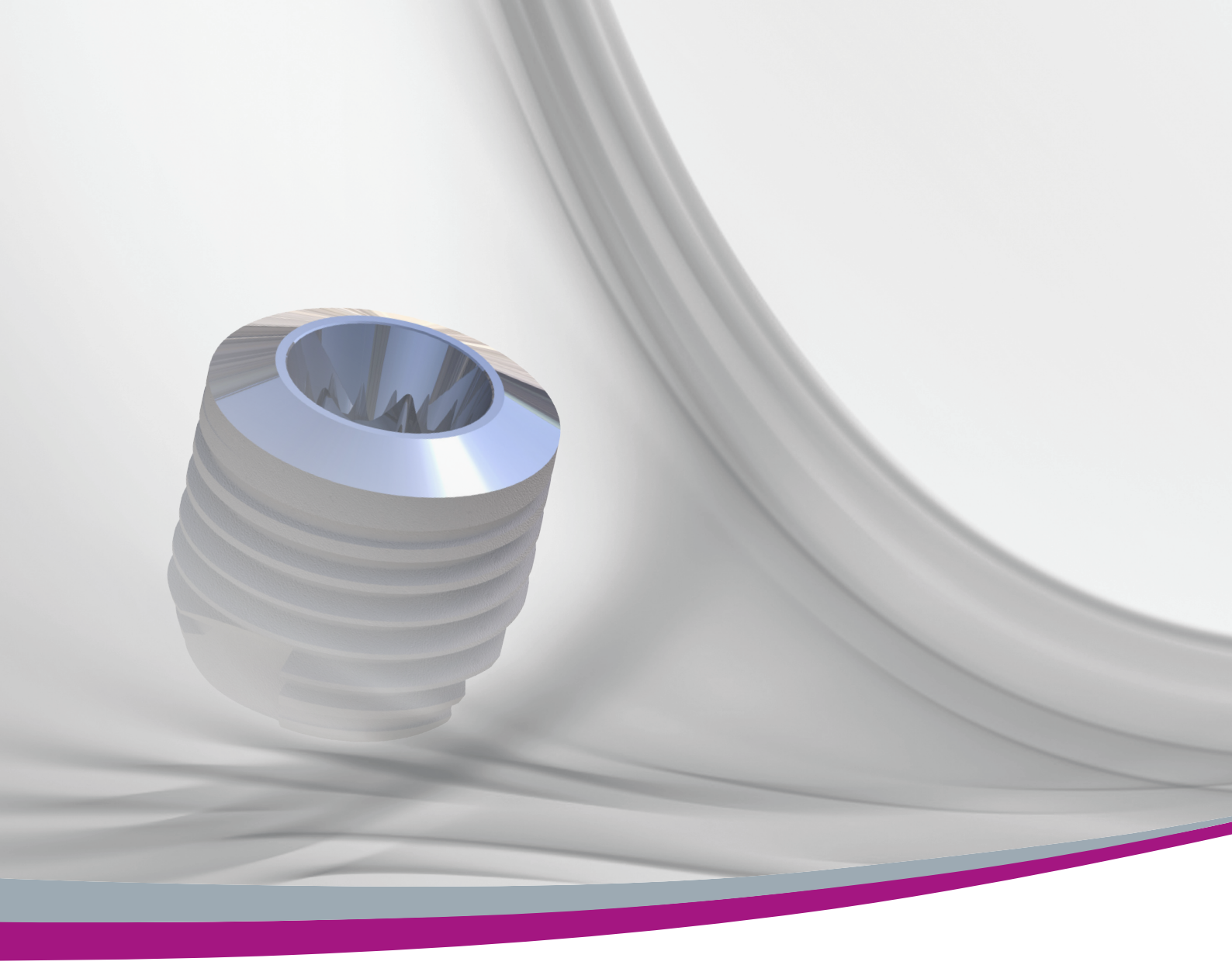

Prodent Italia

CLINICAL PROTOCOL

PROWIDE

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 amendments.

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

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

This policy is implemented and sustained at all corporate levels.

UNI CEI EN ISO **13485:2016**

SISTEMA DI GESTIONE
QUALITÀ CERTIFICATO

CERTIQUALITY
È MEMBRO DELLA
FEDERAZIONE 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 a reference guide to optimise the preparation of the implant site, the insertion of the PROWIDE implants and their subsequent prosthesization: it should therefore not be seen as an alternative to the dentist's training and professional experience.

The Clinical Protocol integrates but does not replace the Instructions for Use that are provided with each Prodent Italia device.

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 its 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

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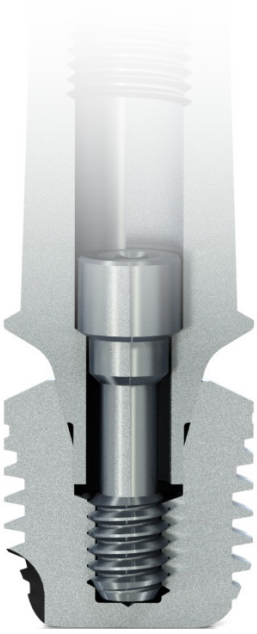
19 IMPRESSION TAKING AND MODEL 

20 RESTORATION COMPONENTS 

PROWIDE®

Short Implant,
High Technology!



INTERNAL HEX CONOMETRIC CONNECTION

The PROWIDE implants are made of pure titanium and characterised by a precise conometric seal connection with engaging internal hex.

UNIQUE CONNECTION FOR 4 IMPLANT DIAMETERS

All the implant diameters available for the PROWIDE implants are made with the same one connection design, which significantly simplifies implantation.

If used appropriately, the PROWIDE 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.

PLATFORM SWITCHING

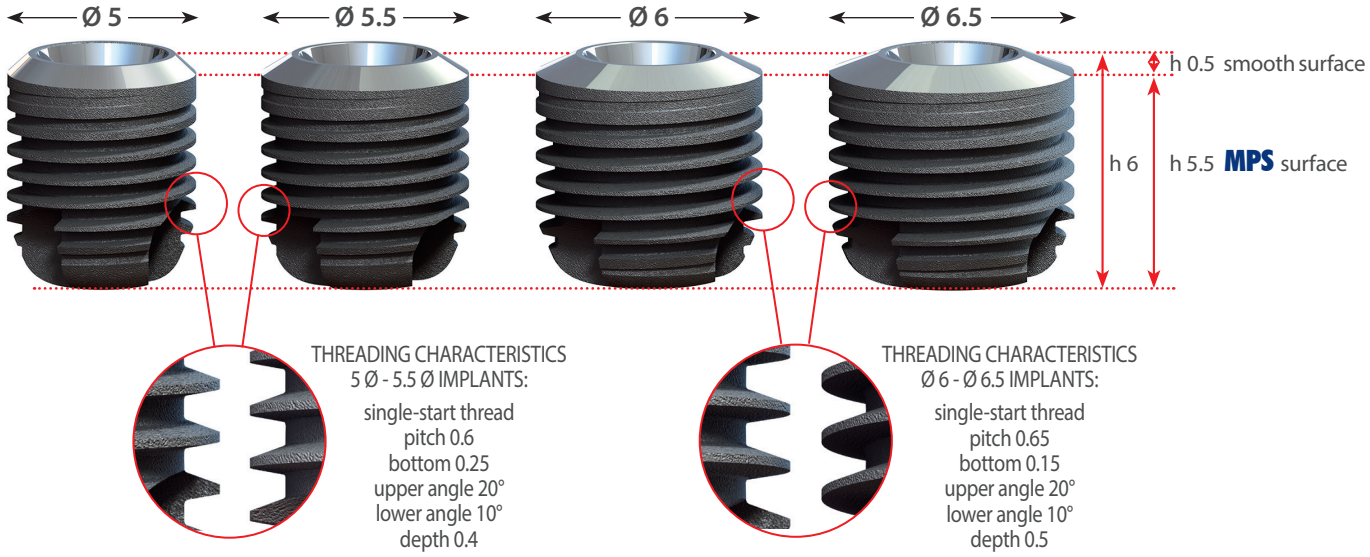
Matching the entire restoration range to the PROWIDE implants generates a platform switching condition that optimises the maintaining of the gingival tissues and reduces the bone resorption phenomena.

IMPLANT CHARACTERISTICS

PROWIDE is the implant range dedicated to the treatment of aesthetic and functional rehabilitation in particular clinical conditions, such as short vertical bone space, where it is decided not to intervene with bone regeneration or maxillary sinus lift techniques. The PROWIDE implants can be inserted into large crests in molar position, both in the upper and the lower jaw, where the amount of bone vertically available for implant surgery is at least 6 millimetres.

The four diameters available allow choosing the most suitable size based on the bone crest thickness and the different clinical cases.

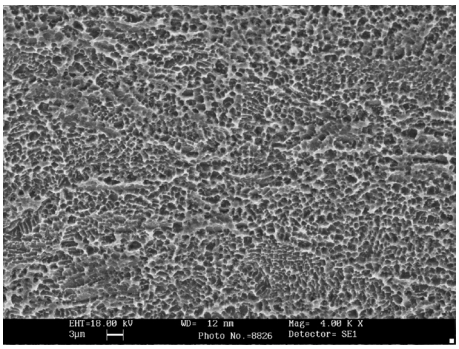
The platform switching condition, available in all the PROWIDE implants, ensures that the gingival tissues and the crestal bone level are maintained: platform switching increases as the implant diameter increases. All the PROWIDE implants share one single restorative platform.

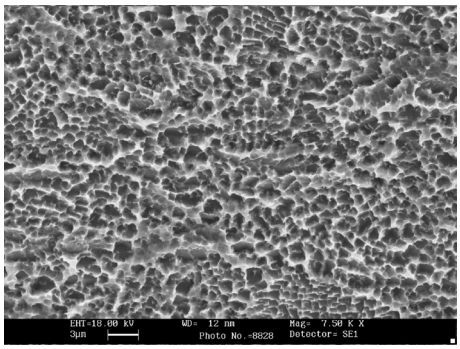


The endosseous surface of the PROWIDE implants is treated with: **MPS Micro Profile Surface** (Double Acid-Etched)

The **MPS** surface treatment, achieved by double etching, ensures homogeneous roughness over the entire implant body with 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 150,000 fixtures.

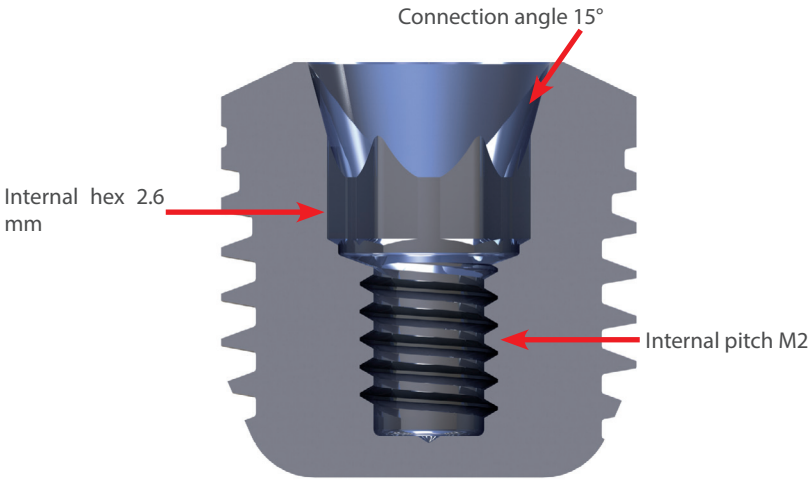

SEM 4.000x

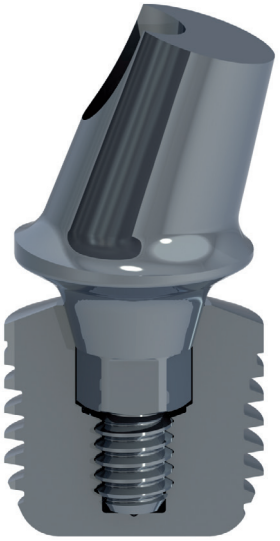

SEM 7.500x

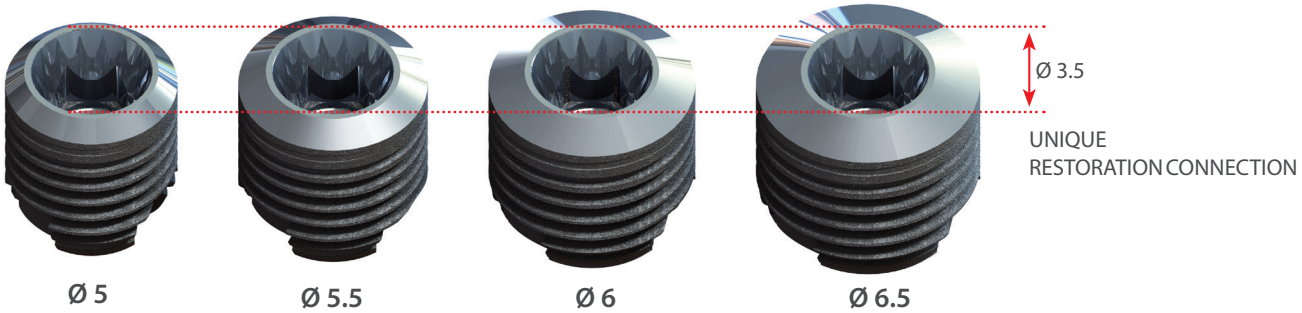
CONIK-FIT is the restoration connection for the PROWIDE implants characterised by an internal hex - that assures engagement of the superstructures - and a tapered section that provides perfect coupling and a bacterial seal between the implant and the restoration component. There is only one connection diameter of 3.5mm for all the implant sizes.

The CONIK-FIT connection provides high stability, which results in efficient distribution of the masticatory stress naturally generated by the mesiodistal and vestibular-lingual movements of the prosthetic action.

The PROWIDE implants provide different restoration solutions: as well as the classic preformed components, other solutions are also possible, such as the Multi Abutments and the Temporary Aesthetic Abutments.







SURGICAL PLANNING

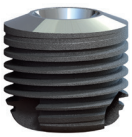
Before surgery, it is of fundamental importance to perform a careful preoperative anamnesis of the patient in order to verify the suitability of the implantation treatment. After excluding any contraindication to the implant-restoration treatment, it is essential that the practitioner carries out careful 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 after obtaining 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 subsequent prosthesization; it is therefore advisable to use conventional surgical techniques that allow for a healing time period of the peri-implant soft tissues. Early/anticipated loading techniques may result in a higher risk of loss of implant stability with the consequent possibility of failure; it is however up to the practitioner to evaluate the surgical treatment suited to the clinical case.

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 PROWIDE implants – contraindicated for single tooth prosthesis – perform best in the upper and the lower jaw. By "discretionary position" we mean a position selected by the practitioner only after a careful evaluation of the implant size in relation to the prosthetic load.

PROWIDE				
ITEM CODE	1001300	1001301	1001302	1001303
IMPLANT Ø	**Ø 5**	**Ø 5.5**	**Ø 6**	**Ø 6.5**
RESTORATION RANGE	**Ø 3.5 ONLY**			

MISSING PARTS				
CENTRAL INCISORS	■	■	■	■
LATERAL INCISORS	■	■	■	■
CANINES	■	■	■	■
PREMOLARS	●	●	△	△
MOLARS	●	●	●	●

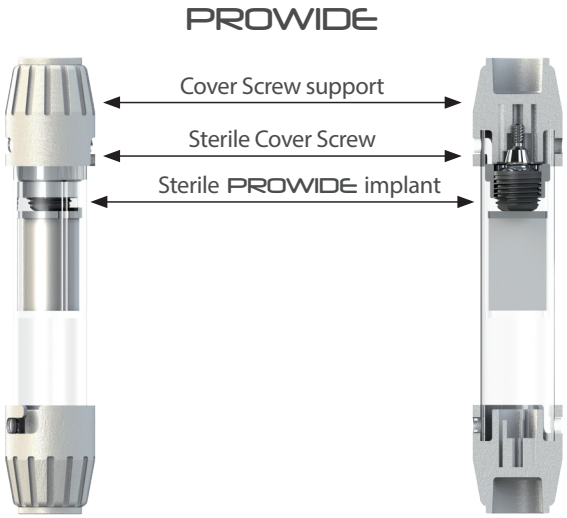
● optimal position △ discretionary position ■ contraindicated position

PACK AND STERILITY

Each implant is supplied in a sterile plastic ampoule, housed on a ring and resting on a disc, both 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 maintain 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 insertion 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's identification details to be attached to the patient's clinical records.

STORING AND HANDLING THE PACK

Implant sterility is guaranteed if the original pack is unopened, intact and stored in a dry place at ambient temperature until the expiry date indicated on the label (5 years from the date of sterilization - shelf-life). Before using the implant, always check that the pack is undamaged and shows no visible signs of damage that could compromise its sterility.
The pack must not be opened until the implant is to be used. The blister must be opened and the implant taken out in asepsis conditions.

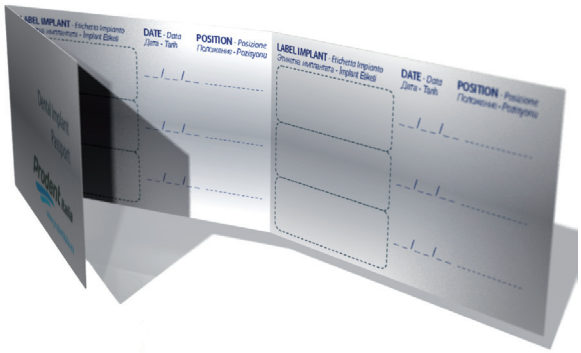


Primary pack for PROWIDE Implants

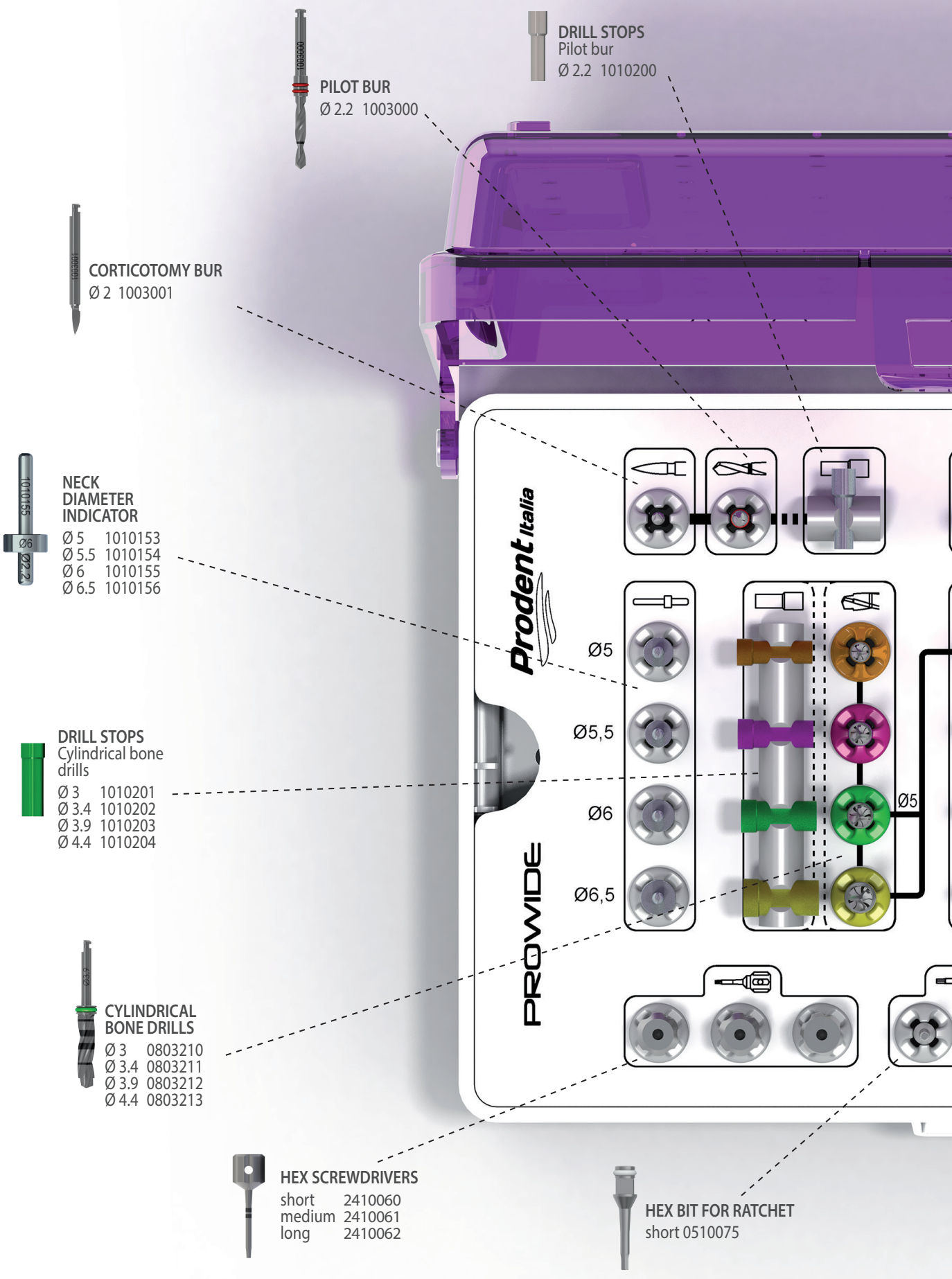
PROWIDE Implants Pack

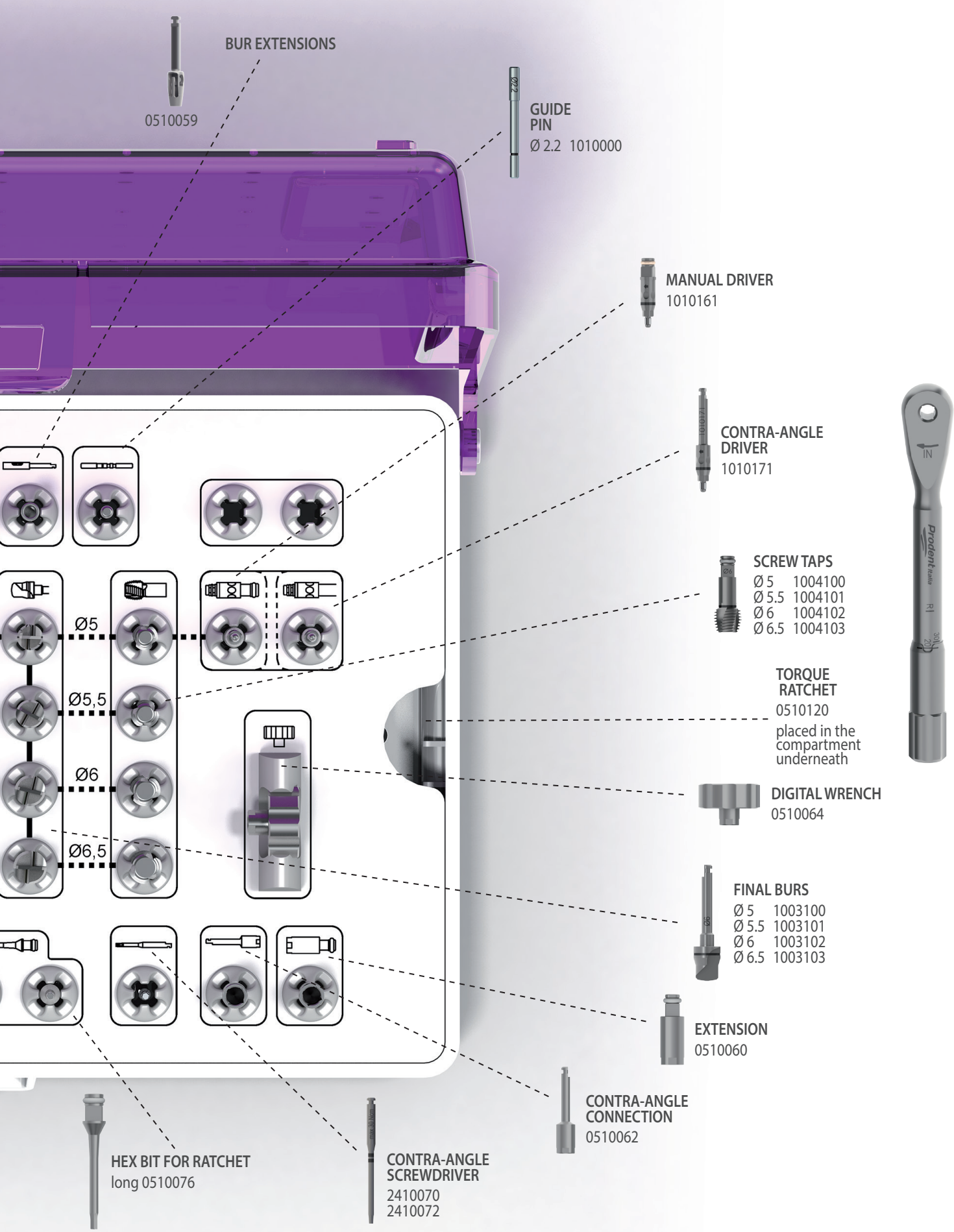
DOCUMENTATION AND IMPLANT IDENTIFICATION

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.



SURGICAL TRAY





BUR EXTENSIONS
0510059

GUIDE PIN
Ø 2.2 1010000

MANUAL DRIVER
1010161

CONTRA-ANGLE DRIVER
1010171

SCREW TAPS
Ø 5 1004100
Ø 5.5 1004101
Ø 6 1004102
Ø 6.5 1004103

TORQUE RATCHET
0510120
placed in the compartment underneath

DIGITAL WRENCH
0510064

FINAL BURS
Ø 5 1003100
Ø 5.5 1003101
Ø 6 1003102
Ø 6.5 1003103

EXTENSION
0510060

CONTRA-ANGLE CONNECTION
0510062

HEX BIT FOR RATCHET
long 0510076

CONTRA-ANGLE SCREWDRIVER
2410070
2410072

SURGICAL ACCESSORIES

TISSUE PUNCHES Circular scalpels to be used in the flapless surgical technique before passing bone burs. They must be connected to the contra-angle with low RPM (25 RPM), to remove gingival tissue, creating holes meant for the subsequent 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 (code 0503070 Ø 4.3 - code 0503071 Ø 5.5).

DIGITAL WRENCH To initiate surgical site tapping or for manual implant insertion (code 0510064).

EXTENSION For increasing the length of the connection to the dedicated screwing instruments (code 0510060).

HEX SCREWDRIVER For screwing and unscrewing all screw types. Available in three different lengths, it can also be easily used for customised restoration components (code 2410060 short, 2410061 medium, 2410062 long).

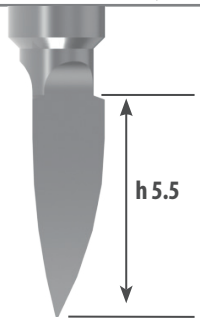
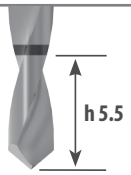
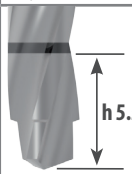
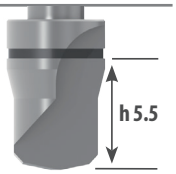
PREMILLED SCREWDRIVER It is suitable for tightening and loosening Premilled Abutments (code 2410065).

BUR EXTENSION To be used when it is necessary to extend the connection between the Bur and the Contra-angle without exceeding a max. torque of 45Ncm (code 0510059).

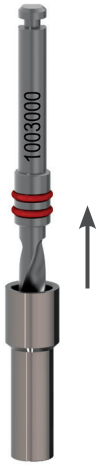
CONTRA-ANGLE CONNECTION For mechanical use of Drivers and Screw Taps without exceeding 25 RPM and a maximum torque of 45Ncm (code 0510062).

TORQUE RATCHET With fixed function to complete manual implant insertion and surgical site tapping operations. 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 (code 0510120).

	Ø 2
CORTICOTOMY BUR	 1003001

	Corticotomy	Pilot	Cylindrical	Final
BUR DEPTH MARKER READING				

The height of the dedicated PROWIDE marker is 0.5, to avoid inserting the implant under the crest, deepen the hole so that the marking is fully visible.

	Pilot 2.2 Ø	Cylindrical 3 Ø	Cylindrical 3.4 Ø	Cylindrical 3.9 Ø	Cylindrical 4.4 Ø	
PILOT BURS and CYLINDRICAL BONE DRILLS	 1003000	 0803210	 0803211	 0803212	 0803213	
DRILL STOPS	 1010200	 1010201	 1010202	 1010203	 1010204	

	Final 5 Ø	Final 5.5 Ø	Final 6 Ø	Final 6.5 Ø
FINAL BURS	 1003100	 1003101	 1003102	 1003103

All the burs 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 cut the cortex. The Pilot Bur is used to determine the final depth of the surgical implant site. The Cylindrical Bone Drills are to be used in sequence and serve to gradually widen the site before using the Final Bur dedicated to the implant to be inserted. To correctly prepare the site, it is recommended to refer only to the marking closest to the bur tip. The Final Burs allow the surgeon to obtain the morphology and the final dimensions in the site suitable to house the implants. For the exact sequence of the burs to use based on the implant to be inserted, please refer to the section "Surgical sequence".

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

The colouring of the burs' O-rings and of the drill stops is only intended to assure proper coupling of the devices.

INDICATORS AND SCREW TAPS

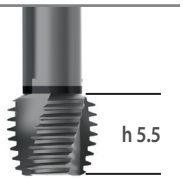
GUIDE PINS
The Guide Pin is used to assess the depth of the surgical channel (also through x-rays) after drilling with the Pilot Bur. In the event that two or more implants are inserted, the pin can be used as reference for parallelism.

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

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

	Ø 2,2
GUIDE PIN	 1010000

	Ø 5	Ø 5.5	Ø 6	Ø 6.5
NECK DIAMETER INDICATOR	 1010153	 1010154	 1010155	 1010156

	Ø 5	Ø 5.5	Ø 6	Ø 6.5	Depth marker reading
SCREW TAPS	 1004100	 1004101	 1004102	 1004103	 h 5.5

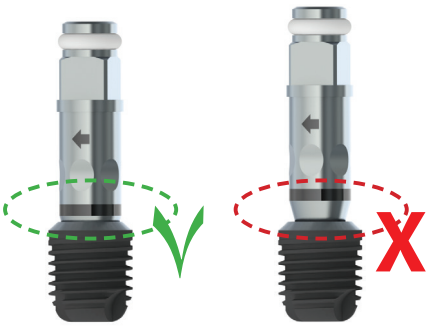
MANUAL DRIVER
Connected to the Digital Wrench, they allow the implants to be taken from the ampoule and be placed in the implant site to then proceed with manual insertion. If necessary, complete insertion using the Driver connected to the Torque Ratchet.

CONTRA-ANGLE DRIVER
Connected to the Contra-angle, they allow the implants to be taken from the ampoule and 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 45Ncm.

Primary stability of the implants is essential to ensure success; it is advisable to solve any unfavourable situations before surgery. During implant insertion, it is recommended not to exceed a torque of 60 Ncm.

	Manual	Contra-angle
DRIVER	 1010161	 1010171

During the procedures for extracting the implant from the plastic container, 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.



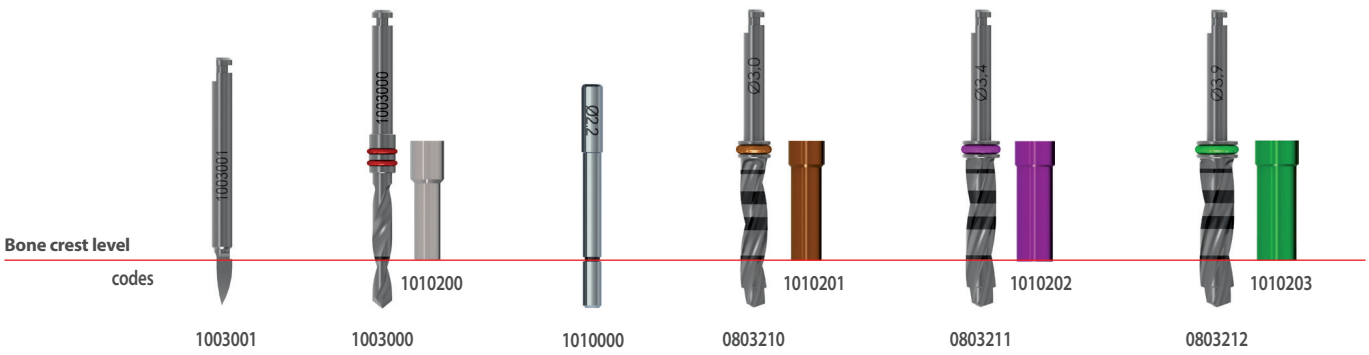
The Drivers have six indents, which, when the driver is inserted in the implant, indicate the position of the hex faces of the connection. If the implant is prosthesized with an Angled Abutment, during the insertion of the implant it is important to let one of the driver's indents coincide with the implant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

SURGICAL SEQUENCE

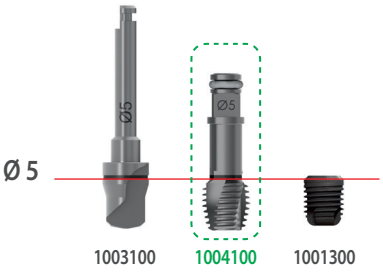
SEQUENCE BASED ON IMPLANT DIAMETER AND HEIGHT

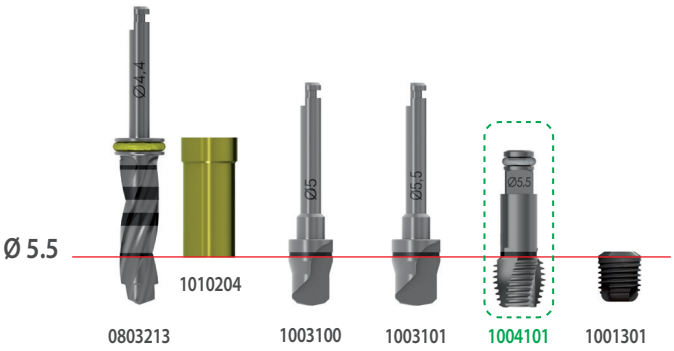
The devices with green code are optional and they must be used in a compact bone.

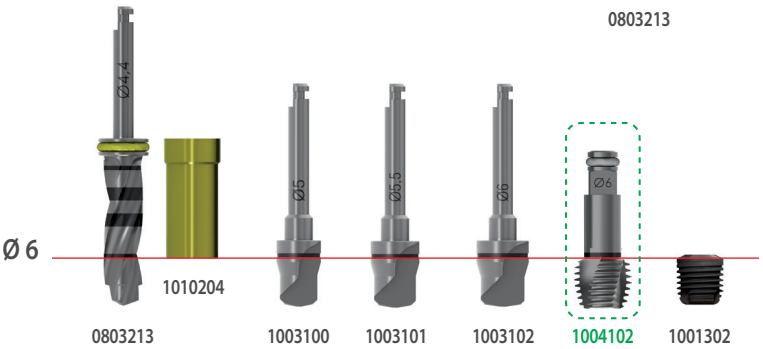
INITIAL SEQUENCE COMMON TO ALL PROWIDE DEVICES

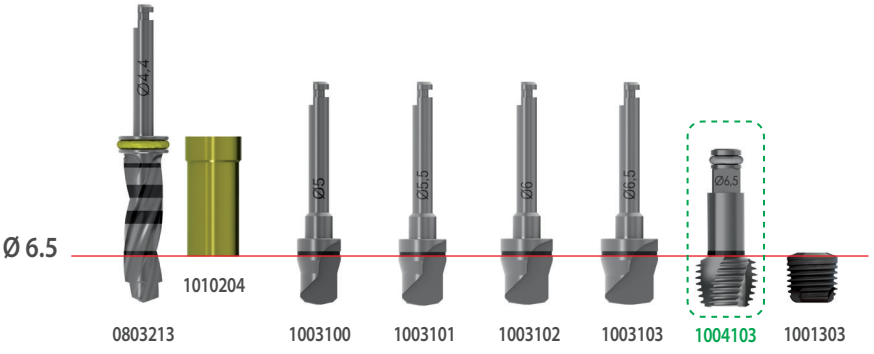


FINAL SEQUENCE BASED ON THE IMPLANT DIAMETER

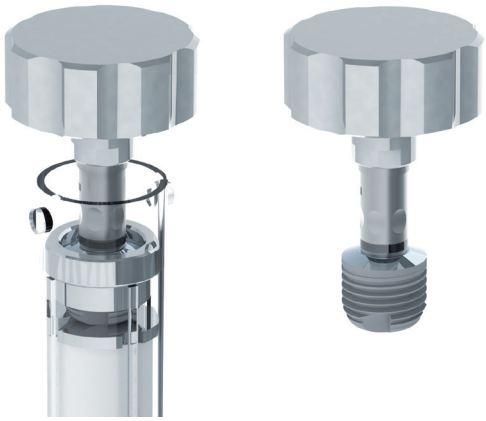








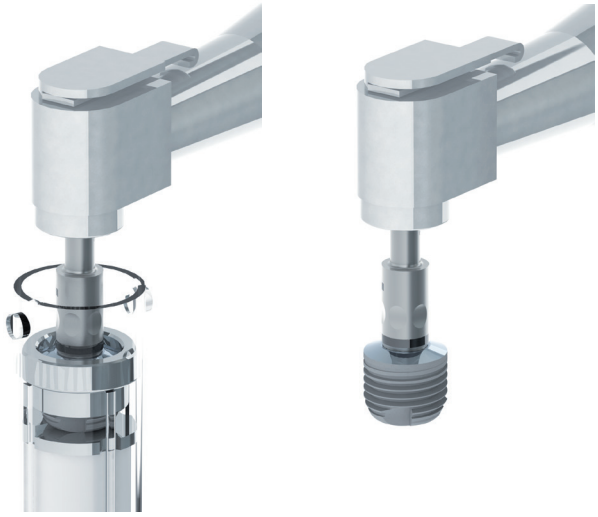
MANUAL PROWIDE IMPLANT INSERTION



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.

MECHANICAL PROWIDE IMPLANT INSERTION

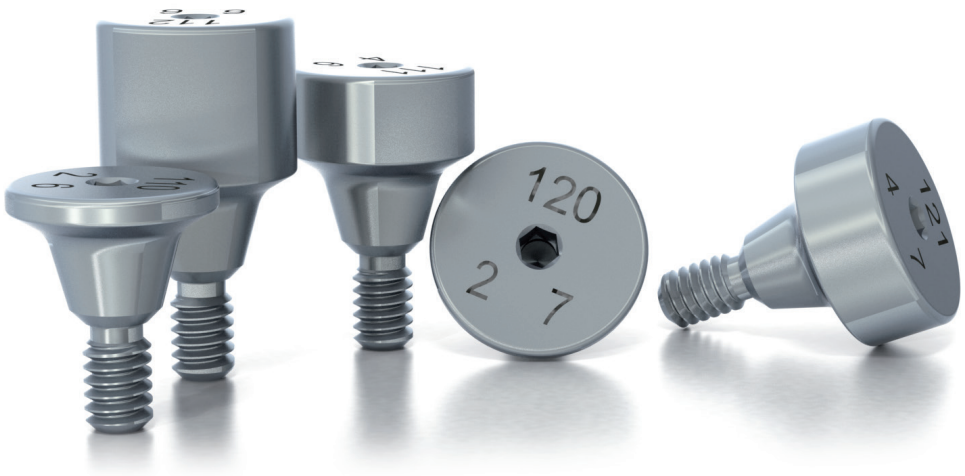


The implant is extracted from the sterile ampoule with the Contra-angle and the Contra-angle Driver for the first screwing phase of the implant into the implant site.

HEALING SCREWS

The Healing Screws have a tapered transmucosal section that allows you to perfectly condition the soft tissues with various horizontal and vertical emergence profiles. Depending on the planned prosthetic restoration, you can choose between two different diameters, each with three possible transmucosal heights.

The marking on the screw head allows the devices to be identified by means of the 5 numerical codes, which, as shown in the image, indicate: the last three digits of the item code, the transmucosal height (ht), and the emergence diameter (Ø).



		Ø 6	Ø 7
TAPERED HEALING SCREWS	ht 2	1006110	1006120
	ht 4	1006111	1006121
	ht 6	1006112	1006122

Based on the planned prosthetic restoration, if devices are available in different diameters (Healing Screws, Transfers, Straight and 17° Abutments), it is recommended to sequentially use devices with the same preselected emergence diameter (6 Ø or 7 Ø).

There are two different types of Transfer that allow faithfully transferring the surgical position of the implants from the oral cavity to the working model. They are both made of grade 5 titanium and they come in two different emergence diameters, marked on the device. The choice between them depends on the planned prosthetic restoration.

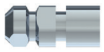
PRECISION IMPRESSION TRANSFER Suitable for taking precision dental impressions by means of a custom tray even in the case of implants with non-parallel axes.

EASYCAP AND TEAR-OFF IMPRESSION TRANSFERS 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 Made of Polyphenylsulphone, it is resistant to high temperatures (up to 207°C) and can be sterilized. To be used connected to Easycap and Tear-off Impression Transfers on which it is to be pressure-fitted.

IMPLANT ANALOGUE Made of grade 5 titanium and available in one variant and therefore has no marking.

Emergence diameter	Ø 6	Ø 7	Spare screw
PRECISION IMPRESSION TRANSFER	 1007110	 1007111	 0807211
EASYCAP AND TEAR-OFF IMPRESSION TRANSFER	 1007210	 1007211	0807221

EASYCAP	IMPLANT ANALOGUE
 0807000	 1009101

There are two types of Scanmarker, for recording digital impressions using both intraoral dental scanners and a laboratory dental scanner.

INTRAORAL SCANMARKER: made of Peek and grade 5 titanium, it is suitable for recording digital impressions using intraoral dental scanners; It will allow you to acquire the position of the implant connection.

SCANMARKER Made of Peek, it is suitable for recording digital impressions using a laboratory dental scanner. It will allow you to acquire the position of the implant connection.

INTRAORAL SCANMARKER	Spare screw	SCANMARKER	Spare screw
 1007400	 0807412	 1005317	 1005001

RESTORATION ACCESSORIES For tightening Fastening Screws to 30 Ncm and Restoration Screws with Cap.

HEX SCREWDRIVER For screwing and unscrewing all screw types. Available in three different lengths, it can also be easily used for customised restoration components (code 2410060 short, 2410061 medium, 2410062 long).

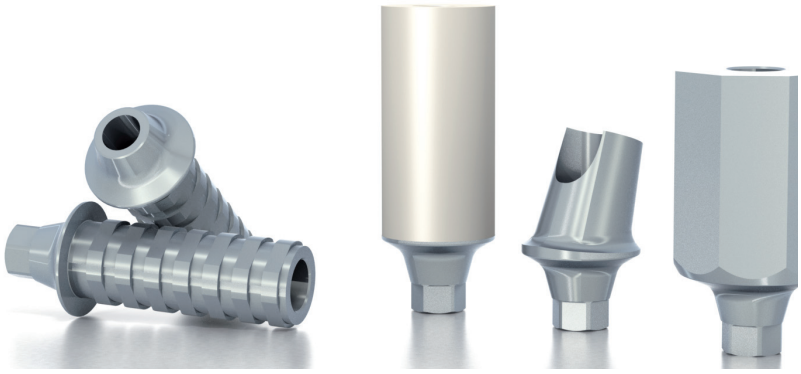
CONTRA-ANGLE SCREWDRIVER Connected to the Contra-angle, for screwing and unscrewing Fastening Screws and Restoration Screws. Available in two different sizes (code 2410070 standard, 2410072 long).

HEX BIT FOR RATCHET Connected to the Ratchet, for the final tightening of Fastening Screws and Restoration Screws. Available in two different sizes (code 0510075 short, 0510076 long).

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 (code 0510120).

RESTORATION COMPONENTS

The PROWIDE implants provide different restoration solutions: as well as the classic preformed components, other solutions are also possible, such as the Multi Abutments and the Temporary Aesthetic Abutments. None of the components are marked as they are all single-use: correct identification is ensured by the indications on their labels.



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

MULTI ABUTMENT CASTABLE SLEEVE They must be combined with the Multi Abutments to make permanent prostheses with adhesive bonding system, in order to obtain total passivation of the secondary structures.

TEMPORARY AESTHETIC ABUTMENT It is composed of an Aesthetic Base in titanium and a Temporary Abutment Peek (that can also be ordered as a spare part). It is suitable for temporary cemented or screw-fitted prostheses of a high aesthetic quality, which provide proper titanium coupling with the implant. The Peek component must not remain in the oral cavity for more than 180 days.

BASE FOR AESTHETIC ABUTMENTS Used in combination with CAD-CAM systems to make customised prostheses, they will allow you to create permanent cemented or screw-retained prostheses with a high level aesthetic quality, also assuring proper titanium coupling with the implant. To obtain an effective restoration solution, the Aesthetic Abutment should not be modified.

STRAIGHT ABUTMENT Suitable for cemented or screw-retained prostheses if combined with the Restoration Screw. Available in two prosthetic diameters and in different transmucosal (ht) and coronal (hc) heights, depending on the planned prosthetic restoration.

RESTORATION SCREW WITH CAP Suitable for screw-retained prostheses. It may be used only in combination with Straight Abutments not ground in the coronal section.

17° ANGLED ABUTMENT Suitable for cemented prostheses, it is available in two different prosthetic diameters. The choice between them depends on the planned prosthetic restoration. The angle option is only one and is suitable to correct disparallelisms up to 17°.

MILLING ABUTEMENT Suitable for making both abutments for prostheses with conometric connection as well as Angled Abutments for cemented prostheses, in those cases where 17° abutments cannot be used. Plan the treatment considering that the loading conditions for abutments with high angulation put more strain on the implant: in these cases, the use of Milling Abutments must be balanced by using other elements in the rehabilitation treatment.

PREMILLED ABUTEMENT 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 one cylindrical section of 11.5 mm (for angulation to 17°). The Premilled abutment is made with Medentika® attachment.

CASTABLE ABUTMENT Suitable for constructing cemented or screw-retained prostheses only in those cases where preformed components cannot be used. It 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.

CEMENTABLE CASTABLE ABUTMENT Suitable for cemented prostheses only in cases where preformed components cannot be used.

Spare parts

TEMPORARY ABUTMENT PEEK SLEEVE May also be used as spare part for Temporary Aesthetic Abutment.

FASTENING SCREW Only one screw for all the restoration components, except screwless components (Cementable Castable and Multi Abutment Castable). Pitch M2. For proper tightening use the 30 Ncm Ratchet. Provided in the restoration component packs and can also be purchased individually (code 1005001).

Material

- PEEK: Temporary abutment peek sleeve.
- Polycarbonate: Castable Abutment, Cementable Castable Abutment, Restoration Screw Cap, Multi Abutment Castable Sleeve.
- Grade 5 titanium: all the metal components, including the Fastening Screw.

	Engaging	Non-engaging
MULTI ABUTMENTS	 1005310	 1005311
MULTI ABUTMENT CASTABLE SLEEVE	 1005312	

		Temporary Abutment Peek Sleeve (spare part)
TEMPORARY AESTHETIC ABUTMENT	 1005315	 1005316
BASE FOR AESTHETIC ABUTMENTS	 1005314	

	Ø 6		Ø 7		Restoration Screw with Cap
	ht 1.5	ht 3	ht 1.5	ht 3	
STRAIGHT ABUTMENTS hc 3	 1005210	 1005212	 1005220	 1005222	
STRAIGHT ABUTMENTS hc 8	 1005211	 1005213	 1005221	 1005223	0805019
17° ANGLED ABUTMENT hc 6	 1005110	 1005111	 1005120	 1005121	
MILLING ABUTMENT AND PREMILLED ABUTMENT	 Milling 1005710		 Premilled Ø 11.5 1005721		

	Engaging	Non-engaging
CASTABLE ABUTMENT	 1005321	 1005322
CEMENTABLE CASTABLE ABUTMENT	 1005351	

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 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.

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