prowital

the implant with system

Surgery Manual

Platform switching is the term used in Germany,
platform shifting is the term used in Austria and Switzerland.

Foreword
A system that can do anything

prowital is the realization of a consistently user-friendly implant system supporting the practice routine before, during and after surgery. With its low number of components the system is always efficient and particularly costeffective.

Please read this manual carefully.

Our best regards

Florian Loos
Product Manager Prowital

Index

Introduction 4

Pre-operative planning

- Measures 10
- Pre-operative measures 16

Surgical procedure

- Preparation 18
- Drilling the pilot hole 19
- Drilling the holes 20
- Use of the triangular bur 23
- Using the countersinks 24
- Using the tap 26
- Diagram showing preparation of the implant bed 27
- Service life of the drills 28
- Parallel pins 29
- Depth stop 30
- Preparation of the implant bed with osteotomes 33
- Manual torque wrench adapter, drill extension 38
- Schematic representation of drivers 39

Packaging 40
Inserting the implant 44
Placing the closure screw 45
Wound closure, Healing time 46
Exposure after healing 47
Shaping the mucosa 48
Impression taking 50
Bite registration 55
Cleaning / preparation / disinfection / sterilisation of the instruments 56

Prosthetic restorations

Temporary restoration 58
Selection measure post 60
Ball abutment 61
Bar abutment 63
Locator® abutment 64
Prosthetic abutments 72

Information

Torque wrench adjustment 74
Symbols used on labels and in the instructions for use 75
Safety information 76
Safety, liability, warranty 77
Maintenance instructions, training and training materials 78
Supply, availability, packaging and sterility 79
Notes 80

Introduction

The prowital implant system contains surgical, prosthetic and laboratory technical components and instruments.

The prowital implant system offers a clearly arranged selection of screw-type implants with diameters of 3.5 mm, 4.3 mm and 5.0 mm. The implants are available in the following lengths: 9 mm, 11 mm, 13 mm and 15 mm.

The implants have an acid-etched surface structure extending all the way to the implant platform for optimum attachment of the bone and mucosa.

prowital implants are made of biocompatible pure titanium (Grade 4 ASTM F 67 titanium).

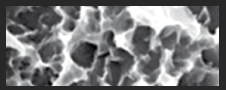
The identical internal geometry of all implants allows “platform switching” and enables particularly ergonomic and accurate working.

Thus, for instance, screws with the same geometry can be inserted with only one implant driver. This implant driver is supplied in two lengths and the hex driver in three lengths.

Identical internal geometry

allows “platform switching”

OsseoAttract surface



for a rapid osseo integration

Single-patient drills

The prowital system is delivered exclusively with sterile-packed disposable drills to be used on one patient only. This makes the time-consuming reprocessing of drills unnecessary. And, at the same time, the most stringent hygiene requirements are satisfied. This enhances the ergonomics of dental practice procedures and facilitates documentation. The single-patient drills are fully billable in Germany.
The drills are equipped with depth marks. Depth stops are also optionally available.

Packaging

The innovative implant packaging already contains the closure screw.
The novel way of arranging the individual components enables the removal of the implant with the implant driver directly from the package, and placement can then be made in the prepared implant site.

Colour coding

- 3.5 mm
- 4.3 mm
- 5.0 mm

The consistent colour coding of the prowital implant system ensures maximum safety when using all components.

Intended conditions of use

The intended conditions of use and operational characteristics of the medical devices, such as single use and sterile packaging, are indicated by the respective symbols. See page 75 for an explanation of all symbols used.

Intended user profile

As the safe application, cleaning and preparation of the products require specialist knowledge, these products may only be used by dentists, maxillofacial surgeons, dental technicians and specially instructed support staff (dental assistants).

Intended medical indications

prowital implants can be used for all indications for oral endosseous implants in the maxilla and mandible, for the functional and aesthetic oral rehabilitation of edentulous and partially edentulous patients and for all bone qualities. The prosthetic treatment involves single crowns, bridges, partial or total prostheses, which are connected to the prowital implants using the relevant elements. There is no limit to indications in regard to the implant diameter. Due to structural reasons, the ratio between the length of the crown and the implant length should be < 0.8 A more unfavourable structural ratio could make interlocking necessary.

NOTE

Products intended for single use must not be reprepared due to the risk of insufficient repreparation possibilities on behalf of the user, diminished cutting efficiency or impaired precision.

Intended patient groups

prowital implants can be used for all patient groups whose bones have finished growing.

Healing phase for prowital implants

With well suited bone quality, the healing phase is at least **6 weeks** and **four months with cancellous bone.**
There is no difference in healing between the maxilla and mandible.

Possible (local) contraindications

If the quantity of bone is insufficient or the bone quality is inadequate, treatment with implants should be refrained from. The final decision lies with the treating physician.

Contraindications

The general contraindications for dental surgery should be regarded when selecting patients. Note: The final decision lies exclusively with the treating practitioner.

These include, among others:

- compromised immune system due to illness or medications (e.g., cortisone therapy, cytostatic drugs)
- uncontrolled diabetes mellitus
- severe cardiac, hepatic, renal or blood disease
- generalised disease of connective tissues or bones (e.g., rheumatic diseases)
- increased risk of bleeding
- severe psychiatric disorders, drug dependency
- nicotine or alcohol abuse
- **Anatomical conditions,** incomplete jaw growth, adverse anatomical bone conditions, previously irradiated bone, temporomandibular joint disorders and treatable pathological jaw diseases

It is the severity of the general disease that will decide whether implant therapy is absolutely contraindicated or whether it may be considered. These should be clarified in advance, if need be in consultation with specialist practitioners.

Possible side effects

Temporary complaints
Pain, inflammation, speech difficulties, gingivitis.

More persistent complaints that may occur in connection with the insertion of dental implants
Chronic pain related to the dental implant, permanent paraesthesia, dysaesthesia, nerve damage, exfoliation, hyperplasia, localised or systemic infections, oroantral or oronasal fistulas, loss of maxillary or mandibular ridge bone, adversely affected adjacent teeth, irreversible damage to adjacent teeth, fractures of the implant, jaw, bone or dental prostheses, aesthetic problems.

Hazards and hazardous situations

All prowital products are constructed so that, when the instructions for use are adhered to, any hazard or hazardous situation can be virtually ruled out.

In individual cases, hazards cannot be excluded due to improper use or in critical clinical situations. All complaints are assessed by the prowital quality management team; suitable measures result in continuous optimisation.

The use of non-system components and instruments can compromise the function and safety of the implant system. PROWITAL GmbH is not liable for warranty claims or replacement services if non-system components are used.

Important

The primary stability of the implant after insertion is an absolute prerequisite for the successful integration of the prowital implant.

Scientific studies have shown that, in a small number of cases, despite careful adherence to instructions, implants may fail to heal.

It is often impossible to determine the causes for this.

Given the small size of prowital products, swallowing or aspiration is possible. Aspiration may lead to breathing difficulties and, in the worst case, to suffocation. This is why swallowing or aspiration of the products should be prevented with a thread or dental floss during intraoral use.

Complications

The following maxillofacial complications may occur when using implants:

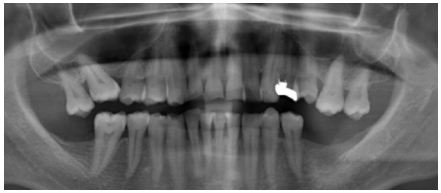
- Heavy bleeding of bones and mucosa
- Hyper/paraesthesia due to nerve overextension or injury
- Bone perforation
- Suture dehiscence/suture granuloma
- Gingival hyperplasia
- Haematoma formation
- Soft tissue swelling
- Tension in the jaw area
- Submucosal abscess, fistula formation
- Periimplant infection
- Implant loosening/implant loss

Pre-operative planning/measures

Pre-operative planning

The surgical intervention must be preceded by detailed surgical and prosthetic planning based on the close cooperation of the doctor, dental technician and patient.

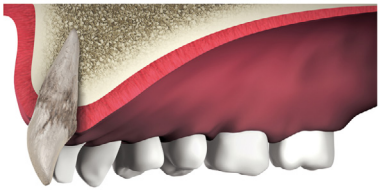
To this end, X-ray images (e.g. oral films and OPTs) or DVT/CT scans, to be evaluated in three dimensions by the doctor, are useful.



When planning, the surgeon must be thoroughly familiar with the specific measurement system used and must allow a suitable safety margin to adjacent teeth and vital structures. If the surgeon fails to measure the actual drilling depth correctly in relation to the radiographic measurements, and drills beyond the intended depth, this can result in permanent injury to nerves or other vital structures. A safe distance of 1.5 mm must be maintained from the mandibular nerve or alveolar nerve.

Every drill is equipped with depth marks, which it is imperative to observe. If the coronal bone crest is smoothed, the available bone height is reduced which must be considered when selecting the implant length.

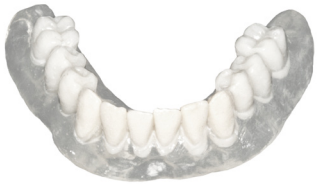
Modern implant dentistry is based on the concept that the planned suprastructure determines the implant position.



Before the surgical intervention, the prosthodontist, surgeon and dental technician should set up an overall prosthetic treatment plan and prepare a wax-up/set-up/mock-up according to functional, phonetic and hygienic requirements with the goal of determining the definitive implant position.

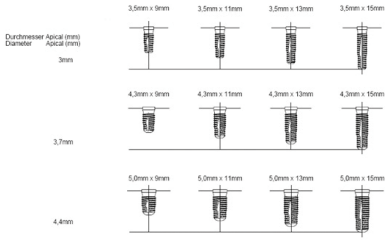
If the implant can be placed near the tooth position, a fixed restoration can be fabricated in that position. If, from a functional point of view, (crown length, load on the implant), this is not possible, a removable restoration should be planned for the patient instead.

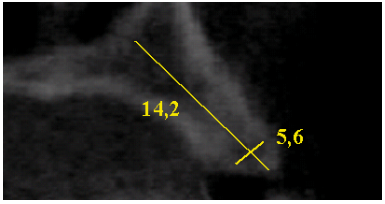
The wax-up/set-up/mock-up fabricated by the dental technician is tried in on the patient by the attending clinician. Thus, the doctor and patient can check the aesthetics and functionality together and make any necessary corrections. Then an X-ray template is made on the basis of detailed and accurate planning.



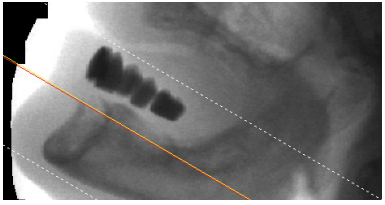
As calibrated measuring points must be visible on the X-ray images, reference objects of defined size (metal spheres, titanium sleeves etc.) are fixed at the planned implant positions.

To evaluate the OPT, planning templates with a scale of 1:1.25 and 1:1.40 or in the original size 1:1, depending on the enlargement ratio, are available. The bone thickness is determined by measuring the diagnostic model and correction of the thickness of the mucosa.





A DVT/CT and a computer-assisted analysis using the appropriate planning programs are indispensable for the three-dimensional bone evaluation. For this, radiologically visible markers (e.g. metal spheres, titanium sleeves, etc.) of defined size are attached to the templates which help determine the implant length and implant diameter when they are evaluated.

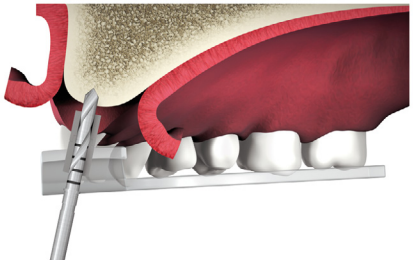


Based on the OPT or the DVT/CT image, the prosthetic treatment plan is again checked and, if necessary, revised.

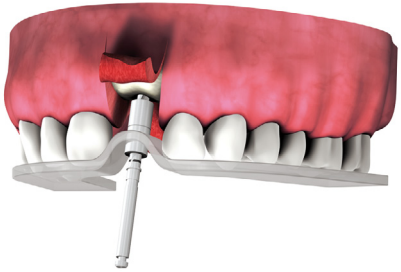
After radiological evaluation, the surgical treatment plan can be prepared. In this way, any periodontal or augmentation measures that may be required will be recognised at an early stage and can be taken before or together with implantation.

The combined information derived from the set up/wax-up/mock-up, the X-ray and an overall clinical evaluation of the case now serves as the basis for the fabrication of a drill template which, in the most favourable case, will definitively define the implant position and implant axis.

The X-ray template, which has already been made, can now be modified to serve as a drill template. Care must be taken to prevent any interference of the drill guide with the incision line.



It is extremely important to fix the template in the correct position during the surgical intervention. Any interference from the raised mucosal flaps must be avoided.



Pre-operative measures

In principle, the same rules apply as to every other dental surgical intervention: The patient must be prepared for the surgical intervention, the surgical area must be sterile, and all persons participating in surgery must comply with the hygiene requirements in order to minimise the risk of complications. Implants, disposable (single-patient) drills, suture material, etc. are to be laid out according to the surgical plan.

Surgical procedure

Preparation

Before drilling, the mucosa must be prepared according to the prevailing conditions, and the surgical site must be exposed.

The sterile-packed single-patient drills, which are cooled externally with sterile saline solution, ensure maximum safety and efficiency during the surgical procedure. To make sure that no damage is caused to the bone, the drill speeds are between 400 and 1500 rpm depending on the drill diameter, the bone density and other local factors. Marking the bone by spot drilling with the pre-drill/round drill usually is unnecessary thanks to the cutting blade geometry. All drills have depth marks corresponding to the implant lengths.

Additionally, a set of depth stops can be used which are recommended for safety reasons.

As the prowital implants are self-tapping, the use of a tap may not be necessary provided the patient's bone quality is D3 or D4.

With compact bone quality (D1-D2), however, a tap must always be used!

Drilling the pilot hole

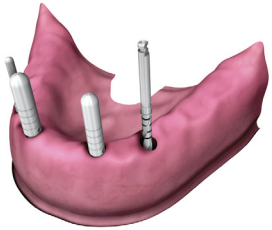
The preparation of the implant site starts with the use of the pilot drill (Ø 2.2mm/1.410.2200). The axis and depth of the implant site are to be determined according to the treatment plan (depth marks correspond to the implant lengths of **9 mm, 11 mm, 13 mm, 15 mm**).

The use of depth stops according to the implant length is recommended.

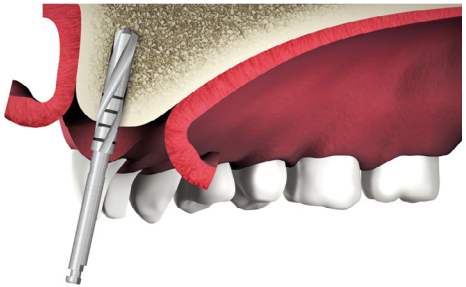
The recommended max. speed is **1,500 rpm.**

If several implants have to be inserted, a parallel pin (1.430.2243) is placed in the first pilot hole to check the axial alignment, this serves to align the axes of all other implants.

Then the other pilot holes are drilled one after the other in the correct sagittal and transverse direction.



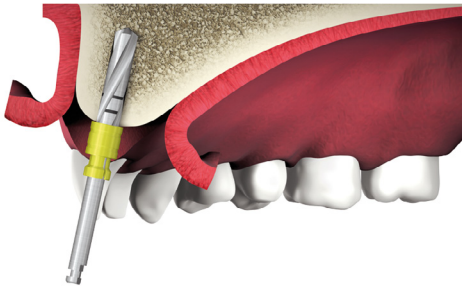
Drilling the 3.5 mm hole



After drilling the pilot hole, the form drill for the 3.5 mm implant diameter (1.415.3501) is used to further prepare the implant site.

The recommended max. speed is **1,000 rpm**.

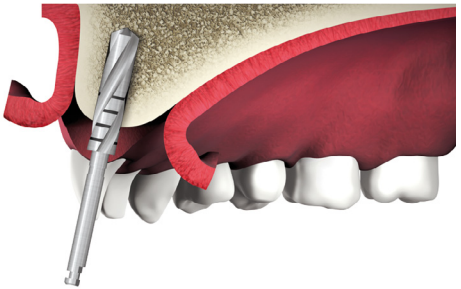
If required as a result of the bone quality, the 3.5 mm tap (1.425.3501) is used.



The use of depth stops according to the implant length is recommended.

Drilling the 4.3 mm hole

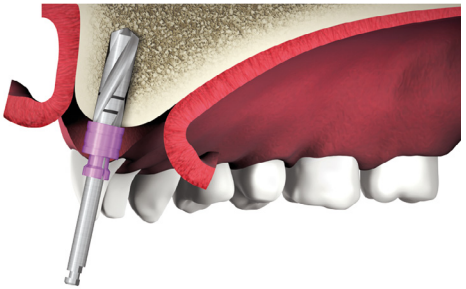
After having prepared the implant site with the form drill for the 3.5 mm implant diameter, the next larger form drill for the 4.3 mm implant diameter (1.415.4301) is used.



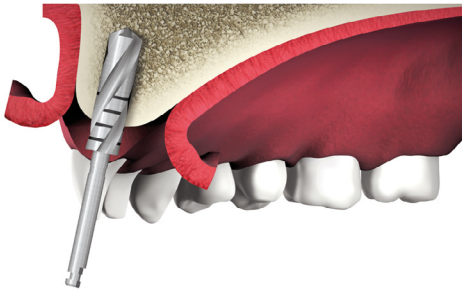
The recommended max. speed of this drill is **800 rpm.**

If implants with a diameter of 4.3 mm are placed, the tap (1.425.4301) is used.

The use of depth stops according to the implant length is recommended.

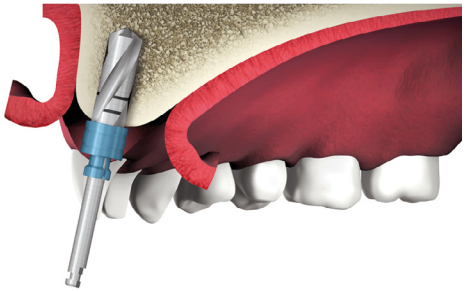


Drilling the 5.0 mm hole



The implant site is prepared with the form drill for the 5.0 mm implant diameter (1.415.5001), the max. recommended speed here is **700 rpm.**

The use of depth stops according to the implant length is recommended.



Then site preparation is continued with the tap (1.425.5001) if required in view of the bone quality.

Use of the triangular bur

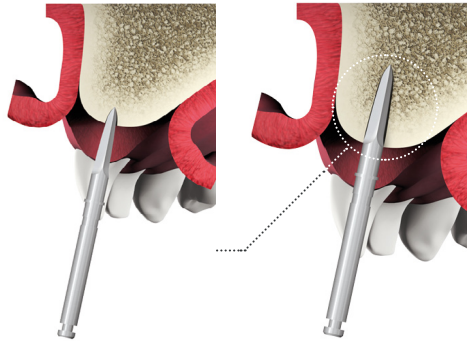
Optional

With very small and pointed jaw bones the triangular bur (1.413.2300) can be used before the pilot drill (1.410.2200). The tip of the triangular bur is placed onto the bone and, starting at a low speed, inserted into the bone.

The speed can be increased as soon as a definite guidance has been reached.

The triangular bur has no depth marks. The maximum length that the triangular bur may be **inserted into the bone is the entire cutting length of 9 mm.**

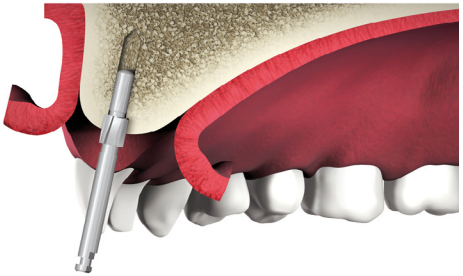
The recommended max. speed is **1,000 rpm.**



The pilot drill is now used to extend the prepared hole, at the same time deepening the hole to the selected implant length.

Use of the half dog point

Optional

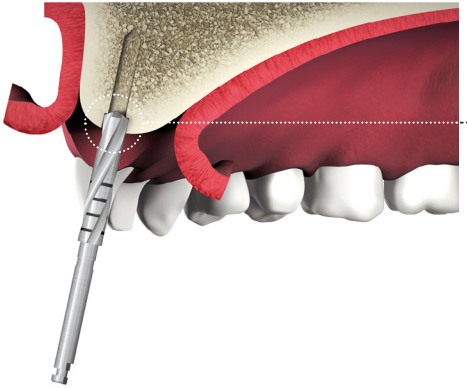


With thin or pointed jaw bones the half dog point (1.412.3100) can be used after application of the pilot drill (1.410.2200).

The non-cutting guide pin is inserted into the hole of the pilot drill.

The cutting portion is placed at the bone crest and used with moderate pressure and a max. drilling speed of **800 rpm.**

The crestal bone is milled out by the half dog point.



Using the form drill ø 3.5mm (1.415.3501), the hole in the bone prepared by the half dog point can be deepened up to the selected implant length.

Using the countersink drill

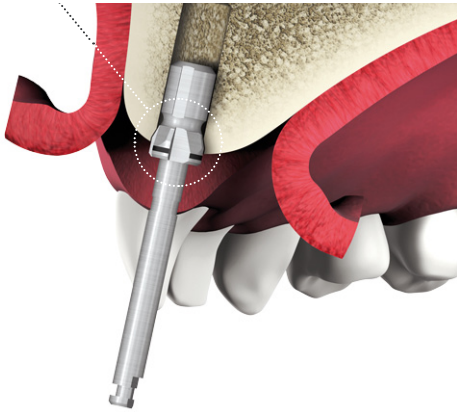
Optional

The use of a countersink drill suitable for the implant diameter is recommended for very hard, crestal bone quality.

This prevents excessive compression on the crestal bone and a positive connection between the implant and the crestal bone is achieved.
For this, the non-cutting guide portion is inserted into the prepared implant hole.

The cutting portion is placed at the bone crest and the final implant site is prepared at a max. drilling speed of **500 rpm** down to the depth mark.

The use of depth stops is optionally possible. Only the depth stop for the 15-mm-long implant (a circular mark) is used here.



Using the tap

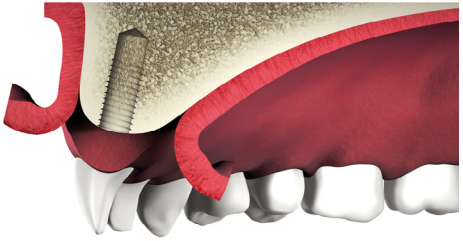
Optional

The tap is required for bone quality D1 + D2 to prevent excessive compression of the bone.

The taps are offered with different diameters (3.5 mm, 4.3 mm, 5.0 mm) and also have depth markings.

They may either be inserted in the handpiece or, in the case of manual thread cutting, in the manual torque wrench adapter (1.560.0100).

When the handpiece is used, the recommended **speed is 15 rpm.**



After the thread has been cut into the bone to the applicable depth mark, the handpiece is simply switched to counter-clockwise rotation, and the tap is rotated out. To avoid damage to the thread, the tap must never be pulled out abruptly.

To reduce the torque required for inserting the implant, it may be necessary to work the tap in and out several times if the bone is very hard.

Diagram showing preparation of the implant bed

prowital 3.5 mm implant


Pilot drill 2.2 mm (1.410.2200)


Form drill 3.5 mm (1.415.3501)

Countersink drill 3.5 mm (1.420.3501)

Tap 3.5 mm (1.425.3501)

prowital 4.3 mm implant


Pilot drill 2.2 mm (1.410.2200)


Form drill 3.5 mm (1.415.3501)


Form drill 4.3 mm (1.415.4301)

Countersink drill 4.3 mm (1.420.4301)

Tap 4.3 mm (1.425.4301)

prowital 5.0 mm implant


Pilot drill 2.2 mm (1.410.2200)


Form drill 3.5 mm (1.415.3501)


Form drill 4.3 mm (1.415.4301)


Form drill 5.0 mm (1.415.5001)

Countersink drill 5.0 mm (1.420.5001)

Tap 5.0 mm (1.425.5001)

Service life of the drills

PLEASE NOTE

The drill, countersink and tap are supplied sterile.

These are single-patient, single-use products (see symbol) and may not be reprepared. Perfect functionality, edge-retention and resistance to corrosion can **not be guaranteed** after preparation, as the materials of the drills, taps and countersinks were not designed for these requirements.

The operator bears sole responsibility for any deviating procedure.

If used according to instructions, the drills designed as single-patient, single-use instruments can be used to make 6 - 8 holes in quality D1 bone.

As soon as excessive pressure has to be applied during drilling, the drill must be replaced immediately to avoid the risk of overheating the bone.

The used drill must be properly disposed of.

Parallel pins

Parallel pins are recommended to control the inclination of the axes.

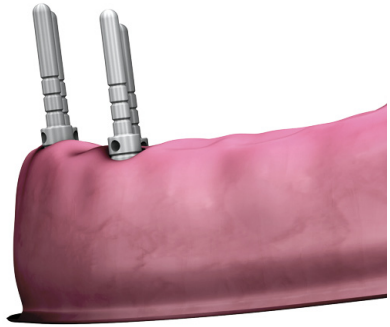
Two parallel pins are available.
These are marked in pairs with the corresponding drill diameters.

This enables every step of the drilling procedure to be checked.

Parallel pins ø 2.2 + 4.3 mm (1.430.2243)

Parallel pins ø 3.5 + 5.0 mm (1.430.3550)

The parallel pins also have depth marks, enabling the previously defined drilling depth to be checked at any time.

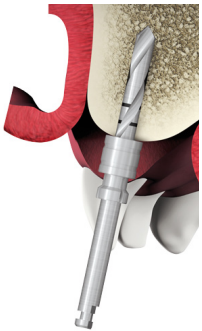


Depth stop

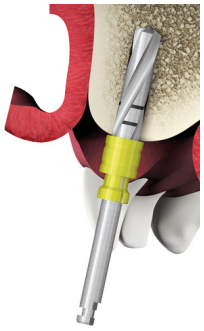
For the safety of the patient, we recommend using depth stops.
They are available for all implant lengths/diameters and prevent the implant site from being drilled too deep. (1.440.0000)

The depth stops are colour-coded and have circular marks for the respective implant lengths.

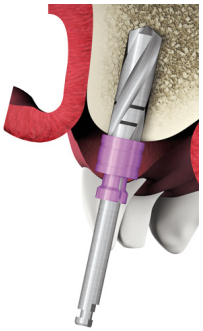
Titanium colours
Pilot drill
ø 2.2mm



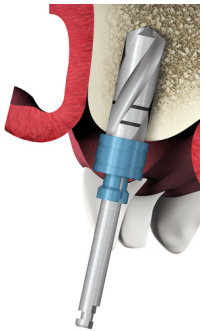
Yellow
Form drill and countersink drill for implant ø 3.5 mm



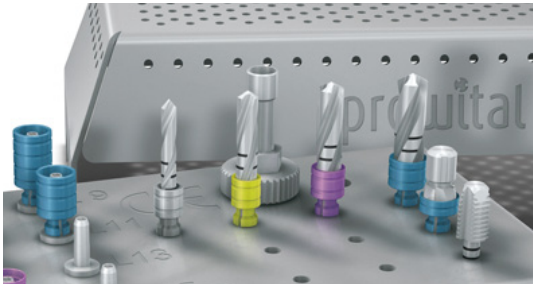
Red
Form drill and countersink drill for implant ø 4.3 mm



Blue
Form drill and countersink drill for implant ø 5.0 mm



Implant length 9 mm: 4 circular marks
Implant length 11 mm: 3 circular marks
Implant length 13 mm: 2 circular marks
Implant length 15 mm: 1 circular mark

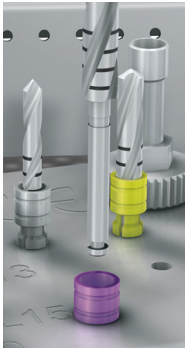


Expl.:
equipped for implant diameter **5.0 mm**
length **13 mm**

The depth stop is simply pulled forward over the ISO shaft until it stops.

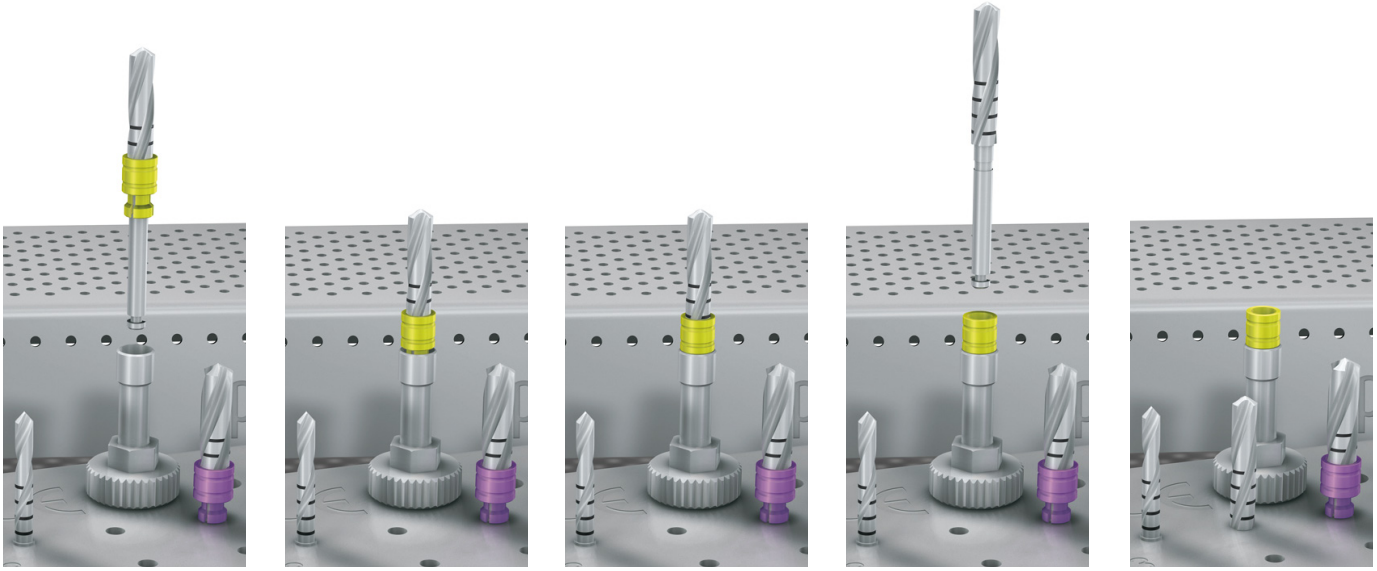
The secure fixation of the depth stop should be checked.

Then the drill is inserted into the dental handpiece, and the implant site is drilled until the depth stop contacts the bone.
(Only use moderate pressure for this procedure).



Depth stop

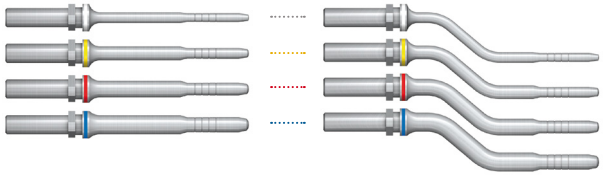
As the bone level may vary around the bone perimeter, the implant site may require some finishing after the depth stop has been removed.



Preparation of the implant bed with osteotomes

The implant bed can also be prepared manually, especially with bone quality D 3 + 4, using an osteotome. These are available in straight and angled versions, depending on the area of application. They are colour-coded to match the prowital system.

White: pre-osteotome ø 2.2mm
Yellow: for implant ø 3.5 mm
Red: for implant ø 4.3 mm
Blue: for implant ø 5.0 mm



The safe use of the prowital osteotomes is only assured in combination with the prowital handgrip (1.540.0000).

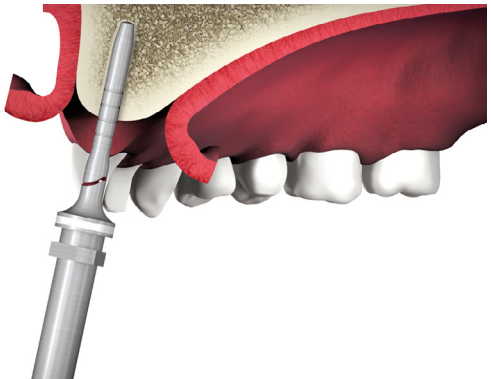
The osteotome inserts are inserted into the handgrip and securely locked.

The osteotomes are used in ascending order up to the prowital screw-type implant used.

Using the osteotome with white colour-coding (pre-osteotome)

Firstly, the pilot drill (Ø 2.2 mm/1.410.2200) is used to make a hole through the hard cortical bone.

In order to maintain the bone substance, it is recommended that this hole is not drilled to the previously defined implant length.

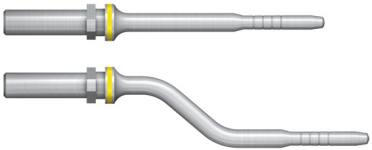


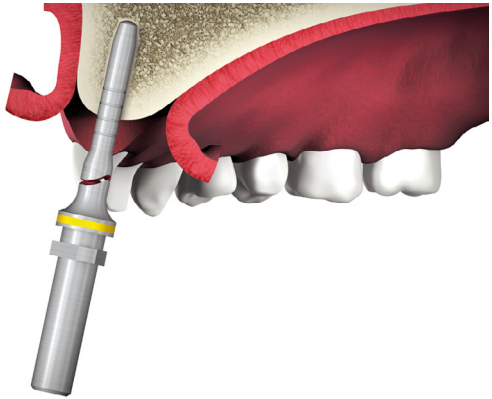
The osteotome (white colour-coding) is used by pushing, careful tapping or rotation.

The depth marks corresponding to the implant lengths 9 mm, 11 mm, 13 mm and 15 mm **must be observed and may, under no circumstances, be inserted deeper than the planned implant length.**

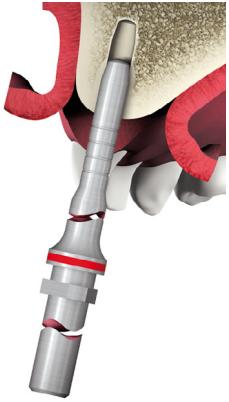
Using the osteotome for the prowital implant ø 3.5 mm

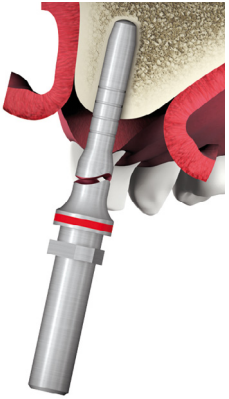
After using the pre-osteotome, the implant bed is prepared with the osteotome for ø 3.5 mm (yellow colour-coding).



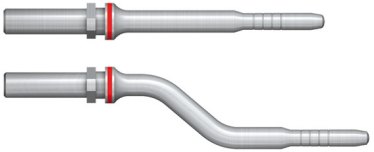


Using the osteotome for the prowital implant ø 4.3 mm



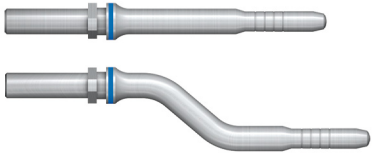


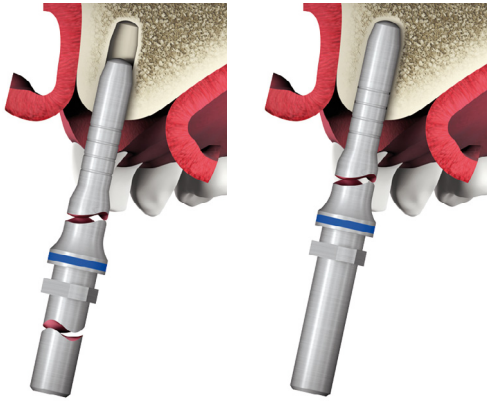
After preparation of the implant bed with the osteotome for ø 3.5 mm (yellow colour-coding), the next largest osteotome (red colour-coding) for implant diameter ø 4.3 mm is used.



Using the osteotome for the prowital implant ø 5.0 mm

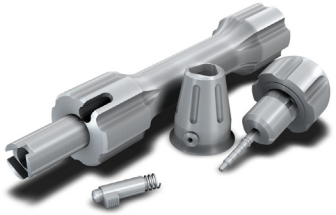
After preparation of the implant bed with the osteotome inserts 2.2, 3.5 and 4.3 mm (colour-codes white, yellow, red) the osteotome (colour-code blue) for implant diameter ø 5.0 mm is used.



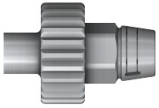


NOTE

The osteotome and the handgrip are cleaned thoroughly after use.
The prowital handgrip (1.540.0000) can be completely disassembled for this and prepared according to preparation instructions K0701AA0021.
The relevant recommendations of the Robert-Koch Institute also provide instructions for cleaning, disinfection and sterilisation.



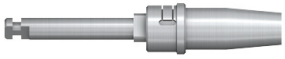
Manual torque wrench adapter



With the manual torque wrench adapter (1.560.0100) all drills, the drill extension, the implant drivers and screw drivers can be picked up.

Thus, the user can insert the threads, implants and abutments either manually or with the torque wrench (1.500.0005) without having to change tools.

Drill extension



If needed, an appropriate drill extension is available which is compatible with both the handpiece and the manual torque wrench adapter (1.560.0100).

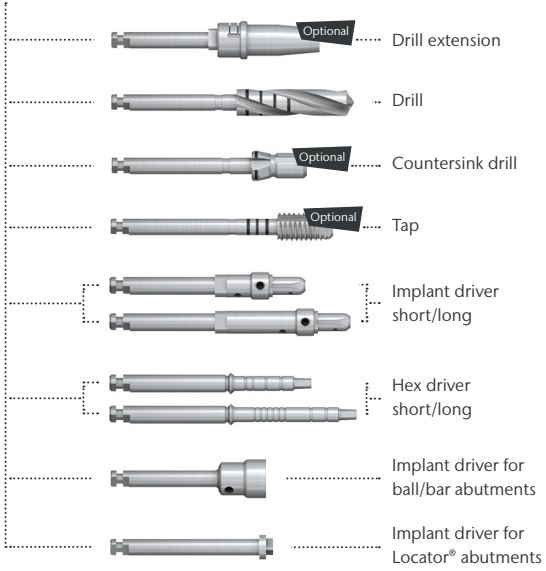
NOTE

For the patient's safety, the implant drivers and screw drivers have a special hole through which dental floss must be threaded before these instruments are used in the mouth. In this way it is assured that the instruments cannot be swallowed or aspirated by the patient.

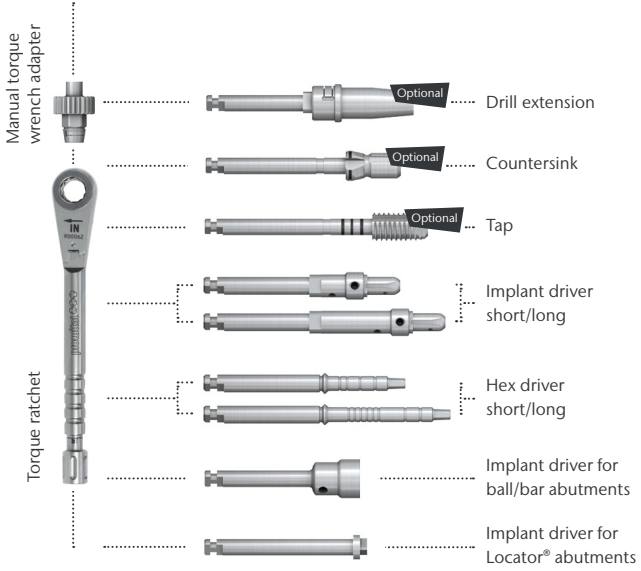
Schematic representation of drivers

With just a few tools, all implants and abutments can be inserted and fastened. The individual components are all adjusted to each other.

Motor-driven



Manual use



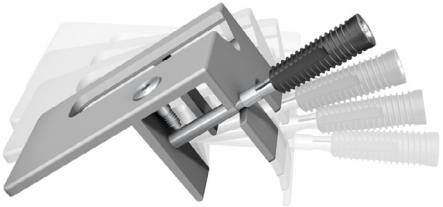
Implant packaging

The prowital implant system is delivered in innovative packaging enabling the user to work efficiently and, at the same time, with a high degree of safety.

The implants are packed in a double sterile package and colour coded corresponding to their respective diameter. The implant packaging, the accompanying documentation strip and the plastic implant holder have the same colour code.

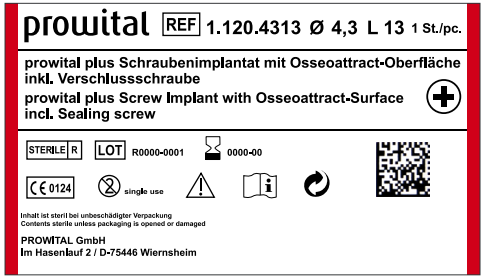
The colour codes:

Yellow	=	3.5 mm diameter
Red	=	4.3 mm diameter
Blue	=	5.0 mm diameter



The prowital implant itself and the closure screw are fixed to the implant holder. The implant can be picked up directly with the implant driver (1.530.0005 or 1.530.0010) in one step. The closure screw can also be picked up directly from the implant holder (1.510.0005 / 1.510.0010 / 1.510.0015).

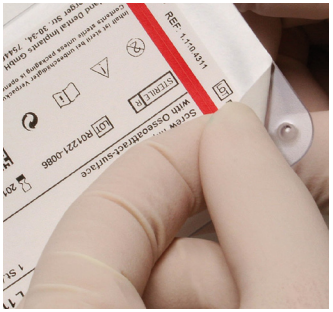
The HIBC matrix code (bar code) on the implant packaging labels and the accompanying documentation strip can be entered using a barcode scanner and documented and recorded in any current computerised dental practice filing system.

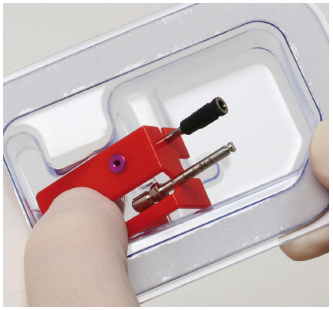


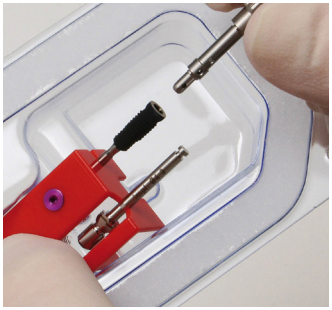
Opening the implant packaging and removing the prowital implant

The prowital implant is protected by an outer cardboard packaging, a sterile film wrapper and a blister pack. Before opening the packaging, make sure that it is intact and that the selected prowital implant has the right diameter and length for the prepared implant site.

The packaging cover which, for safety reasons, again lists all relevant data, is removed. Then the rear end of the colour-coded implant holder is pressed down into the blister package until it locks into place.







Now all components contained in the implant holder can be taken out conveniently. For this purpose, the implant driver (1.530.0005 or 1.530.0010) is attached to the dental handpiece or the manual torque wrench adapter and inserted into the implant up to the stop.

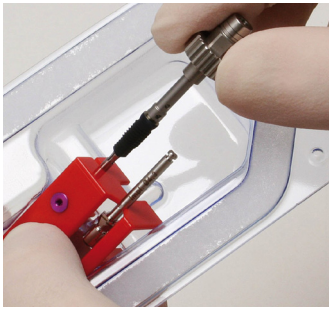
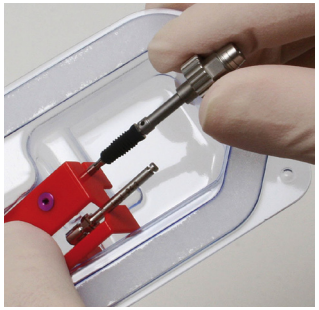
The implant driver, fully inserted into the implant, is bent upward with light pressure.

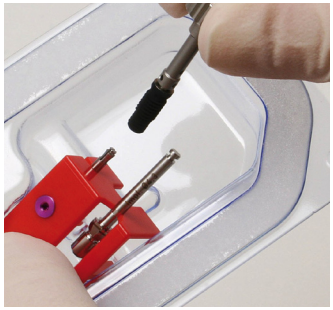
IMPORTANT:
The implant driver must not be pulled backwards.

Now the prowital implant can be rotated into the implant site, prepared as described above.

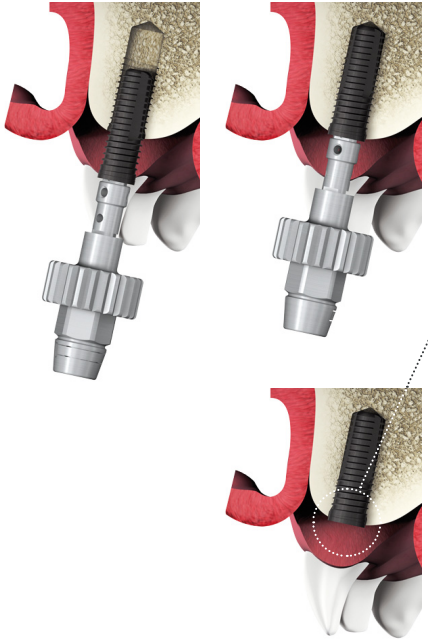
Note

Make sure that the implant is firmly fixed to the implant driver.



Inserting the implant into the implant site



The prowital implant may be screwed into the implant site either manually or mechanically whereby a maximum torque of 40 Ncm should not be exceeded.

The drills and implants are matched to each other with the coronal margin of the implant extending a standard distance of about 0.4mm above the crestal bone level.

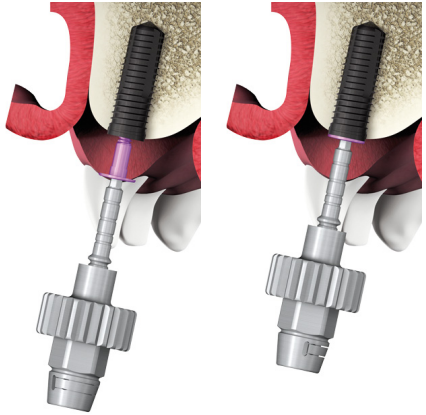
To check the correct alignment of the rotation stop, the implant driver has a mark that has to be aligned with buccofacial bone wall.

When the prowital implant has thus been placed in the right position, the implant driver can be removed from the prowital implant.

Placing the closure screw

The closure screw is picked up from the holder with the screw driver (1.510.0005, 1.510.0010 or 1.510.0015).

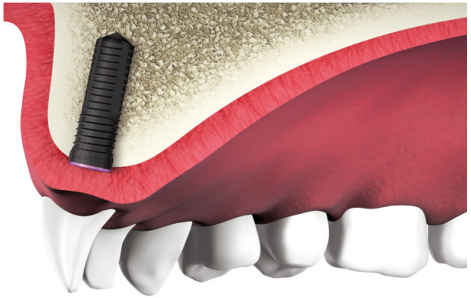
The screw driver has a tapered hex pick-up head that securely grips the closure screw and thus ensures safe removal.



NOTE

Now the closure screw is placed into the prowital implant and tightened manually.
The closure screw must not be machine-tightened under any circumstances!

Wound closure



For prowital implants, we recommend submerged healing as the standard healing method. The wound is closed with the soft tissue flap and carefully sutured.

Non-submerged healing is, of course, also possible.
In this case, an appropriate healing cap or a temporary abutment made of PEEK is screwed into the implant after insertion of the prowital implant, and the mucosal flap is sutured.

Healing time

Depending on bone quality, bone supply and concomitant surgical measures, the healing time of prowital implants is between **6 weeks and 4 months** (so-called shortened healing times).

Exposure after healing

After the precise position of the implant underneath the mucosa has been determined, the prowital implant is exposed by making a gentle and careful incision into the mucosa.

Any bone that may have formed on top of the closure screw is to be removed with the appropriate instruments.

The closure screw is to be removed by turning the screw driver (1.510.0005, 1.510.0010 or 1.510.0015) in an anti-clockwise direction.

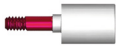
Shaping the mucosa

To shape the mucosa, tapered or cylindrical healing caps are available for all prowital implants in three different heights (2, 4 and 6 mm).

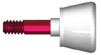
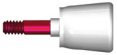
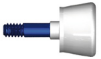
On opening the gingival, the healing cap is selected so that it lies approx. 1-1.5 mm supragingivally.

The healing cap is screwed in with the screw driver (1.510.0005, 1.510.0010 or 1.510.0015) and tightened with a torque of about 20 Ncm. When the periimplant soft tissue has healed, the impressions are taken.

Cylindrical healing cap
for prowital implants

Implant – Ø in mm	**Height** in mm	
3.5	2.0	
3.5	4.0	
3.5	6.0	
4.3	2.0	
4.3	4.0	
4.3	6.0	
5.0	2.0	
5.0	4.0	
5.0	6.0	

Tapered healing cap
for prowital implants

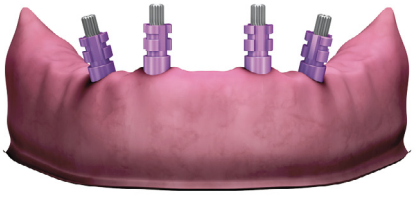
Implant – Ø in mm	**Height** in mm	
3.5	2.0	
3.5	4.0	
3.5	6.0	
4.3	2.0	
4.3	4.0	
4.3	6.0	
5.0	2.0	
5.0	4.0	
5.0	6.0	

Impression taking / transfer of the oral situation

Components are available for both closed-tray and open-tray impression taking, whereby the impression copings are secured against rotation and colour coded in both cases.

To exclude mistakes, especially with closed-tray impression taking, we recommend indicating the implant diameter together with the implant position in the documentation sent to the laboratory. This is particularly important when different implant diameters are used for one and the same case.

Method of impression taking



Depending on the clinical situation and indication, the clinician may vary between open-tray and closed-tray impression taking. Due to the procedure involved, the open-tray method can claim a higher level of precision (no repositioning) although, due to the design of the impression caps, the closed-tray method is very similar to the open-tray method in terms of precision and accuracy.

The use of prefabricated impression trays and the resulting low cost and effort make the closed-tray technique the standard method. However, in the case of rather diverging implant positions or in combination with a functional impression, the open-tray method of impression taking must be chosen.

Impression material

For both the closed-tray and the open-tray method of impression taking, all current materials available for precision impression taking can be used.

Closed-tray impression taking

The colour-coded impression copings are supplied with the fixing screw, impression cap and cap for bite registration.

Immediately after removing the healing cap, the impression coping is placed into the prowital implant. First the (tapered) screwdriver is inserted in the fixing screw – now the impression coping is fixed for insertion.

A slight rotary movement of the impression coping causes the rotation lock to engage, and the impression coping reaches its final position. Now the fixing screw is inserted in the implant manually with the screw driver (1.510.0005, 1.510.0010 or 1.510.0015).

Then the impression cap is placed on the fixed impression coping and locked into position. By appropriately arranging the two extensions on the impression cap it is ensured that no adjacent teeth and/or impression copings are touched.

After removing the tray – whereby the impression cap remains in the impression material – the fixing screw is loosened, and the impression coping is pulled off from the implant.

NOTE

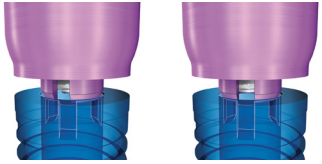
For reasons of accuracy, the impression cap and the bite registration cap should only be used once.

Open-tray impression taking

Open-tray impression taking requires a customised tray. As a rule, an interim impression must be taken first. Along the extension of the implant axis, perforations for the fixing screws and impression aid have to be made in the impression tray.

First, an impression coping corresponding to the implant diameter is selected. It is inserted in the prowital implant immediately after removal of the healing cap. The fixing screw of the impression coping is pushed apically to facilitate the orientation relative to the implant axis. Now the impression coping is placed on the implant and slightly rotated until the rotation lock engages. Then the fixing screw is screwed manually into the implant with the screw driver (1.510.0005, 1.510.0010 or 1.510.0015).

If necessary, an X-ray can be made to check the accurate position of the impression coping on the implant.



Open-tray impression taking

The prepared customised impression tray is tried in the patient's mouth, and any defects on the tray are eliminated. The impression coping, the fixing screw and the impression aid must not touch the impression tray. The impression aid can be cut back to the circular mark if required.

The impression is taken using appropriate silicone or polyether impression material.

After successful impression taking, the impression aid is removed, the fixing screw is loosened and retracted until a resistance can be felt.

Then the impression tray can be removed.

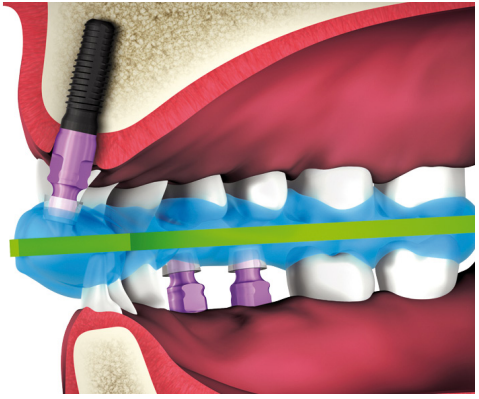
Bite registration

A bite registration can be made with the components of the prowital implant system for closed-tray impression taking.

To this end, the impression coping for the closed tray, as described in the chapter “Closed-tray impression taking”, is first inserted into the implant.

Then the bite registration cap is placed on the impression coping where it engages perceptibly. Now the bite can be registered. The material used for the bite record should not stick to the cap.

After bite registration, the caps are included in the material sent to the dental laboratory.



NOTE

For reasons of accuracy, the impression cap and the bite registration cap should only be used once.

Cleaning / preparation / disinfection / sterilisation of the instruments

The procedure for preparation (cleaning, disinfection, sterilisation) is described in the instructions K0701AA0021.

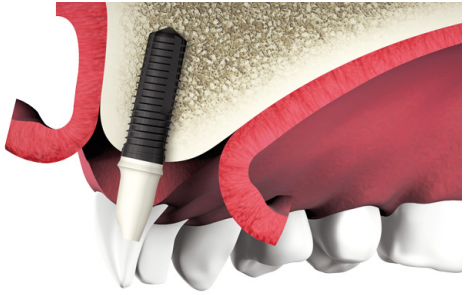
Information is also provided in the relevant recommendations of the Robert-Koch Institute.

Prosthetic restorations

Temporary restoration

The advantage of temporary restorations is that the periimplant soft tissue can be maintained and/or built up, especially in the aesthetically relevant region.

A PEEK abutment with the same diameter as the implant is placed in the implant. The circumferential chamfer can be somewhat adjusted in the apical direction, if necessary.



The PEEK abutment is prepared outside the mouth. For easy preparation, we recommend fixing the PEEK abutment to a laboratory implant.

For grinding, diamond-coated grinding tools are recommended for use at high speed, but without water cooling and at low pressure.

The chamfer preparation is thus placed subgingivally so that the soft tissue (emergence profile) can be designed and shaped by a temporary crown.

The temporary abutment can be inserted immediately after implant placement, i.e. in case of “immediate loading”, or after the healing phase.

The soft tissue is shaped ideally, and a perfect emergence profile is obtained. The temporary crown can be made in the lab even during the preoperative planning stage (CT evaluation, fabrication of the drill template).

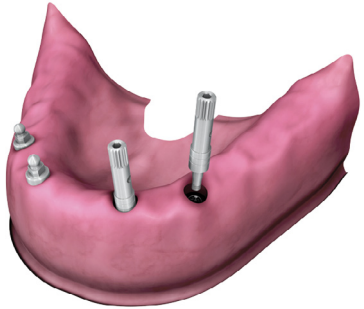
The temporary crown / bridge is fabricated in the usual way. We recommend making the temporary restoration from plastic. This makes it easier to adapt and shape the periimplant soft tissue according to the anatomical / aesthetic requirements while the patient is wearing the temporary restoration.

Placement of the temporary restoration in the mouth

To assure that the accurate position will be found again, the PEEK abutment is marked vestibularly. Before inserting the temporary restoration in the mouth, all components (PEEK abutment, fixing screw, crown) must be cleaned and disinfected. The fixing screw (green) is tightened into the implant with 20 Ncm. The screw channel is temporarily closed and the temporary restoration is fixed with temporary cement.

Selection measure post

The selection measure post (1.430.0110) can be used to select the components for the hybrid prosthesis (ball, bar or Locator® abutments).



The selection measure post is screwed into the implant after exposure.

The circular marks on the selection measure post make the height of the mucosa easy to determine.
The marks are spaced at 1.75/3.0 and 4.25 mm from the implant platform.

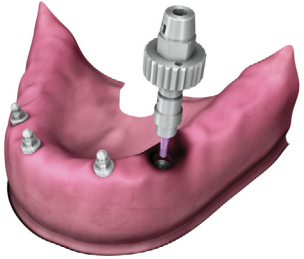
PLEASE NOTE

acc. to Implantology Consensus Conference
(a cooperation of the following associations: BDIZ, BDO, DGI, DGZI, DGMKG), for removable restorations, at least 4 implants should be used in an edentulous mandible and 6 in the maxilla.

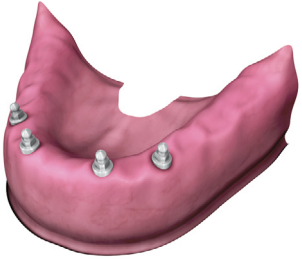
Ball abutment (Direct)

Prosthetic restorations with ball abutments can render the use of healing caps after exposure unnecessary.
The ball abutments are selected according to the implant diameter and the mucosal height.

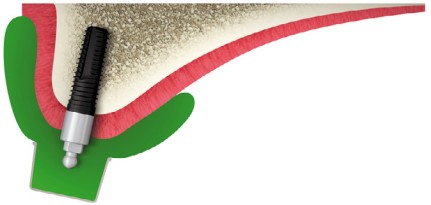
The selection measure post (1.430.0110) can be used to determine the height of the mucosa.



The ball abutments are inserted with the implant driver (1.520.0020) and tightened to a torque of **30 Ncm.**



After healing of the periimplant soft tissue (usually taking 10 – 14 days), the impressions are taken.



This is done directly over the ball abutments; a transfer aid is not necessary. A functional impression is made.

A matrix system that is suitable for the ball diameter 2.25 mm can be used for fabrication.

e.g., Ecco-System (Kaladent-Unor), Dalbo System (Cendres + Metaux)

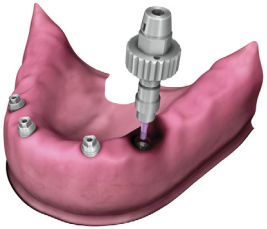
When incorporating the matrices into an existing prosthesis, care should be taken that the prosthesis base is sufficiently ground out so that the matrices do not come into contact.

The matrices must be aligned parallel to each other, independently of the implant axis.

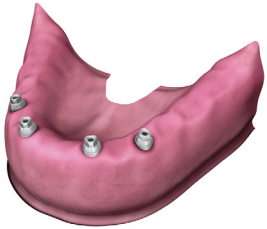
Bar abutment (Direct)

The bar abutment can be screwed into the implant immediately after exposure.
The bar abutments are selected according to the implant diameter and the mucosal height.

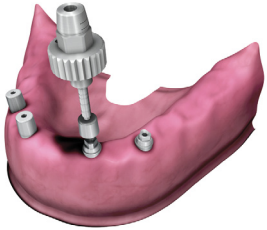
The selection measure post (1.430.0110) can be used to determine the height of the mucosa.



The implant driver (1.520.0020) is used for insertion. The bar abutment is tightened to a torque of **30 Ncm.**



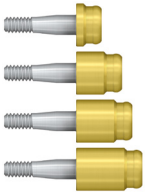
The bar abutment is covered with the closure cap for bar abutments (1.274.0000) during the healing period of the periimplant soft tissue.



After healing, the impressions are taken over the bar abutment. After removing the closure cap, the impression coping for bar abutments (1.203.0000) is screwed manually into the bar abutment using controlled force.

A functional impression is taken. The prepared customised impression tray is tried in the patient's mouth, and any defects are remedied.
The impression coping and the fixing screw must not touch the impression tray.

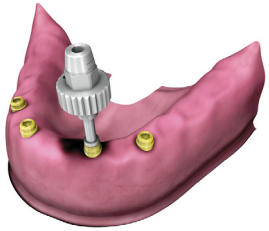
Locator® abutment (Direct)



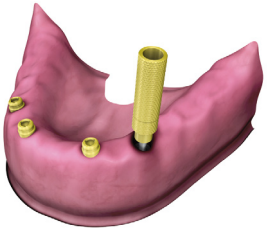
Prosthetic restorations with Locator® abutments can render the use of healing caps after exposure unnecessary.

The Locator® abutments are selected according to the implant diameter and the mucosal height.

The selection measure post (1.430.0110) can be used to determine the height of the mucosa.



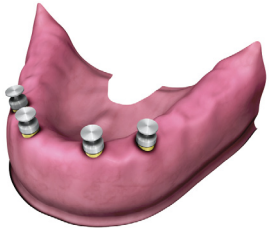
The Locator® abutments are screwed in using the implant driver (1.277.0005) and tightened with a torque of **30 Ncm.**



Tip: The Locator® abutments can be screwed into the implant with the gold-coloured part of the Locator® instrument (1.277.0010).

WARNING:

It is not possible to check the correct torque! Always use the implant driver (1.277.0005) to definitively tighten the implant.



After healing of the periimplant soft tissue (usually taking 10–14 days), the impressions are taken on the Locator® abutment. The Locator® impression coping (1.277.0100) is used for this.

A functional impression is recommended. The prepared customised impression tray is tried in the patient's mouth, and any defects are remedied. The Locator® impression coping must not touch the impression tray.

After completion of the prosthesis, the appropriate, colour-coded replacement males are inserted into the prosthesis. These are available with pull-off forces of

Can be used at an angle of up to 10° per implant

Replacement males	Pull-off-force
transparent	22.3 N
pink	13.4 N
blue	6.7 N

At an angle of between 10 – 20°/implant, replacement males are available for the extended angulation with pull-off forces of

Replacement male extended angulation	Pull-off-force
green	17.8 N
orange	9.0 N
red	6.7 N

If no pull-off force is desired, the grey replacement male (1.277.1115) can be used.

NOTE

All replacement males can only be used once.

The angle of the implants can be checked with the Locator® angle measurement guide (1.277.0020) and the parallel posts (1.277.0030).

The parallel posts are placed on the Locator® abutments. The angle measurement guide is placed on the mucosa. The angle of the implants can now be easily determined and the appropriate replacement males can be selected.

The replacement males are inserted with the Locator® instrument (1.277.0010) and replaced if required.
The instrument is in 3 parts and performs three functions:

1. Insertion of the Locator® abutments –
   Caution: It is not possible to check the correct torque! Always use the implant driver (1.277.0005) to definitively tighten the implant. (Gold-coloured end piece)
2. Removal of the replacement males or the processing male. (Silver-coloured end piece with sharp circular edge)
3. Insertion of the replacement males or the processing male with rebasing (grip piece).

Removing replacement males or processing male

To remove the replacement or processing male, the silver end is screwed out until the bolt disappears in the Locator® instrument and a gap appears between the grip and the tool for removing the matrix.

The instrument is now pressed into the replacement male/processing male to be removed. The sharp circular edge engages with the males.

The replacement or processing male is pulled out of the retention cap by rotation of the tool for removing matrices in the opposite direction (clockwise rotation).

Inserting replacement males or processing male

To insert the replacement male, the tool for removing matrices is removed from the grip piece by anti-clockwise rotation. The replacement male is now placed on the abutting face of the grip piece.

CAUTION

The replacement male is placed without friction!

The replacement male is now pressed into the retention cap.
The male connects audibly.

Procedure for rebasing

If the prosthesis requires rebasing, it is necessary to remove the existing Locator® replacement male from the retention cap.

The replacement male is replaced by a processing male (1.277.0500) Rebasing can now be carried out with a suitable impression material.

When rebasing is complete, a new replacement male is inserted into the retention cap.

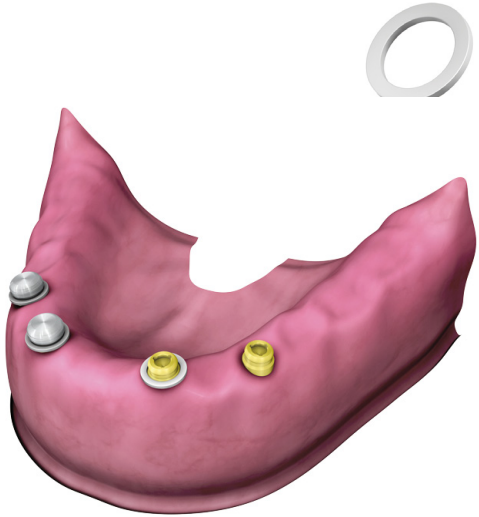
Procedure for fitting Locator® abutments into an existing prosthesis

The matrix is supplied with the fitted processing male, a block-out spacer and three replacement males with different pull-off forces.

The prosthesis must be generously hollowed out in those areas containing the Locator® abutments including the matrices.

For incorporation into the prosthesis, the block-out spacer is pushed over the Locator® abutment and the matrix is fixed on the Locator® abutment. The previously hollowed out prosthesis is now checked to ensure there is no contact to the matrix.

The matrix can now be polymerised into the prosthesis.
After the prosthesis has been incorporated and completed, the processing male (black) is removed from the retention cap and replaced by a suitable replacement male.



Prosthetic abutments

PLEASE NOTE:

The prosthetic abutments (with the exception of ball abutments, bar abutments and Locator® abutments) are always delivered with two screws.

CAUTION:

For the definitive fixation of the prosthetic restoration, always use the (titanium) fixing screw (1.213.1600).

The **(black) laboratory screw (1.305.1600)** may **only** be used for the fabrication and try-in of the prosthetic restoration.

Information

Torque wrench adjustment

Implant closure screw	tightened by hand with controlled force
Bar abutment closure cap	tightened by hand with controlled force
Healing cap	20 Ncm
Temporary PEEK abutment	20 Ncm
Abutments Standard abutment, straight / 15° angulation Universal abutment Ceramic abutment Gold-plastic abutment	30 Ncm
Bar abutment	30 Ncm
Bar bases Bar base, laser-weldable Bar base, cast-on / solder-on Bar base, burn-out	20 Ncm
Ball abutment	30 Ncm
Locator®	30 Ncm
Inner matrice (Ecco system) ball abutment Use torque wrench (23831)	7 Ncm

NOTE

We recommend retightening all abutments about 5 minutes after insertion with the same torque.

Symbols used on labels and in the instructions for use

	Sterilisation by irradiation		Do not re-use
	Non-sterile		Do not use if packaging is damaged
	Do not sterilise again		Article number
	Important, observe the documents supplied		Batch designation
	Observe instructions for use		Date of manufacture
	Expiry date		

Safety information

For the patient's safety, the implant drivers and screw drivers have a special hole through which dental floss must be threaded threated before these instruments are used in the mouth. In this way, it is assured that the instruments cannot be swallowed or aspirated by the patient.

The values stated as the maximum speeds for the drills must not be exceeded as the rotational characteristics can otherwise not be assured. Local overheating may also occur.

Products labelled as sterile may only be used if their packaging is undamaged.

NOTE

Further safety information, in the form of the symbols described above, is contained in the labels of the respective products and, where applicable, in the accompanying instructions for use.

Safety, liability, warranty

prowital implants are part of an overall concept and may only be used in conjunction with the original components and instruments belonging to it, in accordance with PROWITAL's instructions and recommendations.

The use of non-system components will impair the function of the prowital implant system and will void any warranty or replacement obligation by PROWITAL GmbH.

Advice on the application and handling of our products is provided verbally, in writing, by electronic media or by demonstrations. Such advice is based on the latest state of the art known to PROWITAL GmbH at the time the product was placed on the market.

This does not free the user from his personal duty to determine whether the product is suitable for the intended purposes, indications and procedures. The handling and application of the product are outside of the control of PROWITAL GmbH and are the sole responsibility of the user. Any liability for damages caused as a result of this is excluded.

The perfect quality of the products is guaranteed under our Conditions of Sale and Delivery.
Errors in the evaluation of patients, the preoperative diagnostics and therapy planning may result in the loss of the implant. The surgical part of implant treatment must be preceded by a thorough patient evaluation, preoperative diagnostics and therapy planning.

Maintenance instructions

Products that require regular maintenance (e.g., torque wrench, handle) can be identified in the accompanying instructions for use.

Training and training materials

To ensure effective and safe use of our implant system, we recommend an intensive training course at least every two years.

Training materials can be ordered from PROWITAL GmbH and their distributors or downloaded from the website www.prowital.de.

PROWITAL GmbH provides regular training courses.
These may be led by external experts or by trained specialists.

Supply, availability

prowital system products are only supplied to dental practitioners and dental laboratories.

Packaging and Sterility

prowital implants are supplied in sterile packaging. The intact sterile packaging protects the implant, sterilised by gamma irradiation, from outside influences and, with correct storage, assures sterility until it reaches the expiry date which is printed on the label.

The prowital implant may not be used after this date. PROWITAL GmbH rejects any responsibility for resterilised dental implants, regardless of how or by whom they were resterilised. A prowital implant that has already been used or which is not sterile must not be implanted under any circumstances. If the implant's outer original packaging is damaged or accidentally opened, please return the implant to PROWITAL GmbH. PROWITAL GmbH will then replace the implant, subject to a processing fee, with a sterile implant of the same type.

The label on the implant packaging includes a LOT/serial number, which must be entered in the patient file, in order to assure that the implant can be tracked back if required.
prowital implants must be stored dry, protected from direct sunlight and at room temperature.

For technical questions or further product information, please contact the manufacturer.

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