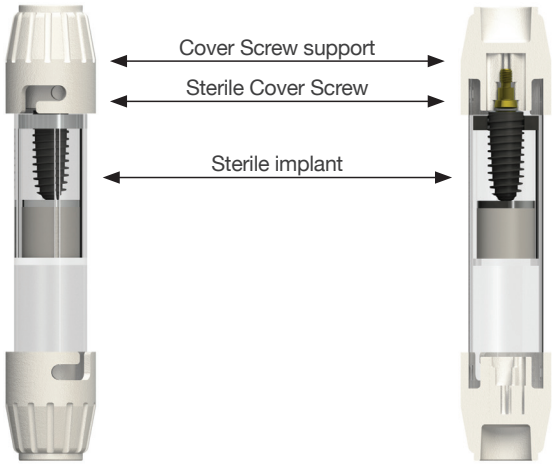
PACK AND STERILITY

The PROSHAPE 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.

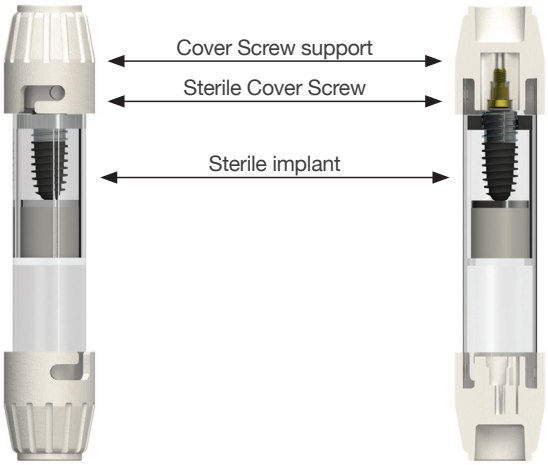
The ampoule is contained in a sealed plastic blister pack to preserve sterility and the blister pack comes in a sealed cardboard box suitable for storage.

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 PROSHAPE INTEGRAL implants



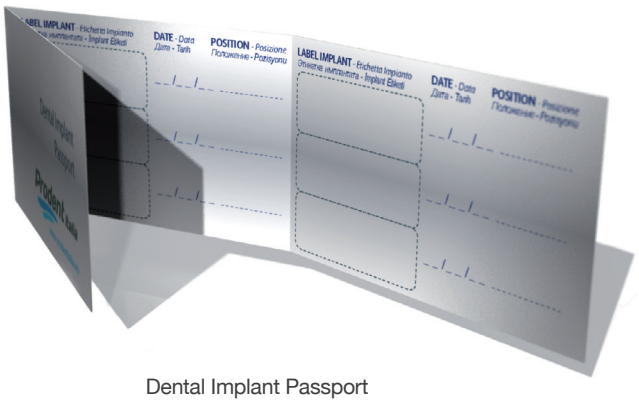
Primary pack for PROSHAPE HYBRID implants

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.



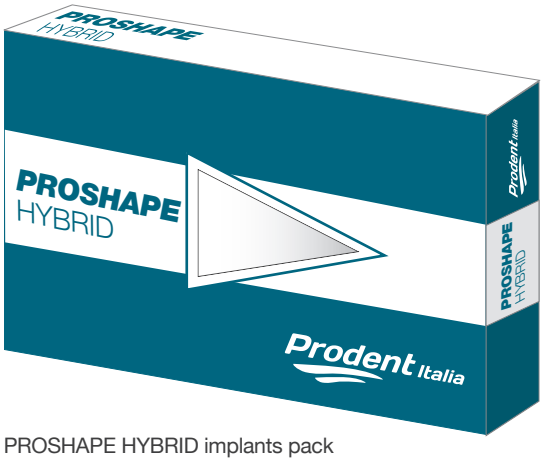
Dental Implant Passport

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.

PROSHAPE INTEGRAL implants pack



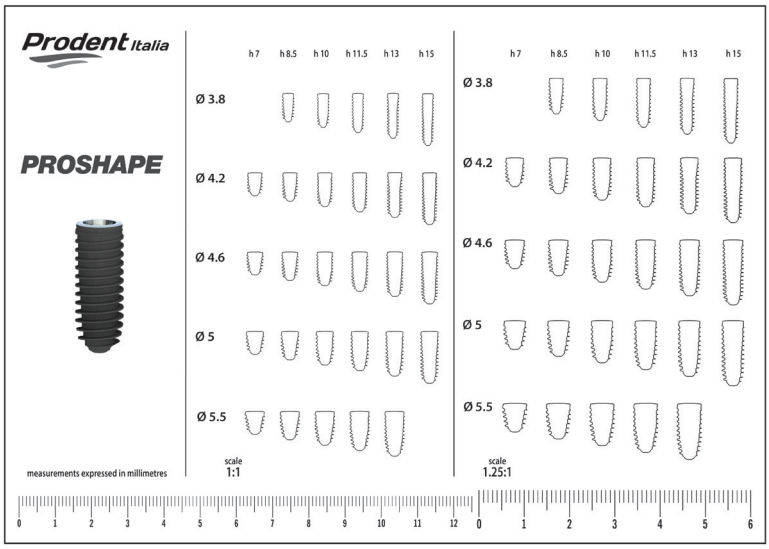
PROSHAPE HYBRID implants pack

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 PROSHAPE 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	Ø 3.8	Ø 4.2	Ø 4.6	Ø 5	Ø 5.5
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

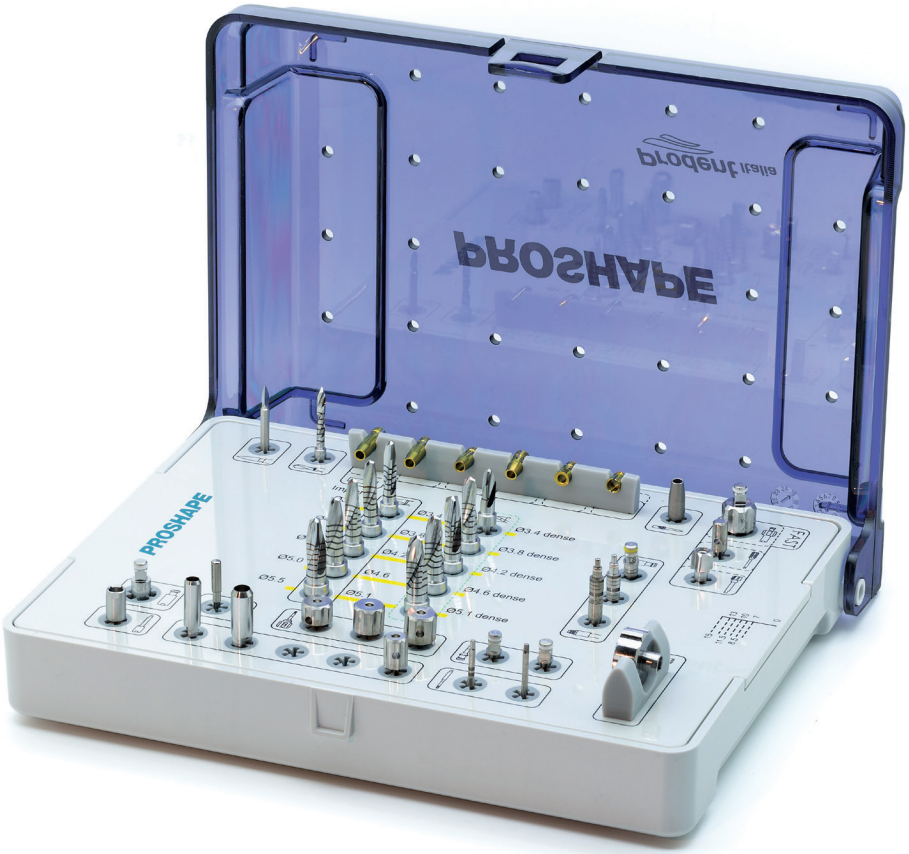
If used in DISCRETIONARY position, do not prosthesize Ø 4.2 PROSHAPE implants with abutments having an angulation **greater than 17°**.

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

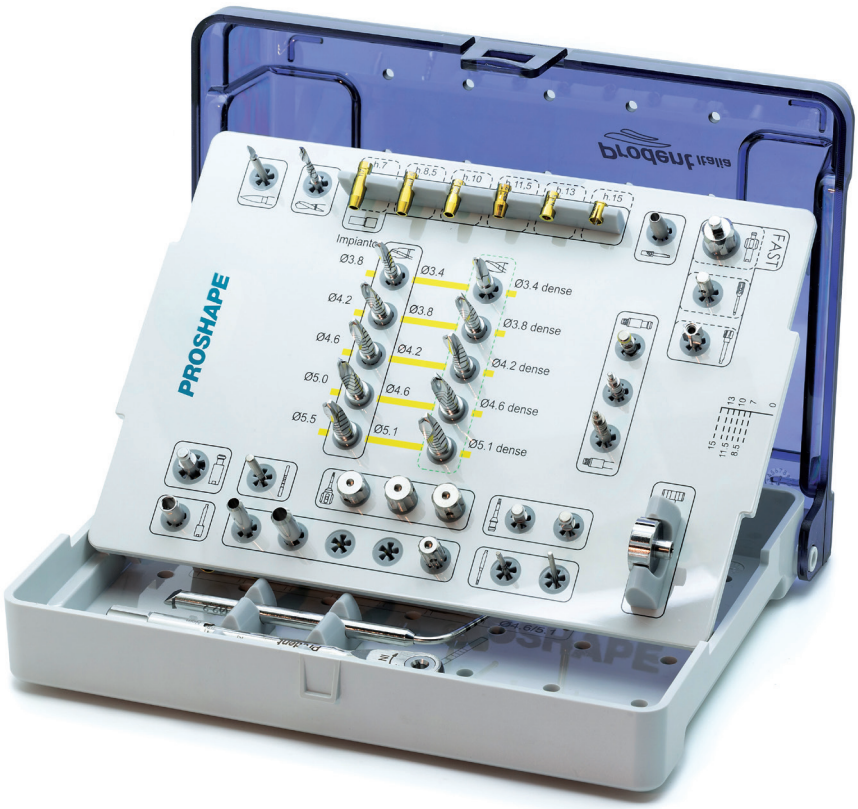
SURGICAL TRAY

The Surgical Tray PROSHAPE 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 Tray **PROSHAPE**
2410900



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. 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.

0503070
Ø 4.3

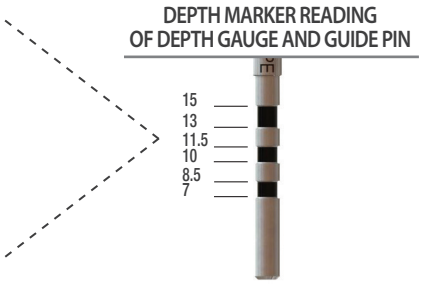
0503071
Ø 5.5

GUIDE PIN PROSHAPE

It is used to assess the depth of the surgical channel (also by using radiography) after drilling with the PROSHAPE Pilot Bur.

In the event that two or more implants are inserted, the pin can be used as reference for parallelism.

2410101



DEPTH GAUGE PROSHAPE

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

2410100

BUR EXTENSION

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

0510059

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.

0510064

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).

long
2410062

medium
2410061

short
2410060

CONTRA-ANGLE CONNECTION

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

0510062

EXTENSION

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

0510060

TORQUE 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.

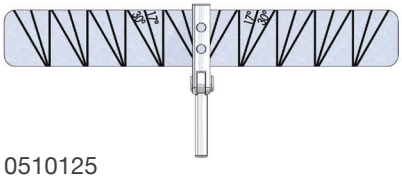
0510120

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 Ø 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.



0510125

BURS AND DRILL STOPS

The same Corticotomy Bur and Proshape Pilot Bur with corresponding Drill Stops are used for all PROSHAPE implants. The specific Proshape Burs and the corresponding Drill Stops 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 **Proshape Pilot Bur** is used to determine the final depth of the surgical implant site.

When used as a *final bur*, the **Proshape 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.
They are marked with the surgical site diameter they achieve.

Proshape Burs for Compact Bone must be used only to prepare sites in compact bones, usually in the mandible, as they create larger surgical sites and therefore reduce the torque used for implant insertion. They must be used to complete the preparation of the surgical site, after the *final* corresponding Proshape Bur has been applied.
They are marked "**COMP**" or "**dense**" and with the same diameter present on the corresponding Proshape Bur whose site they are used to enlarge.

The Ø 3.4 Proshape Bur for Compact Bone must only be used in the presence of compact bone and it achieves a hole with a depth of 7.8 mm, regardless of the height of the implant to be inserted.

In the "*Bur depth marker and cutting edge reading*" table, the markers of all the Burs for Proshape implants indicate the depth of the surgical site they achieve, which is 0.5 mm greater than the height of the implant to be inserted.

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 marked with the diameter of the burs they are intended for use with and the height of the surgical site they achieve.

The only exception is **the Drill Stop for the Ø 3.4 Proshape Bur for Compact Bone**, which is available in a single variant, marked "Ø 3.4" and "dense". All Drill Stops are manufactured using grade 5 titanium.

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
PROSHAPE PILOT

2403010

Ø 2.2
DRILL STOP PROSHAPE PILOT

h 7	2410001
h 8.5	2410002
h 10	2410003
h 11.5	2410004
h 13	2410005
h 15	2410006

direction of drill stop insertion on the bur

PROSHAPE BURS

Ø 3.4	Ø 3.8	Ø 4.2	Ø 4.6	Ø 5.1
2403140	2403100	2403110	2403120	2403130

PROSHAPE BURS FOR COMPACT BONE

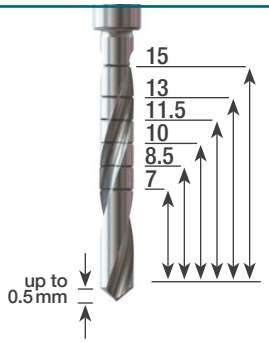
Ø 3.4 DENSE	Ø 3.8 DENSE	Ø 4.2 DENSE	Ø 4.6 DENSE	Ø 5.1 DENSE
2403240	2403200	2403210	2403220	2403230

DRILL STOP FOR PROSHAPE BURS

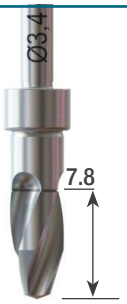
	Ø 3.4	Ø 3.4	Ø 3.8 / Ø 4.2	Ø 4.6 / Ø 5.1
h 7	2410030	2410040	2410010	2410020
h 8.5	2410031	usable only with the *Proshape Bur Ø 3.4 for Compact Bone*	2410011	2410021
h 10	2410032		2410012	2410022
h 11.5	2410033		2410013	2410023
h 13	2410034		2410014	2410024
h 15	2410035		2410015	2410025

BUR DEPTH MARKER AND CUTTING EDGE READING

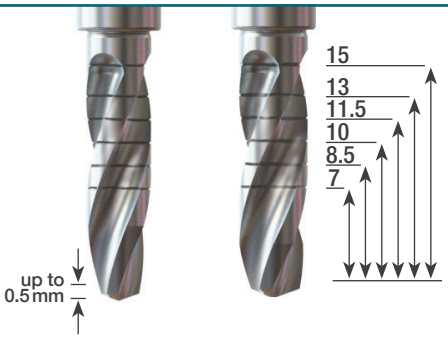
PROSHAPE PILOT



PROSHAPE BUR Ø 3.4 FOR COMPACT BONE



PROSHAPE BURS and PROSHAPE BURS FOR COMPACT BONE

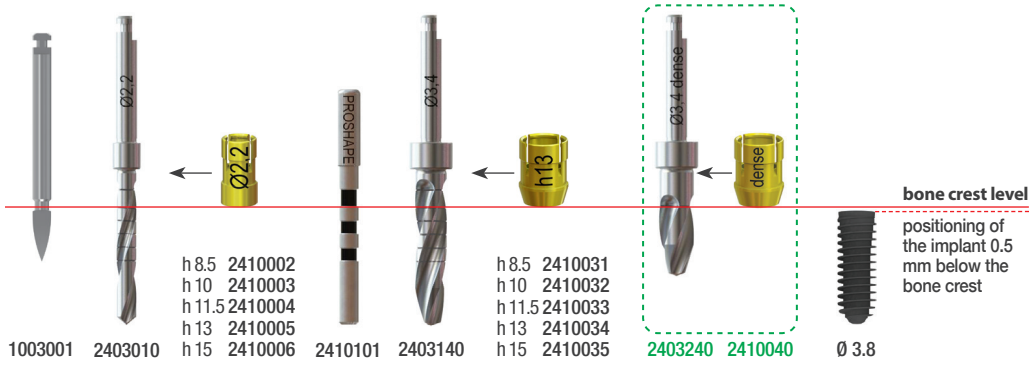


SURGICAL SEQUENCE

SEQUENCE BASED ON IMPLANT DIAMETER AND HEIGHT

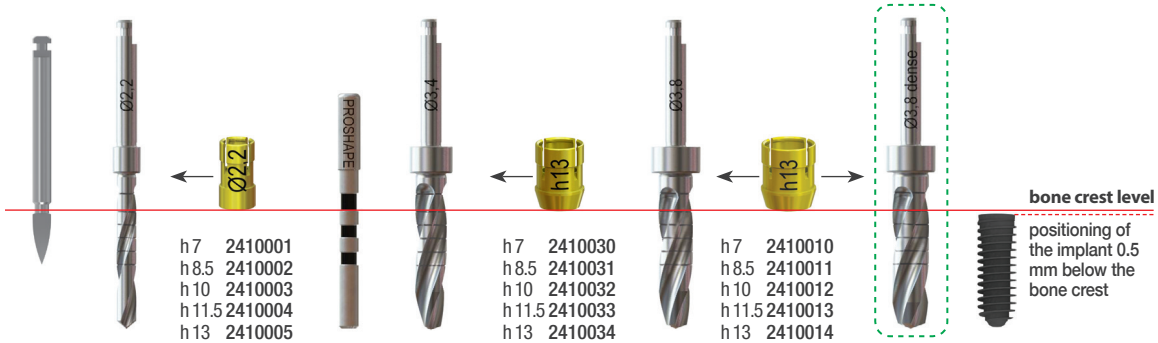
The devices with green code are optional and they must be used **only** in a compact bone.

Ø 3.8



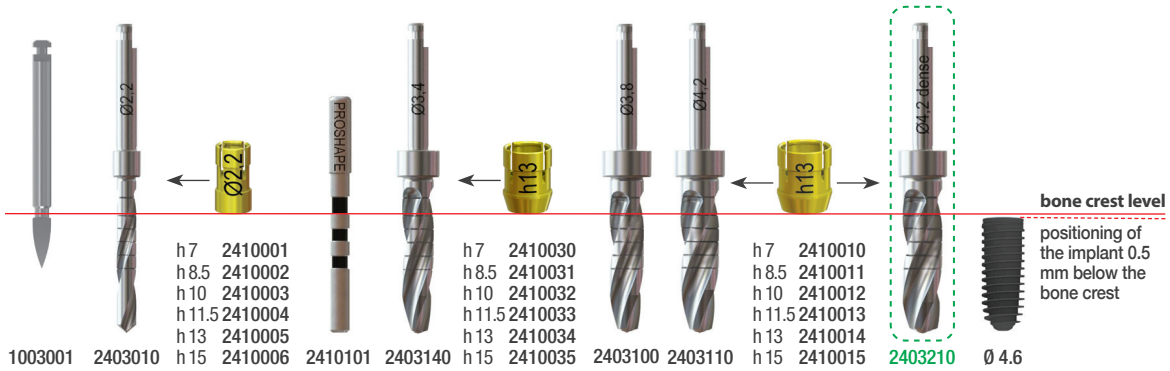
1003001	2403010		2410101	2403140		2403240	2410040	Ø 3.8
		h 8.5 2410002			h 8.5 2410031			
		h 10 2410003			h 10 2410032			
		h 11.5 2410004			h 11.5 2410033			
		h 13 2410005			h 13 2410034			
		h 15 2410006			h 15 2410035			

Ø 4.2



1003001	2403010		2410101	2403140		2403100		2403200	Ø 4.2
		h 7 2410001			h 7 2410030		h 7 2410010		
		h 8.5 2410002			h 8.5 2410031		h 8.5 2410011		
		h 10 2410003			h 10 2410032		h 10 2410012		
		h 11.5 2410004			h 11.5 2410033		h 11.5 2410013		
		h 13 2410005			h 13 2410034		h 13 2410014		
		h 15 2410006			h 15 2410035		h 15 2410015		

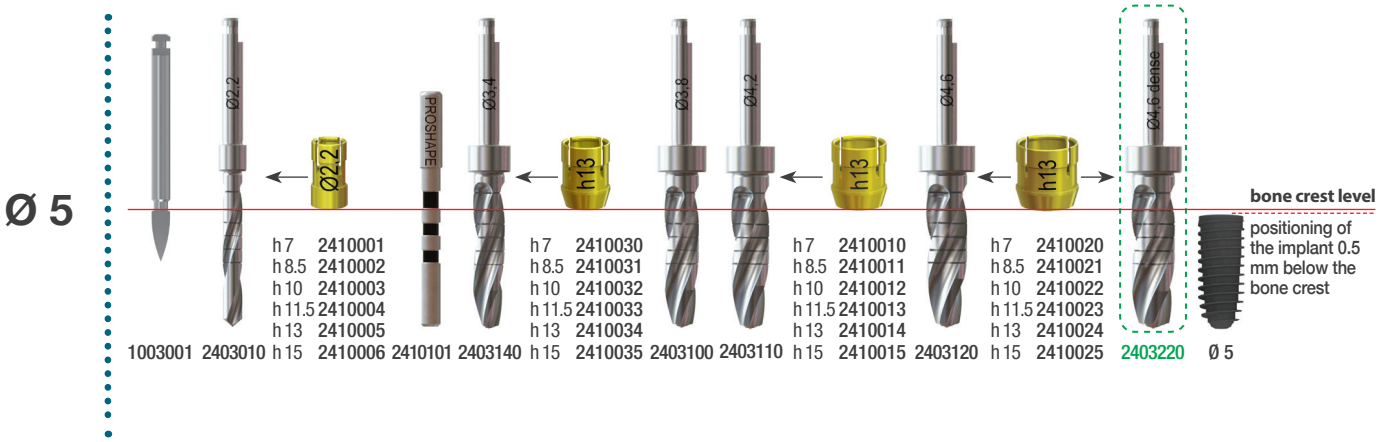
Ø 4.6

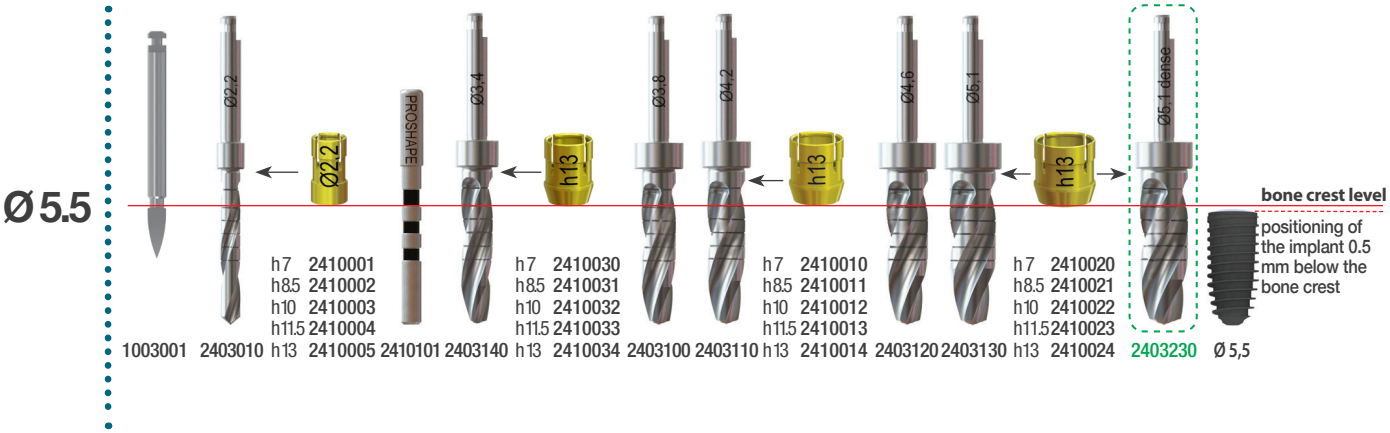


1003001	2403010		2410101	2403140		2403100	2403110		2403210	Ø 4.6
		h 7 2410001			h 7 2410030			h 7 2410010		
		h 8.5 2410002			h 8.5 2410031			h 8.5 2410011		
		h 10 2410003			h 10 2410032			h 10 2410012		
		h 11.5 2410004			h 11.5 2410033			h 11.5 2410013		
		h 13 2410005			h 13 2410034			h 13 2410014		
		h 15 2410006			h 15 2410035			h 15 2410015		

SEQUENCE BASED ON IMPLANT DIAMETER AND HEIGHT

The devices with green code are optional and they must be used **only** 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

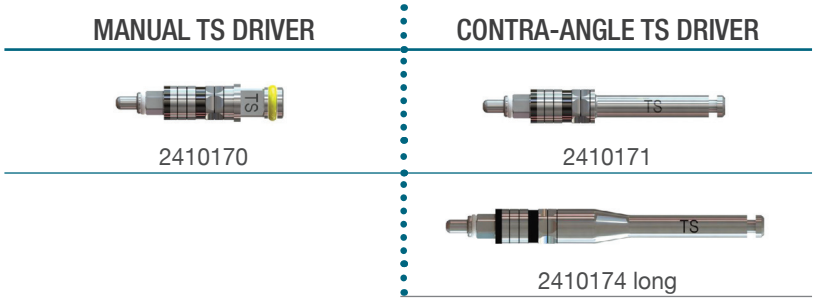
Connected to the Digital Wrench, they allow the implants to be taken from the ampoule and to be placed in the implant site to then proceed with manual insertion. If necessary, complete insertion using the Driver connected to the Torque Ratchet.

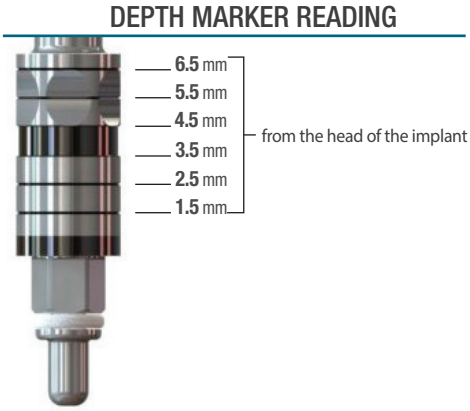
CONTRA-ANGLE TS DRIVER

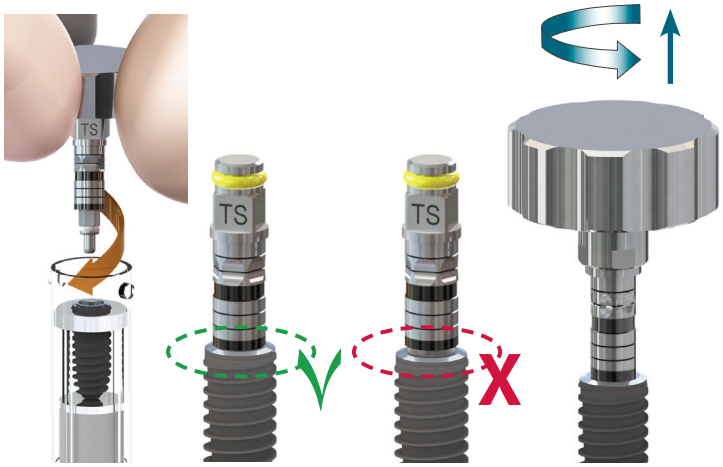
Connected to the Contra-angle, they allow the implants to be taken from the ampoule and to be placed in the implant site to then proceed with mechanical insertion. Complete insertion by screwing in. Never exceed 25 RPM and a maximum torque of 45 Ncm. Available in two variants: standard and long.

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.





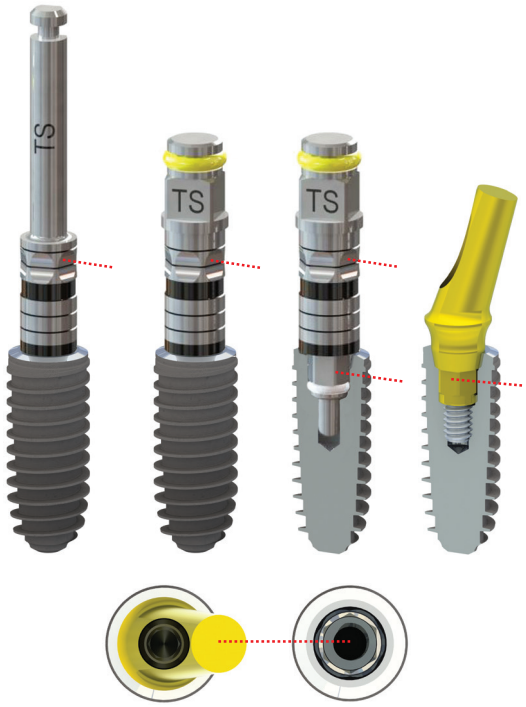


During the procedures for extracting the implant from the ampoule, we recommend that you **gently press the Driver and at the same time rotate it to perfectly connect the Driver and the implant.** Incorrect procedures would prevent proper use of the device: in these events, **it is recommended to repeat the connection procedure.**

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.

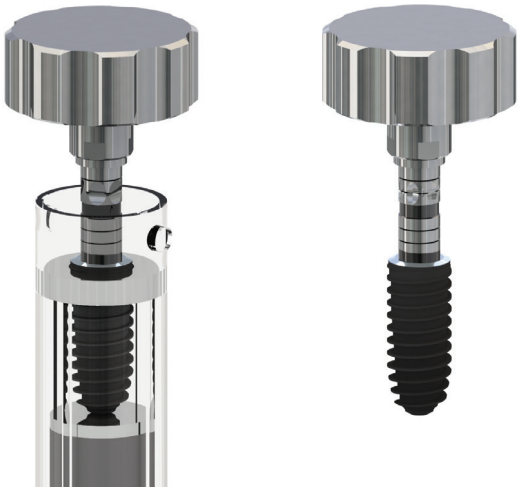
In order to extract the Driver, it can be useful to use the Digital Wrench.

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

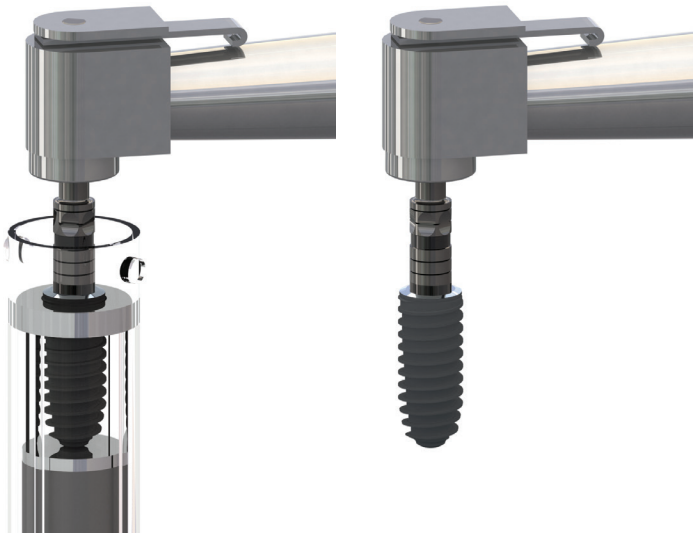


The implant is extracted from the sterile ampoule with the Digital Wrench and the Manual Driver for the first screwing phase of the implant into the implant site.

Insertion of the implant completed with the Ratchet 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 the Contra-angle Driver for the first screwing phase of the implant into the implant site.

HEALING SCREWS

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
ht 2	 2406000	 2406002	 2406010	 2406012	 2406020	 2406022
ht 4	 2406001	 2406003	 2406011	 2406013	 2406021	 2406023

hc = coronal height
ht = 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.

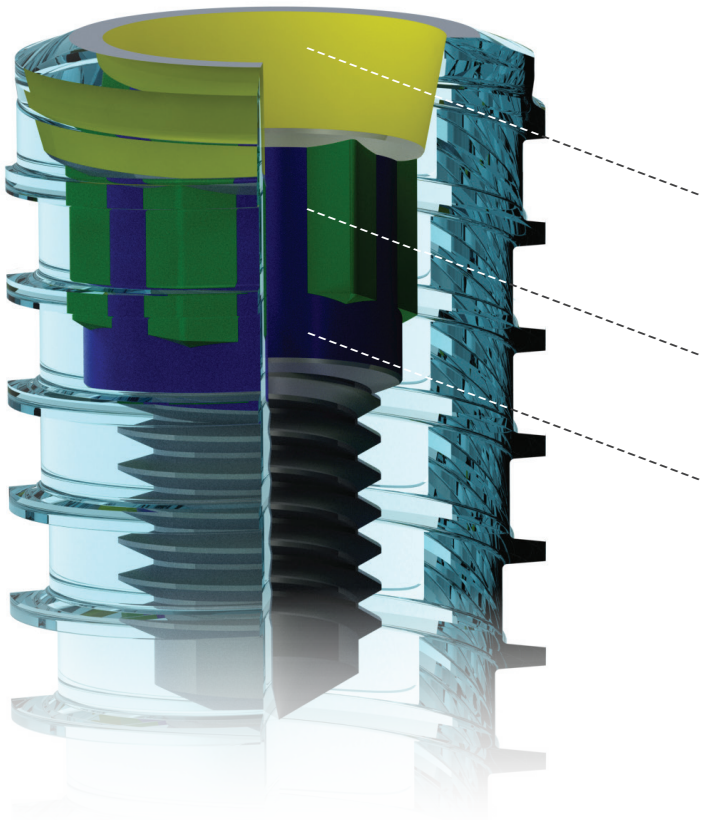

RG4

PROSTHETIC PLATFORM

All PROSHAPE 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.

	Ø 3.8 - Ø 4.2 - Ø 4.6 - Ø 5 - Ø 5.5
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.


WD4

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.
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.

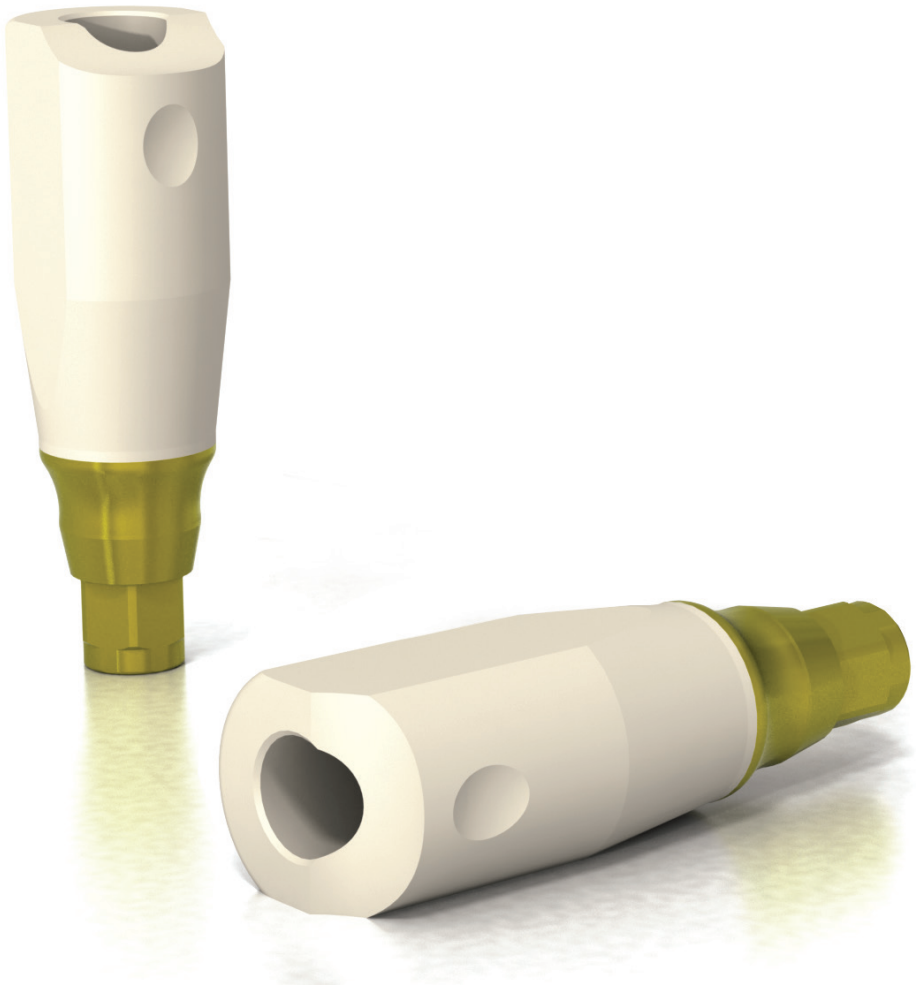
		Design		
		NR=Narrow	**RG=Regular**	**WD=Wide**
PRECISION IMPRESSION TRANSFER	**ht 2**	 2407000	 2407002	 2407004
	ht 4	 2407001	 2407003	 2407005
EASYCAP AND TEAR-OFF IMPRESSION TRANSFER			 2407020	
EASYCAP			 0807000	
IMPLANT ANALOGUE			 2409000	

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.



SCANMARKER	 2407100

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	 2405721
PREMILLED ABUTMENT Ø 15.8	 2405722

MULTI ABUTMENTS

MULTI ABUTMENTS

Multifunctional components 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.

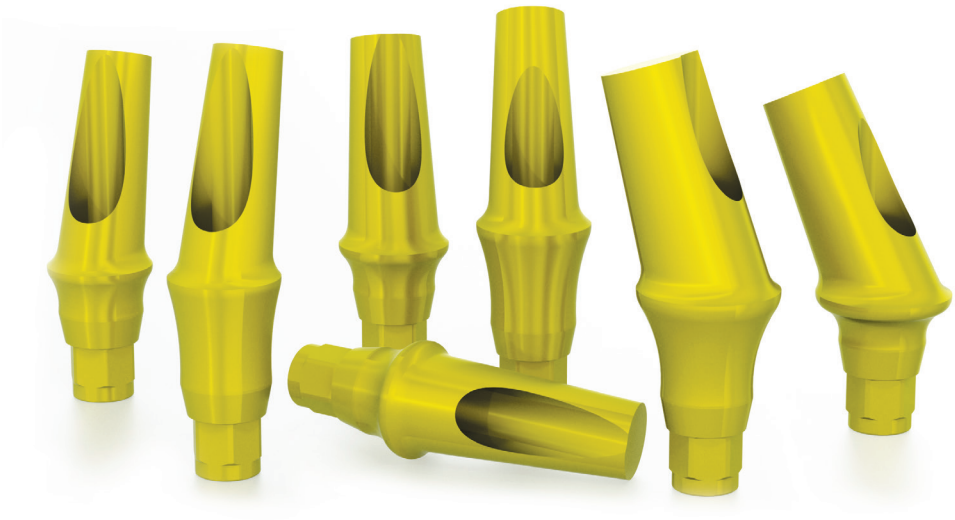
		Design
		NR=Narrow
MULTI ABUTMENTS engaging version	ht 2	 2405301
MULTI ABUTMENTS non-engaging version	ht 2	 2405300
MULTI ABUTMENTS castable version		 2405302

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
CASTABLE ABUTMENT engaging	ht 2	 2405401
CASTABLE ABUTMENT non-engaging	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

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.

	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

CAPS	PURPLE STRONG retention 2.7 Kg  1108057 (4 pack)	WHITE STANDARD retention 1.8 Kg  1108058 (4 pack)	PINK SOFT retention 1.2 Kg  1108059 (4 pack)	YELLOW EXTRA SOFT retention 0.6 Kg  1108060 (4 pack)	BLACK only for LABORATORY USE  1108061 (4 pack)
CAP CONTAINERS	STAINLESS STEEL CAP CONTAINER  1108062 (2 pack)		TITANIUM CAP CONTAINER  1108064 (2 pack)		
SPARE PARTS KIT	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) 	
	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)

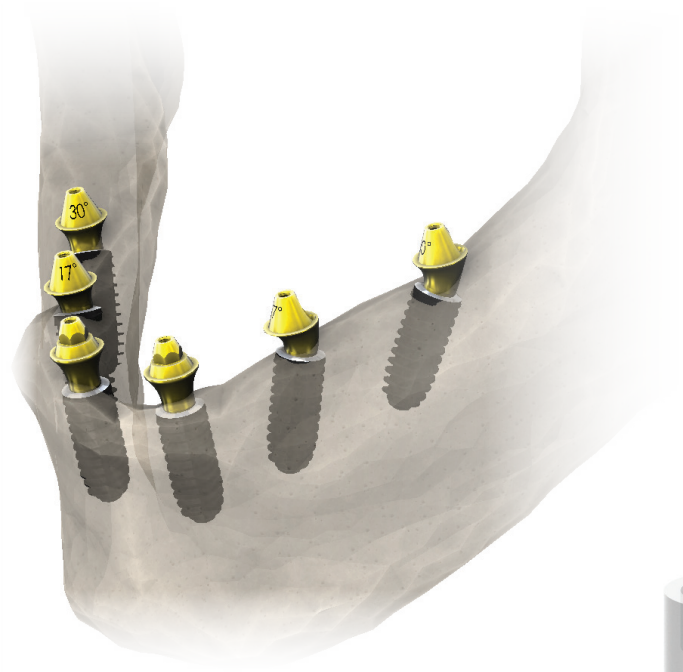
Instruments

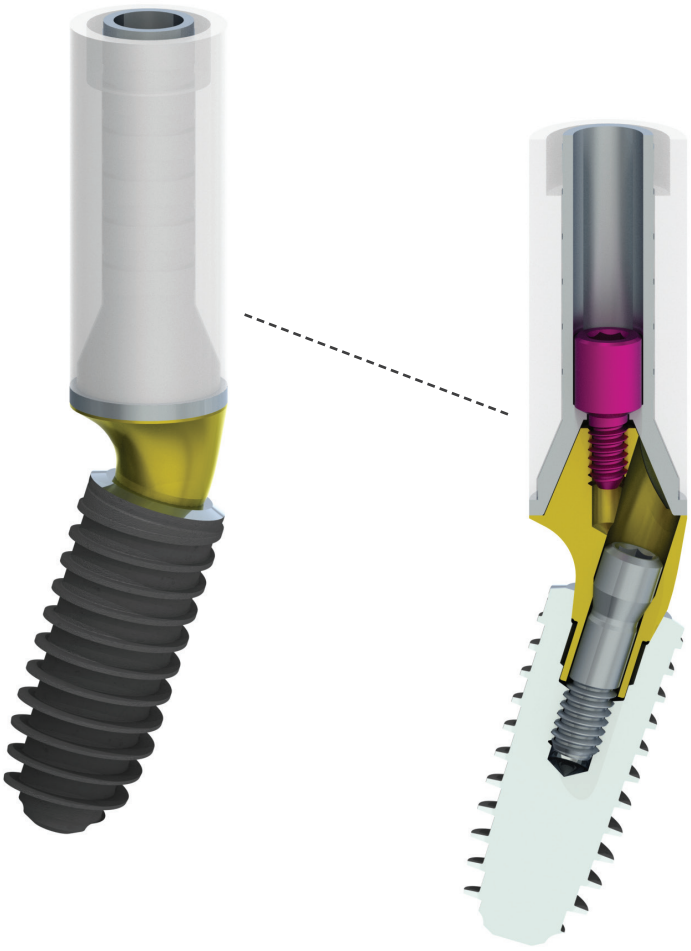
OT EQUATOR DRIVER FOR TORQUE RATCHET	 1110000
WRENCH FOR PARALLELOMETER NORMO	 1108081
SQUARE WRENCH + HOLDER (for OT EQUATOR screwing) 1.25 mm square	 1108082
INTERCHANGEABLE HOLDER	 1108083
CONNECTOR FOR TORQUE CONTROLLER 1.25 mm square	 1108084
CAP INSERTION TOOL EQUATOR - NORMO - MICRO	 1108085
CURVED 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

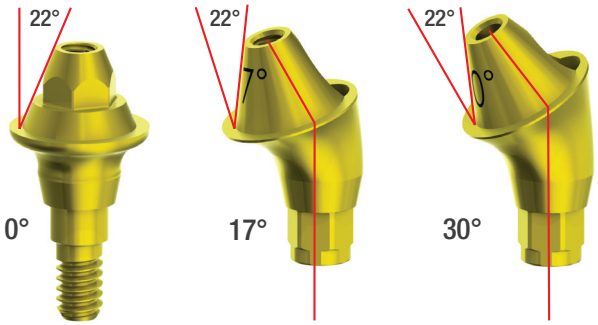
In the case of immediate loading of screw-retained prostheses used in multiple implants, restoration components are required to convert - simultaneously with insertion of the fixtures - the engagement of the implants and their disparallelism into a non-engaging transmucosal connection. These shall also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

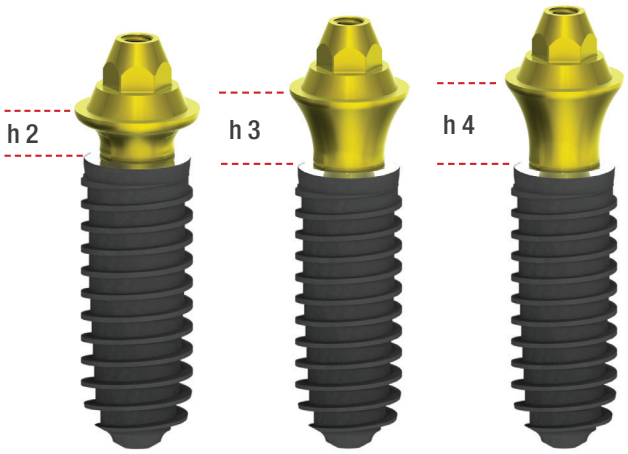




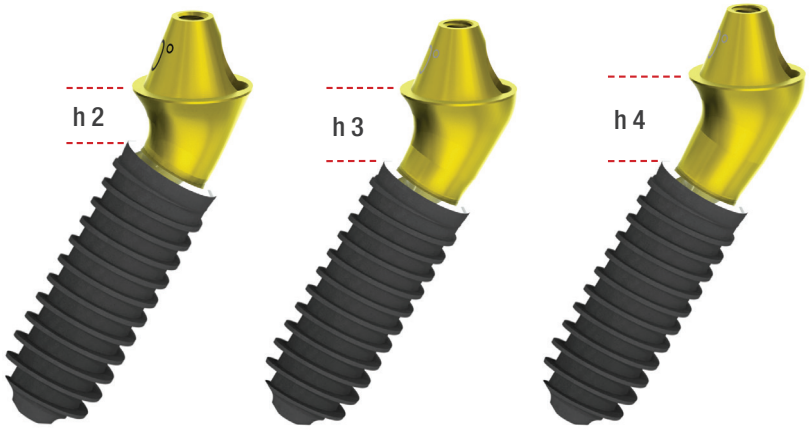
The FAST restoration range has been designed to simplify the construction of immediate loading full threaded prostheses, parallelizing implants with significant divergences (a usual condition in the distal region) in complex restoration projects, such as treatment of toothless patients. The immediate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

Ø Implants	Ø 3.8	Ø 4.2	Ø 4.6	Ø 5	Ø 5.5
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

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

0803300

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).**

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

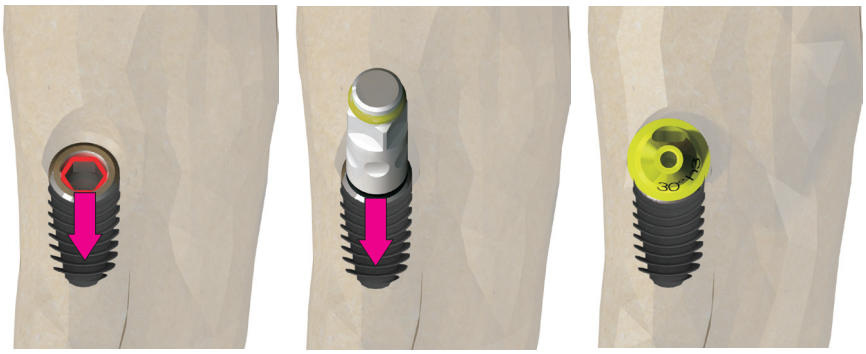
FAST HEALING CAP

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

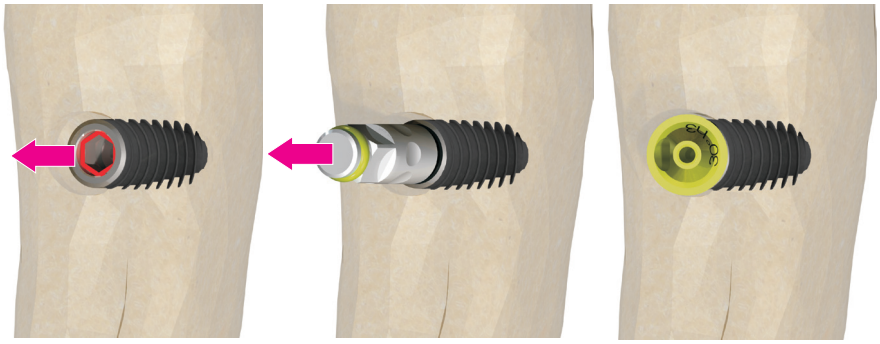
0806300

IMPLANT POSITIONING

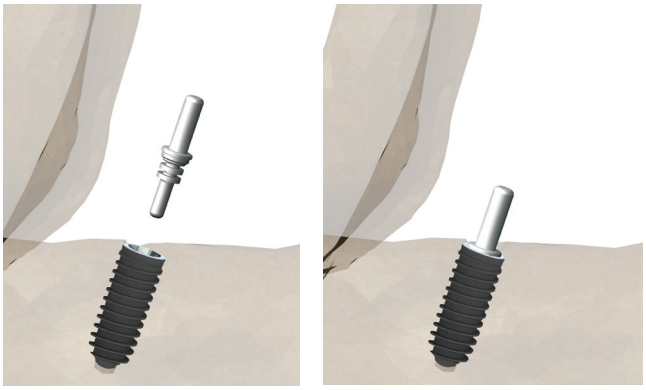
Total rehabilitation of toothless patients through an Immediate Loading Threaded Implant, a removable screw-on prosthesis, is normally carried out on at least 6 fixtures with an implant insertion torque of not less than 35 Ncm. In these rehabilitation cases, it is advisable not to exceed an angulation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



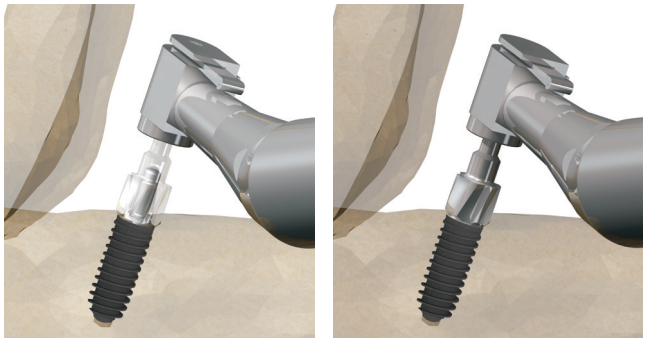
In the case of mesiodistal disparallelism (or vice versa), the implant shall be positioned leaving one side of the internal hex in mesial or distal direction - using the six oval indents on the Drivers corresponding to the six sides of the hex - to optimise recovery of the implant axis through the 17°/30°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

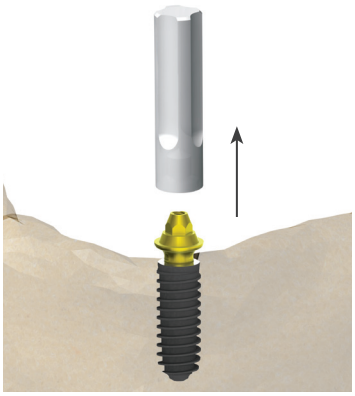


Before inserting the FAST 17°-30° Angled Bases in the implants, use the FAST Countersink Bur over the head of the implants. To protect the implant head while passing with the Bur, use the Guide for FAST Countersink inserting it in the implant.



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.

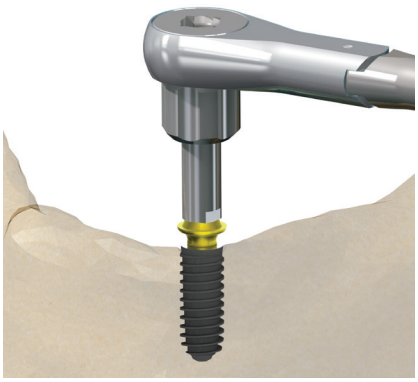
FAST 0° BASES



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.

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



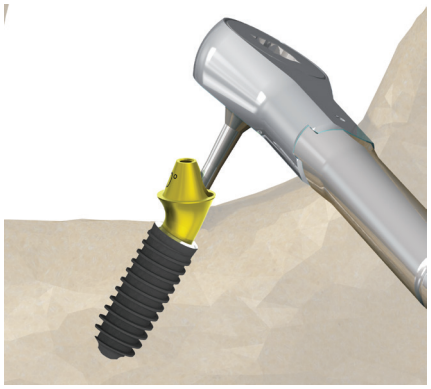
Finally tighten using the torque ratchet adjusted to 30 Ncm on the wrench square.

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.

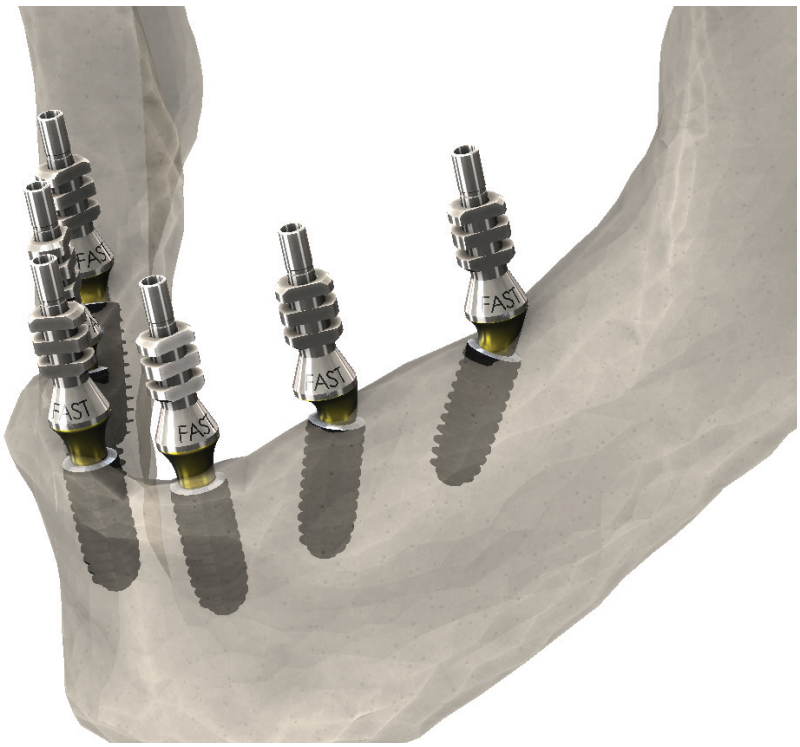
Manually screw in the Fastening Screw of the FAST 17° or 30° Base using the Hex Screwdriver, or mechanically using the Contra-angle Hex Screwdriver (max. 30 Ncm).



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.

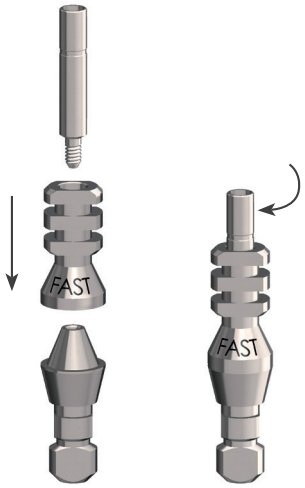
After inserting all the FAST Bases (straight and angled), it is advisable to take an intraoral X-ray to check that the implants and the FAST Bases are correctly coupled.

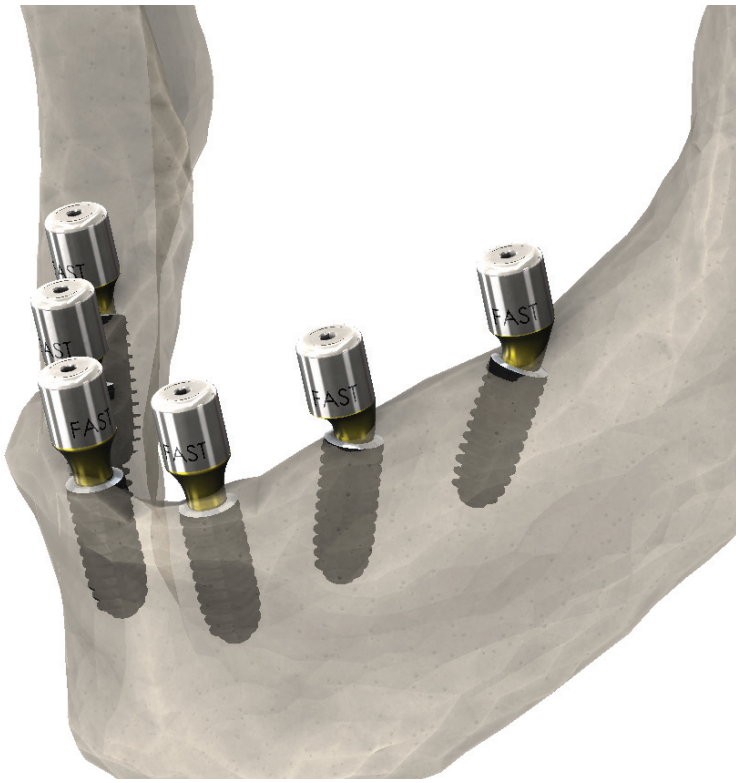
At this point, you can proceed with impression taking using the FAST Precision Impression Transfers.



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.

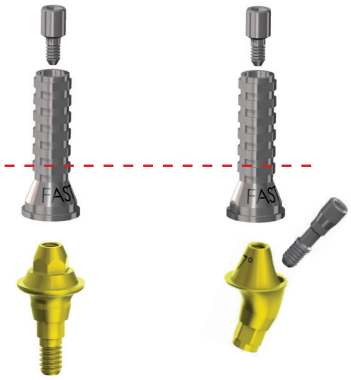


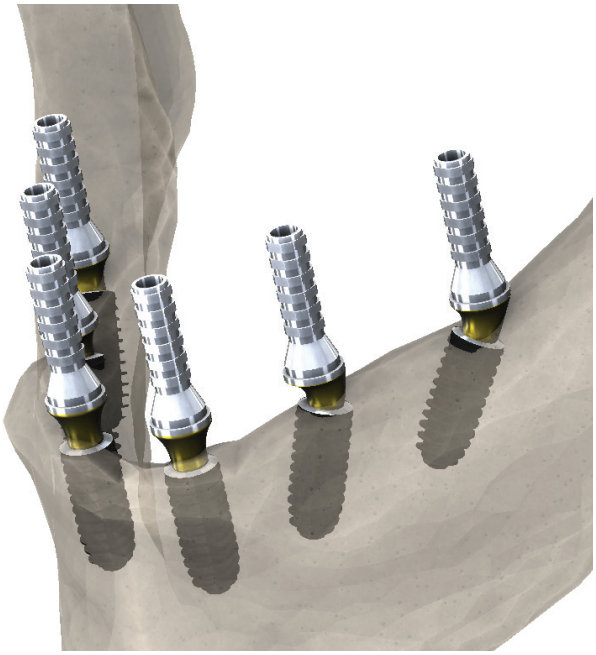


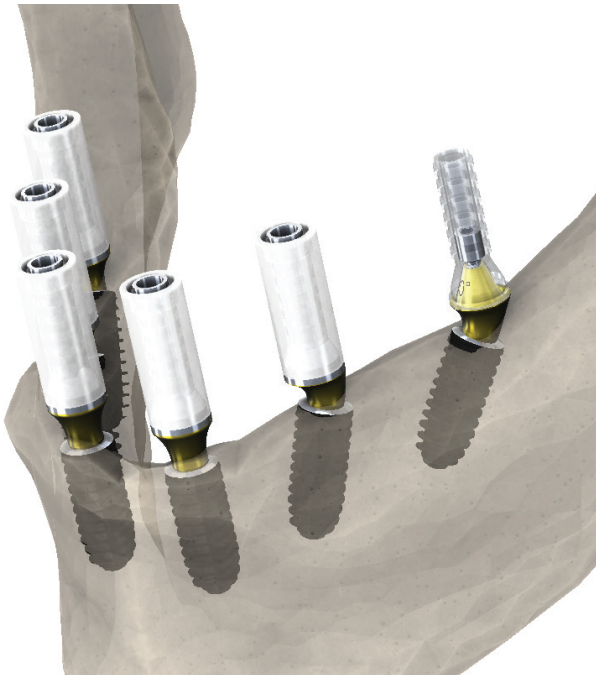
During the temporary laboratory phases, the FAST Healing Caps can be placed to consolidate the soft tissues.

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 FAST Temporary 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).

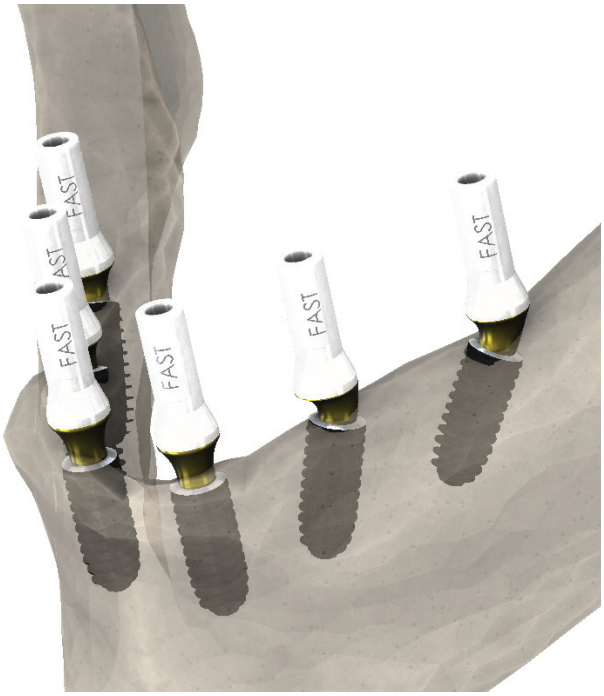






To construct the final prosthesis through passivation, use the FAST Castable Temporary Abutments connected to the FAST Temporary Abutment for the construction and gluing of the final device.
Do not exceed a torque of 20 Ncm to tighten the final prosthesis.

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.



	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).

long 2410062 | medium 2410061 | short 2410060

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).

2410070 | long 2410072

PREMILLED SCREWDRIVER

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

2410065

TORQUE 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

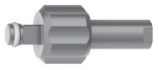
HEX BIT FOR RATCHET

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

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 Ratchet (final tightening).



0510019

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.

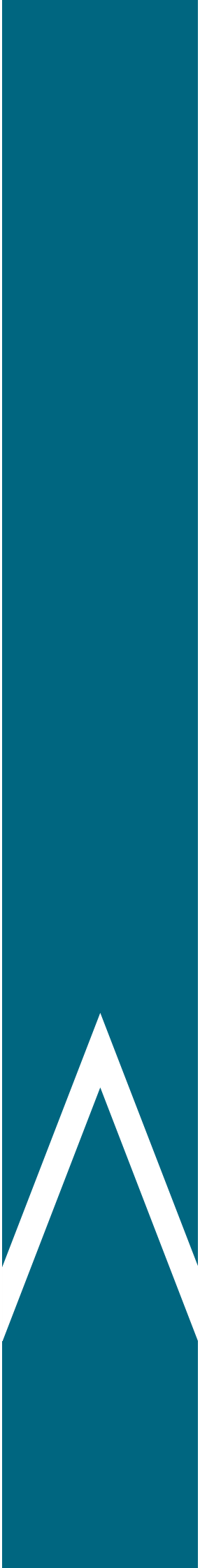
The screws for the following items must be tightened with the Hex Screwdriver only:

- Castable Abutments.
- Rod Abutments.
- Scanmarker.

FASTENING SCREWS

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

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



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