



# **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 RANGE implants (with the exception of PRIME CONOMET implants, for which Clinical Protocol CL 010 should be consulted): it must not, however, be considered a substitute for the practitioner's professional experience and training. 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 SM, PRIME SM FREE and PRIME SM COLLAR implants are referred to in the Information for the User as **PRIME IMPLANTS**; PRIME TWINNER SM and TWINNER SM COLLAR are referred to as **TWINNER IMPLANTS** and PRIME CONOMET TS implants are referred to as **TWINNER IMPLANTS** and PRIME CONOMET TS implants are referred to as **CONOMET IMPLANTS**. PRIME SM and PRIME SM FREE implants are physically identical but packaged differently; when no mention is made of the packaging, the term PRIME is used to refer to both types.

In this Clinical Protocol, when mention is made of "PRIME" implants without referring to their packaging, neck or surface treatment, the term refers to the overall implant morphology and, therefore, to PRIME SM, PRIME SM FREE and PRIME SM COLLAR implants.

In this Clinical Protocol, when mention is made of "TWINNER" implants without referring to their packaging, neck or surface treatment, the term refers to the overall implant morphology and, therefore, to PRIME TWINNER SM and TWINNER SM COLLAR implants.

The symbol SM is used to identify those devices with a SM connection: it is present in the name of the implants with this kind of connection and in all the devices to be used with them, which, where possible, are also marked. The symbol is also included in certain Surgical Instruments that were initially intended exclusively for implants with SM connections, but that can also be used for CONOMET implants. It 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.I. Via Pitagora, 9 - 20016 Pero (MI) - Italy www.prodentitalia.eu

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### **GENERAL CHARACTERISTICS**

The PRIME 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 various types of PRIME 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.

They are available in two morphologies (PRIME and TWINNER), both in three different versions.

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



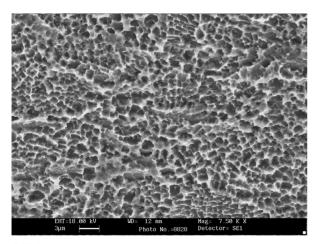
The **PRIME** implants with "root-form" design are available in the following versions:

- **PRIME**: **MPS** treatment on the entire implant body and fully microthreaded collar, combined with the main spiral, to always provide optimal primary stability in the cortical area.
- **PRIME COLLAR:** MPS treatment on the entire implant body, except the first section of the collar, which is provided with a 1.2 mm smooth and machined area without micro-thread. The remaining section of the collar has a micro-thread combined with the main spiral.

**TWINNER** implants with cylindrical design, double spiral pitch and conical apex are available in the following versions:

- **PRIME TWINNER**: **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.
- **TWINNER COLLAR:** MPS treatment on the entire implant body, except the first section of the collar, which is provided with a 1.2 mm smooth and machined area without micro-thread. The remaining section of the collar has a micro-thread combined with the main spiral.





### **MPS Micro Profile Surface**

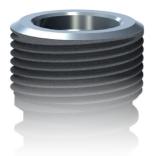
(Double Acid-Etched)

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.

SEM 7.500x

### **GENERAL CHARACTERISTICS**



4 5

The PRIME and PRIME TWINNER 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.



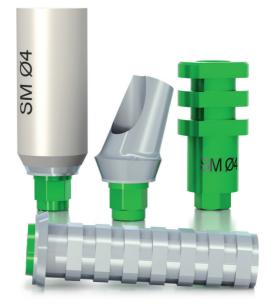
PRIME COLLAR and TWINNER COLLAR implants are mainly suitable in those cases where the practitioner believes, based on his evaluation of the clinical case, that the implant collar will protrude with respect to the bone crest.



SM Ø4

The PRIME RANGE implants are made with a deep internal engaging cylindrical-hex-cylindrical connection that optimises the distribution of the masticatory loads. 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 the PRIME RANGE implants creates a platform switching condition that optimises preservation of the gingival tissues and reduces bone resorption events.

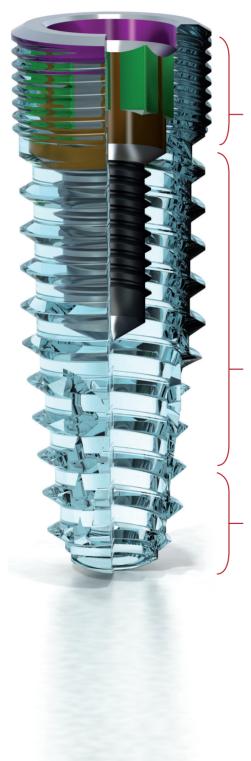
The PRIME RANGE implant restoration range has been designed and developed to allow practitioners to construct all types of modern prostheses, both in terms of aesthetics and immediate-loading.



### **GENERAL CHARACTERISTICS**

# PRIME

# **PRIME**COLLAR



1.2 mm smooth area, without micro-thread and machined.

**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.

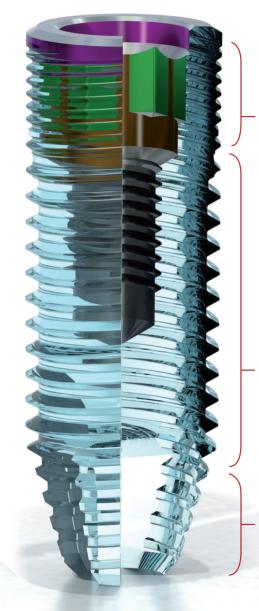
**Root-form** morphology, characterised by a first cylindrical section and a second more apical/conical section; this will allow you to always get a reliable grip even if the bone quality is poor.

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



# PRIME**TWINNER**

# **TWINNER**COLLAR

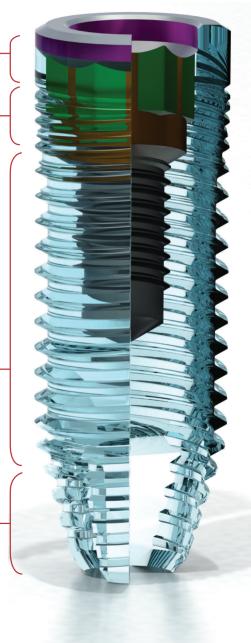


1.2 mm smooth area, without micro-thread and machined.

Quadruple 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.

**Tapered** morphology characterised by a cylindrical body and a conical apex; the main pitch of the **doublethreaded** implant body allows a faster insertion when screwing the implant into the surgical site.

**Flat-bottomed tapered apex** that provides an excellent grip and helps to facilitate the insertion of the implant into the surgical site.



### **RESTORATION CONNECTION - PLATFORM SWITCHING**

**SM** is the restoration connection for the PRIME RANGE implants characterised by an internal hex that assures engagement of the structures. It is positioned underneath a cylindrical-shaped part that prevents transverse and flexural stresses, thus hindering them from overloading the hex or the Connection Screw. Where the restoration components allow it, an additional cylindrical part is provided, which is positioned further down underneath the hex, aimed at further stabilizing the main prosthetic loading stresses.

The **connection diameter** varies in relation to the implant diameter and defines the restoration range of the implant identified by colour code.

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

The **colour coding** dramatically simplifies the identification of the surgical devices and the secondary components, in relation to the implant to be inserted and naturally prosthesized.

The device **marking** and **colour-code** (where applicable) identify the size and the relative restoration range. For details, please refer to the pages describing the operating procedures of each device.

The **devices** (cutting instruments, surgical instruments, restoration components and accessories) dedicated to the SM connection are marked **SM** to identify and distinguish them from the devices of other Prodent Italia's implant ranges.

All the devices are moreover identified by labels bearing the code, batch number, device characteristics and other pertinent indications by means of standard symbols.

RESTORATION RANGE	RESTORATION RANGE	RESTORATION RANGE	RESTORATION RANGE	RESTORATION RANGE
Ø 3.3	Ø 3.6	Ø 4	Ø 4.5	Ø 5
ORANGE	FUCHSIA	GREEN	YELLOW	BLUE
PRIME Ø 3.3 TWINNER Ø 3.5	PRIME Ø 3.8 - 4.2 TWINNER Ø 4	PRIME Ø 4.6 TWINNER Ø 4.5	PRIME Ø 5.1 TWINNER Ø 5	<b>PRIME Ø 5.9</b>

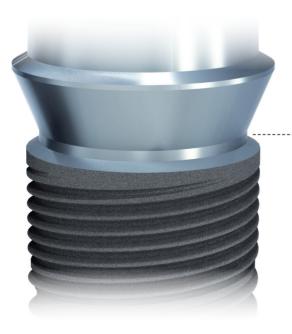


### **RESTORATION CONNECTION - PLATFORM SWITCHING**

All implants are provided with "Platform Switching" system - with the exception of the 3.3 diameter ones - which assures that the gingival tissues and consequently the crestal bone level are maintained.

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 maintaining the crestal bone level.





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

### **PRIME IMPLANTS RANGE**

The **PRIME** and **PRIME FREE** implants provide the same implant morphology, although the pack includes different components:

- **PRIME**: provided with Cover Screw and Straight Abutment (code with letters MF);
- PRIME FREE: provided with Cover Screw (code with letter F).

They are available in six diameters and five heights for the most used diameters ( $\emptyset$  3.8 to  $\emptyset$  5.1).

The small 3.3 diameter is available in three heights, while the larger 5.9 diameter is available in four heights.





### **PRIME** IMPLANTS

### PRIME

### **PRIME**FREE

The pack contains a Straight Abutment ht 1.5 - hc 8

			implant height	codes	Abutment codes	codes		
Ø 3.3			h 10 h 11.5 h 13	0801351MF 0801352MF 0801353MF	0805190 0805190 0805190	0801351F 0801352F 0801353F		
	restoration range Ø 3.3	Ø1.7	1115	000100000	0003190	00015551		
		<sup>1</sup> Ø2.6 <sup>1</sup>	• • • •					
Ø 3.8			h 8.5	0801300MF	0805204	0801300F		
0.0	restoration range		h 10 h 11.5	0801301MF 0801302MF	0805204 0805204	0801301F 0801302F		
	Ø 3.6	Ø1.8	h 13 h 15	0801303MF 0801304MF	0805204 0805204	0801303F 0801304F		
		Ø2.8	0 0 0 0 					
<i>G</i> 4 0			h 8.5	0801310MF	0805204	0801310F		
Ø 4.2	restoration range		h 10 h 11.5	0801311MF 0801312MF	0805204 0805204	0801311F 0801312F		
	Ø 3.6	<b>6</b> 2	h 13 h 15	0801313MF 0801314MF	0805204 0805204	0801313F 0801314F		
		Ø2 Ø3				• • • •		
<b>~</b> 4 0			h 8.5	0801320MF	0805214	0801320F		
Ø 4.6	restoration range		h 10 h 11.5	0801321MF 0801322MF	0805214 0805214	0801321F 0801322F		
	Ø 4	ŧ	h 13 h 15	0801323MF 0801324MF	0805214 0805214	0801323F 0801324F		
		Ø2.1 Ø3.2	• • •					
~			h 8.5	0801330MF	0805224	0801330F		
Ø 5.1	restoration range		h 10 h 11.5	0801331MF 0801332MF	0805224 0805224 0805224	0801331F 0801332F		
	Ø 4.5	ŧ	h 13 h 15	0801333MF 0801334MF	0805224 0805224	0801333F 0801334F		
		Ø2.5 Ø3.5	- - - - - - - -					
			695		0005004	00010405		
Ø 5.9			h 8.5 h 10 h 11.5	0801340MF 0801341MF 0801342MF	0805234 0805234 0805234	0801340F 0801341F 0801342F		
	restoration range Ø 5	E	h 13	0801343MF	0805234	0801343F		
		Ø3.4 Ø4.4	•					

### PRIME IMPLANTS RANGE

The **PRIME COLLAR** implants are available in six diameters and five heights for the most used diameters (Ø 3.8 to Ø 5.1). The small 3.3 diameter is available in three heights, while the larger 5.9 diameter is available in four heights. They come all equipped with the related Cover Screw.



### **PRIME** IMPLANTS

### **PRIME**COLLAR

		implant height	codes
Ø 3.3	restoration range Ø 3.3	h 10 h 11.5 h 13	0801551 0801553 0801555
Ø 3.8	restoration range Ø 3.6	h 8.5 h 10 h 11.5 h 13 h 15	0801501 0801503 0801505 0801507 0801509
Ø 4.2	restoration range Ø 3.6	h 8.5 h 10 h 11.5 h 13 h 15	0801511 0801513 0801515 0801517 0801519
Ø 4.6	restoration range Ø 4	h 8.5 h 10 h 11.5 h 13 h 15	0801521 0801523 0801525 0801527 0801529
Ø 5.1	restoration range Ø 4.5	h 8.5 h 10 h 11.5 h 13 h 15	0801531 0801533 0801535 0801537 0801539
Ø 5.9	restoration range Ø 5	h 8.5 h 10 h 11.5 h 13	0801541 0801543 0801545 0801547

### **TWINNER IMPLANTS RANGE**

The **PRIME TWINNER** implants are available in four diameters and five heights for each diameter. They come all equipped with the related Cover Screw.



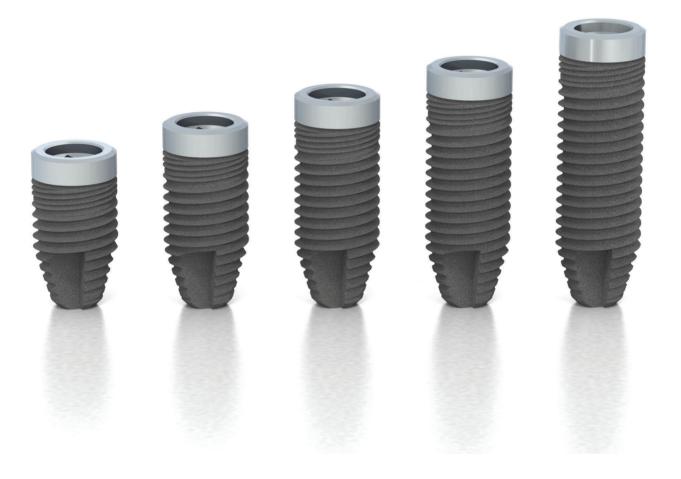
# PRIME**TWINNER** IMPLANTS

### PRIME**TWINNER**



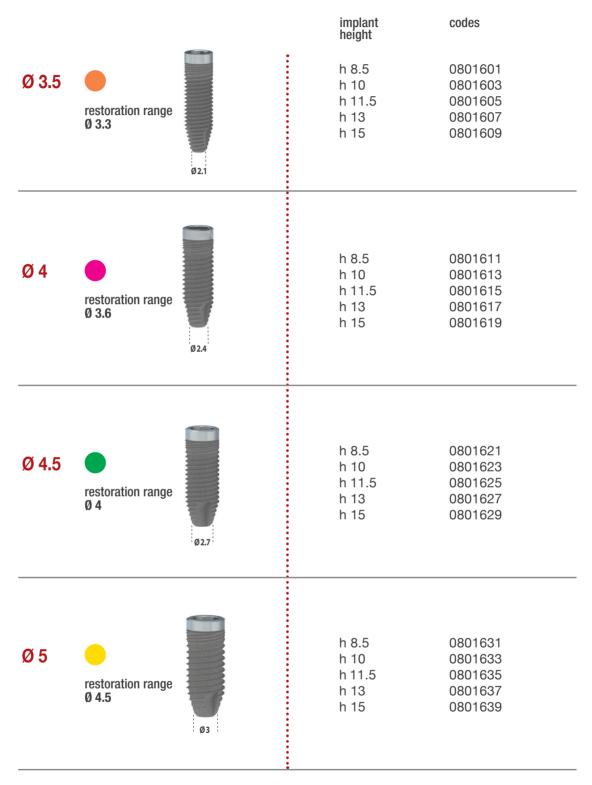
### **TWINNER IMPLANTS RANGE**

The **TWINNER COLLAR** implants are available in four diameters and five heights for each diameter. They come all equipped with the related Cover Screw.



### TWINNER IMPLANTS

### **TWINNER**COLLAR



#### PACK AND STERILITY

The PRIME RANGE implants are delivered in a sterile plastic ampoule, housed on a ring in pure titanium and, in the case of the TWINNER implants, they are placed on a pure titanium disc. The Cover Screw is fitted into the cap which closes the implant housing. The Straight Abutment, for the applicable packaging and as described below, is fitted into the cap on the opposite side of the Cover Screw. Use the Screwdriver to unscrew it.

They are available in the following packs:

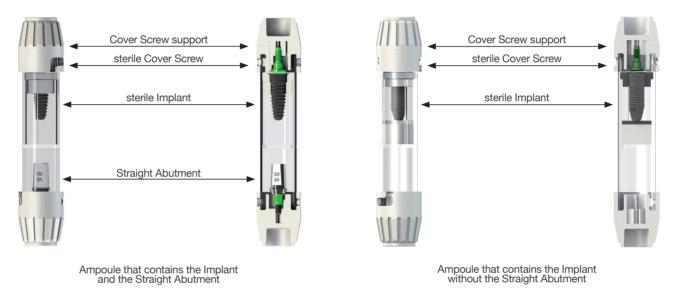
- **PRIME**: Implant + Cover Screw + Straight Abutment.

- PRIME FREE, PRIME COLLAR, PRIME TWINNER, TWINNER COLLAR: Implant + Cover Screw.

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.



#### DOCUMENTATION AND IMPLANT IDENTIFICATION

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

The implant and the prosthetic component 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 (prosthetic 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 pack, filling in all the required data and applying the peel-off labels in the spaces provided.

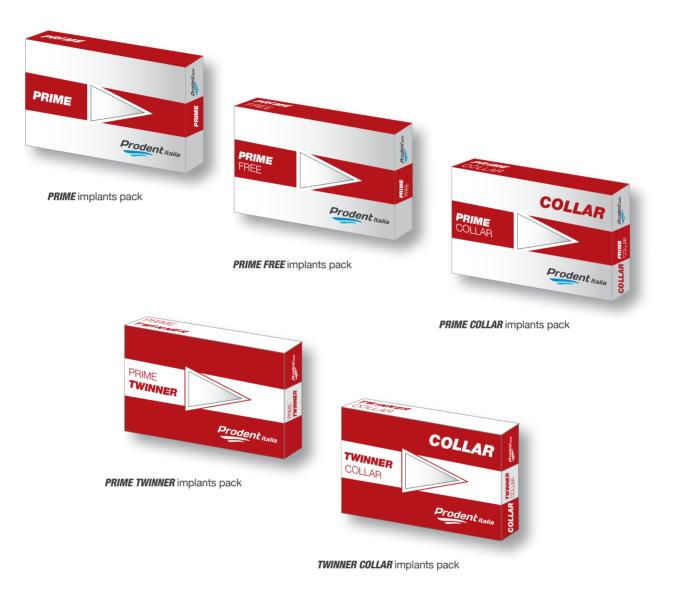
The Card should then be handed to the patient providing him or her with all the instructions to follow after the operation.

Nome Implantologo	passion. care.		
	love. experience.	Nome Implantologo	passion. care.
	<b>Prodent</b> Italia		love. experience.
Timbro Studio Dentistico IC 004-0 2023-03-27 ITA	Tessera per il Portatore di Impianto Modello Impianto Dentale Macle with	Timbro Studio Dentistico IC 005-0 2023-03-27 ITA	Tessera per il Portatore di Impianto Modello Componente Protesica
Paziente	Gentile Paziente,		Made with
Elichetta Impianto Dentale Posizione Impianto Dentale Data inserimento Impianto Dentale	conservi con cura la presente Tessera che consente di identificare il dispositivo che le stato impiantato. Le raccomandiamo di prendere visione e di attenersi alle relative avvertenze e precazioni utilizzando il QR Code di seguito riportato oppure accedendo all'Area Pazienti del nostro sito internet al seguente indirizzo:	Paziente Elichetta Componente Protesica Posizione Componente Protesica	Gentile Paziente, conservi con cura la presente Tessera che consente di identificare il dispositivo che le è stato impiantato. Le raccomandiamo di predere visione e di attenera alle relative avvertenze e precauzioni utilizzando il OR Code di seguito riportato oppure accedendo all'Area Pazienti del nostro sito internet al seguente indirizzo:
		Data inserimento Componente Protesica	Via Pitagora 9 - 20016 (MI) Italy

Implant Card - Dental Implant Model

Implant Card - Prosthetic Component Model

Each implant in the PRIME RANGE is packed in a specific box, which allows the type of implant contained to be easily and immediately identified.



#### STORING AND HANDLING THE PACK

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

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

### SURGICAL PLANNING

Before surgery, it is of fundamental importance to perform a careful preoperative anamnesis of the patient in order to verify the suitability of the implantation treatment. After excluding any contraindication to the implant-restoration treatment (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 RANGE implants perform best. By "discretionary position" we mean a position selected by the practitioner only after careful evaluation of the implant size in relation to the prosthetic load.

colour code Ø Restoration range	Ø	3.3	Ø 3.6		04 04.5		Ø 5			
	PRIME	TWINNER	PRIME	TWINNER	PRIME	TWINNER	PRIME	TWINNER	PRIME	PRIME
Ø Implants	Ø 3.3	Ø 3.5	Ø 3.8	Ø 4	Ø 4.2	Ø 4.5	Ø 4.6	Ø 5	Ø 5.1	Ø 5.9
UPPER mssing parts	•			· · · · ·				,		
CENTRAL INCISORS										$\land$
LATERAL INCISORS	(							$\land$		
CANINES										$\land$
PREMOLARS										
MOLARS										
LOWER mssing parts										
CENTRAL INCISORS	(						<u>\</u>			
LATERAL INCISORS	(						<u>\</u>			
CANINES										$\land$
PREMOLARS										$\land$

If used in DISCRETIONARY position, do not prosthesize  $\emptyset$  4 TWINNER and  $\emptyset$  4.2 PRIME 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".

### **PRIME SURGICAL TRAY**

There are two different Surgical Trays available, which are easy to distinguish since they have printed - both on their cover and on their inside - the name of the type of implant they are intended for: PRIME or TWINNER.

Depending on the type of implant chosen, the relative 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 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.





TWINNER Surgical Tray 0810901

### 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.

 $\emptyset$  4.3 and  $\emptyset$  5.5 Tissue Punches create a hole with a diameter 3.3 and 4 respectively. The diameter marked on the device refers to its maximum outer dimensions. 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 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.



#### DEPTH MARKER READING Ø2.2 OF DEPTH GAUGE 0810100 AND OF GUIDE PIN Ø 2.2 DEPTH GAUGE/ GUIDE PIN 15 To be used after the Slim Pilot Bur passage, to assess the depth of the 13 11.5 Ш surgical site also radiographically. In the event that two or more implants 10 Ш are inserted, the pin can be used as reference for parallelism. 8.5 Ø 2.2 DEPTH GAUGE 15 0810102 13 This instrument allows you to assess the depth of the surgical site 11.510 created by means of the Slim Pilot Bur. 8 6 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 0510059 Contra-angle without exceeding a torque of 45 Ncm. . . . . . . . . . . . **DIGITAL WRENCH** To be used connected to the Screw Taps in order to start tapping the

surgical site and connected to the Manual Drivers 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 screwing and unscrewing all Screw types. Available with three different lengths, they allow comfortable use, even with customised restorations.



2410062

0510062

0510060

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.

#### **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.

#### **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.



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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  $(0^{\circ})$  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.



### **BURS AND DRILL STOPS**

All the PRIME RANGE implants share the Corticotomy Bur and Slim Pilot Bur with relative Drill Stops. Based on the type of implant to be inserted, specific intermediate and final burs are provided: Tapered for PRIME, Cylindrical and Countersink for TWINNER.

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 and Cylindrical Drills** 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 Burs for Compact Bone allow you to adapt to the surgical site to avoid excessive torques during the implant insertion in case of compact bone, keeping it suitable for the stability of the implants.

The Countersink Burs allow you to correctly obtain the exact dimension of the neck of TWINNER implants in the cortical bone.

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.

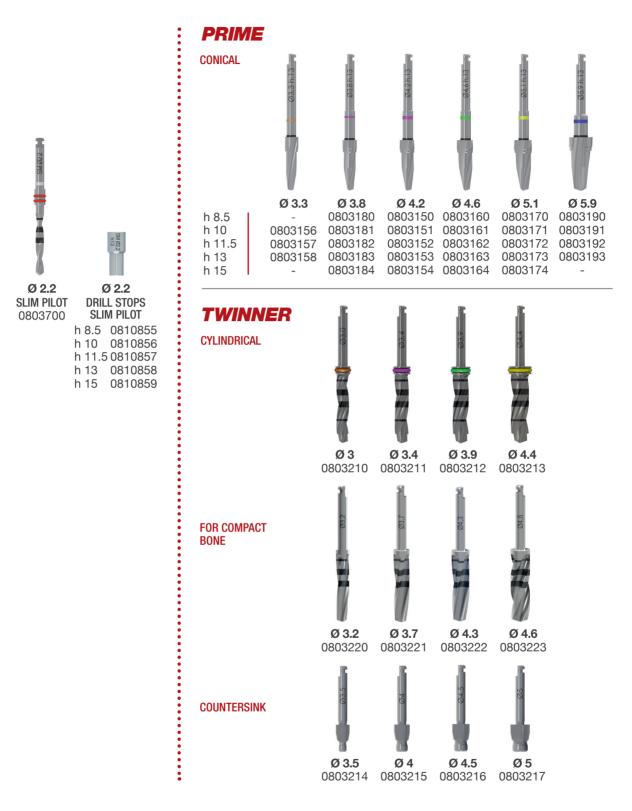
The colour of the **o-rings** of the Cylindrical Bone Drills is important only when used as final bur. In this case, it follows the PRIME RANGE colour coding. The red double O-ring of the Slim Pilot Bur is only intended to assure a proper coupling of the Bur to the relative Drill Stops.

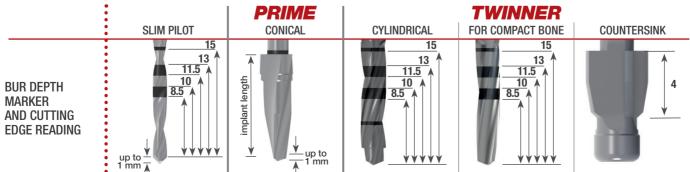
For the exact sequence of the burs to be used according to the implant to be inserted, please consult the "Surgical sequence" section.



### **BURS AND DRILL STOPS**







Ø 2

CORTICOTOMY

1003001

### **INDICATORS AND SCREW TAPS**

According to the type of implant to be inserted - PRIME or TWINNER – and to the relative implant sizes, there are specific Screw Taps and Neck Diameter Indicators available. All the devices are marked with the diameter corresponding to the implant they are intended for. All the Neck Diameter Indicators are also marked with the relative item code. Moreover, the Neck Diameter Indicators for PRIME are colour coded. All Screw Taps bear specific depth markers.

#### 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**

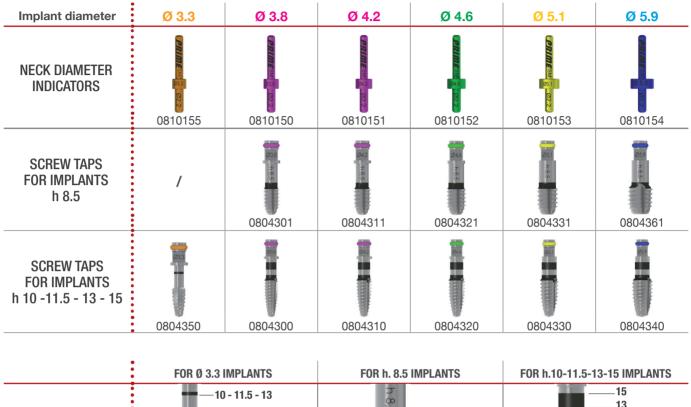
In the event of compact bones - after producing the surgical site, using the burs - the Screw Taps allow you to screw the bone, reducing the implants insertion torque. It is possible to screw manually the tap with the Digital Wrench and/or with the Torque Wrench. If you proceed mechanically, use the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

The Screw Taps for TWINNER implants must only be used in the cases indicated in the dedicated table at the end of the "TWINNER Surgical Sequence" of the Clinical Protocol.



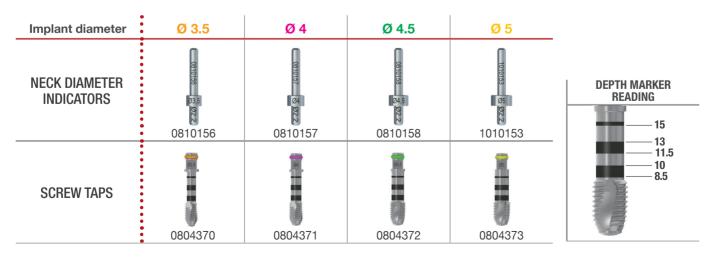
### **IINDICATORS AND SCREW TAPS**

PRIME





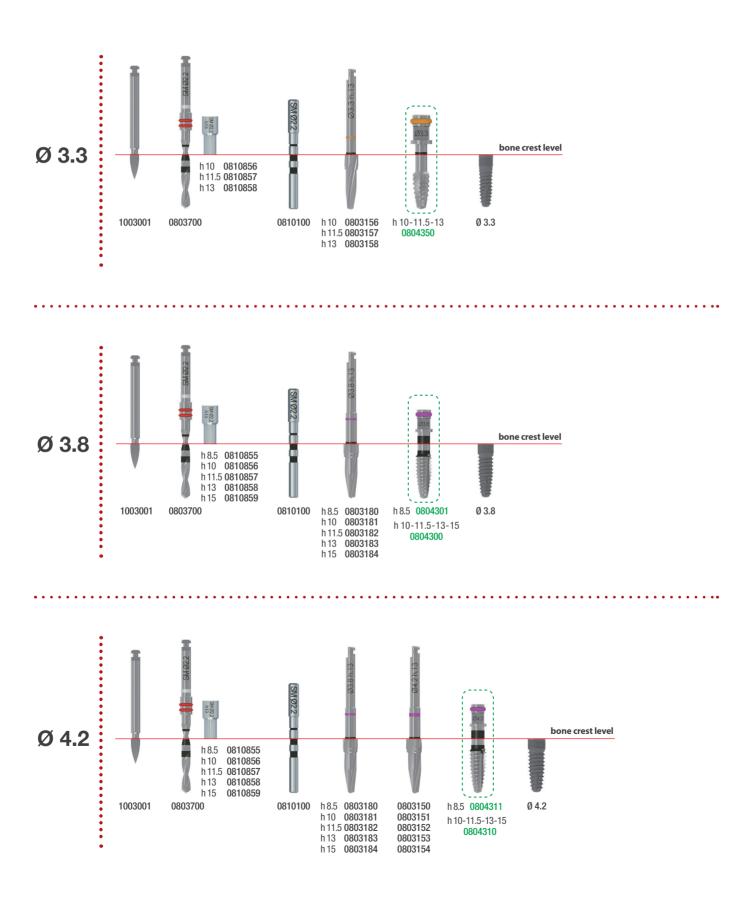
# TWINNER



### **PRIME** IMPLANTS SURGICAL SEQUENCE

#### SEQUENCE BASED ON IMPLANT DIAMETER AND HEIGHT

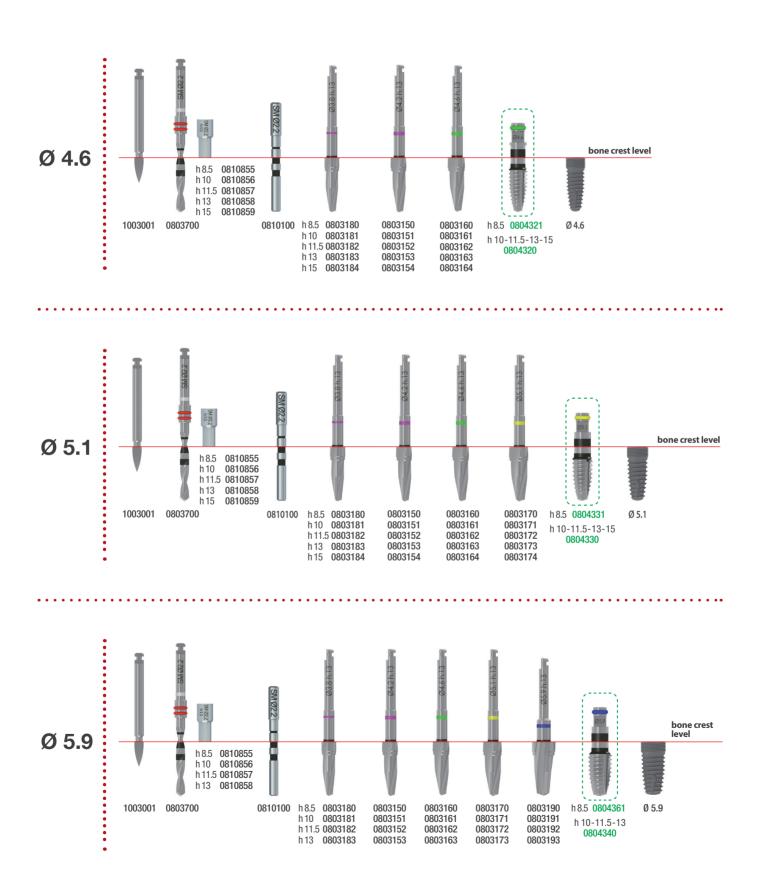
The devices with green code (in the dotted box) are optional and they must be used only in a compact bone.



### **PRIME** IMPLANTS SURGICAL SEQUENCE

#### SEQUENCE BASED ON IMPLANT DIAMETER AND HEIGHT

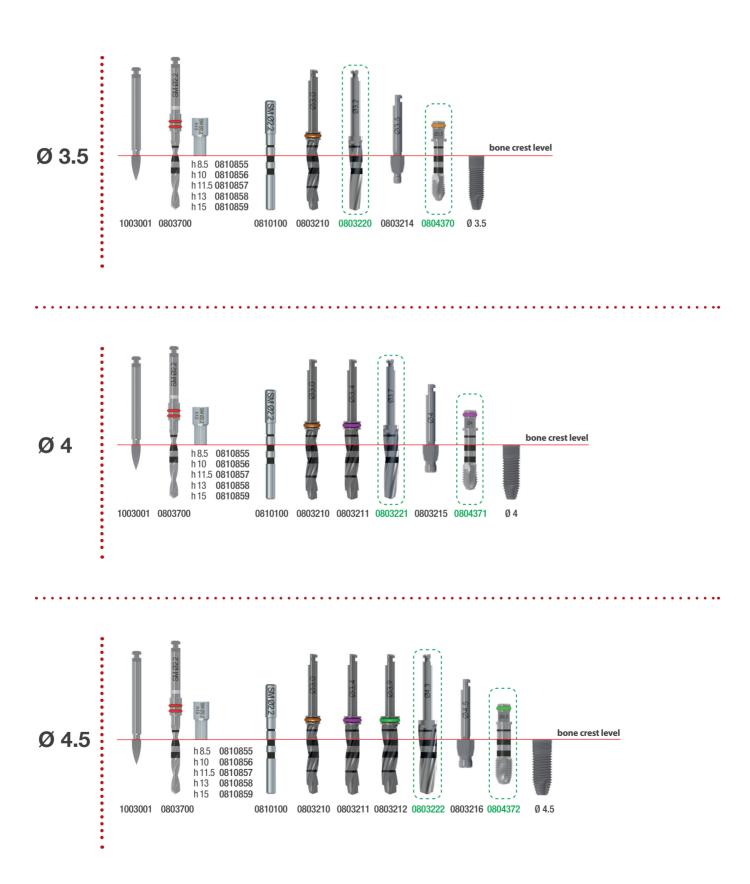
The devices with green code (in the dotted box) are optional and they must be used only in a compact bone.



### **TWINNER** IMPLANTS SURGICAL SEQUENCE

#### SEQUENCE BASED ON IMPLANT DIAMETER AND HEIGHT

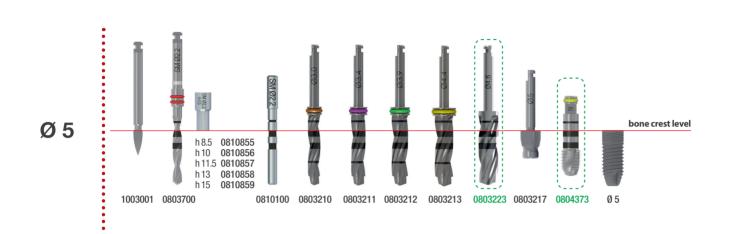
The devices with green code (in the dotted box) are optional and they must be used only in a compact bone.



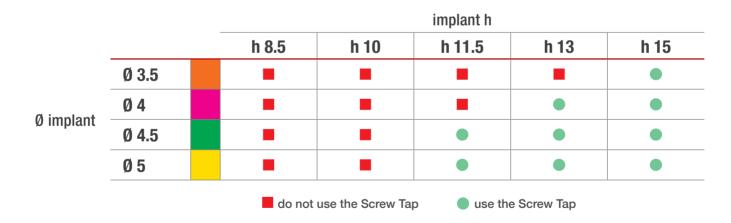
### **TWINNER** IMPLANTS SURGICAL SEQUENCE

#### 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.



The practitioner shall be responsible for evaluating the quality of the receiving bone and choose whether using the devices for compact bone. In the **Surgical Sequence for Compact Bone, the Bur for Compact Bone must always be used, while the Screw Tap must be used only for the diameters and heights indicated in the following table:** 



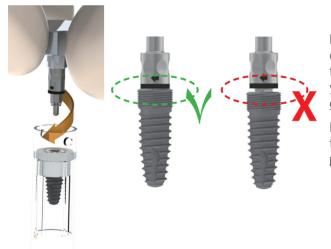
#### MANUAL DRIVERS

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

#### **CONTRA-ANGLE DRIVERS**

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

Restoration Range	Ø 3.3	Ø 3.6	Ø 4	Ø 4.5	Ø 5
MANUAL DRIVERS	0810170	0810171	0810172	0810173	0810174
CONTRA-ANGLE DRIVERS	0810175	0810176	0810177	0810178	0810179



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.

#### **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 Torgue 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.

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

### 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.

## **HEALING SCREWS**

### **HEALING SCREWS**

Intended to be screwed directly into the connection of the implant to which they are dedicated. The Healing Screws allows you to condition the soft tissues healing until the subsequent assembly of the final component and the final prosthetic handwork. The tapered design responds to the practitioner need to condition the mucous membrane with tapered morphology.

The cylindrical design responds to the practitioner need to condition the mucous membrane with cylindrical morphology and in case there is little space between the nearby or converged implants or between tooth and implant.

The marking on the Screw head allows the devices to be identified by means of the Restoration Range diameter and the transmucosal height (ht).

Restoration Range		Ø 3.3	Ø 3.6	Ø 4	Ø 4.5	Ø 5
	ht 2	0806148	0806150	0806153	0806156	0806159
TAPERED HEALING SCREWS	ht 4	0806149	0806151	0806154	0806157	0806160
	ht 6	/	0806152	0806155	0806158	0806161
CYLINDRICAL	ht 4	0806205	0806200	0806201	0806202	0806203
HEALING SCREWS	ht 6	0806210	0806206	0806207	0806208	0806209

Based on the soft tissue conditioning carried out with the cylindrical or tapered Healing Screw, it is recommended to sequentially use devices with the same configuration both for impression taking and for the subsequent prosthesization, so that there are no dimensional interferences that might irritate the soft tissues surrounding the implants.



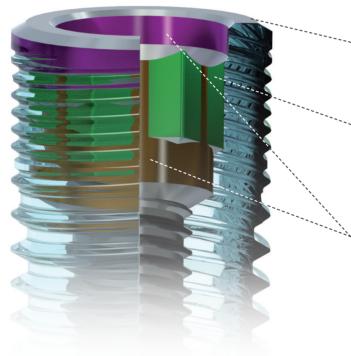
## **PROSTHETIC PLATFORMS**

The PRIME RANGE implants share the same **SM** implant-restoration connection, which in the secondary components is identifiable by the laser marking and colour code pertaining to the **restoration range**: this dramatically simplifies the identification of the secondary components to be used in relation to the implant inserted. Where possible, the symbol SM is marked.

Different restoration solutions are available: as well as the classic preformed components, you can choose other solutions, such as Multi Abutments, Link Bases, Equator and the FAST range dedicated to Immediate Loading Threaded Implants.

The connection diameter varies in relation to the implant diameter and defines the reference **restoration range**.

	PRIME	TWINNER	PRIME	TWINNER	PRIME	TWINNER	PRIME	TWINNER	PRIME	PRIME
	Ø 3.3	Ø 3.5	Ø 3.8	Ø 4	Ø 4.2	Ø 4.5	Ø 4.6	Ø 5	Ø 5.1	Ø 5.9
	Ø	TION RANGE 3.3 ANGE		TORATION RA Ø 3.6 FUCHSIA		RESTORATIO	4	RESTORATIO Ø4 Yell	.5	RESTORATION RANGE Ø 5 BLU
HEX	2	.2	2.4		2.5		2.7		3	
SCREW	1	.6		1.8		1.8	3	2		2



**Connection surface:** it allows distributing the compressive masticatory load.

**Engaging hex:** 1.6 mm high, it withstands torsional stresses preventing restoration component rotation and micromovements of the interface that contribute to loosening of the through screw.

**Cylindrical surfaces:** they avoid 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 are available in a cylindrical and tapered variant, depending on the conditioning previously selected by means of the Healing Screws.

#### EASYCAP AND TEAR-OFF IMPRESSION TRANSFERS

Designed for use connected to implants with their Screws, they are used to take impressions with an unperforated impression tray by means of tear-off technique for a maximum number of three implants with disparallelism within 8°. Connected to the Easycap, they are suitable for taking dental impressions with a high level of precision. Used without Easycap, they are 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

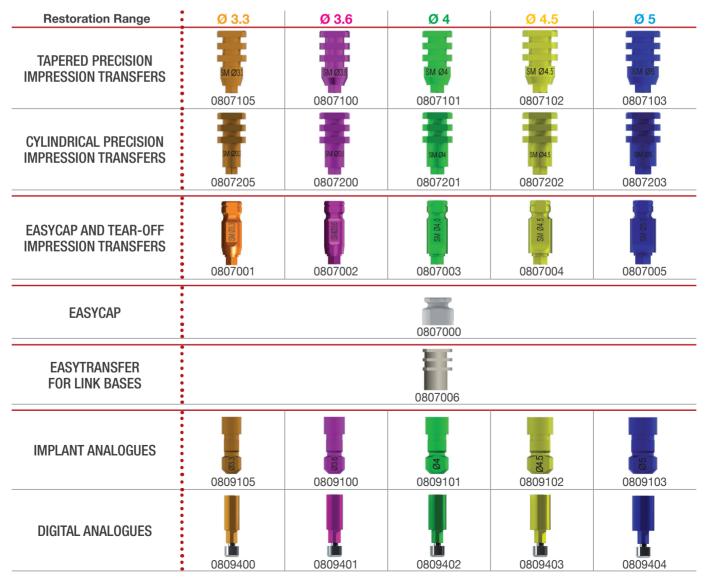
Used to take conventional impressions with unperforated impression tray on single implant. Designed for use connected to Link Base, on which it is to be pressure-fitted.

#### **IMPLANT ANALOGUES**

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

### **DIGITAL ANALOGUES**

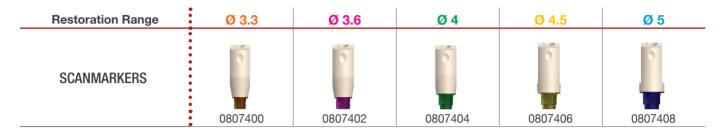
Taking the impression with Scanmarker, they are used to create the prototyped and 3D printed working model on which the dental technician builds the prosthetic handwork.



## SCANMARKERS AND SCANMARKERS FOR LINK BASES

### **SCANMARKERS**

Designed for use connected to implants with their Screws, they are used to record intraoral digital impressions using intraoral dental scanners; they will allow you to acquire the position of the implant connection. They are 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.



### SCANMARKERS FOR LINK BASES

Designed for use connected to Link Bases with their Screws, they are suitable for recording intraoral digital impressions using intraoral dental scanners. Positioned directly on Link Bases and screwed together in the implant, they allow you to acquire the position of the implant connection. They are 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 1.5 they must be screwed using the Screw for Scanmarker Link Base ht 1.5, already provided in the Scanmarker pack (for Ø 3.3 use code 0807413; for Ø 3.6 and Ø 4 use code 0807415 and for Ø 4.5 and 5 use code 0807416), not colour-coded.

Only for  $\emptyset$  3.3,  $\emptyset$  4.5 and 5, if used combined with **Link Bases ht 3**, the Scanmarkers for Link Bases must be screwed using the **Screws for Scanmarker Link Base ht 3** (for  $\emptyset$  3.3 use code 0807414 - orange-coloured; for  $\emptyset$  4.5 and 5 use code 0807417 - yellow-coloured). The Screw, that is contained in the pack of  $\emptyset$  3.6 and  $\emptyset$  4 Scanmarker for Link Bases, can be used with both Link Base ht 1.5 and with Link Base ht 3.

Restoration Range	Ø 3.3	Ø 3.6	Ø 4	Ø 4.5	Ø 5
SCANMARKERS FOR LINK BASES	SM Ø3,3	SM Ø3.6	SM Ø4	SM Ø4,5	SM Ø5
	0807421	0807422	0807423	0807424	0807425

### 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** version with two transmucosal heights (ht) to be chosen according to the restoration planned.

Link bases can be connected either to a Scanmarkers for Link Bases, to be retained using a dedicated screw, in order to take an impression digitally or to a 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.

Restoration Range		Ø 3.3	Ø 3.6	Ø 4	Ø 4.5	Ø 5
LINK BASES	ht 1.5	0805360	0805362	0805364	0805366	0805368
engaging	ht 3	0805361	0805363	0805365	0805367	0805369

## **CONNECT BASES**

### **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.

Restoration Ran	<b>Restoration Range</b>		Ø 3.6	Ø 4	Ø 4.5	Ø 5
CONNECT BASES	ht O	0805856	0805857	0805858	0805859	/
engaging	ht 2	0805880	0805881	0805882	0805883	/
CONNECT BASES	ht 0	0805866	0805867	0805868	0805869	/
non-engaging	ht 2	0805890	0805891	0805892	0805893	/

### **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 ABUTMENTS 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.





## **STRAIGHT ABUTMENTS**

### STRAIGHT ABUTMENTS

Suitable for cemented prostheses on individual implants or bridges. They are available in two different transmucosal heights (ht), to be chosen according to the restoration planned.





## **ANGLED ABUTMENTS**

### 17°- 25° ANGLED ABUTMENTS

Suitable for cemented prostheses on individual implants or bridges in case of disparallelism. They are available in two transmucosal heights (ht), to be chosen according to the restoration planned, in order to correct disparallelisms of up to 17° or 25°, respectively.

Restoration R	lange	Ø 3.3	Ø 3.6	Ø 4	Ø 4.5	Ø 5
17° ANGLED	ht 1.5	0805150	0805100	0805110	0805120	0805130
ABUTMENTS	ht 3	0805151	0805101	0805111	0805121	0805131
25° ANGLED	ht 1.5	/	0805102	0805112	0805122	0805132
25° ANGLED ABUTMENTS	ht 3	/	0805103	0805113	0805123	0805133



## MILLING AND PREMILLED ABUTMENTS

### MILLING ABUTMENTS

Designed to be worked to make customized prosthetic components. They are indicated to make abutments with a maximum angulation of 20°.

Do not use to make prosthetic components with angulation greater than 20°.

Restoration Range	Ø 3.3	Ø 3.6	Ø 4	Ø 4.5	Ø 5
MILLING ABUTMENTS	/	SM Ø3.6	SM Ø4	SM Ø4.5	SM Ø5
		0805250	0805251	0805252	0805253

### 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 Ø 15.8 mm, respectively. Use only the dedicated Premilled Screwdriver to tighten and loose the intact abutment.

Restoration Range	Ø 3.3	Ø 3.6	Ø 4	Ø 4.5	Ø 5
PREMILLED ABUTMENTS Ø 11.5	SM Ø3.3	SM 03.6	SM 64	SM 04,5	SM @5
PREMILLED ABUTMENTS Ø 15.8	0805720	0805721	0805722	0805723	0805724
	0805725	0805726	0805727	0805728	0805729



## CASTABLE ABUTMENTS AND CEMENTABLE CASTABLE ABUTMENTS

### **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.

### CEMENTABLE CASTABLE ABUTMENTS

Suitable for cemented prostheses only in those cases where preformed components cannot be used.

Restoration Range	Ø 3.3	Ø 3.6	Ø 4	Ø 4.5	Ø 5
CASTABLE ABUTMENTS	0805325	0805320	8 8 0805321	97 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	8 8 0805323
CASTABLE ABUTMENTS non-engaging	0805330	ଞ୍ଚ ଞ୍ଚ 0805331	8 W 0805332	97 8 10 10 10 10 10 10 10 10 10 10 10 10 10	ଞ ଞ 0805334
CEMENTABLE CASTABLE ABUTMENTS	020E2EE	980 WS	120005251	08062550	58 X S
	0805355	0805350	0805351	0805352	0805353



## **ROD ABUTMENTS**

### **ROD ABUTMENTS**

Designed to be worked in the castable part to make overdenture bars.

Composed of a titanium base and a customisable coronal section (that can also be ordered as spare part). The bases have a cylindrical-shaped transmucosal section and they are available in two different transmucosal heights (ht). The bases feature an engaging system that connects with the implant and a sloping surface that supports the customised section.

Do not use to make prostheses on individual implants.

<b>Restoration Ra</b>	inge	Ø 3.6	Ø 4	Ø 4.5	Ø 5
	ht 1.5	SM Ø3,6 0805510	SM Ø4 0805512	SM Ø4,5 0805514	0805516
ROD ABUTMENTS	ht 3	SM Ø3,6 0805511	0805513	0805515	0805517
CASTABLE SPARE	PARTS	SM Ø3,6 0805295	SM Ø4 0805296	SM Ø4,5 0805297	SM Ø5 0805298



### **BALL ATTACHMENTS**

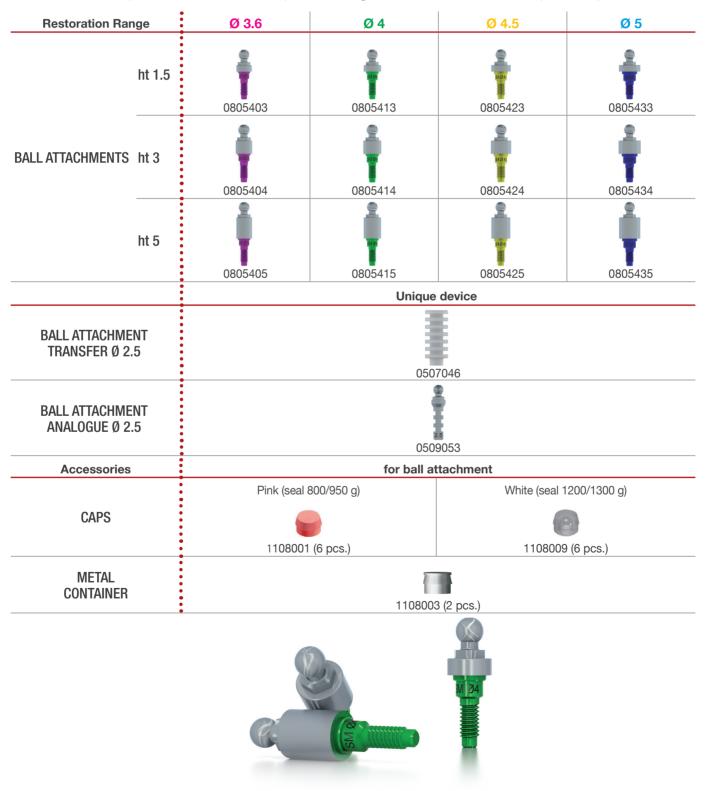
Connected to the relative caps and containers, that are indicated in the table below, the ball attachments are suitable for holding overdenture removable prostheses resting on gums.

They are supplied housed on a peek support that can also be used as Impression Transfer and for placing and first screwing the Ball Attachment in the oral cavity.

The Ball Attachments Transfers allows you to obtain the registration of impressions by means of the unperforated impression tray. When the impression tray is removed from the oral cavity, the device is incorporated into the impression material. In case of little clinical space, the device can be cut to reduce its height. The device must not be cut below the second ring.

Available with a ball diameter of 2.5 mm and in three different transmucosal heights (ht). The metal containers for Caps and retentive Caps, the latter available in two different types and colours depending on the sealing degree, are to be incorporated in the full prosthesis.

Do not use to make prostheses on individual implants or bridges. Do not use in case of non-parallel implants.



## **OT EQUATOR**

### FASTENING SYSTEM FOR OVERDENTURE

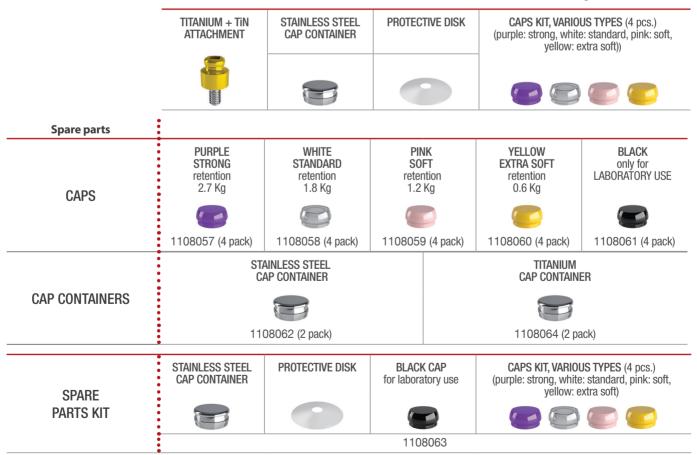
**OT EQUATOR** low-profile removable restoration attachments are available for the main platforms of the PRIME Range and they are amongst the smallest on the market; this system offers a number of options, allowing various overdenture solutions, depending on the space available. The caps come with 4 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.

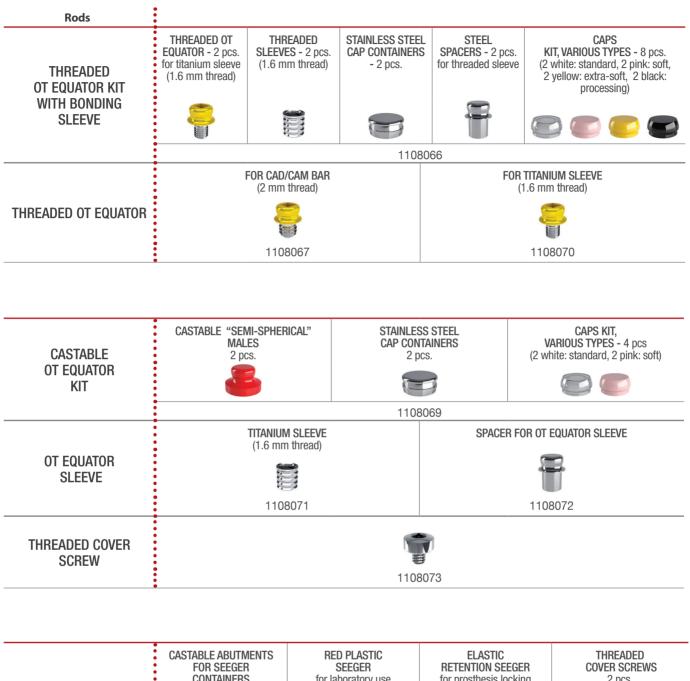
	PRIME	TWINNER	PRIME	TWINNER	PRIME	TWINNER	PRIME	TWINNER	PRIME
	Ø 3.3	Ø 3.5	Ø 3.8	Ø 4	Ø 4.2	Ø 4.5	Ø 4.6	Ø 5	Ø 5.1
	RESTORATION RANGE		RESTORATION RANGE Ø 3.6 FUCHSIA		RESTORATION RANGE Ø 4 GREEN		RESTORATION RANGE Ø 4.5 YELLOW		
	EQUAT	OR Ø 3.3	EQL	JATOR Ø	3.6	EQUAT	ORØ4	EQUATO	RØ4.5
h 1	110	8033		1108039		1108	045	1108	051
h 2	110	8034	1108040		1108046		1108	052	
h 3	110	8035		1108041		1108	047	1108	053
h 4	110	8036		1108042		1108	048	1108	054
h 5	110	8037		1108043		1108	049	1108	055
h 6	110	8038		1108044		1108	050	1108	056

### CONTENT OF THE OT EQUATOR PACK

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

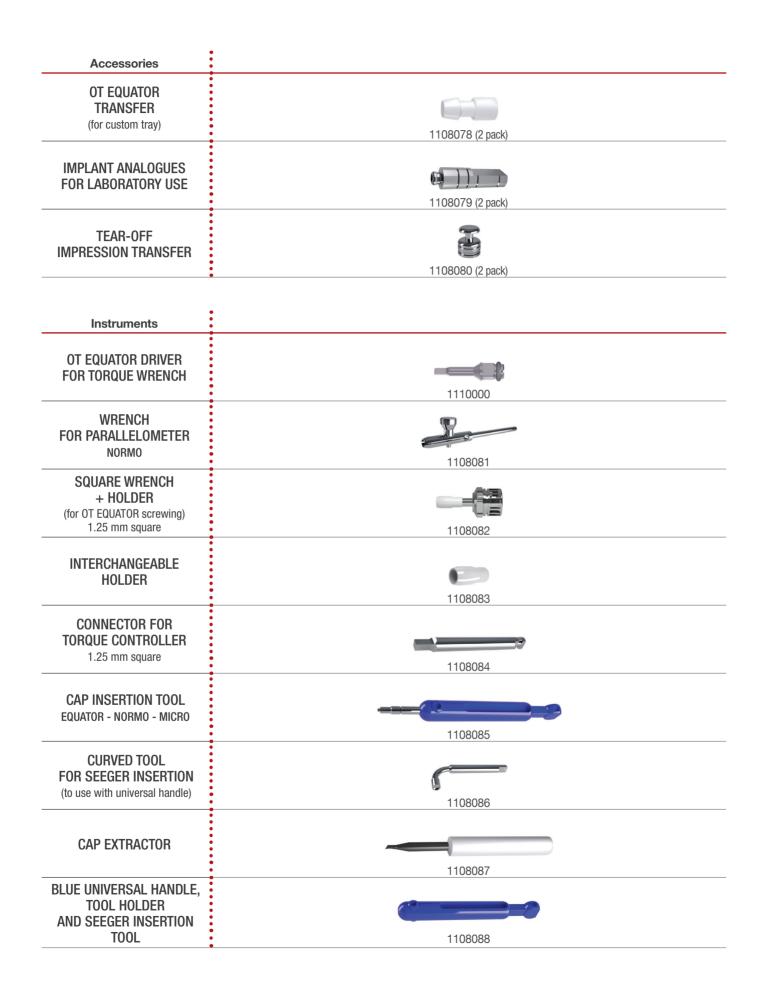


## **OT EQUATOR**



PASSIVE BAR Connection System	CONTAINERS 2 pcs. 3 pcs.		for prosthesis locking 3 pcs.	2 pcs.			
"ELASTIC SEEGER"		0					
	1108068						
		ED atory use)	WHITE (for bar locking)				
SEEGER	¢						
	1108074	4 (6 pack)	1108075 (6 pack)				
	h.	2.5	h. 3.5				
CASTABLE CYLINDERS FOR SEEGER	Ĩ						
	110807	6 (6 pack)	1108077 (6 pack)				

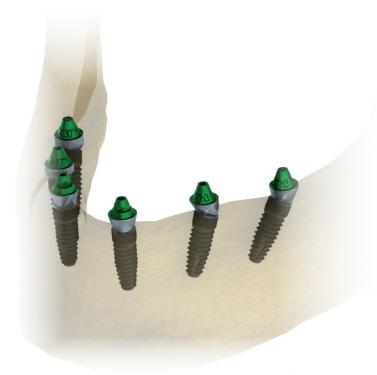
## **OT EQUATOR**

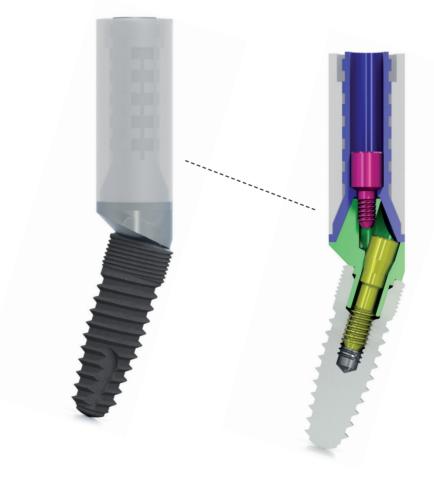


## **FAST** RESTORATION RANGE

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.



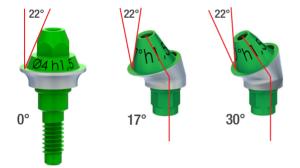


### **FAST** RESTORATION RANGE

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".

Depending on the angle of the PRIME RANGE implants, different types of FAST restoration components are available to parallelise the implant insertion axis of the screwed overstructure.

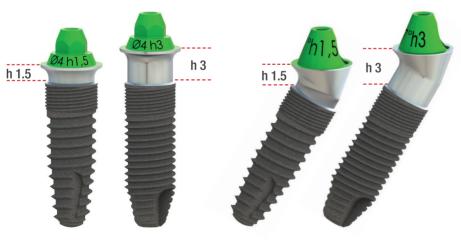
	FAST SLI	M BASES	FAST BASES		
RESTORATION RANGE	RESTORATION RANGE Ø 3.6 FUCHSIA RESTORATION RANGE Ø 4 GREEN		RESTORATION RANGE Ø 4.5 YELLOW	RESTORATION RANGE	
AVAILABLE BASES	0° - 17° - 30°	0° - 17° - 30°	<b>0</b> °	<b>0</b> °	



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 SLIM 0° BASES

FAST SLIM 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 RANGE implants perform best in Immediate Loading Threaded Implants. By "discretionary position" we mean a position selected by the practitioner only after careful evaluation of the implant size in relation to the prosthetic load.

### IMPLANT SIZE INDICATIONS FOR IMMEDIATE LOADING THREADED IMPLANTS

colour code	Ø 3.6			Ø 4		Ø 4.5		Ø 5
Ø Restoration range								
Ø Implants	PRIME	TWINNER	PRIME 1	TWINNER	PRIME	TWINNER	PRIME	PRIME
	Ø 3.8	Ø 4	Ø 4.2	Ø 4.5	Ø 4.6	Ø 5	Ø 5.1	Ø 5.9
UPPER missing parts								
CENTRAL INCISORS								$\land$
LATERAL INCISORS							7	
CANINES								
PREMOLARS								
MOLARS		$\land$	1					
LOWER mssing parts								
CENTRAL INCISORS								
LATERAL INCISORS							7	
CANINES								
PREMOLARS								
	_							

### SURGICAL ACCESSOIRES

### 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.

### **GUIDES 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. For PRIME and TWINNER implants, do not use Guides for FAST Countersink Bur that are intended to be used for implants with TS connection only (code 2410300).

### CARRIER FOR FAST BASES

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

### FAST HEALING CAP

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

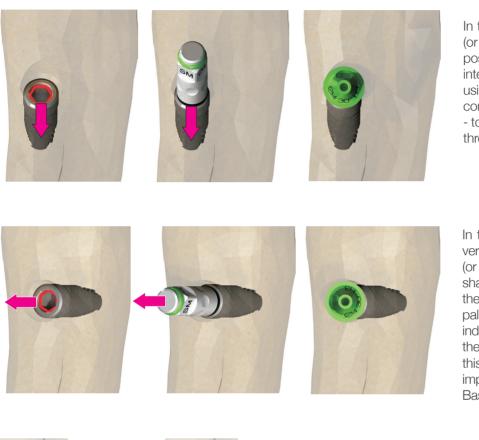


0810141



### **IMPLANTS POSITIONING**

Total rehabilitation of toothless patients through an Immediate Loading Threaded Implant, with 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 RANGE implants is described in detail in the dedicated section.



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

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





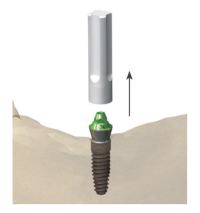
Before inserting the FAST 17°-30° angled Bases in the implants, use the FAST Countersink Bur over the head of the implants. To protect the implant head while passing with the Bur, use the Guide for FAST Countersink inserting it in the implant.





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

### FAST 0° BASES



Use the 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.



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.



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



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



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



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

FAST 17° - 30° BASES

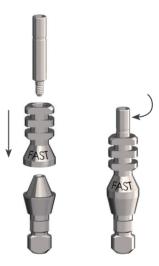
After inserting all the FAST Bases (straight and angled), it is advisable to take an intraoral X-ray to check that the implants and the FAST Bases are correctly coupled.

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.



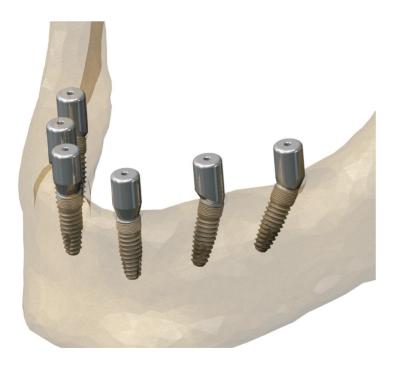
Only screw manually the FAST Transfers or the FAST Scanmarkers onto the FAST Bases using the Screwdriver and take an impression using a custom perforated impression tray in case of FAST Transfer or using the Intraoral Digital Scanner in case of FAST Scanmarker.

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.



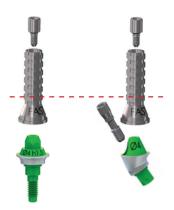
During the temporary laboratory phases, the FAST Healing Caps can be placed to consolidate the soft tissues.

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.

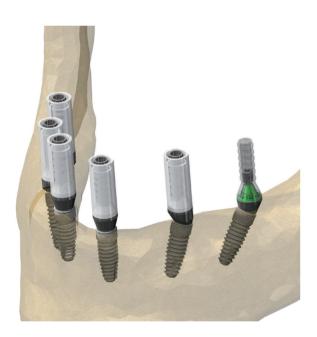


The temporary prosthesis can be constructed using the FAST Abutments. In case of a preventive construction of the prosthesis - opened in correspondence of the FAST Bases - the prosthesis may be directly attached to the FAST Abutments.

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).





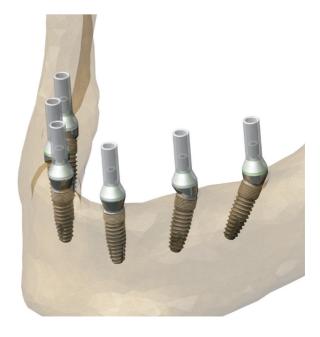


To construct the final prosthesis through passivation, use the Castable Sleeve connected to the FAST Abutment for the construction and gluing of the final device.

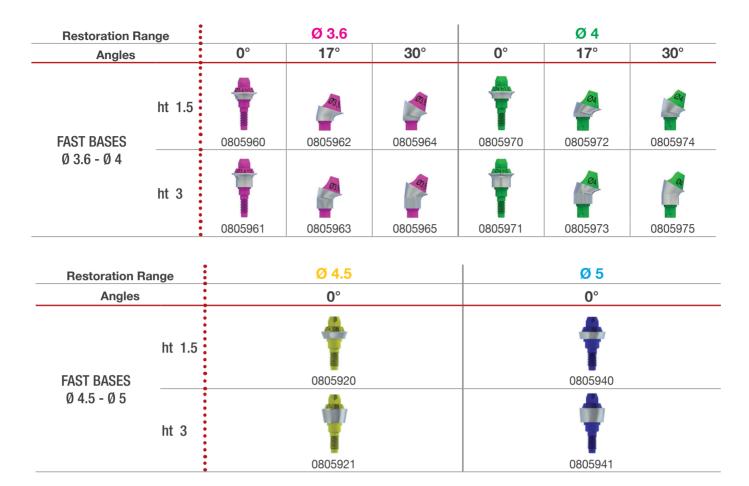
Do not exceed a torque of 20 Ncm to tighten the final prosthesis.

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.



## **FAST** RESTORATION RANGE



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**

60 61

For screwing and unscrewing all Screw types. Available in three different lengths, they can be easily used also in the case of customised restoration components.

### **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 torgue wrench.

### SCREWDRIVER FOR PREMILLED

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

### **TORQUE WRENCH**

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

### HEX BIT FOR TORQUE WRENCH

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

### **HEX WRENCH CH 2.6**

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

### **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

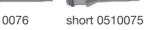


max 30 Ncm	max 30 Ncm
2410070	long 2410072











2410065

0510120

## **FASTENING SCREWS**

Restoration Range	Ø 3.3	Ø 3.6	Ø 4	Ø 4.5	Ø 5	
Components STRAIGHT ABUTMENT			~ .		20	
ANGLED ABUTMENT	0810526	0805001		0805002		
CASTABLE ABUTMENT						
MILLING ABUTMENT	/					
ROD ABUTMENT	/	IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII	0805650 ht 1.5 0805651 ht 3		0805652 ht 1.5 0805653 ht 3	
CONNECT BASES						
MULTI ABUTMENT			0805661	0805662		
PREMILLED ABUTMENT	0805660					
LINK BASES				0805663		
SCANMARKERS	0807410	0807411		0807412		
SCANMARKERS FOR LINK BASES ht 1.5	0807413	0807415		0807416		
SCANMARKER FOR LINK BASES ht 3	0807414			0807417		
PRECISION IMPRESSION TRANSFERS	0807213	0807210F	0807210V	0807211G	0807211B	
EASYCAP AND TEAR-OFF Impression transfers	0807223	0807220F	0807220V	0807221G	0807221B	
FAST 17° - 30° BASE	/	Ĩ	0805906	/	/	
FAST COMPONENTS: ABUTMENTS, CASTABLE ABUTMENTS, SCANMARKERS	/	0805935				
FAST PRECISION IMPRESSION TRANSFER	/	0807301				
DIGITAL ANALOGUE FAST DIGITAL ANALOGUE		0809410				

# PRIME IMPLANTS







# **TWINNER IMPLANTS**





