myplant two

BACK TO
THE ROOTS,
SHAPING THE
FUTURE

Made in Germany. Made by MEISINGER.

MANUAL

THE TWO-PIECE IMPLANT SYSTEM

The concept of a two-piece titanium implant with special expansion thread and self-locking cone as abutment connection was already developed by Prof. Dr. med. dent. Nentwig and Dr. Ing. Moser 30 years ago and brought to clinical maturity. High primary stability, minimum construction height, micro-movement-free and a bacteria-proof implant-abutment connection as well as deep platform switching soon proved to a superior combination in terms of achievable bone and soft tissue stability, and thus guarantors of exceptional long-term success.

With the myplant two implant system, Prof. Nentwig and Dr. Moser have further advanced and optimized this concept, which has been documented over decades, and adapted it to the criteria of modern, future-oriented implant therapy.

We, as myplant GmbH, have made it our mission to provide patients and users of myplant two with an implant system that provides the best possible preconditions to ensure long-term implant success with sustainable hard and soft tissue stability.

With more than 30 years of dental implant manufacturing and development competence, as well as many years of experience in the commercialisation of implants, myplant GmbH represents an alliance that gives the user the reassuring feeling that myplant two is a long-term functional, mechanically stable, as well as tissue-compatible and sophisticated aesthetic solution.

myplant two Made in Germany. Made by Meisinger since 1888

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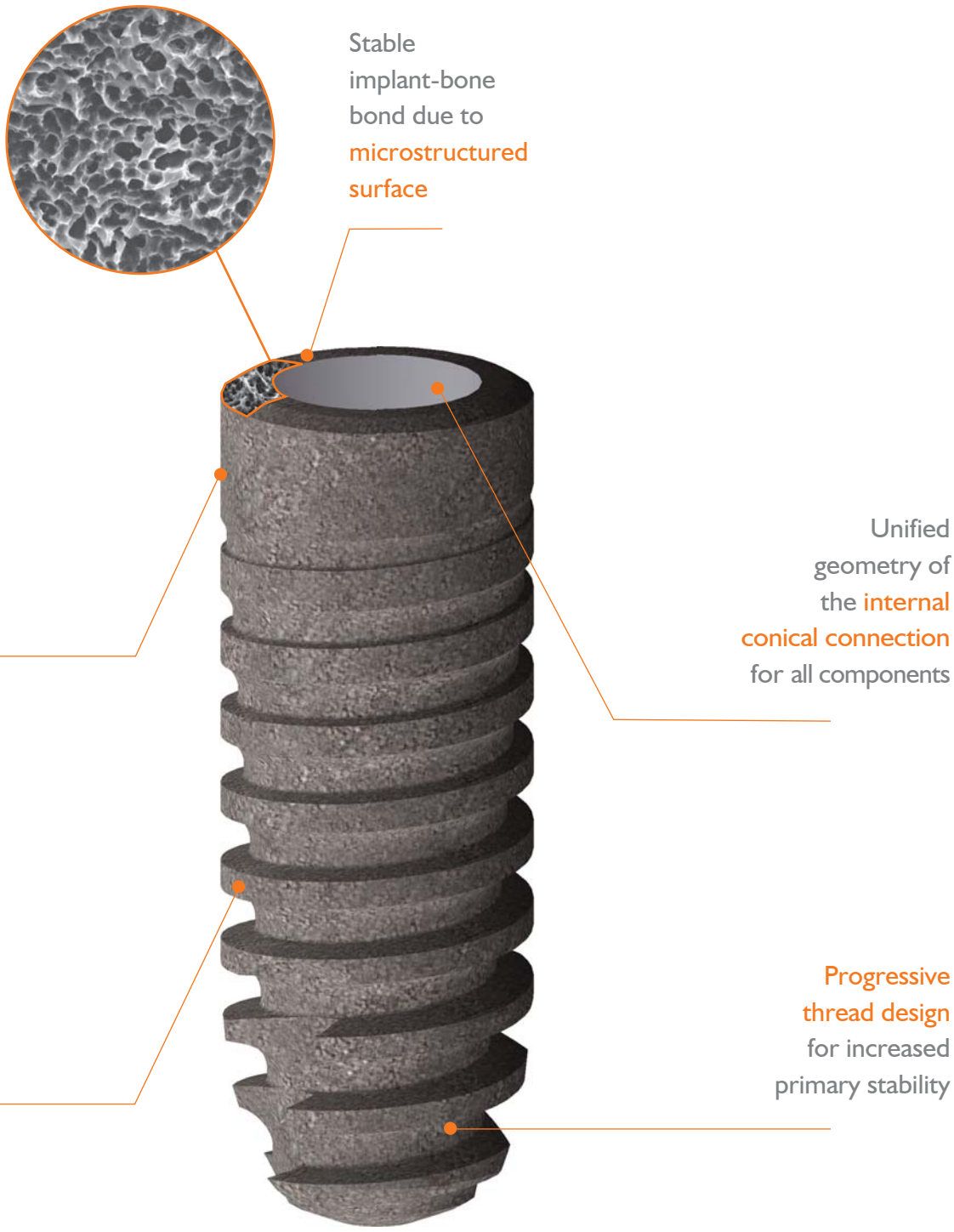
SYSTEM

THE MYPLANT TWO SYSTEM

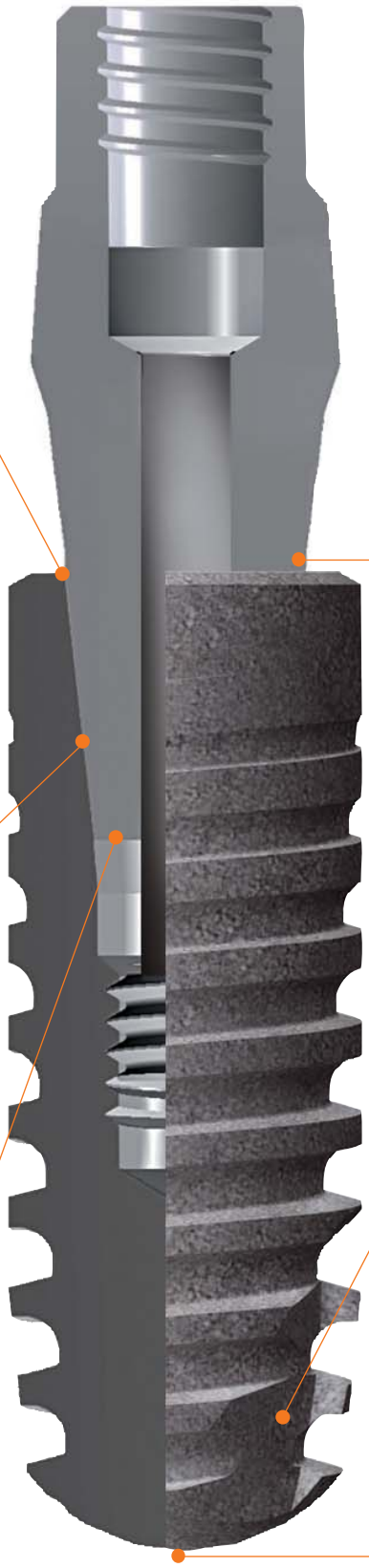
The myplant two system is based on the proven principles of over 30 years in terms of progressive thread design and a bacteria-proof, self-locking, rotation-stable conical connection.



Deep platform switching provides an increased area for bone deposition (on the implant shoulder)

Self-locking, absolutely rotation-stable internal conical connection provides a virtually bacteria-proof seal

Free positioning of angled abutments through non-indexed conical connection



Can be inserted subcrestally by up to 2 mm if bone supply is adequate

Apical bevel for simplified insertion of the implant

Rounded implant tip for gentle sinus floor elevation

THE IMPLANTS

The myplant two implant system is a two-piece system based on state-of-the-art technology. The implants are manufactured from Grade 4 pure titanium according to ISO 5832-2. This material stands for the highest level of biocompatibility and outstanding mechanical properties, thus offering optimal conditions for secure osseointegration. Grade 4 pure titanium demonstrates a perfect combination of ductility and strength. It offers excellent corrosion resistance and does not contain any toxic constituents. Owing to its outstanding properties, Grade 4 pure titanium has been successfully employed as a material for implantology and general medical technology for over 25 years.

myplant two implants are available in three diameters and five different lengths. Due to the practice-oriented graduation of implant sizes the system is suitable for all indications in dental implantology, even in difficult bone conditions.

The letter and color coding system allows fast and safe identification of the various implant diameters. Corresponding instruments for the implant bed preparation are marked with the same color code.

Color coding

	Red	Implant diameter 3.5 mm
	Orange	Implant diameter 4.0 mm
	Yellow	Implant diameter 4.5 mm

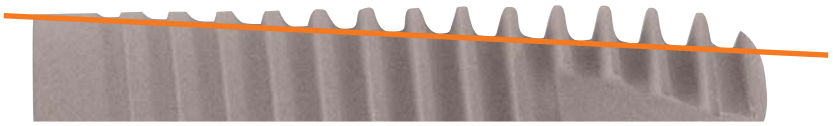
The implant name includes a capital letter which, same as the colour, identifies the implant diameter. The following numbers define the length of the implant in millimeters.

L [mm] / Ø [mm]	6.6	8.0	9.5	11.0	14.0
3.5	A 6.6	A 8	A 9.5	A 11	A 14
4.0	M 6.6	M 8	M 9.5	M 11	M 14
4.5	B 6.6	B 8	B 9.5	B 11	B 14

THE MACRO DESIGN

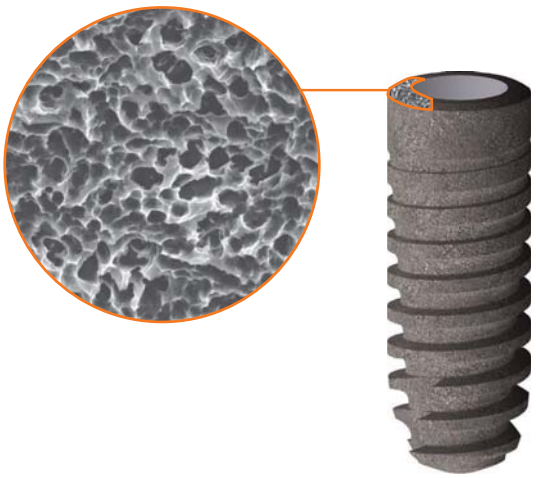
The thread design

The progressive thread design in combination with the three-stage preparation technique lead to very high primary stability, even in cases of average bone qualities. The thread depth increases in apical direction and shows an arch-shaped curve of the thread shanks, thus achieving favorable biomechanical load distribution into the bone. The apically enlarging thread depth allows good anchorage in differing bone qualities as well as promoting a bone stimulating load distribution during mastication. Vertical and lateral forces are primarily deflected to the elastic cancellous bone, whereas the cortical bone is relieved, which is essential for the long-term maintenance of the marginal bone level and the resulting esthetics. Stress concentration in the emergence area of the implant, as proven for implants with consistent threads, is thus avoided. The preparation technique and the special macro design are matched perfectly to the natural bone structure and result in high primary stability with maximum bone to implant contact, even when bone quality is compromised.



The implant surface

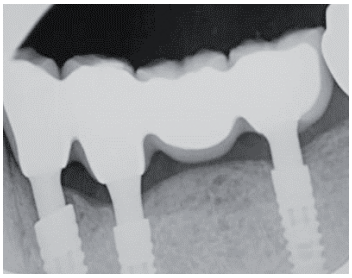
The enossal surface of the implants is blasted with corundum and thus creates a macro-roughness on the titanium surface. This is followed by acid etching adding a micro-roughness to the implant surface. The resulting maximum increase in surface area promotes the ongrowth of bone tissue, leading to a stable implant-bone connection and supporting the natural healing process. In contrast to many other systems, this surface treatment is also performed on the implant shoulder. Therefore a subcrestal implant insertion is possible which reduces stress during the healing period enabling a strong osseointegration and consequently offering superior support of peri-implant tissues.



SUBCRESTAL PLACEMENT

In contrast to most implant systems, the myplant two implant was developed specifically for subcrestal placement and can be inserted up to 2 mm below bone level if bone supply is adequate and taking into account the surrounding structures. This allows the crestal bone to grow over the implant shoulder up to the abutment diameter, which benefits increased implant stability and biological support of the peri-implant soft tissue. Various cover screws are available to avoid complete overgrowth of the implant with bone during submerged healing. Each implant packaging includes a sterile cover screw exceeding the implant by 1 mm.

Note:
Subcrestal placement must be taken into consideration when selecting the length of the implant.

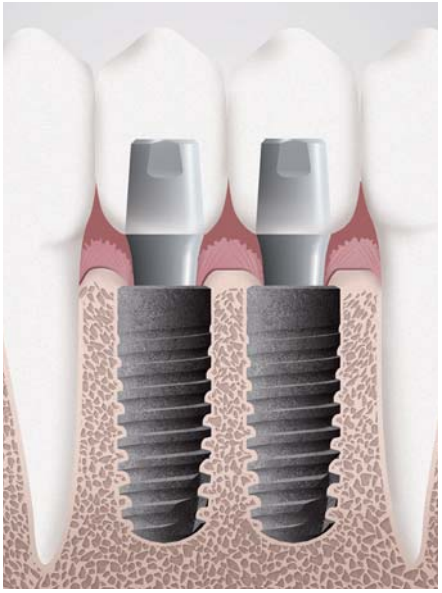


© Prof. Dr. med. dent. Georg-Hubertus Nentwig

If epicrestal implant positioning is desired or indicated, a flush cover screw is available separately.

Stable soft tissue support

Deep platform switching and the resulting wide implant shoulder allow more interproximal space at the abutment level than non-conical connections. In combination with the bony deposition on the implant shoulder, this is decisive for establishing a stable and healthy soft tissue cuff and consequently for esthetics. Due to the enlarged interproximal space esthetically pleasing results can also be achieved with tightly placed implants.



THE PROSTHETIC CONCEPT

The key to successful prosthetics is a firm and tight tapered conical connection. The 360° rotation option of the prosthetic components ensures optimum positioning of angled abutments without making any compromise.

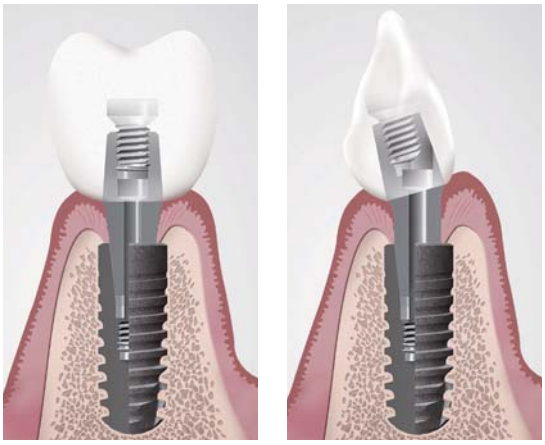
A major advantage of the interface is the fact that all implants have the same internal geometry, allowing each prosthetic component to fit into each implant. The choice of implant is made exclusively on the basis of the available bone and is not restricted by the prosthetics. This also keeps storage space and costs as low as possible. All indications, ranging from single crowns via bridges to partial dentures and implant-supported full dentures, can be restored with the various abutments.

Standard | Shoulder | Titanium Base | Multi Unit | Ball Anchor | LOCATOR®

Note:
The abutment screw is not removable from the (abutments.)

The different abutment series allow friction-based, screw-retained, bonded or cemented fixation to the corresponding abutments.

To enable cement-free mounting, both the straight as well as the angled abutments are equipped with occlusal screw channels. This not only allows improved esthetics due to deeper crown margins but also avoids the risk of cementitis.



A further alternative in conjunction with standard abutments is the friction-based retention of the superstructure via precisely fitting taper caps, which can be incorporated into the prosthesis without difficulties. Whether polymerized into acrylic or bonded into a tertiary structure, conical caps offer full flexibility.

The shoulder abutments offer the option of cementing or screw-retaining the prosthetic restoration. This offers the clinician the freedom to choose the attachment mode according to need and indication.

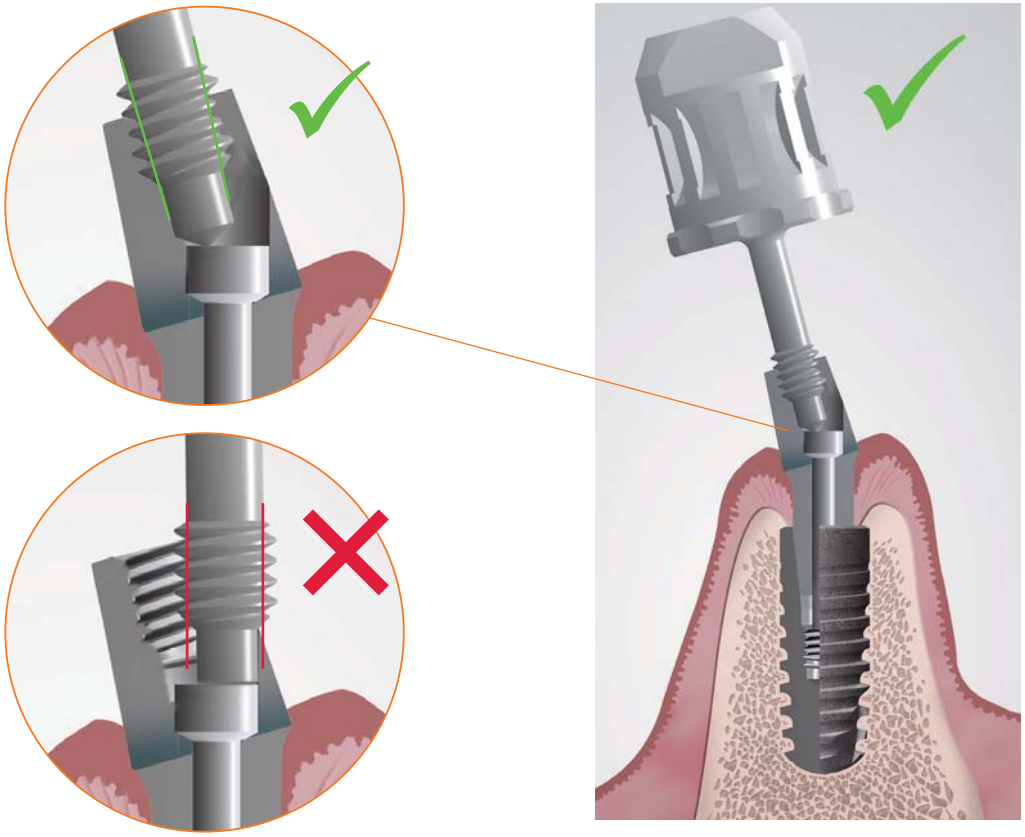
When fabricating individual all-ceramic restorations on the titanium base, the fabricated stump is bonded extraorally to the titanium base and the final restoration is fixated in the patient‘s mouth.

ABUTMENT REMOVAL

Note:
If the abutment screw is not completely loosened, it can block the reverse implant driver.
In this case remove the reverse implant driver and loosen the abutment screw completely.

The self-locking cone enables an absolutely rotation-stable implant-abutment-connection which provides a virtually bacteria-proof seal. This connection can be disengaged again with the aid of the abutment remover.

First, the straining screw of the abutment is completely loosened with the screwdriver. The abutment remover is then screwed into the occlusal screw seat. Once resistance is felt, the abutment remover has made contact with the head of the abutment. If it is now rotated further with care, the abutment remover lifts the abutment out of the implant enabling it to be removed easily.



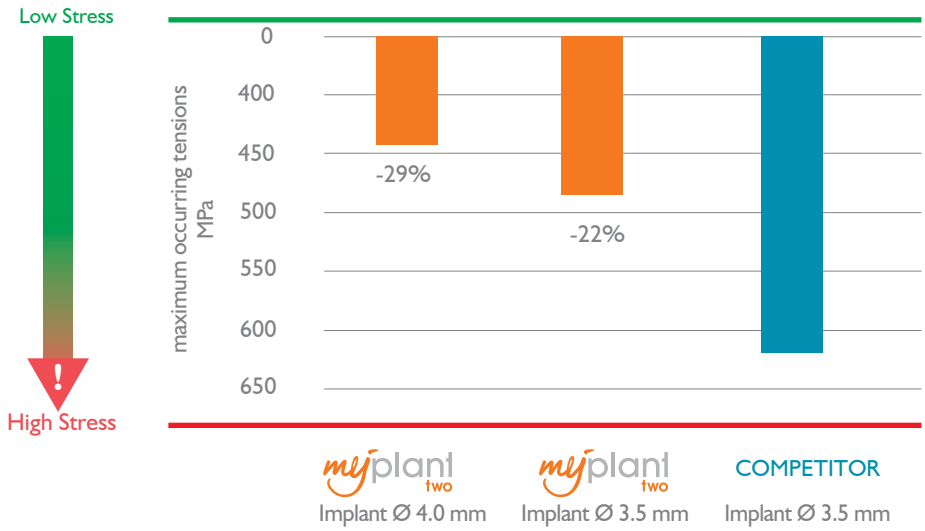
Important: To avoid jamming, it is essential to ensure that the abutment remover is screwed into the screw channel of the occlusal screw seat in the case of angled abutments.

HIGHLY RESILIENT ABUTMENT-IMPLANT CONNECTION

The special design of the myplant two system results in an outstanding mechanical load capacity with high fatigue strength. The design of the inner cone results in a highly resilient and virtually bacteria-proof connection between abutment and implant.

Significant stress reduction in the abutment

In combination with different implants



Load according to ISO14801 / 250 N

Standardized conical connection

The non-indexed conical connection allows free positioning as well as simple parallel alignment of angled abutments.
Despite different implant diameters, all implants have a uniform prosthetic interface. As a result, the choice of implants can be made exclusively depending on the bone supply, while in the selection of the abutments, the focus can be completely placed on the prosthetic requirements. In addition, this results in a reduced prosthetic assortment and leads to lower storage requirements.

THE INSTRUMENTS

Note:
As a rule, the instruments are supplied non-sterile. If supplied sterile, they are marked specifically. This means that reprocessing is necessary before using the instruments for the first time as well as after each use. Prior to being used, the instruments must be checked for operational suitability.
Please also observe the General Instructions for Use and Safety for MEISINGER products in the medical field and the Notes for reprocessing (cleaning, disinfection and sterilization) of medical devices by Hager & Meisinger GmbH. Care should be taken to use the instruments intended specifically for the implant variant.

Taking the anatomical and spatial conditions into account, the suitable position and number of implants along with corresponding implant diameters and lengths are to be selected individually for every patient.

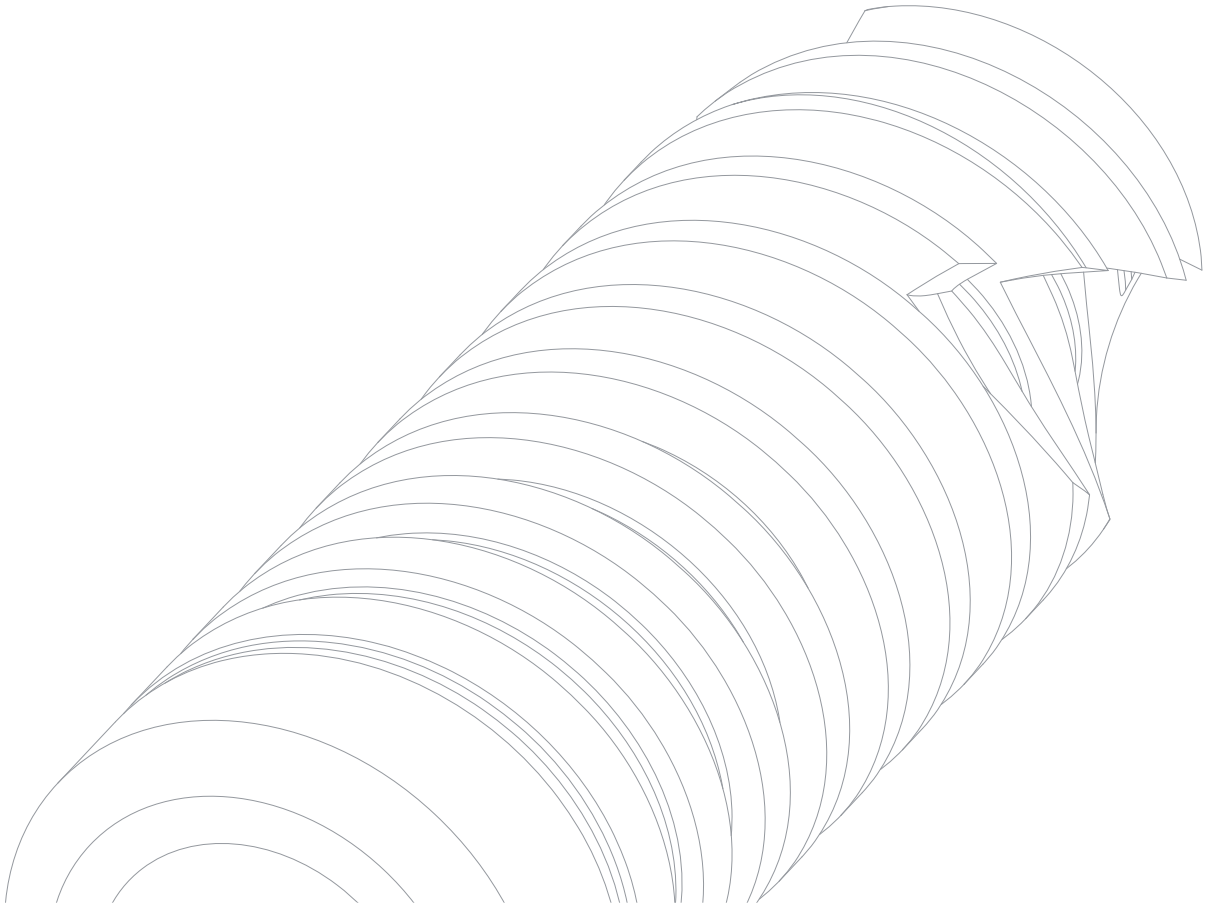
A systemized surgical technique for the preparation of the implant bed was developed to provide Enhanced Primary Stability (EPS). This technique provides options for immediate restorations in all bone densities. Based on the measured torque and bone density, the implant bed can be prepared in three steps for optimal primary stability.

PREPARATION OF INSTRUMENTS

As a rule, the instruments are supplied non-sterile. If supplied sterile, they are marked specifically. This means that reprocessing is necessary before using the instruments for the first time as well as after each use. Prior to being used, the instruments must be checked for operational suitability. Please also observe the General Instructions for Use and Safety for MEISINGER products in the medical field and the Notes for reprocessing (cleaning, disinfection and sterilization) of medical devices by Hager & Meisinger GmbH. Care should be taken to use the instruments intended specifically for the implant variant.

SURGICAL INSTRUMENTS

The instruments of the Meisinger MyPlant II implant system are perfectly matched and thus allow precise and atraumatic preparation of the implant bed.



QUICK OVERVIEW OF SURGICAL PROCEDURE

	Ø 3.5 mm	Ø 4.0 mm	Ø 4.5 mm	opt. rotary speed	Torque
Smoothing of the Alveolar Ridge	Round Drill 0RB01			2.000 min^{-1}	-
Initial Drilling	Initial Bur 0IB01 0IB02			1.000 min^{-1}	-
Pilot Drilling Ø 2.0 mm	Twist Drill 0SB01 0SB02			800 min^{-1}	-
1. Expansion of the implant bed Ø 2.4 mm for A, M & B Implants	Tri-Spade Drill A ATS01 ATS02 ATS03			800 min^{-1}	-
2. Expansion of the implant bed Ø 2.9 mm for M & B Implants		Tri-Spade Drill M MTS01 MTS02 MTS03		800 min^{-1}	-
3. Expansion of the implant bed Ø 3.3 mm for B Implants			Tri-Spade Drill B BTS01 BTS02 BTS03	800 min^{-1}	-
Conical Expansion of the implant bed	Conical Reamer A AKA01 / AKA02 / AKA03 / AKA04	Conical Reamer M MKA01 / MKA02 / MKA03 / MKA04	Conical Reamer B BKA01 / BKA02 / BKA03 / BKA04	50 min^{-1}	max. 50 Ncm
Optional: Conical Extension of the Implant bed for low bone qualities and/or thick cortical plates	Cortical Countersink A AKS01	Cortical Countersink B MKS01	Cortical Countersink C BKS01	50 min^{-1}	max. 50 Ncm
Pretapping the Implant Thread	Tap A AGS01	Tap M MGS04	Tap B BGS02	15 min^{-1}	max. 50 Ncm
Implant Insertion	Implant A A3566 / A3580 / A3595 / A3511 / A3514	Implant M M4066 / M4080 / M4095 / M4011 / M4014	Implant B B4566 / B4580 / B4595 / B4511 / B4514	15 min^{-1}	max. 50 Ncm

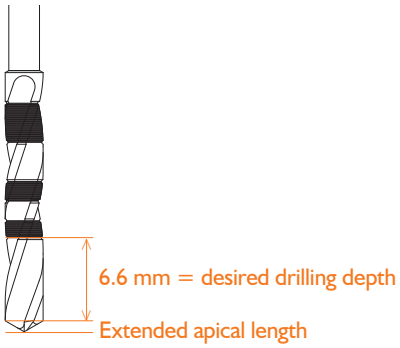
SURGICAL INSTRUMENTS

EXTENDED APICAL LENGTHS

When preparing the implant bed, one should take into account that the effective drilling depth varies apically by 0.4 - 0.6 mm and, depending on the diameter of the implant drill, is deeper than the desired implant length. This additional length must already be taken into account during the planning phase.

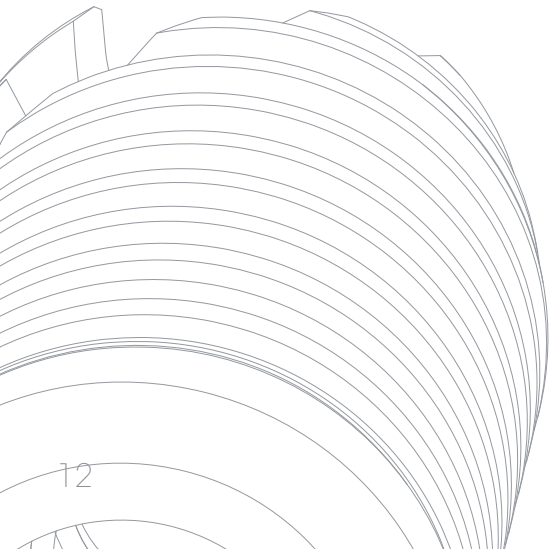
Tri-Spade Drill A	Tri-Spade Drill M	Tri-Spade Drill B
0.4 mm	0.5 mm	0.6 mm

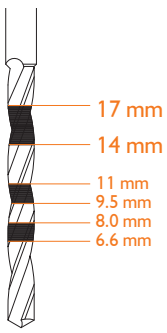
An example of extended apical length

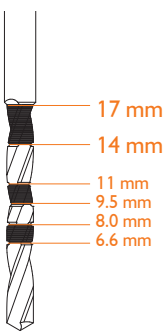


EXPLANATION OF LASER MARKINGS

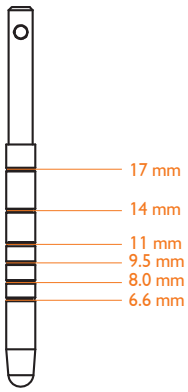
Twist drills



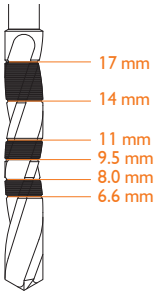


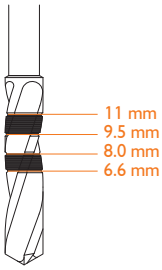


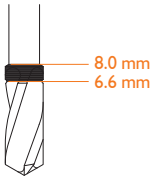
Parallel Gauge



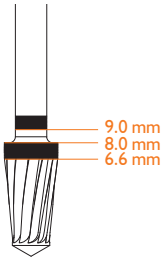
Tri-Spade Drills

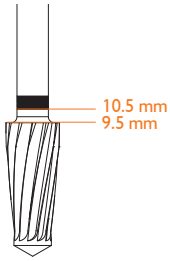


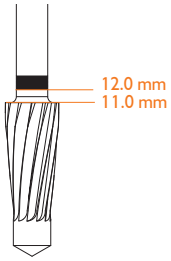


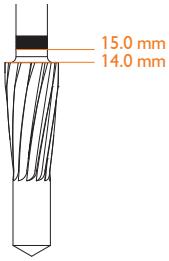


Conical Reamer

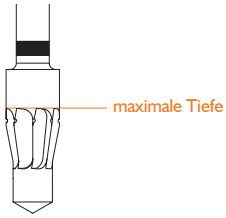




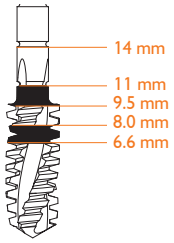




Cortical Countersink

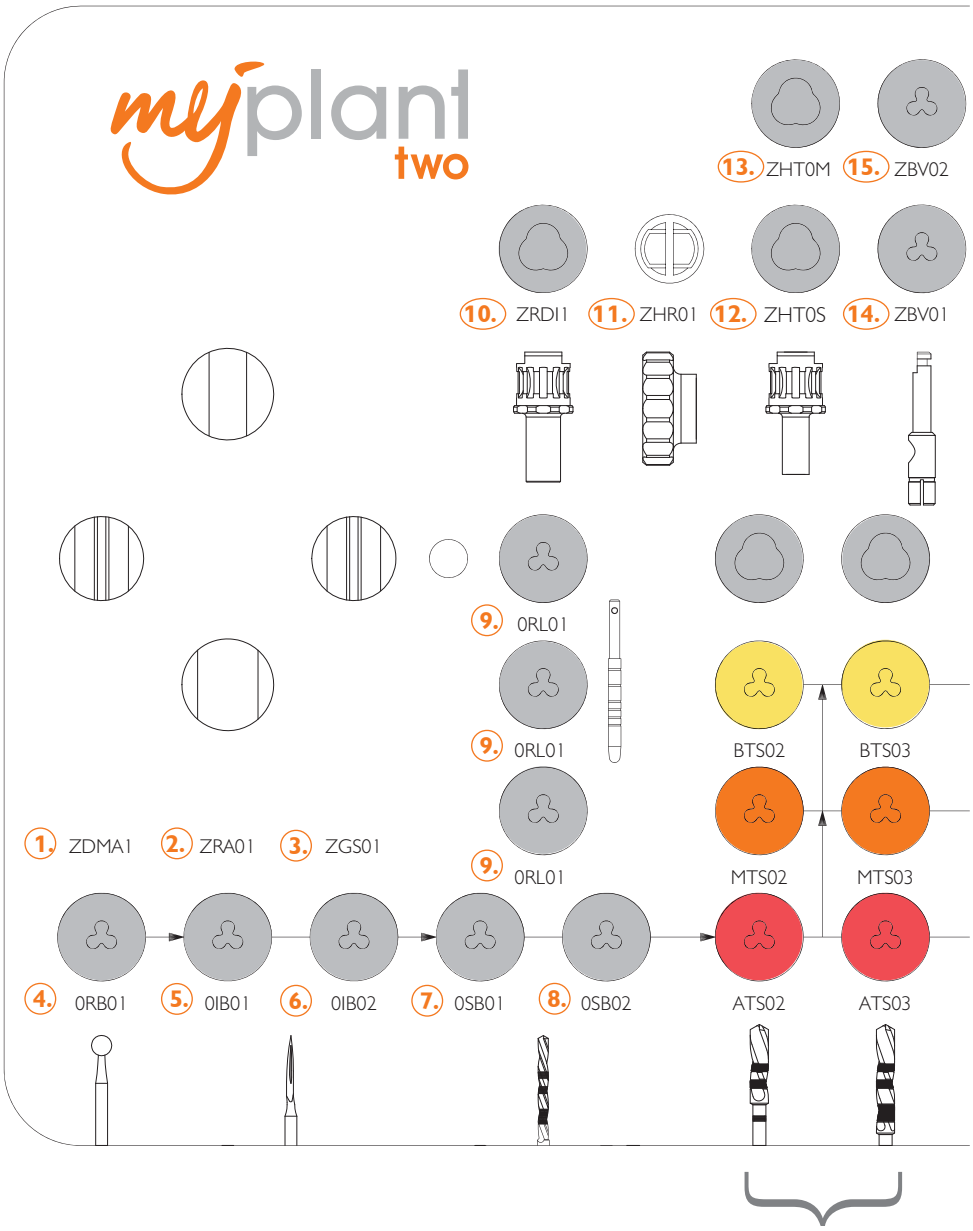


Tap



SURGICAL KITS

All instruments for surgical use are available in the myplant two surgical kit. This allows for particularly structured and user-friendly storage and the color coding of the instruments facilitates orientation during implant surgery.



1. Torque Ratchet
Order No. ZDMA1

2. Ratchet
Order No. ZRA01

3. Open-end Wrench
Order No. ZGS01

4. Round Drill
Order No. ORB01

5. Initial Bur
Order No. OIB01

6. Initial Bur long
Order No. OIB02

7. Twist Drill
Order No. OSB01

8. Twist Drill short
Order No. OSB02

9.Parallel Gauge
Order No. ORL01 (3x)

Tri-Spade Drill
AØ 3.5: Order No. ATS01/ ATS02/ ATS03
MØ 4.0: Order No. MTS01/ MTS02/ MTS03
BØ 4.5: Order No. BTS01/ BTS02/ BTS03

10. Reverse Implant Driver
Order No. ZRDI1

11. Handwheel
Order No. ZHR01

12. High Torque Adapter
Order No. ZHT0S

13. High Torque Adapter
Order No. ZHT0M

14. Drill Extension
Order No. ZBV01

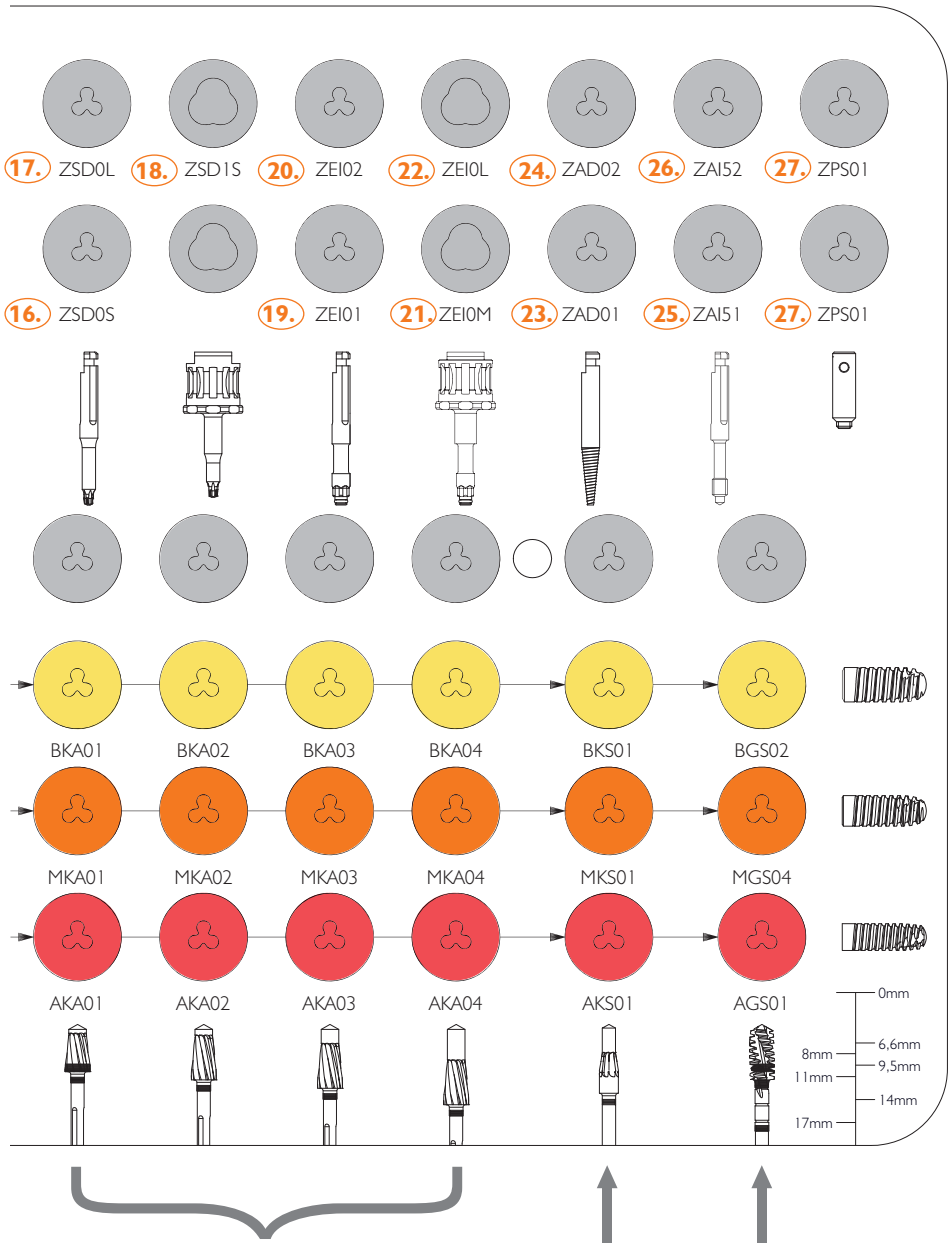
15. High Torque Drill Extension
Order No. ZBV02

16. Screw Driver Right Angle short
Order No. ZSD0S

17. Screw Driver Right Angle long
Order No. ZSD0L

18. Screw Driver one-piece
Order No. ZSD1S

19. Seating Instrument Right Angle short
Order No. ZEI01



Instruments for Implants with Ø 4.5 mm

Instruments for Implants with Ø 4.0 mm

Instruments for Implants with Ø 3.5 mm

Conical Reamer
AØ 3.5: Order No. AKA01/ AKA02/ AKA03/ AKA04
MØ 4.0: Order No. MKA01/ MKA02/ MKA03/ MKA04
BØ 4.5: Order No. BKA01/ BKA02/ BKA03/ BKA04

Cortical Countersink
Order No.
AKS01/MKS01/BKS01

Tap
Order No.
AGS01 / MGS04 / BGS02

20. Seating Instrument Right Angle long
Order No. ZEI02

21. Seating Instrument short
Order No. ZEI0M

22. Seating Instrument long
Order No. ZEI0L

23. Cover Screw Remover short
Order No. ZAD01

24. Cover Screw Remover
Order No. ZAD02

25. Abutment Remover Right Angle short
Order No. ZAI51

26. Abutment Remover Right Angle long
Order No. ZAI52

27. Parallel Post
Order No. ZPS01 (x2)

INDICATIONS AND CONTRAINDICATIONS

A diligent and structured planning method between dentist, patient and laboratory is essential for satisfactory and long-term surgical and prosthetic success.
As with any surgical procedure, a comprehensive consultation with the patient forms the basis for treatment planning. This includes taking a thorough patient history, the exclusion of contraindications and an analysis of the initial situation. The objective is to be able to implement an efficient and adequately predictable treatment outcome.

Note:
All indicators and contra-indicators to be observed can be found in the Application and Safety Instructions for the myplant two System from Hager & Meisinger GmbH.

The implants can be used for all indications for oral, enossal implants in the maxilla and mandible, functional and esthetic rehabilitations of edentulous and partially edentulous patients. If the requirements for appropriate occlusal loading are met, then the implants can be used for immediate restoration in case of sufficient primary stability. The success of implantation largely depends on the prosthetic.
Intensive communication between dentist and dental technician, careful pre-prosthetic planning and the involvement of the patient are important requirements for the successful restoration with implants. Prosthetic restoration can be performed as single crowns, bridges, partial or full prostheses. These can be integrated (cemented, firmly screw-retained or removable) on appropriate abutment elements which connect the restoration with the myplant two implants.

INDICATIONS AT A GLANCE

IMPLANTS			PROSTHETICS		
myplant two	Length	Anterior | Canine | Premolar | Molar	Single Tooth	Bridge	Telescope Crowns | Ball Anchors | LOCATORS®
Ø 3.5 mm	 6.6 mm	✓*	X	✓	✓*
	 8.0 mm	✓	✓	✓	✓
	 9.5 mm	✓	✓	✓	✓
	 11.0 mm	✓	✓	✓	✓
	 14.0 mm	✓	✓	✓	✓
Ø 4.0 mm	 6.6 mm	✓*	X	✓	✓*
	 8.0 mm	✓	✓	✓	✓
	 9.5 mm	✓	✓	✓	✓
	 11.0 mm	✓	✓	✓	✓
	 14.0 mm	✓	✓	✓	✓
Ø 4.5 mm	 6.6 mm	✓*	X	✓	✓*
	 8.0 mm	✓	✓	✓	✓
	 9.5 mm	✓	✓	✓	✓
	 11.0 mm	✓	✓	✓	✓
	 14.0 mm	✓	✓	✓	✓

✓* Special indications for implants with 6.6 mm length:

Due to the reduced surface for anchorage in the bone, the implants with a length of 6.6 mm are only recommended for the following indications until appropriate clinical studies are available:

- In edentulous jaws: as auxiliary implant/supporting implant for implant-supported bar constructions or splinted bridges.
- Partially edentulous jaws: as auxiliary implant/supporting implant in connection with longer implants splinted to a suprastructure.

Important: Attention should be paid to the load distribution of the restoration.

SPECIAL INDICATIONS FOR IMPLANTS WITH 6.6 MM LENGTH

Due to the reduced surface for anchorage in the bone, the implants with a length of 6.6 mm are only suitable for the following indications until appropriate clinical studies are available:

- Edentulous jaw: as auxiliary implant/supporting implant for implant-supported bar constructions or splinted to a superstructure.
- Partially edentulous jaw: as auxiliary implant/supporting implant in connection with longer implants splinted to a superstructure.

Important: Attention should be paid to the load distribution of the prosthetics.

SPECIAL CONTRAINDICATION FOR IMPLANTS WITH 6.6 MM LENGTH

The risk of implant loss increases with single-tooth restoration with implants of length 6.6 mm and with free-end bridges if increased chewing forces must be expected - especially in the molar region. Under these circumstances, implants with a length of 6.6 mm, especially 3.5 mm in diameter, must not be inserted.

OPTIONS FOR PROSTHETIC RESTORATIONS

Abutmenttype	Single Tooth	Bridge	Partial prosthesis	Total Prosthesis
Standard Abutment	✓	✓	✓	✓
Shoulder Abutment	✓	✓	-	-
Titanium Base	✓	✓	-	-
Multi Unit Abutment	-	✓	✓	✓
LOCATOR®	-	-	✓	✓
Ball Anchor	-	-	✓	✓

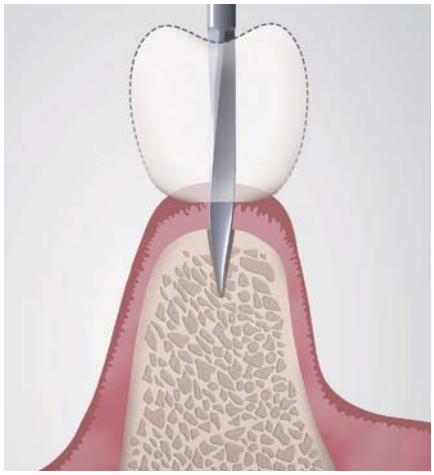
THE SURGICAL PROCEDURE

PREPERATION OF THE IMPLANT BED

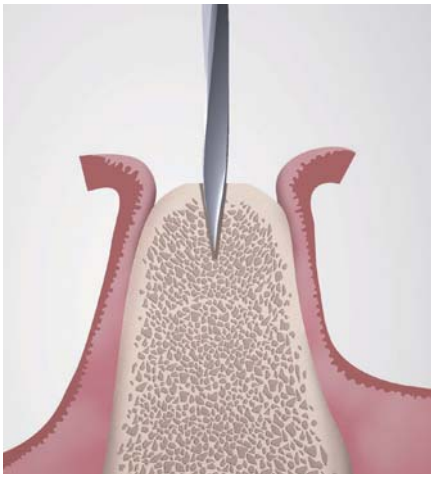
MARKING THE IMPLANT POSITION

When using rotating instruments, observe the selection of diameter-specific instruments as well as the corresponding depth markings. Diameter-specific instruments can be recognized by their corresponding color coding.

The positioning can be determined prior to exposure with the aid of a transgingival marking drill using an initial drill at a maximum of 1000 rpm and a suitable template. The template can preferably be a transparent thermoforming sheet that has been drawn over the prosthetic set-up.



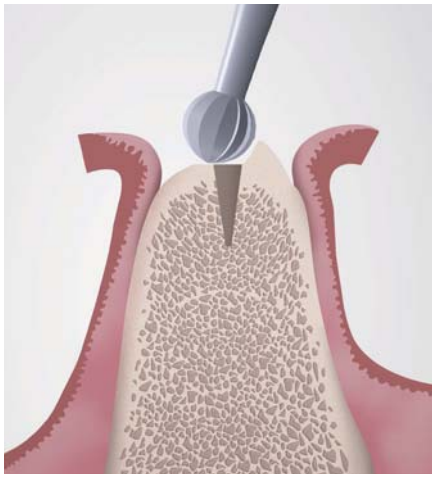
The incision depends on the prevailing situation and the planned method of healing (subgingival or transgingival) and is therefore performed in the center or slightly offset. If augmentation is not required, then, as a matter of principle, only the crestal region of the alveolar ridge should be exposed.



SMOOTHING OF THE ALVEOLAR RIDGE

Local irregularities can be smoothed carefully using the round bur contained in the surgical kit.Max. Speed: 2.000 min^{-1}

Note:
The performed vertical reduction of the alveolar ridge must be taken into consideration when selecting the length of the implant!

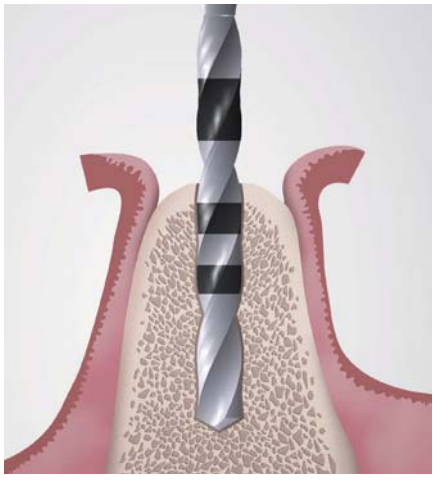


PILOT DRILLING

Final alignment and depth of the implant is performed with the aid of a twist drill Ø 2.0 mm. The penetration resistance can be used to feel the bone quality:

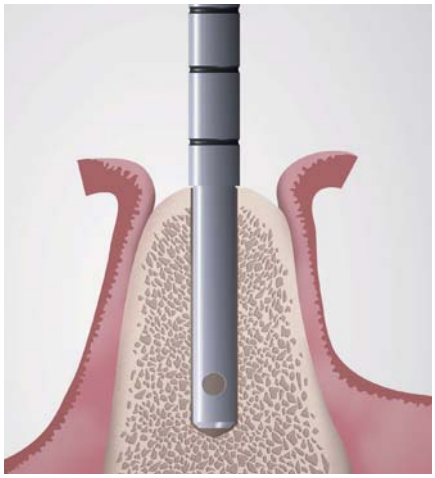
- little resistance
- normal resistance
- high resistance

Further preparation of the implant site must be carried out accordingly. For gentle preparation of the implant bed, drilling should be performed intermittently at a maximum speed of 800 rpm and with moderate force. It should be ensured, that the instrument and the bone are cooled adequately to avoid overheating of the bone and adhesion of bone chips to the cutting edges of the drill.

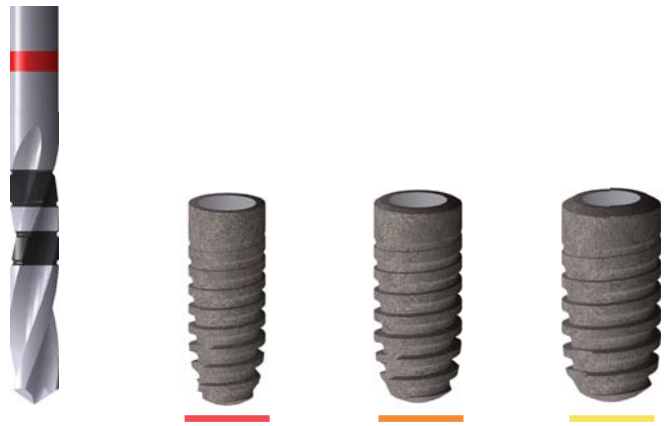


PARALLEL GAUGE

The parallel gauge is a combination instrument. The slim end of the parallel gauge is used after pilot drilling to check the correct orientation of the implant axis and to have a visual aid for aligning further implants.



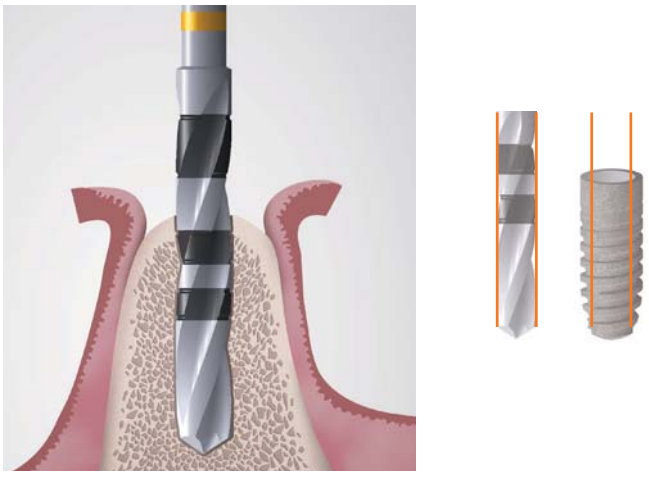
PREPARATION OF THE IMPLANT BED – TRI-SPADE DRILLS



Preparation of the implant bed is performed with Tri-Spade drills. The Tri-Spade drill A is used first for every implant diameter to be placed. This Tri-Spade „A“ drill expands the implant bed to Ø 2.4 mm. When using an A implant with a diameter of Ø 3.5 mm, the parallel-walled preparation is completed after this step.

Preparation is continued for M or B implants. The Tri-Spade drill M is used for preparing the implant site. The Tri-Spade „M“ drill expands the implant bed to Ø 2.9 mm. When using a M implant with a diameter of Ø 4.0 mm, the parallel-walled preparation is completed after this step.

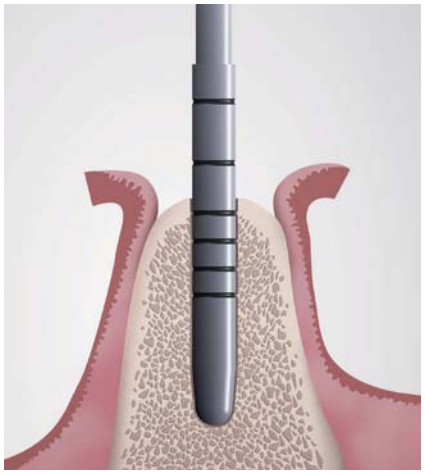
Expansion of the implant bed is continued for B implants. The Tri-Spade drill B is used after the Tri-Spade drill M. This expands the implant bed to Ø 3.3 mm. After using the Tri-spade drill B, the parallel-walled preparation is completed after this step.



For gentle preparation, drilling should be performed intermittently at a speed of approximately 800 min^{-1} and with moderate force. It should be ensured that the instruments are cooled adequately and that no bone chips adhere to the cutting edges of the drill tips.

CHECKING THE DEPTH OF IMPLANTPREPARATION

The wide end of the parallel gauge is used after the extension of the implant bed to check the correct depth of the drilling.



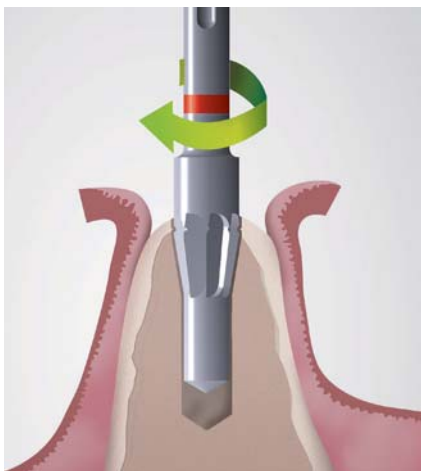
USE OF THE CORTICAL PINCER

With a very soft cancellous bone structure (hardly any penetration resistance after perforation of the cortex with the pilot drill), the cortical pincer only serves to expand the cortical bone analogously to the diameter of the implant. The implant can then be inserted directly into its final position through this opening.

Important: In all other bone structures, the cortical pincer is not used.

The preparation is carried out at a maximum speed of 50 rpm and with very little force. A torque of 50 Ncm must not be exceeded.

The preparation is now complete.



Note:
Since the primary stability is achieved exclusively in the cortical bone, the implant must not be positioned subcrestally as a rule!

For all other bone qualities, the conical preparation described below is carried out after the Tri-Spade drilling.

CONICAL PREPARATION OF THE IMPLANT BED

A conical reamer matching the implant diameter and length is used for the conical preparation of the implant bed.

Four different conical reamers are available for the desired implant diameter:

Note:
The color marking of the conical reamer is used for easier positioning in subcrestal placement. The lower edge of the shade ring serves as a guide for a subcrestal placement of one millimeter, the upper edge for a subcrestal placement of two millimeters.

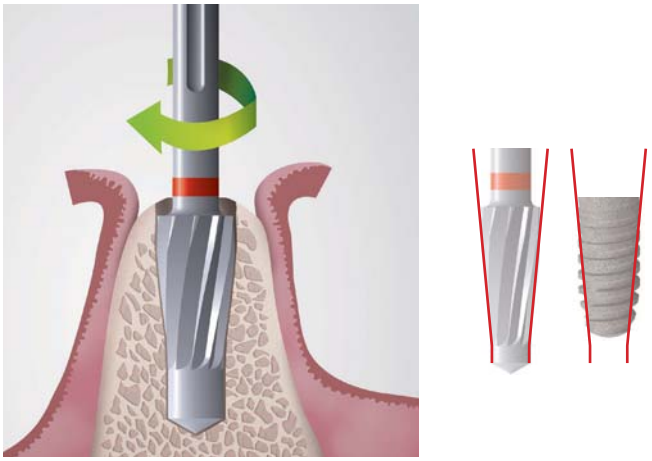
MKA01	MKA02	MKA03	MKA04
6.6 - 8.0 mmm	9.5 mm	11.0 mm	14.0 mm

The conical preparation can be carried out manually with a ratchet or mechanically with a contra-angle piece.

Option 1: Clockwise / cutting

If the bone is well structured, the instrument is inserted clockwise into the prepared cavity. The preparation is carried out mechanically at a maximum speed of 50 rpm intermittently and with cooling.
A torque of 50 Ncm must not be exceeded.
An alternative is manual preparation using a ratchet. For the preparation of the ratchets, please refer to the information in the appendix.

Note:
The conical reamers also serve as “measuring implants” because they correspond to the final position of the implant. If the colored marking ring is at bone level, the implant shoulder is later 1 mm deeper. In well structured bone, the flutes fill with bone chips. These must be removed manually in order not to impair the cutting performance. The chips can be used as augmentation material if required.

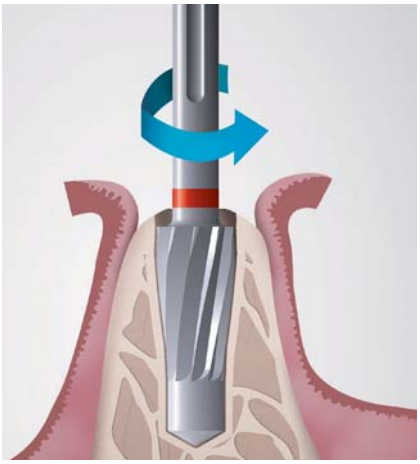


Clockwise / cutting

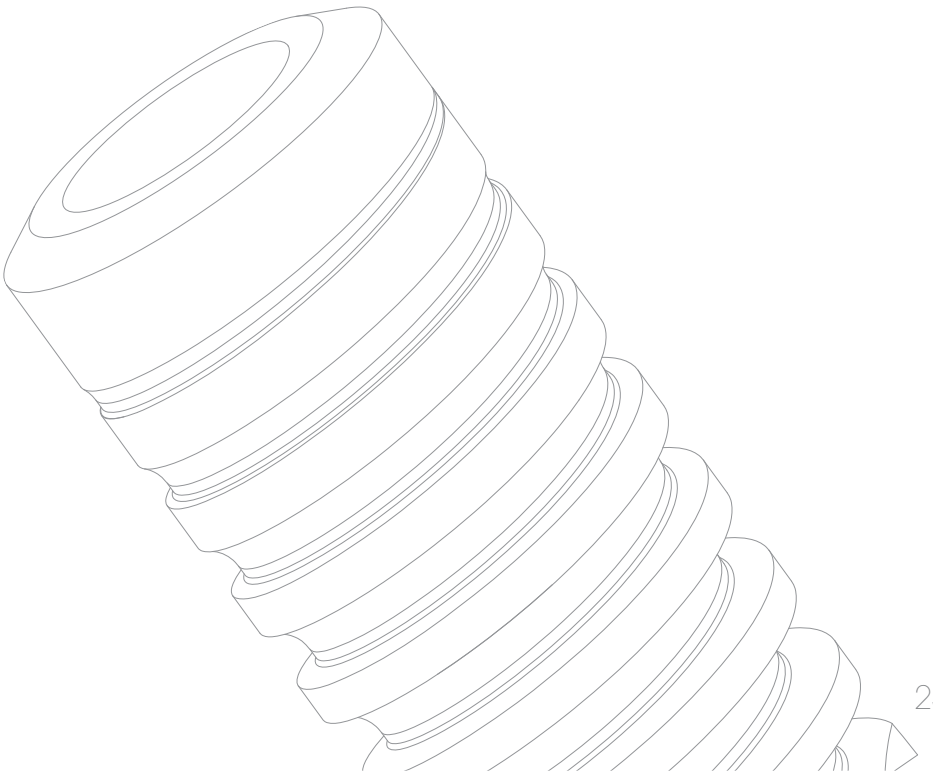
The non-toothed tip avoids a deepening of the implant bed. To facilitate the removal of the instrument, the conical reamer should be turned one turn to the left.

Option 2: Counterclockwise / condensing

In order to achieve sufficient primary stability with a bone quality of D3-D4, the conical reamer can also be used as a bone compressor. You use the conical reamer automatically or manually in an analog counterclockwise setting. This results in a slight compression of the bone, which leads to increased primary stability of the implant.



Counterclockwise / condensing



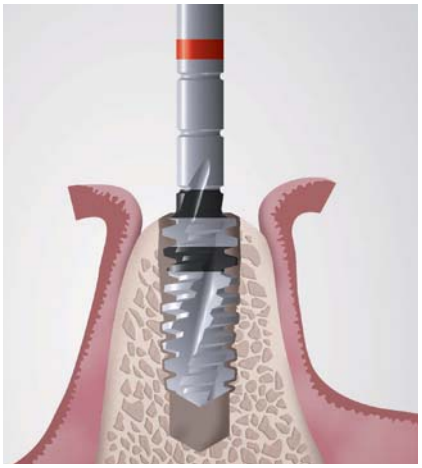
PRETAPPING THE IMPLANT THREAD

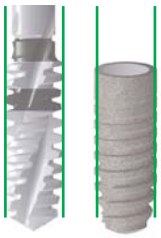
Definitive implant bed preparation is achieved with the aid of the tap. A suitable tap is available for each implant diameter. It serves to pretap the implant thread and facilitates insertion.

The thread should only be pretapped as long as resistance of the bone can be felt. This feeling of resistance is best perceived if the tap is used via ratchet insert and hand wheel. As the MyPlant II implants cut into the bone by themselves due to the progressive thread design in conjunction with the newly designed implant tip, one can dispense with use of a tap in case of compromised bone quality (D3-D4).

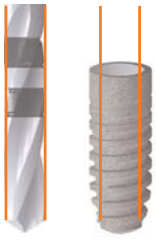
The tap is inserted clockwise into the cavity. The preparation is carried out at a maximum speed of 15 rpm and with very little force. A torque of 50 Ncm must not be exceeded.
Close attention is to be paid to the depth marking of the instrument during the entire preparation. As soon as no resistance of the bone can be felt, cutting the thread should be terminated immediately. If the tap is screwed in too deep, this can have a negative effect on the primary stability of the implant to be inserted. To extract the tap after completed preparation, unscrew fully in anti-clockwise direction.

Note:
In order not to damage the prepared thread, it is essential to slowly unscrew it counterclockwise.

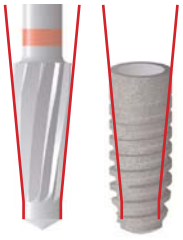




If the alveolar ridges are inclined in an oro-vestibular direction, the implant should be aligned at the lowest level of the bone profile.

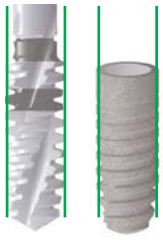


Tri-Spade Drill



Conical Reamer

Cortical Countersink



Tap

INSERTION OF THE IMPLANT

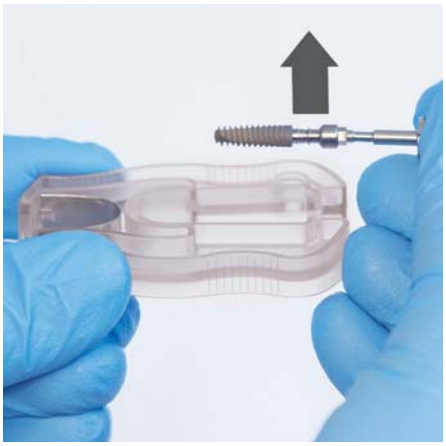
UNPACKING OF THE IMPLANT

All myplant two implants are supplied sterile and are intended for single use only. If the packaging is damaged, do not use the implant. Prior to or during removal, the operational suitability and safety of the product need to be reviewed. For unpacking, the implant is removed from the folded box in its outer blister.

Note:
The O-ring of the insertion instrument can become porous after several sterilization cycles and must be replaced to ensure a secure hold of the implant.

After complete removal of the outer packaging and the outer blister, open the inner blister only until you can remove the implant retaining bracket. The cover screw remains covered.

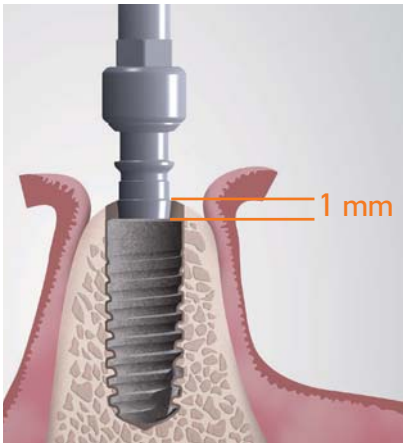
Secure the holding clamp to the front grip recesses with your finger and thumb and place the insertion instrument on the insertion unit so that a clamping fit is created between the insertion unit and the insertion instrument.



Now slightly squeeze the implant holding clamp at the rear recessed grips and remove the implant.

INSERTION OF THE IMPLANT

The insertion of myplant two implants can be performed either mechanically or manually. In the case of subcrestal insertion, the auxiliary lines on the insertion instrument must be observed at millimeter intervals.

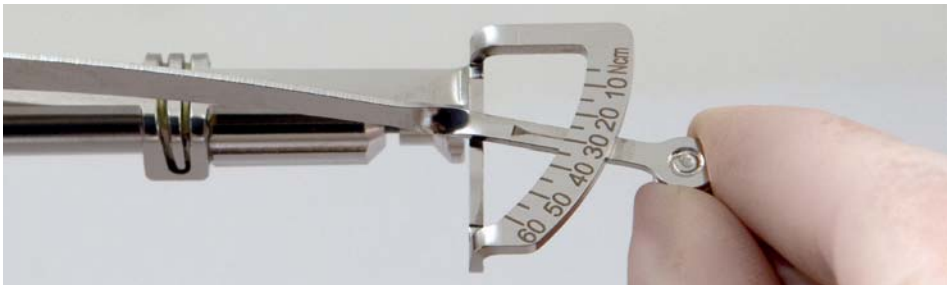


Mechanical:

The implant is inserted into the prepared implant bed with the aid of the machine-applicable insertion instrument and brought into the final position clockwise at a maximum speed of 15 rpm. The torque in the end position must be taken from the surgical drive unit and documented. If the torque is not recorded electronically, the torque in the end position is determined and documented with the aid of the ratchet and the torque control device.

Manually:

With the aid of the insertion instrument and the handwheel, about two thirds of the implant is inserted manually into the prepared implant bed. The final positioning is done using the ratchet. The torque in the end position is determined and documented with the torque control device. The handling of the torque control device is explained in detail on p. 65 et seq.



The following classification is recommended:

- <15 Ncm: Low primary stability: load-free healing (subgingival or transgingival) required. Due to the possibility of thermal necroses occurring, the implant insertion speed of 15 rpm should not be exceeded
- >15 Ncm <30 Ncm: Adequate primary stability; transgingival healing or immediate restoration in conjunction with other implants
- >30 Ncm: Good primary stability; immediate restoration of single, standing non-splinted implants

A maximum torque of 50 Ncm should not be exceeded for insertion of myplant two implants. The insertion torque climbs increasingly the deeper the implant works into the implant bed. If the insertion torque reaches the maximum allowed value before the final implant position has been reached, the implant must be removed using the reverse rotation instrument to prevent bone damage.

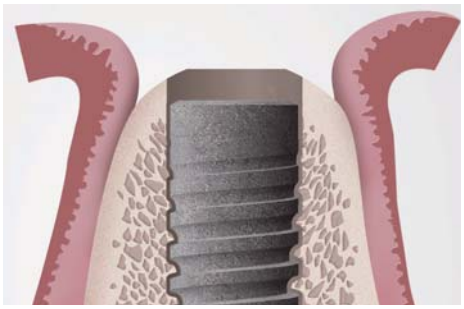
Further post-processing of the implant bed, using a reamer and/or tap, can influence the insertion torque depending on the situation and the implant can be re-installed. It is important that the inserted implant is primarily stable in order to enable a subsequent successful osseointegration.

Note:
The torque control device is usually attached at the end of the screwing process to read off the final torque. If required, it can also be used during implantation to determine the current torque.

SUBCRESTAL PLACEMENT

The front surface of the MyPlant II implant is also surface-finished and thus offers a micro-roughness which promotes the agglomeration of natural bone. Therefore, the MyPlant II implants should ideally be positioned approximately 1 mm subcrestally if sufficient vertical bone is available. Subcrestal placement allows growth of bone directly on the implant shoulder, which supports the stability of the soft tissue cuff and provides for high stability of the osseous integrated implant in the long term. An improvement of the prosthetic result can also be achieved with low soft tissue availability.

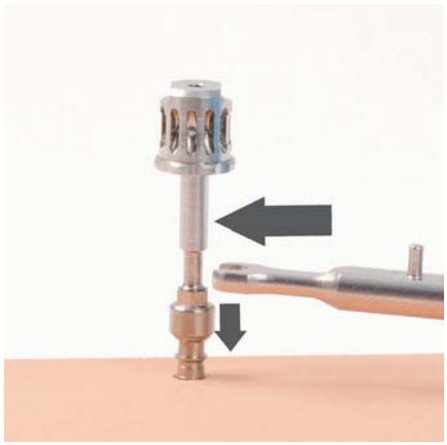
Note:
The vertical space requirements in terms of subcrestal implant positioning should already be considered during pre-implant planning.



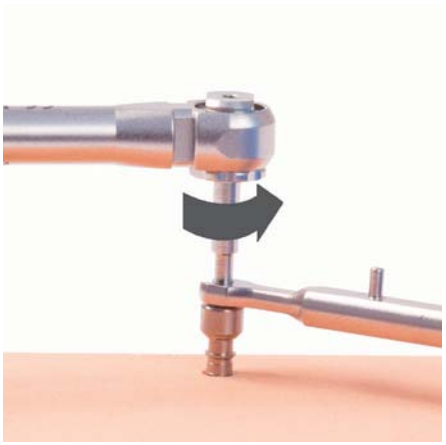
RELEASING THE INSERTION UNIT

After insertion of the implant, the insertion unit is removed. This can be done mechanically or manually.
To release the insertion unit from the implant after insertion, the insertion unit is first fixed against rotation with the holding key. For this purpose, the holding key is pushed over the tapered part of the insertion instrument and then placed on the insertion post. The holding key grips the hexagon of the insertion unit and cannot slip off. The screw of the insertion unit is then loosened counterclockwise using the insertion instrument. It should be noted that the loosening torque of the screw increases again after a few turns when the insertion unit is lifted vertically out of the implant.

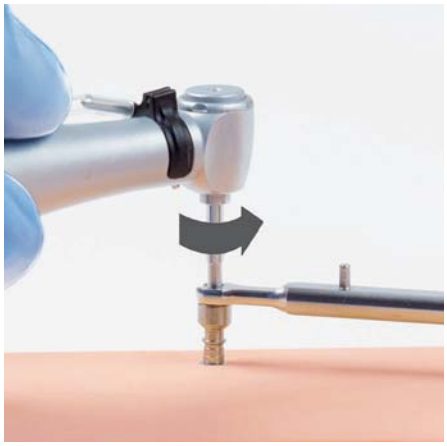
Note:
The holding key can only be placed on the insertion unit in one direction.



mounting of the open-end wrench



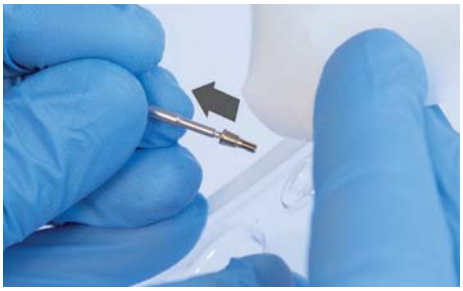
manually

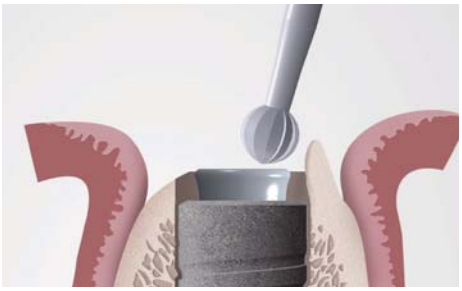


mechanically

After removing the insertion unit, the enclosed sterile end cap with a height of 1 mm can be inserted. If the implant has been placed at bone level or approx. 2 mm subcrestally, suitable variants of the end cap from the myplant two product range can be used.
If necessary, the bony excess can be reduced with the rose drill to ensure a tension-free seam closure.

Note:
If you remove the insertion unit with the ratchet, the ratchet may idle. In this case it is sufficient to apply some pressure to the ratchet head with your finger in order to overcome the idle speed.

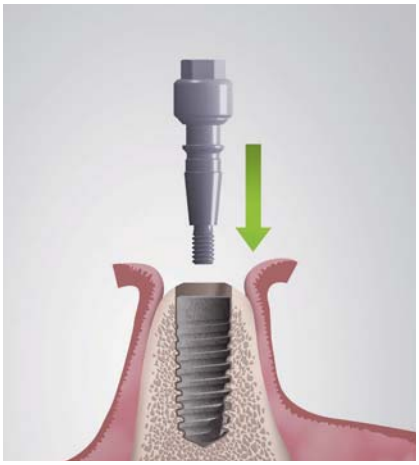


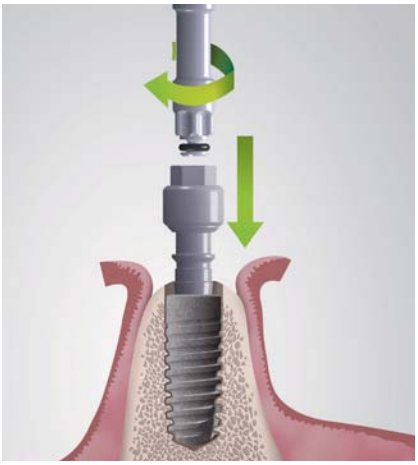


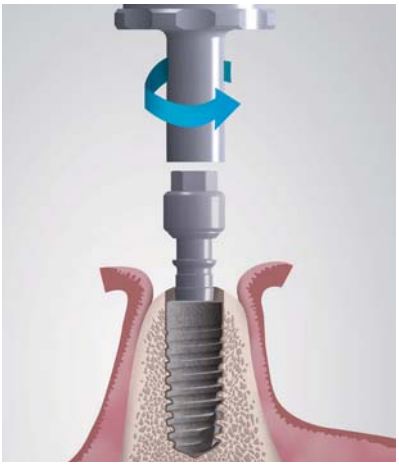
REASSEMBLY OF THE INSERTION INSTRUMENT TO CORRECT THE INSERTION DEPTH

If a subsequent correction of the insertion depth is necessary after removal of the insertion unit, the insertion unit can be placed on the implant again and screwed. For this purpose, place the insertion instrument on the insertion unit so that a clamping fit is created between the insertion unit and the insertion instrument. The insertion unit can now be screwed into the implant again. If the implant is to be placed lower, the use of the fork wrench is not necessary.

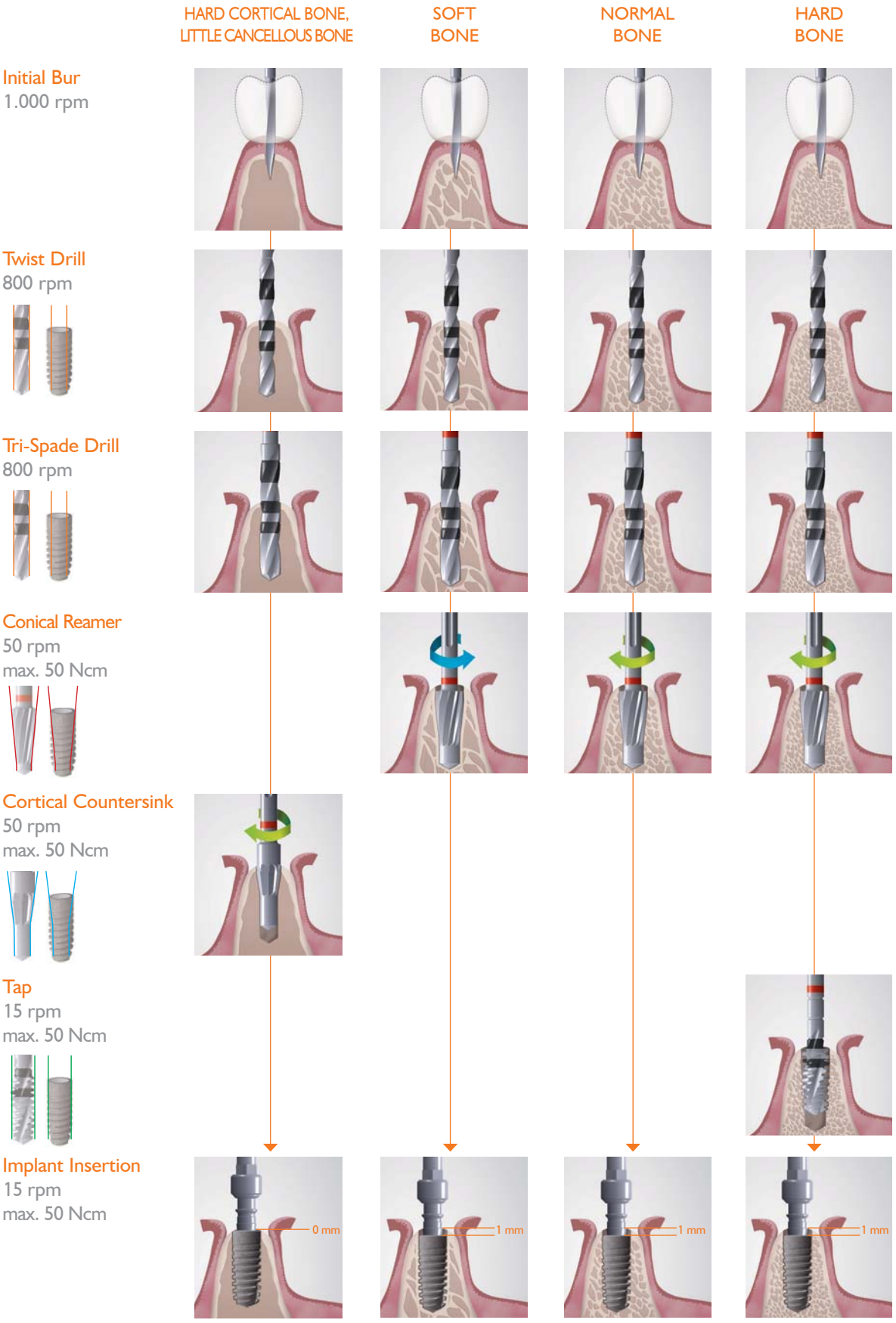
For a removal, i.e. a back-turning of the implant, the mounting torque of the insertion post must be equal to or greater than the original insertion torque when retightening. To do this, counter the implant with the help of the fork wrench and tighten the insertion post to at least the original torque. The implant can then be moved counterclockwise to the desired position or removed using the reverse rotation instrument, which acts on the hexagon socket. After correction of the implant position, the insertion unit is removed as described above.







SURGICAL WORKFLOW STEP BY STEP



THE HEALING PHASE

In order to achieve reliable osseointegration, a stable condition needs to exist at the interface between implant and bone during the static phase of bone healing (duration as a rule: 6 weeks). Relative movement, for example, too early loading effects at compromised bone quality and low mechanical stability of the implant site, prevent mineralization of the immature bone tissue and thus osseointegration.
The mechanical stability of the bone is determined by measuring the final insertion torque. This results in recommendations on how to proceed during the healing phase:

Subgingival healing: insertion torque < 15 Ncm (A)

Subgingival healing for 6 weeks represents the safest way of complying with the conditions for the static healing phase. The implants are sealed with the supplied cover screw. The mucosa is sutured over the cover screw.

Transgingival healing: insertion torque > 15 Ncm < 30 Ncm (B)

Immediate restoration of individual implants is risky, open healing at a mucosal level is possible. The choice of healing abutments depends on the thickness of the soft tissue. If several implants can be splinted in a stable manner via the temporary restoration (for example, in edentulous jaws), then immediate temporary restoration with reduced occlusion contacts is possible. In all cases of immediate restoration, the patient is to be instructed only to take a soft diet for the next 6 weeks.

Temporary immediate restoration: insertion torque > 30 Ncm (C)

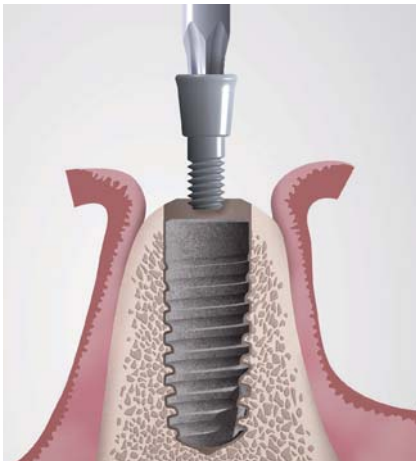
Good to very good bone stability prevails. Selection of the abutments in terms of transgingival dimension, post height and angle is performed after a trial insertion of the trial abutments. The crown margin for forming the emergence profile with the aid of the crown base should be at a subgingival level.

SUBGINGIVAL HEALING

In subgingival healing, the implant heals under a closed mucoperiostal flap. A second surgical procedure is always necessary to remove the cover screw, to shape the gingiva in a second and third step and to provide an abutment.

PLACEMENT OF THE COVER SCREW

After removing the insertion guide, the implant is sealed with the cover screw. Ensure a clean inner implant connection free of blood and tissue debris. A sterile cover screw is included in the blister package of every implant and can be picked up with a screwdriver and screwed hand-tight with 5 - 7 Ncm into the implant. The fit is designed such, that the cover screw is attached securely to the screw driver and assures safe handling.

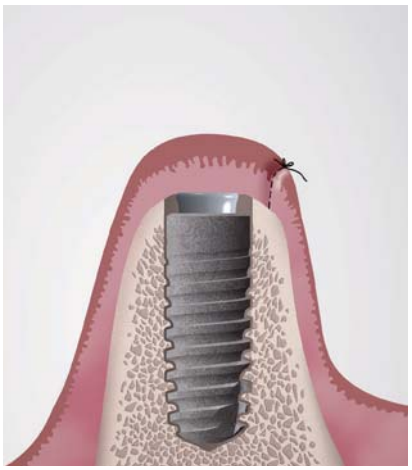


The enclosed sterile end cap has a height of 1.0 mm and is therefore optimally suited for the closure of a 1 mm subcrestally placed implant. For 2 mm subcrestally inserted implants, the end cap with a height of 2.0 mm is selected accordingly. If the implant is placed equicrestally, the flush-fitting end cap (H= 0.0 mm) must be selected. The end caps of heights 0.0 mm and 2.0 mm are not included with the implant and must be purchased separately.

Note:
All separately available screw plugs are supplied non-sterile and must be prepared before use. Please refer to the "Notes on reprocessing (cleaning, disinfection and sterilization) of medical products from Hager & Meisinger GmbH".

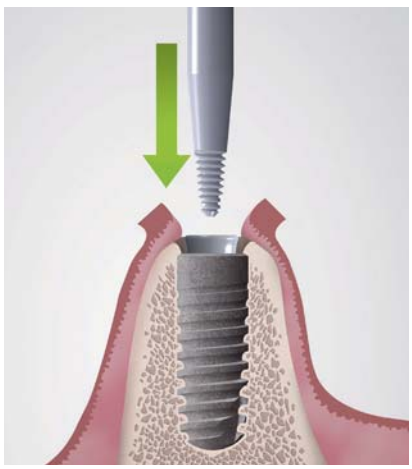
WOUND CLOSURE

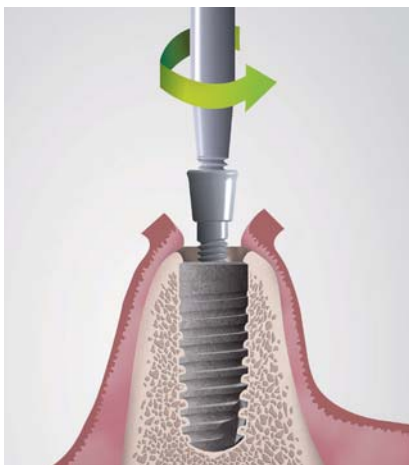
The implant is to be closed with individual sutures as free of tension as possible. It is important to ensure a tight seal to make penetration by bacteria difficult and to prevent infections.



EXPOSURE

Exposure of the implant is performed as part of a minimally invasive procedure. In order to preserve as much hard and soft tissue as possible, the procedure should be performed in a tissue saving manner. After localization of the implant via the positioning template and selective anesthesia, a small crestal incision of the soft tissue is performed over the implant surface. The soft tissue is slightly spread and the cover screw is removed using the unscrewing mandrel. This is screwed into the screw plug by turning it counterclockwise and becomes wedged in the screw. Thus, the unscrewing mandrel achieves a firm hold in the end cap and allows the screw to be safely removed by continuing the left-hand rotation. It is not necessary to clean the screw plug before using the unscrewing mandrel. This screw is available separately and is not included with the implants. It is delivered non-sterile.





Note:
The closure screw is a disposable product that must be disposed of after removal.

TRANSGINGIVAL HEALING

In transgingival healing, the implant is sealed with a healing abutment. The soft tissue is placed around the healing abutment and sutured. This allows for formation of the soft tissue and makesa second intervention unnecessary.

PLACEMENT OF THE HEALING ABUTMENT

After removing the insertion guide, the implant is sealed with a suitable healing abutment. The healing abutment is selected according to the thickness of the soft tissue. Before the selected healing abutment is screw-retained in the implant with the aid of the screwdriver, the inside of the implant should be thoroughly rinsed with sterile saline solution with sterile saline solution to ensure a clean inner implant connection.

Note:
All healing abutments are supplied non-sterile and must be sterilized before use. Please refer to the "Notes on reprocessing (cleaning, disinfection and sterilization) of medical products from Hager & Meisinger GmbH".

WOUND CLOSURE

The soft tissue is adapted around the healing abutment and closed with individual sutures as free of tension as possible. It is important to ensure a tight seal to make penetration by bacteria difficult and to prevent infections.

DETERMINING THE CORRECT GINGIVA HEIGHT

The following special features must be taken into account when forming the soft tissue with the help of the gingiva former:

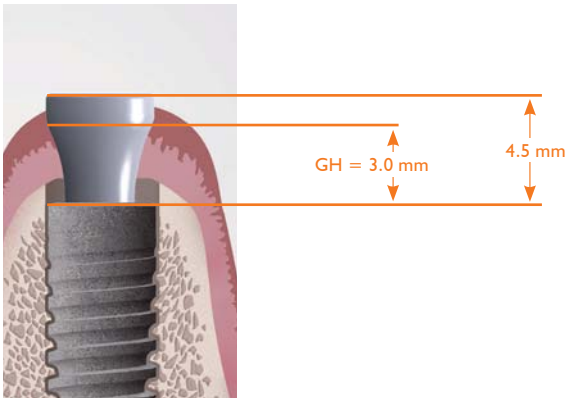
Note:
The choice of gingiva former depends on the intended abutment line.

1. DEEP PLATFORM SWITCHING

The wide, circular implant shoulder leads to deep platform switching due to the design. The interface between implant and abutment is thus moved centrally, so that the diameter of the prosthetic component at the implant shoulder is significantly smaller than the implant diameter. This allows the soft tissue to accumulate under the flanks of the structure.

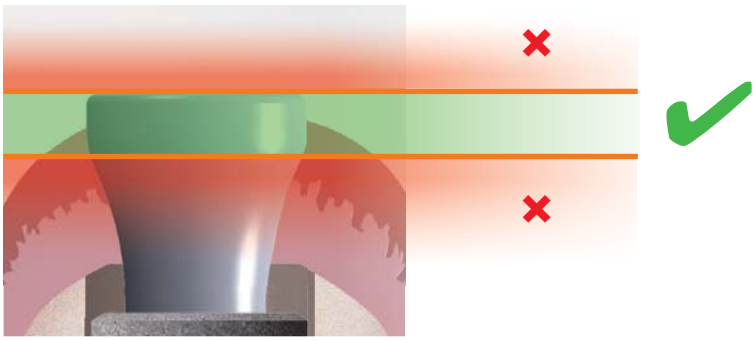
2. DETERMINATION OF THE GINGIVA HEIGHT

To form the starting crown profile, the entire gingiva former is always 1.5 mm higher than the nominal dimension when viewed from the interface level. A gingiva former with a height of 3.0 mm therefore has a total height of 4.5 mm.



The gingiva level should always be within the range of the first 1.5 mm of the gingiva former.

- If the gingiva level is within the range of the lines drawn, the gingiva former was selected correctly.
- If the gingiva level is above the upper line drawn, a higher gingiva former should be selected.
- If the gingiva level is below the lower drawn line, a lower gingiva former should be selected.



THE PROSTHETEC RESTORATION POSSIBILITIES

SELECTION OF THE ABUTMENT

The abutment should be selected in the gingiva height analogous to the gingiva former. A mismatching profile of the structure may result in compression of the gingiva. This occurs when

- the gingiva former is significantly higher than the gingiva level and the abutment subsequently used (see page 38)
- or the abutment used has a lower gingiva height than the correctly selected gingiva former used.

Note:

- In order to ensure sufficient stability of the abutment and a sufficient retention surface, the abutment should be at least 4 mm high.
- In occlusally screw-retained planning, occlusal shortening of the abutment is not possible because the occlusal screw receptacle is located there.
- Incorrect selection of the gingiva former or an incorrect abutment with correct gingival shaping has a direct effect on the aesthetics of the prosthetic restoration and may have a negative effect on papilla development.
- The conical, non-indexed implant/abutment internal connection leads to easier positioning of the abutments, so that a stable transfer key is absolutely necessary when the abutment is selected by the laboratory for transfer back into the patient's mouth.
- The abutment screw in the implant should be tightened with the torque wrench after approx. one week.

The myplant two selection posts can be used to help you select a suitable standard abutment. The abutment is selected according to the soft tissue conditions. The abutment is screwed into the patient's mouth taking into account the prescribed torque of 15 Ncm. The tapered connection ensures that the abutment does not rotate in the implant.

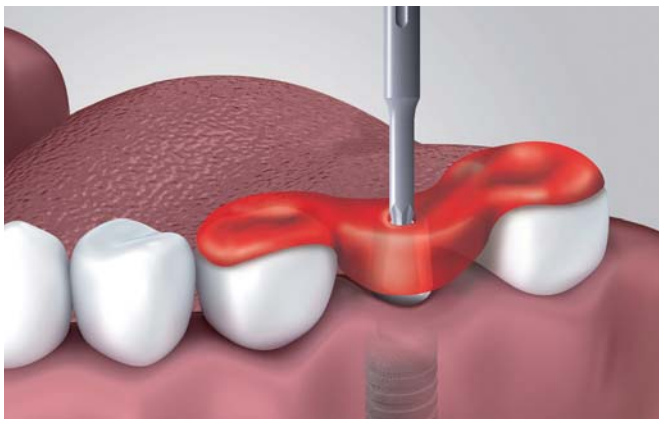
Using the positioning key, angled standard abutments can be integrated directly into the patient's mouth. The one-piece screwdriver is inserted into the 15° hole of the positioning key and the abutment is correctly positioned on the key. Together with the positioning key, the abutment is then positioned in the implant and screwed directly into the desired prosthetic position.

If access is difficult (in the molar region), the angled abutment is positioned with the key and fixed by occlusal pressure. The positioning key is then removed and the abutment screw tightened with the short screwdriver.

When positioning several angled abutments, the paralleling post can be screwed into the occlusal thread of the abutment with one to two turns for better control of parallelism and thus serves as an alignment aid for further angled abutments.

TRANSFER KEY

If the impression was taken at implant level and the abutment was selected by the dental technician, the abutments should always be inserted into the patient's mouth using a transfer key fabricated by the laboratory. For detailed instructions on how to use the transfer key, see : https://youtu.be/f11pYfyF0Ss

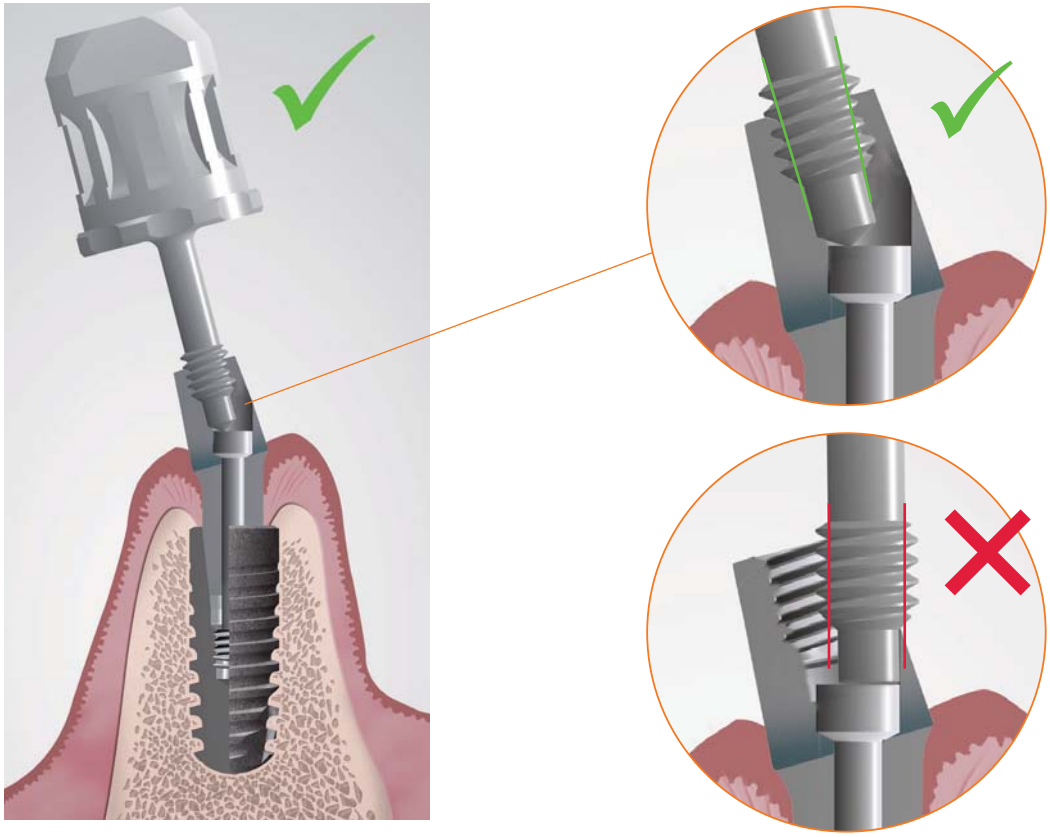


ABUTMENT REMOVAL

The self-locking cone enables an absolutely rotation-stable implant-abutment-connection which provides a virtually bacteria-proof seal. This connection can be disengaged again with the aid of the abutment remover.

First, the straining screw of the abutment is completely loosened with the screwdriver. The abutment remover is then screwed into the occlusal screw seat. Once resistance is felt, the abutment remover has made contact with the head of the abutment. If it is now rotated further with care, the abutment remover lifts the abutment out of the implant enabling it to be removed easily.

Note:
If the abutment screw is not loosened completely, the abutment remover could be blocked.
Shoud the abutment not come out easily the abutment remover should be disconnect and the screw driver used to fully loosen the straining screw and remove the abutment from the implant.



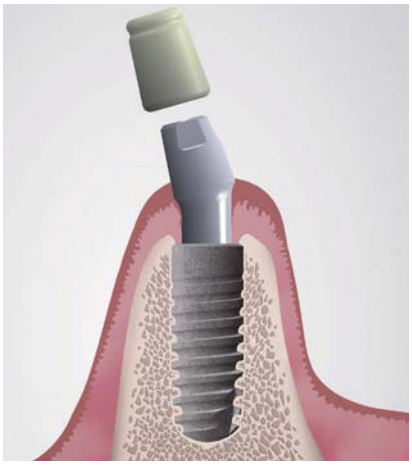
Important: To avoid jamming, it is essential to ensure that the abutment remover is screwed into the screw channel of the occlusal screw seat in the case of angled abutments.

TEMPORARY RESTORATION

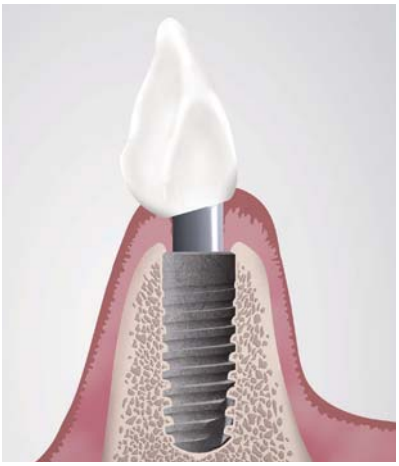
It is advisable to carry out a temporary restoration first in order to wait for the healing of the soft tissue and to form the emergence profile. Since the bone quality does not improve during the unloaded healing phase, temporary restorations should be designed similar to the immediate temporary restoration with reduced occlusal load and, where possible, the implants should be blocked during this phase. A soft diet for the following weeks is recommended. This type of „bone training“ usually results in a significant improvement of the bone mineral framework on the implant interface after approximately 6 weeks so that the final prosthetic restoration can then be carried out without the risk of early loss.

CHAIRSIDE-FABRICATED TEMPORARY RESTORATION

The trial abutment can be used as an aid for selecting a suitable abutment.
A deep drawn splint, prepared on the basis of the set-up situation, acts as control whether the trial abutment correspond to the prosthetically required situation. The selected abutment is screw-retained until shortly before it reaches full friction and alignment (< 15 Ncm). Should you need to perform splinting, one should also observe parallelism. The position of the abutment is to be secured with the positioning key so that the central screw can be retained securely at 15 Ncm.
The corresponding healing cap is mounted on the abutment and shortened to the desired working height if necessary.



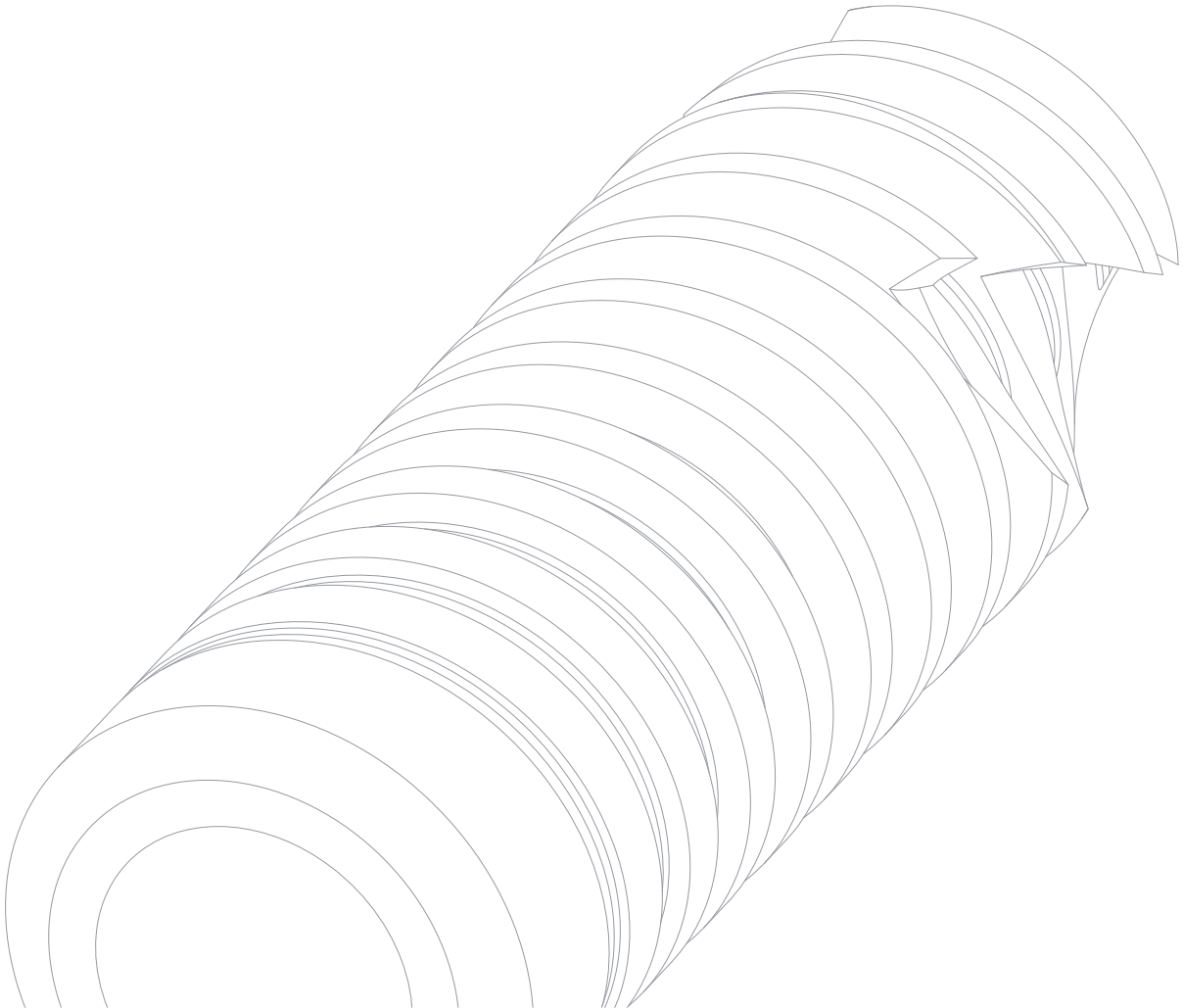
After adaptation of the healing cap, the crown shape is replaced with a light-curing or selfcuring resin. Care should be exercised in terms of a precise margin design with the later emergence profile in mind. This work should be performed outside the oral cavity (for example, with light-curing flowable composite) on an analog abutment. This can be mounted on the laboratory handle for easier handling.
As a rule, cementing is not required due to the „snap function“ of the healing caps. However, if cementing should prove necessary, a temporary cement should be used.



Note:
The provisional solution must not be used for longer than 6 months.

LAB-FABRICATED TEMPORARY RESTORATION

The impression is taken using the closed or open tray method. The abutments are selected by the dental laboratory. The access to the implants up to the insertion of the temporary restoration is kept open by gingiva formers. The impression is taken using the closed or open tray method. The abutment is selected by the dental laboratory. Access to the implant is kept open via the healing abutments until the temporary restoration is integrated.



THE IMPRESSION TAKING ON IMPLANT LEVEL

CLOSED IMPRESSION TAKING

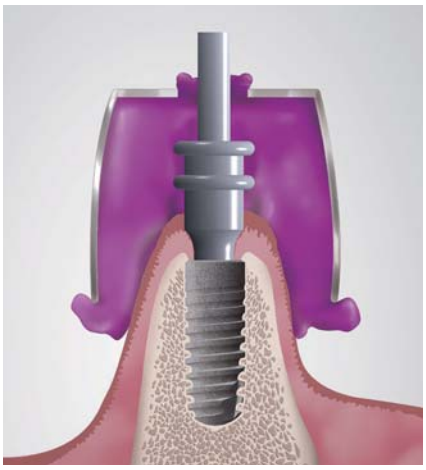
After removing the healing abutment or abutment respectively, it must be ensured that the inner surface of the implant is not contaminated. The repositioning post is subsequently screwretained in the implant and screwed hand-tight with 5 - 7 Ncm. The opening on the face of the repositioning post should be sealed flush with wax. The impression is taken with the aid of a closed tray.

Note:
Care must be taken to select a suitable impression material. This must be used according to the manufacturer's instructions.

The impression tray can be removed carefully after setting and curing of the impression material. The repositioning post remains in the implant during this process. After detaching the post, this can be repositioned in the impression. Then the temporary restoration of the patient can be remounted. The laboratory receives the impression for fabrication of the model. The suitable abutment is selected in the laboratory in consultation with the clinician.

OPEN IMPRESSION TAKING

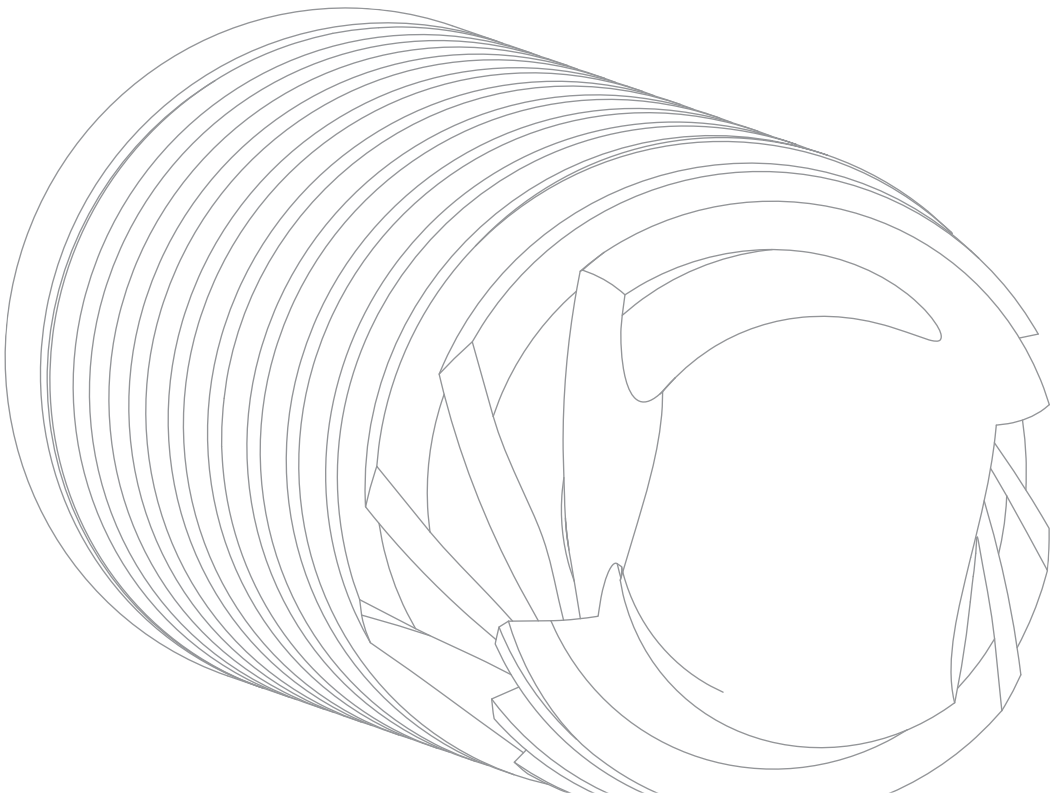
The already placed abutments should be indexed for subsequent transfer using self-curing resin. The screw accesses are to be kept open. After removing the healing abutment or abutment respectively, it must be ensured that the inner surface of the implant is not contaminated. The transfer post is subsequently screw-retained in the implant and screwed hand-tight 5 - 7 Ncm. The impression is taken with the aid of a customizable impression tray. This is perforated at the implant position where the impression is to be taken, to be able to disengage the guide screw of the transfer post when removing the impression tray.



Note:
Care must be taken to select a suitable impression material. This must be used according to the manufacturer's instructions.

After setting and curing of the impression material, the guide screw is disengaged and the impression removed, whereby the transfer post remains in the impression. The temporary restoration of the patient can be then remounted. The laboratory receives the impression for fabrication of the model. The suitable abutment is selected in the laboratory in consultation with the clinician.

Impression taking at abutment level is explained in more detail in the separate chapters below.



THE PROSTHETIC RESTORATION WITH STANDARD ABUTMENTS

Abutment type	Single Tooth	Bridge	Partial prosthesis	Total prosthesis
Standard abutment	x	x	x	x

PVS00 PVS01 PVS02

Cover Screw

PGF15 PGF30 PGF45

Healing Abutment

IMPRESSION VIA IMPLANT

PUP01 PUP02

Transfer Post

PRP01 PRP02

Repositioning Post

PLI01

Implant Analog

PAB01 PAB02 PAB03 PAB04 PAB05 PAB06 PAB51 PAB52 PAB53 PAB54

Abutment

IMPRESSION VIA ABUTMENT

PAP01 PAP02 PAP03 PAP04 PAP51 PAP52 PAP53 PAP54

Trial Abutment

PAB01 PAB02 PAB03 PAB04 PAB05 PAB06 PAB51 PAB52 PAB53 PAB54

Abutment

PHK01 PHK02

Healing Cap

PAK01 PAK02

Transfer Cap

PLA04 PLA06 PLA54 PLA56

Laboratory Analog one-piece

PKK04 PKK06 PKK14 PKK16

Taper Cap

PMK01 PMK02 PMK03 PMK04

Wax-Up Coping
Rotation secured

Final restoration
only with occlusal screw connection

POS01 POSK1

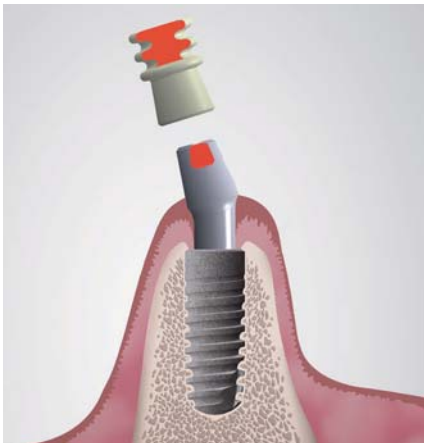
Occlusal Screw

Occlusal Screw for Ceramic

IMPRESSION VIA ABUTMENTS

After the control of the abutment position and dimensioning with respect to parallelism and subgingival crown margin (emergence profile, aesthetics), the corresponding transfer cap is mounted on the abutment and pressed down firmly. When placing the impression cap, make sure it is correctly aligned. The surface on the impression cap (marked red) must have the same orientation as the parallel surfaces on the abutment (marked red). Make sure that the impression cap is correctly seated on the abutment. Subsequently, a closed impression is taken and forwarded to the laboratory together with the cap remaining in, or if applicable, repositioned in the impression. In order to insert the corresponding laboratory analogs, the laboratory must be informed about the abutment used. Until the final prosthesis is integrated, the patient can be provided with a chair side fabricated temporary restoration.

Note:
The MyPlant II transfer caps are designed exclusively for single use and may not be re-sterilized. Multiple use of the transfer caps can lead to a loss in precision.



Impression taking at implant level is explained in more detail on pages 44 - 45.

THE INTEGRATION OF PROSTECTICS

With the myplant two Standard abutments different restorations can be realized.

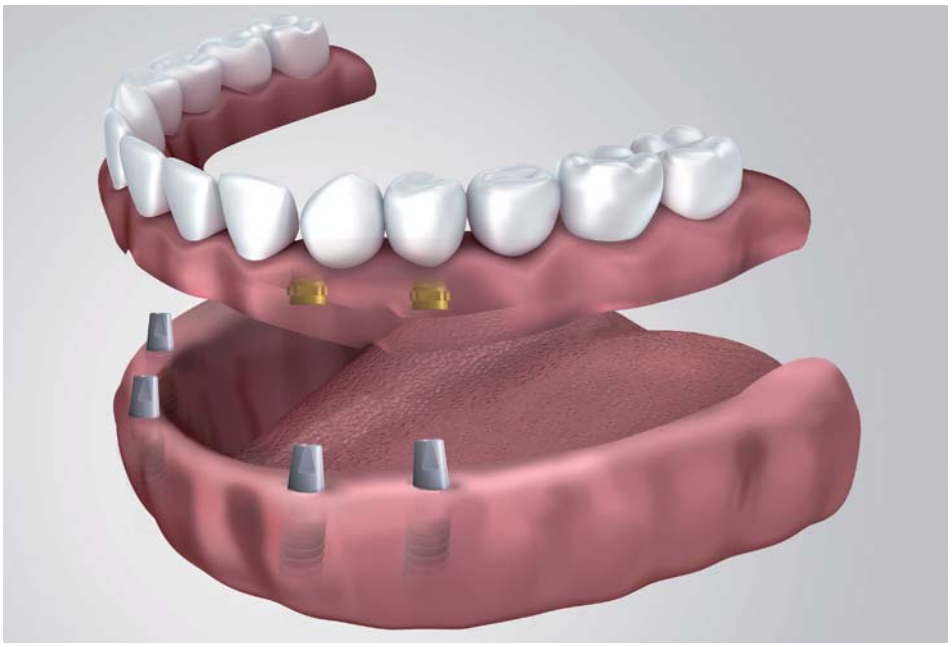
Occlusal screw connection

Both straight and angled abutments have occlusal screw channels for cementless cementation. After fitting and testing a tension-free fit, the prosthetics is screwed occlusally onto the abutment. The occlusal screw is tightened to 10 Ncm using the screwdriver.

Finally, the screw access is closed with a composite.

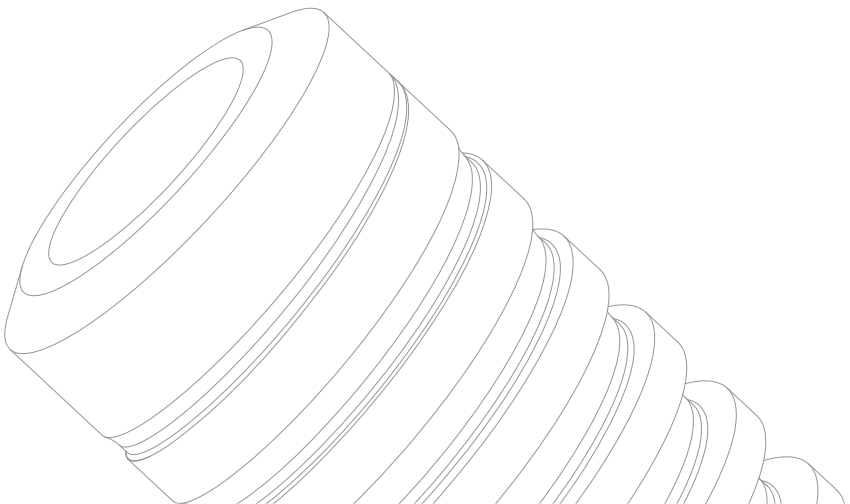
Cone caps

An alternative is the fixation of the superstructure with precisely fitting cone caps. These can be incorporated into existing prosthetics in an uncomplicated and tension-free temporary manner for immediate restoration, thus shortening the duration of treatment. A final restoration is made after healing. The cone caps are used in conjunction with myplant two standard abutments and can be used on both straight and angulated standard abutments. The cone caps are available with and without external retentions and can be integrated into metal frameworks and plastic prosthetics. Thanks to the free cone of the abutments, they can be optimally aligned for the application of the cone caps. The cone caps are bonded or polymerized directly to the prosthetics or metal framework by the dentist without tension and intraorally.



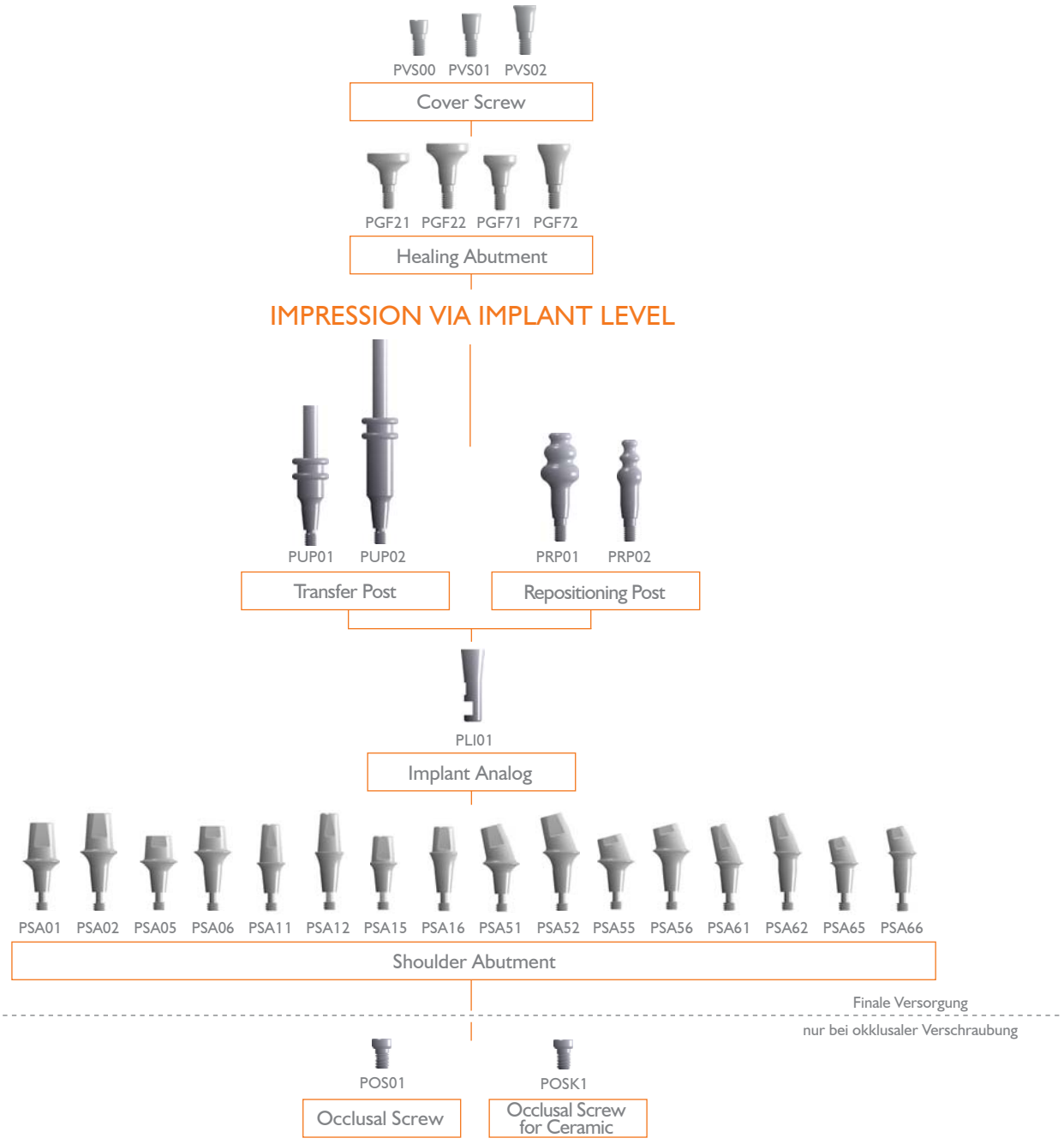
Modeling caps

A prefabricated, high-precision modeling aid is available to the dental technician for the fabrication of accurately fitting prosthetic restorations. These consist of residue-free combustible plastic.
The modeling aid can be shortened in height according to the required restoration. The occlusal canal is closed for contouring. The wax model is applied directly to the modeling aid. Before embedding, the occlusal screw channel must be opened again.



THE PROSTHETIC RESTORATION WITH SHOULDER ABUTMENTS

Abutment type	Single Tooth	Bridge	Partial prosthesis	Total prosthesis
Shoulder abutment	x	x	-	-



The myplant two shoulder abutment allows the abutment to be selected according to individual space conditions. The slightly concave design of the gingiva-forming portion reduces the pressure on the sulcus for an optimal aesthetic result. Special gingiva formers in both diameters are available for the shoulder abutments.

The impression is taken via the implant level (see page 44 - 45).

The laboratory selects the appropriate abutments from the model and then fabricates the prosthetics.

INTEGRATION OF THE PROSTECTICS

With the myplant two shoulder abutments different restorations can be realized. The shoulder abutment is screwed into the implant with 15 Ncm. The abutments should always be inserted into the patient's mouth using a transfer key prepared by the laboratory (see page 40)

Cementation

All-ceramic restorations or restorations with a ceramic shoulder should be cemented. Cement surpluses must be removed thoroughly.
Before cementation, the access cavity to the abutment screw must be closed with a revisable filling material (applies analogously before each cementation).

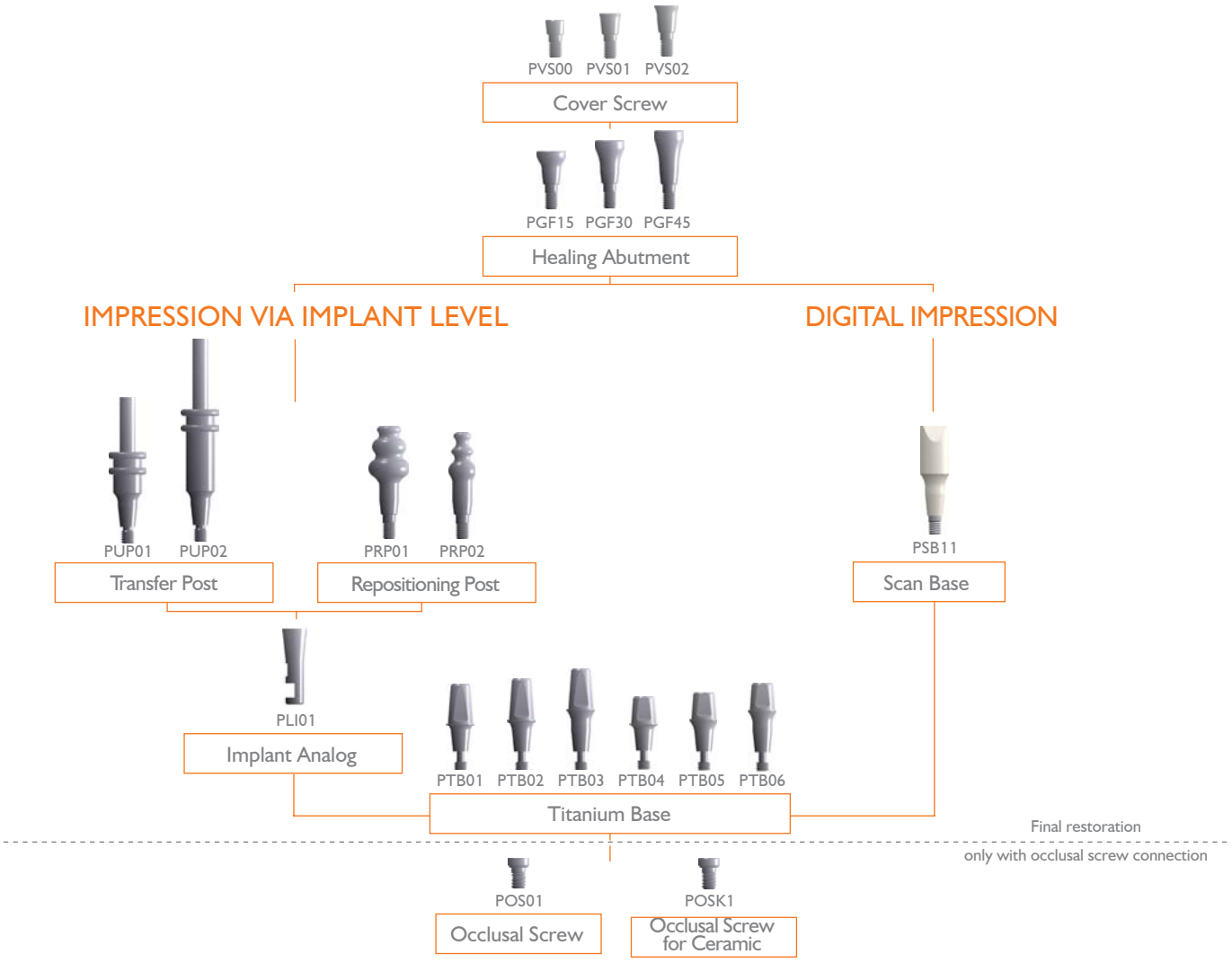
Occlusal screw connection

Both straight and angled shoulder abutments have occlusal screw channels for cementless cementation. After fitting and testing a tension-free fit, the prosthetics is screwed occlusally onto the abutment. The occlusal screw is tightened to 10 Ncm using the screwdriver.

Finally, the screw access can be closed with a composite.

THE PROSTHETIC RESTORATION WITH TITANIUM BASE

Abutment type	Single Tooth	Bridge	Partial prosthesis	Total prosthesis
Titanium Base	x	x	-	-



The myplant two Titanium Base achieves the best aesthetic goals. Thanks to digital technologies, the patient receives individual restoration that meets all aesthetic requirements. The deep shoulder of the Titanium Base allows an individual design of the emergence profile. If required, the structure with the extraorally bonded die can be used as an individual gingiva former. The die can be scanned and modeled by the dental technician in the classical way or digitally created with the help of the Scan Base and 3D software.

THE DIGITAL IMPRESSION BASED ON THE CLINICAL SITUATION

The scan base is hand-tightened in the implant. The digital impression is taken directly on the patient using an intraoral scanner.

THE DIGITAL IMPRESSION BASED ON THE MODEL IN THE LABORATORY

If the digital impression is taken in the laboratory, generally an impression will first be taken at implant level (see page 44 - 45). The laboratory receives the impression for model fabrication and hand-tightens the scan base to a maximum of 5 - 7 Ncm in the laboratory implant. The entire plaster model is scanned in the laboratory using an appropriate scanner.

INTEGRATION OF THE PROSTECTICS

Note:
The manufacturer's specifications of the respective material manufacturers must be taken into account for the correct procedure of the bonding.

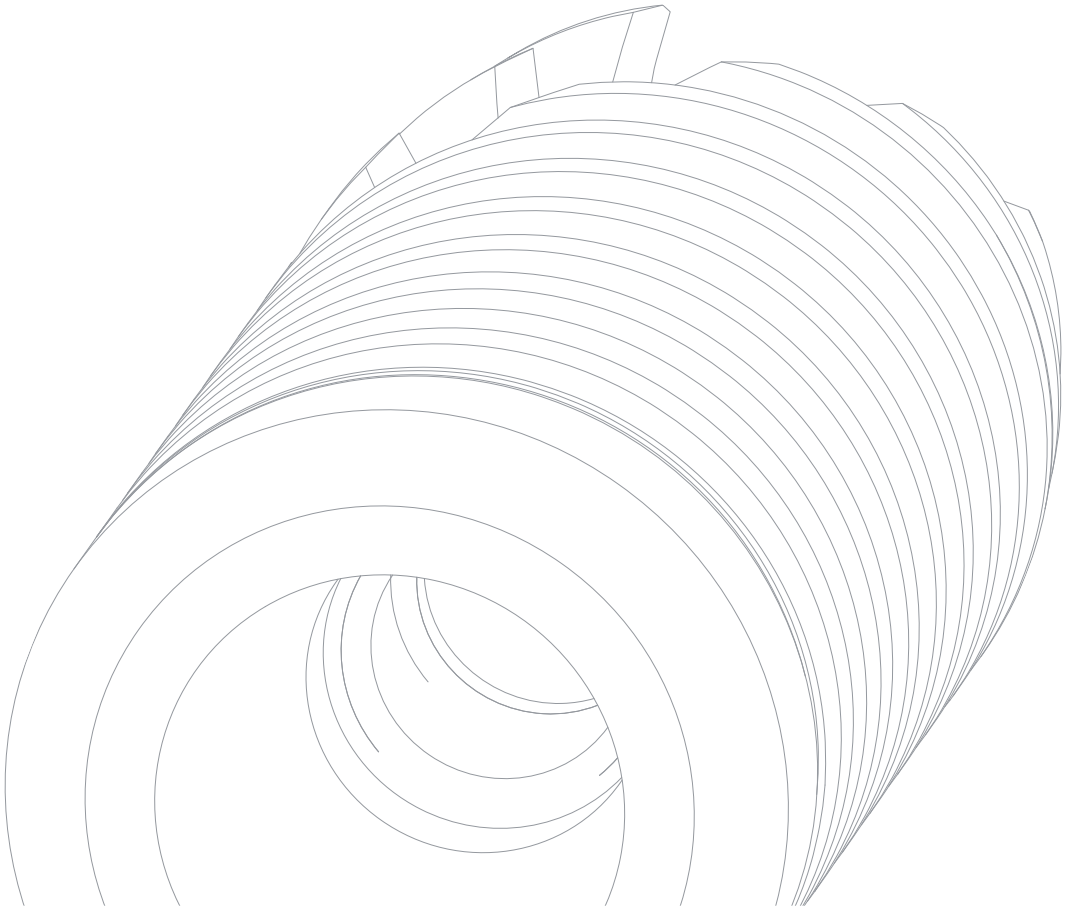
The individual die is glued extraorally to the titanium base. The adhesive residues are carefully removed. Using a transfer key, the abutment is transferred into the patient's mouth with an individual die and screwed into the implant with 15 Ncm. The final restoration is cemented to the die. Cement residues must be removed thoroughly.

The Titanium Base has an occlusal screw channel for cementless cementation. After fitting and testing a tension-free fit, the prosthetics is screwed occlusally onto the die. The occlusal screw for ceramics is tightened to 10 Ncm using the screwdriver.

Finally, the screw access can be closed with a composite. With myplant digital you can have your individual abutments produced within 24 hours.

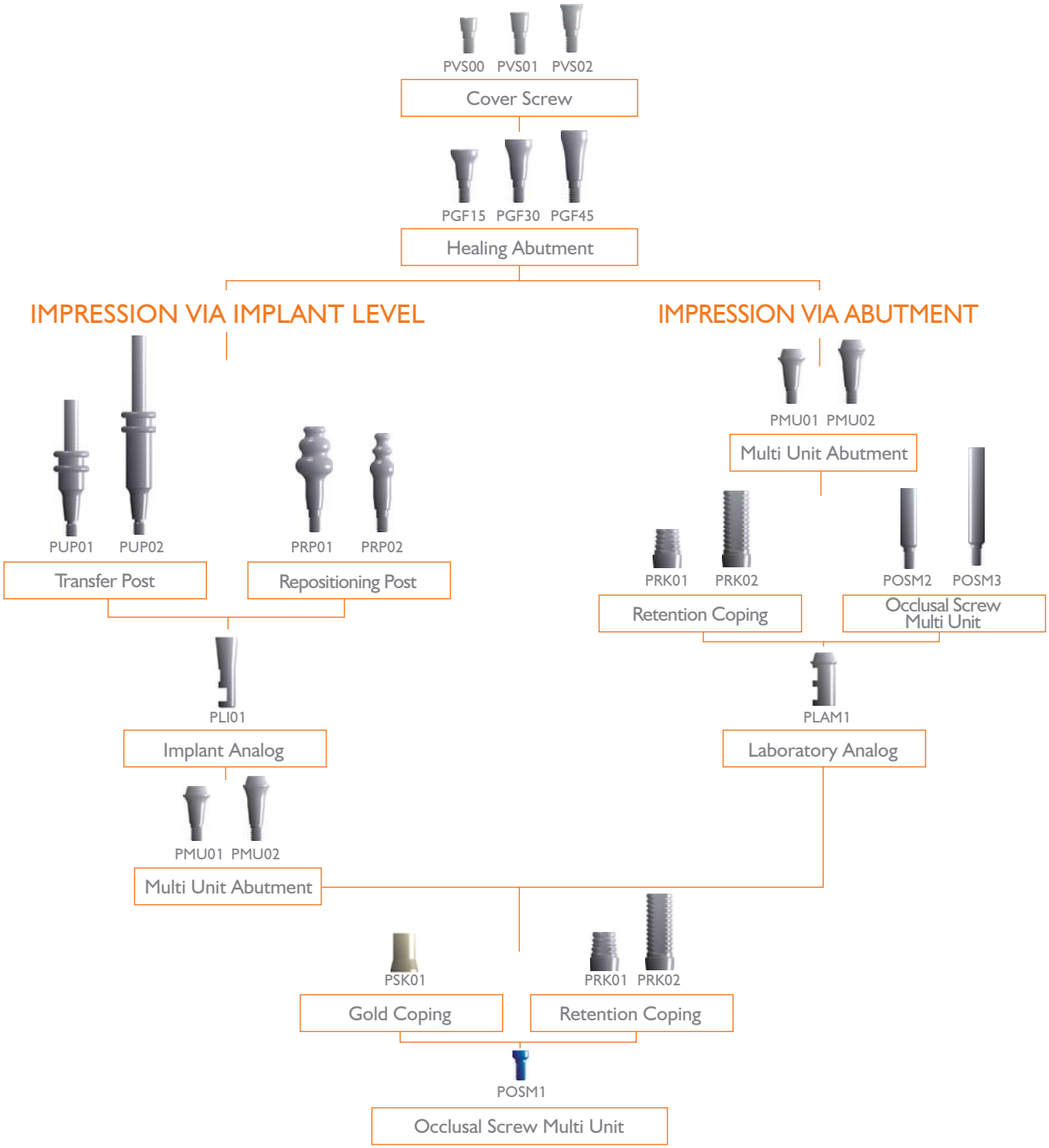
For further information, please refer to the separately available brochure on myplant digital.

myplant digital



THE PROSTHETIC RESTORATION WITH MULTI UNIT ABUTMENTS

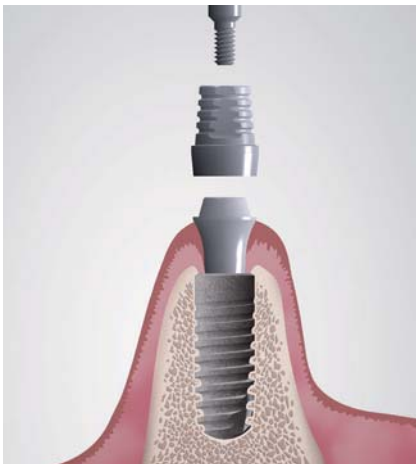
Abutment type	Single Tooth	Bridge	Partial prosthesis	Total prosthesis
Multi unit abutment	-	x	x	x

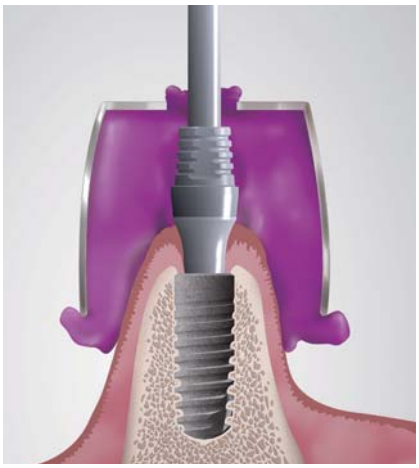


The myplant two Multi Unit abutments allow different restoration possibilities. With the aid of prefabricated components such as bar caps or retention caps, the Multi Unit abutments offer a precise and simple restoration, both over prosthetics and bar constructions can be realized. Screw-retained bridges with ceramic or plastic covering are also possible on these structures. Since there is no rotation lock between the structure and the superstructure, at least two myplant two Multi Unit abutments must always be used together.

THE IMPRESSION ABOVE SECONDARY PART LEVEL

For highly precise transfer of the patient situation in the mouth to the master model, it is recommended that the impression be taken in several treatment sessions in close cooperation between the dentist and the laboratory.
The corresponding retention caps are used for impression taking at abutment level. These are fixed to the abutment with the long occlusal screw with a torque of 7 to 10 Ncm and an open impression is taken.
This first impression is used to fabricate a model on which an individual impression tray is made. In addition, a transfer key is fabricated on the retention caps, which is separated between the caps and finally locked tension-free in the patient's mouth. The final impression is taken over this with the individual tray.
For each impression, care must be taken to ensure that the curing time of the impression material is sufficient. Please refer to the respective manufacturer's specifications.
The Multi Unit laboratory analog is available for transferring the impression to the master model.





Impression taking at implant level is explained in more detail on pages 44 - 45.

THE INTEGRATION OF PROSTECTICS

The final restoration is always screwed to the Multi Unit abutments in the patient's mouth at 15 Ncm. Here, care must be taken to ensure that the prosthetics are seated tension-free.

THE PROSTHETIC RESTORATION WITH LOCATOREN®

Abutment type	Single Tooth	Bridge	Partial prosthesis	Total prosthesis
LOCATOR®	-	-	x	x

PVS00 PVS01 PVS02

Cover Screw

PGF15 PGF30 PGF45

Healing Abutment

PLOC2 PLOC3 PLOC4

LOCATOR®

IMPRESSION VIA ABUTMENT

PAKL1

LOCATOR® Impression Coping

PLAL1

Female Analog

PLPE1

Black Processing Replacement Male

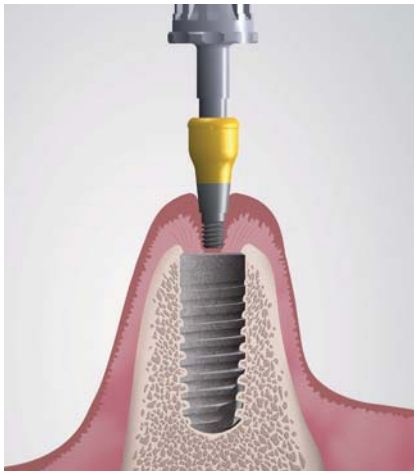
PLLS1

Male Processing Package

PLLS2

Male Processing Package - Extended Range

The LOCATOR® is selected according to the soft tissue situation of the patient. It should be noted that the retention element of the LOCATORS® must lie above the mucous membrane. The LOCATOR® is screwed into the implant using the insertion tool with the specified torque of 25 Ncm.



THE IMPRESSION ABOVE SECONDARY PART LEVEL

After checking the LOCATOR® position and dimensions with regard to parallelism and subgingival crown edge (emergence profile, aesthetic), the corresponding impression cap is placed on the LOCATOR® and pressed tight. A closed impression is then taken and transferred to the laboratory with the cap remaining in the impression or reduced if necessary.
Until the final prosthetics is placed, the patient can be supplied hair side-fabricated temporary prosthetics.

PLOC4

THE INTEGRATION OF PROSTECTICS

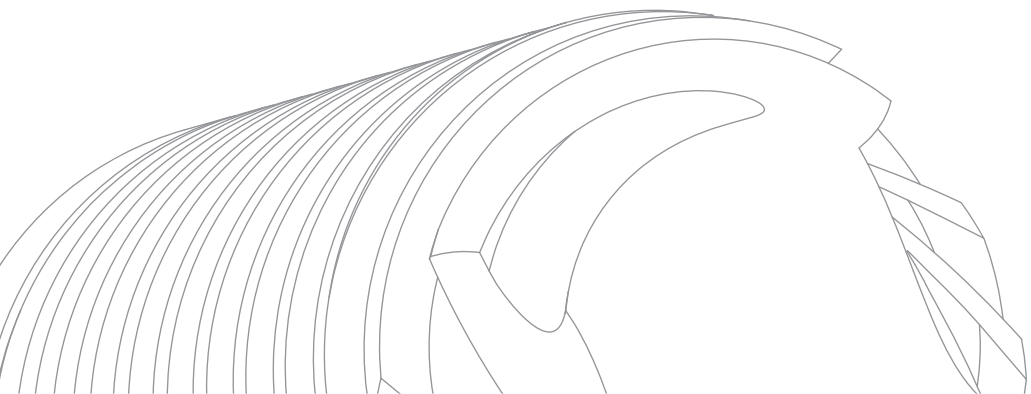
f a prosthetics is fabricated in the laboratory, an impression is taken with the help of the impression caps. Make sure that the black process insert is integrated in the impression cap and remains there even after the impression has been taken. The laboratory can use the impression to fabricate the prosthetics.
The matrices can also be integrated directly chair side into an existing prosthetics. For this purpose, the matrice is selected with the corresponding pull-off force. The following assignment applies:

Matrix	Pull-off force
Blue	0.68 kg
Pink	1.36 kg
Transparent	2.27 kg

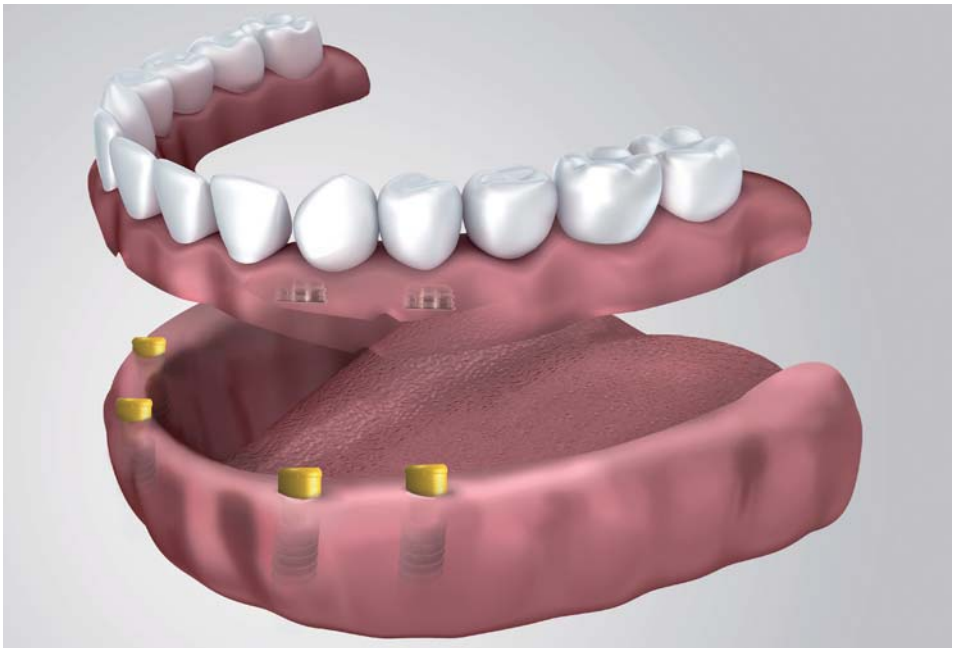
With axle divergence up to 10° for individual implants

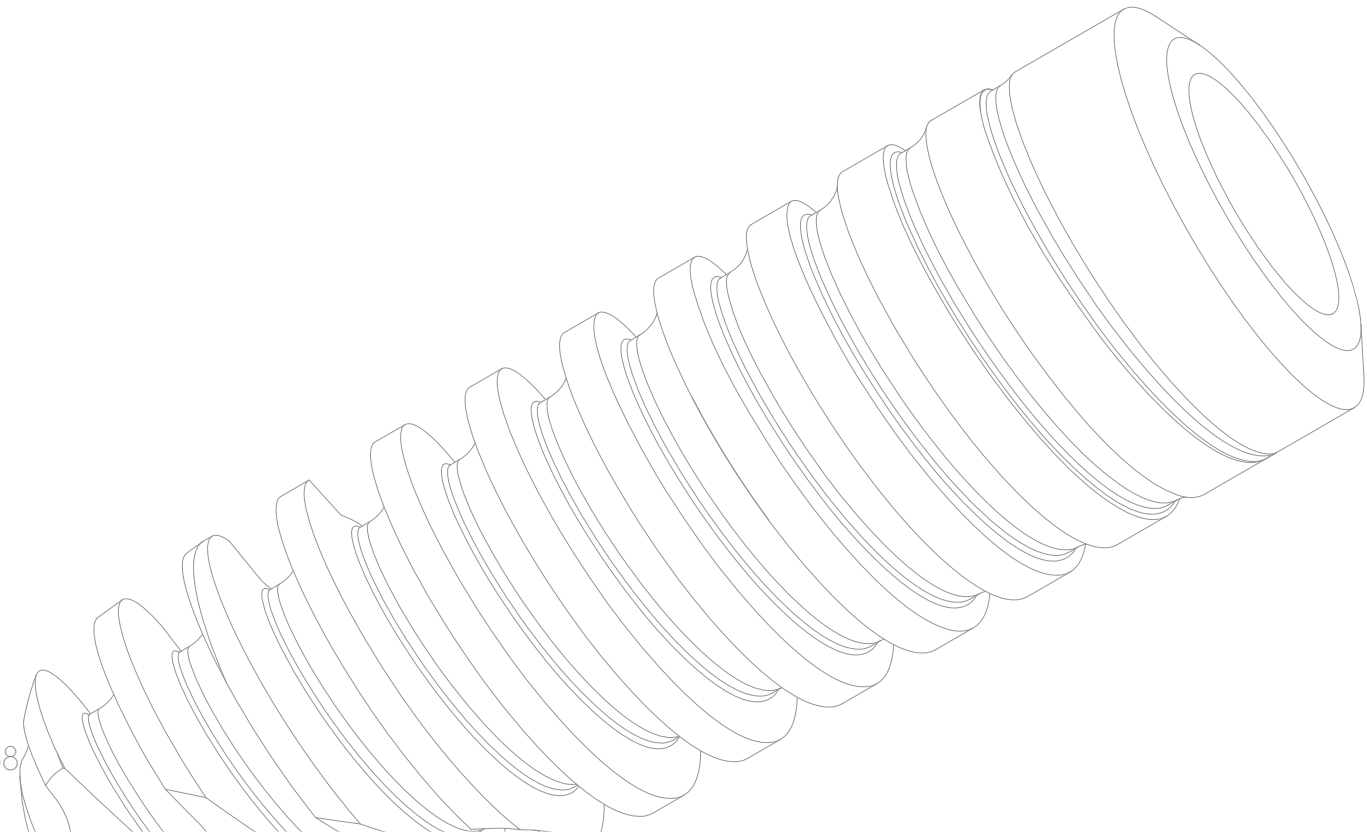
Matrix	Pull-off force
Red	0.23 - 0.68 kg
Orange	0.91 kg
Green	1.36 - 1.82 kg

For axial divergence between 10° and 20° for individual implants



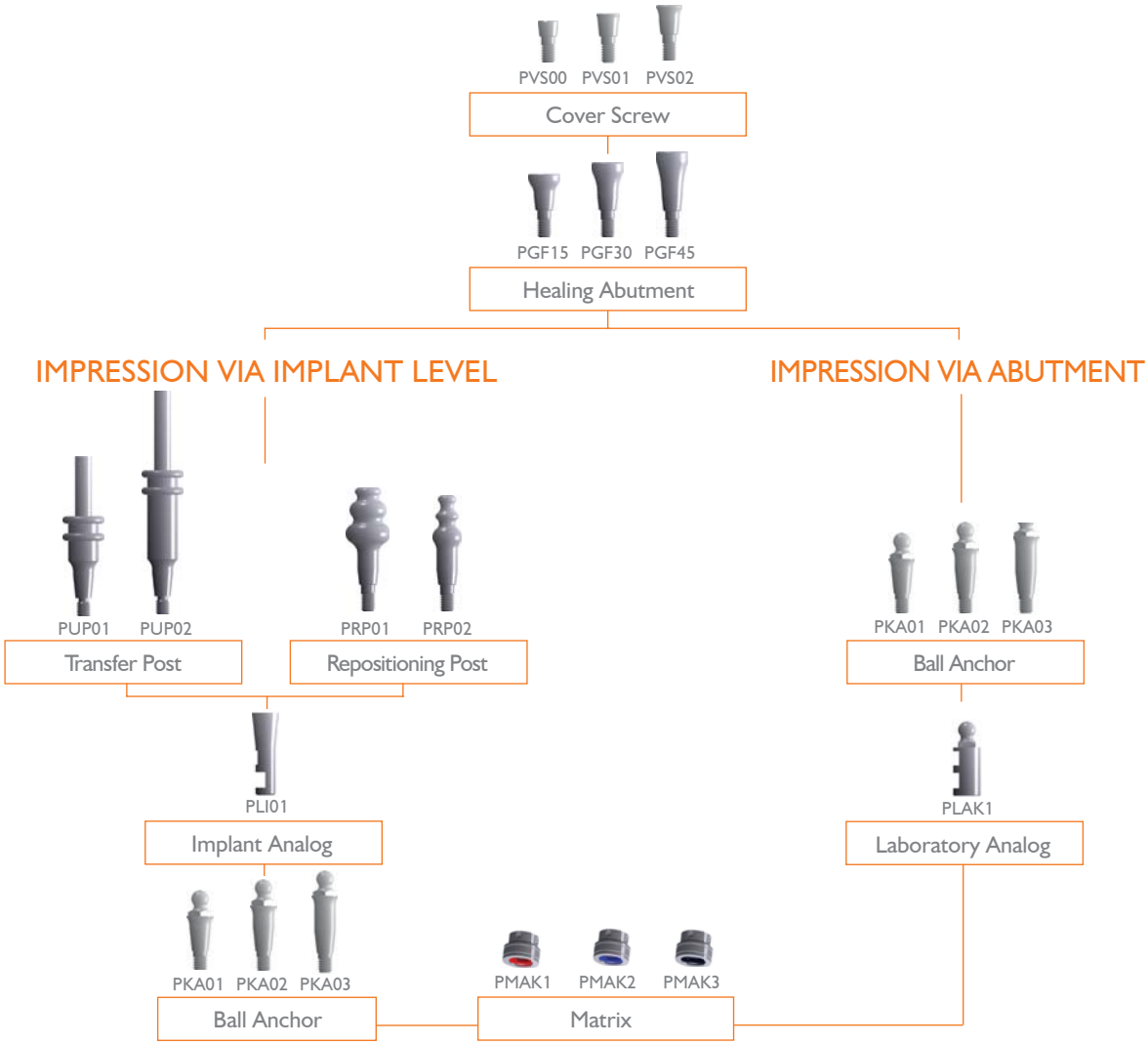
The white block-out ring is placed on the LOCATOR® and the black process insert including the die is placed over it. If there is a gap between the block-out ring and the die, it is closed with further block-out rings. There must be no gap left in the prosthetics for fixing the matrice. In the area of the matrice, the plastic is ground out of the prosthetics so that there is no contact between the matrice and the prosthetics. The prosthetics is then filled with acrylic and inserted and fixed until polymerization is complete. The specifications of the plastic manufacturer must be observed. The prosthetics is then removed and sharp edges smoothed. Now the prosthetics can be attached to the LOCATOREN®.





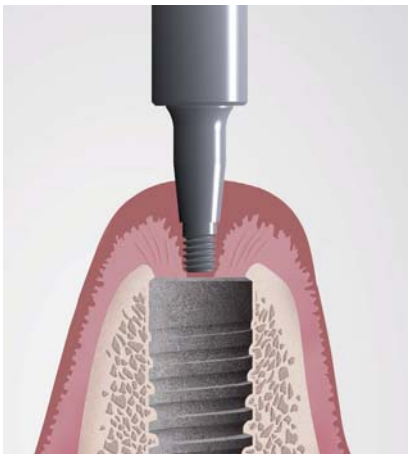
THE PROSTHETIC RESTORATION WITH BALL ANCHOR

Abutment type	Single Tooth	Bridge	Partial prosthesis	Total prosthesis
Ball Anchor	-	-	x	x



The ball anchors are selected according to the soft tissue situation of the patient. It should be noted that the retention ball must lie above the mucous membrane. The ball anchor is screwed into the implant using the insertion tool with the specified torque of 25 Ncm.

The impression is taken at implant level and is explained in detail on pages 44 - 45.



THE INTEGRATION OF PROSTECTICS

The matrices can be integrated directly chair side into an existing prosthetics. For this purpose, the matrice is selected with the corresponding pull-off force.
The following assignment applies:

Matrix	Hardness	Pull-off force
PMAK1 (red)	70 Shore	0.5 kg
PMAK2 (blue)	80 Shore	1.0 kg
PMAK3 (black)	90 Shore	1.5 kg

The matrice is placed on the ball anchor so that it snaps into place. The matrice can now be attached to the prosthetics using cold polymerization. For this purpose, the prosthetics is ground at the appropriate points so that there is no contact between the matrice and the prosthetics. The prosthetics is then filled with acrylic and inserted and fixed until polymerization is complete. The specifications of the plastic manufacturer must be observed. The prosthetics is then removed and sharp edges are smoothed. Now the prosthetics can be attached to the ball anchors.

RECOMMENDED TORQUES FOR THE MYPLANT TWO PROSTHETICS

	Product	Torque
	Cover Screw	5 - 7 Ncm
	Healing Abutment	
	Transfer Post	
	Repositioning Post	
	Scan Base	
	Protective Cap	
	Occlusal Screw	10 Ncm
	Occlusal Screw for Ceramics	
	Occlusal Screw for Multi Unit	
	Standard Abutment	15 Ncm
	Shoulder Abutment	
	Titanium Base	
	Multi Unit Abutment	25 Ncm
	LOCATOR®	
	Ball Anchor	

Note: The images are examples only. The torque specifications are valid for all variants of the products mentioned.

FURTHER INFORMATION

NOTES ON MYPLANT TWO IMPLANTS

The myplant two implants produced by Hager & Meisinger GmbH MyPlant II are supplied sterile (sterilization with gamma irradiation, radiation strength at least 25 kGy). They are supplied in double sterile blister packs. The labels on the blisters can be detached and used for transferring the implant data to the patient file (batch number). The MyPlant II implant is only intended for single use!

The implant is sterile if the packaging is unopened and undamaged. In the case of damaged or non-tight inner packaging there is a risk of contamination with pathogens, e.g. application may not be performed, and also no own resterilization. After expiry of the given sterilization expiry date (hourglass symbol), the implant may no longer be used. Unprotected touching of the implant by the user is to be avoided (use sterile gloves).

All components of the MyPlant II implant system are to be stored dry at room temperature and ideally without being exposed directly to light. When re-using single-use products, the infection risk is increased and riskfree functional safety (i.e. related to stability or precision of fit) cannot be guaranteed.

All application and safety instructions, including the positioning instructions, can be found in the Application and Safety Instructions for myplant two Implant System.

STORAGE, CARE AND REPROCESSING OF SURGICAL INSTRUMENTS

With the exception of the implant and the cover screw in the packaging, all abutments and instruments/accessories are supplied non-sterile. All items for re-use must be reprocessed properly prior to first use on the patient and after every use. See Meisinger “Notes for reprocessing”. When working with contaminated instruments, always wear gloves. The items are to be cleaned and disinfected prior to sterilizing, in case of pronounced spoiling an ultrasonic bath can be used. To avoid damage, the instruments must not be in contact with each other during reprocessing. Disassemble the instruments as far as possible for cleaning and disinfection. Mechanical cleaning and disinfection is recommended. After cleaning and disinfection, the instruments must be rinsed well with running water and dried immediately. Prior to sterilization the instruments must be checked for various signs of wear and can then be reassembled accordingly. Instruments may not be cleaned and disinfected in the instrument tray.

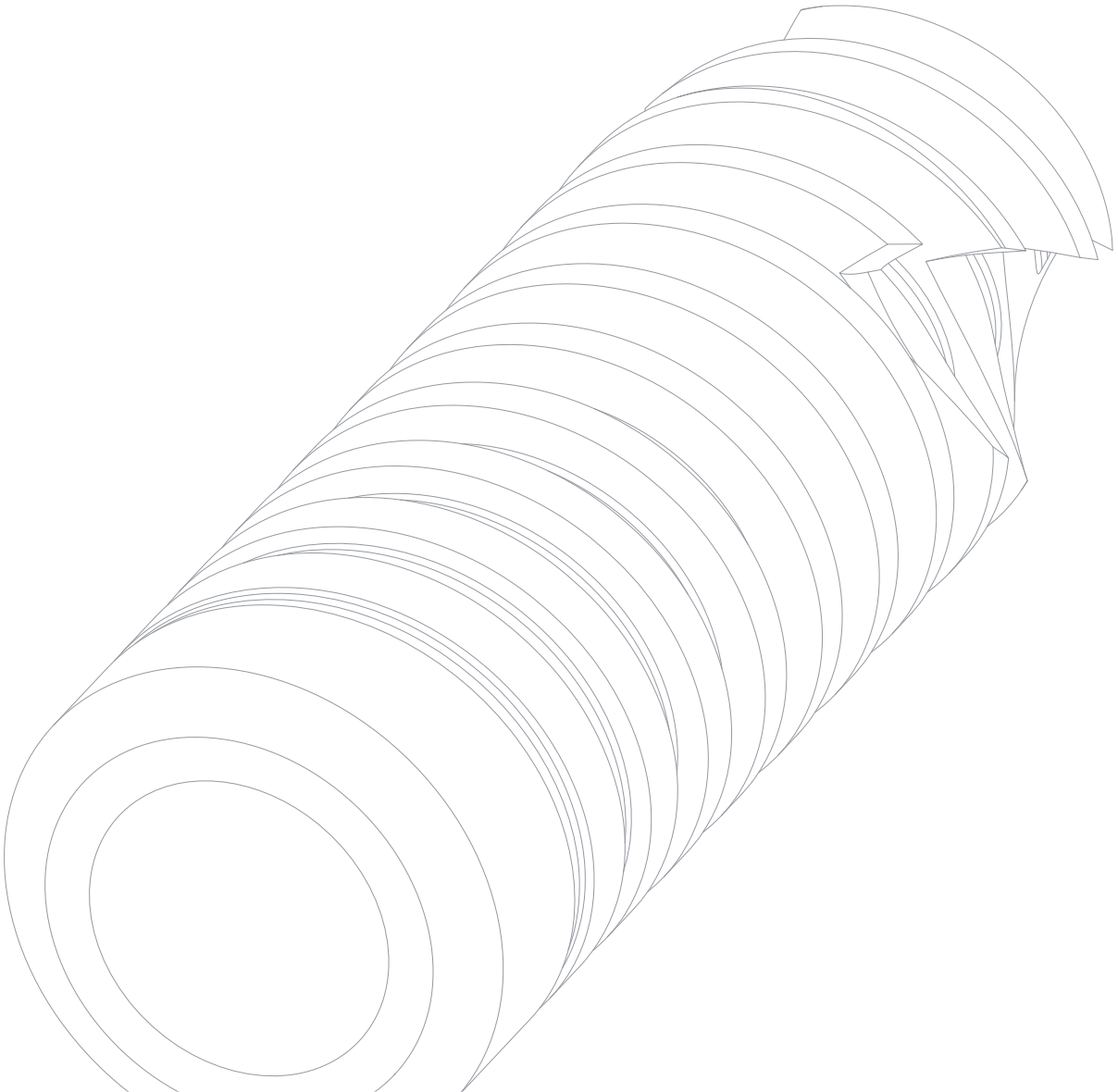
Incorrect reprocessing of the instruments can lead to infection of the patient with harmful pathogens. In this connection we also refer to the list of the disinfection procedures that have been examined according to the guidelines for the testing of chemical disinfectants and found to be effective by the German Society for Hygiene and Microbiology (Deutsche Gesellschaft für Hygiene und Mikrobiologie, DGHM). The same applies to the list of the Robert Koch Institute (RKI). Information on suitable and validated disinfectants and disinfection procedures (including all parameters) can also be found on the Internet at www.rki.de or www.dghm.de. Contact of the instruments with hydrogen peroxide (H_2O_2) is to be avoided. The instruments should be stored in suitable hygienic containers. The same also applies to sterilized instruments. Storage must be protected against dust, humidity and recontamination. The maximum storage duration must not be exceeded.

The products can be re-assembled prior to sterilization. MEISINGER recommends sterilization via the steam sterilization method. All suitable components can be sterilized according to DIN EN ISO 17665 - Sterilization of Products for Healthcare - Humid heat and ST79 (30 min. at 121 °C (250 °F) gravitation method with 20 minutes drying time and / or 4 minutes at 132 °C (270 °F)/ 134 °C (273 °F) fractionated vacuum with 20 minutes drying time).

The parts need to be wrapped for sterilization. Please use sterilization pouches. It is essential to observe the manufacturer‘s instructions for use for sterilization. Sterilization temperatures in excess of 134 °C must be avoided. Excess temperatures to a loss in hardness of the work components and thus a reduction in shelf-life. An indicator strip featuring the date of sterilization and the use-by date should be applied to every package of sterilized goods.

The instruments should be stored in suitable hygienic containers. The same also applies to sterilized instruments. Storage must be protected against dust, humidity and recontamination. The maximum storage duration must not be exceeded.
Rotating instruments are subject to wear. For this reason, the instruments need to be checked before any use. The option and responsibility of multiple use of a product and the frequency of application is solely the decision and own responsibility of the treating clinician based on the application in each case and the possible wear of the

products. If in doubt, the products should always be sorted out early and replaced. If cared for and reprocessed properly, the rotating instruments can be used up to ten times (one time = placing of an implant).



HANDLING OF THE RATCHET

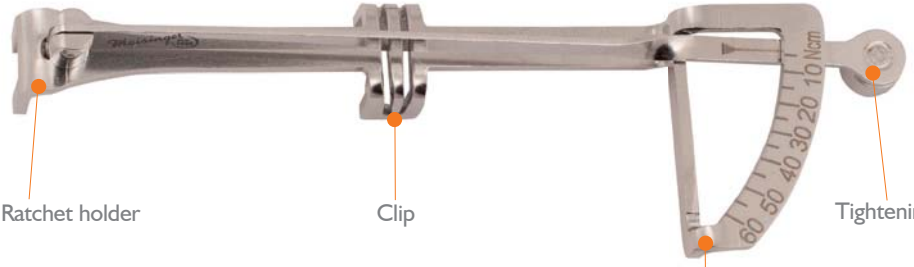
The myplant ratchet including torque control device is designed for manual implant bed preparation and implant placement.

Below you will find information on handling and preparation:

Ratchet

Retaining adapter Guide grooves Nut for disassembly Release button with direction indicator

Torque Indicator



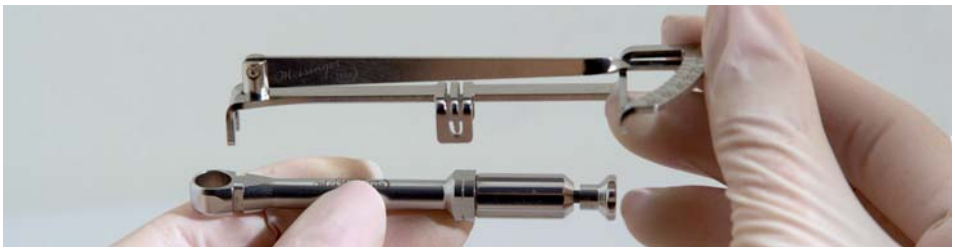
Ratchet holder Clip Tightening spring

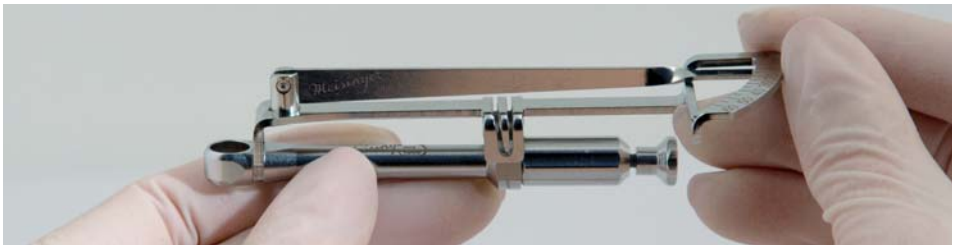
Torque scale

Assembly of the Torque attachment

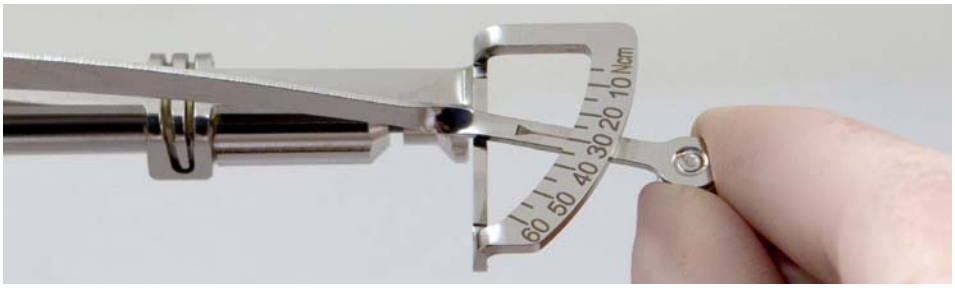
The torque indicator is mounted on the center of the ratchet. The ratchet holder of the torque indicator is placed in the guide grooves of the ratchet head so that the torque indicator can be attached. The ratchet is now ready for use.

Important: The torque control device is usually attached at the end of the screwing process to read off the final torque. If required, it can also be used during implantation to determine the current torque.





To place an adapter into the ratchet, pull out the release button. To measure the applied torque, the ratchet head including adapter is fixated with the finger and the tightening spring tightened with the other hand. This allows the tightening force to be controlled and read.



Sterilization of the ratchet

In order to sterilize the ratchet, the instrument must be disassembled completely into its individual components.

Disassembly

The ratchet disassembly nut can be completely loosened so that the entire bolt can be removed from the ratchet.

Then the release button is pressed downwards and rotated anti-clockwise through 180°. The release button as well as the disassembly nut and the spring located below can be removed from the bolt. The ratchet is now disassembled completely and can be reprocessed.

Assembly

To reassemble the ratchet after processing, the spring is placed on the bolt and the disassembly nut slipped over the bolt. The release button with bayonet lock can now be attached to the bolt again. Then the assembled bolt is screwed to the ratchet.

HANDLING THE TORQUE RATCHET

The torque ratchet is used for the defined screw-in and unscrew of the prosthetic components.
The required torque can be infinitely adjusted with the adjusting nut via the spring. The setting can be read off the scale of the scale sleeve.

To insert or remove a ratchet adapter, retract the two pins on both sides in the direction of the arrow with thumb and index finger.

Note:
The two screws (X) on the adjusting nut must not be loosened as this will lead to a loss of calibration.

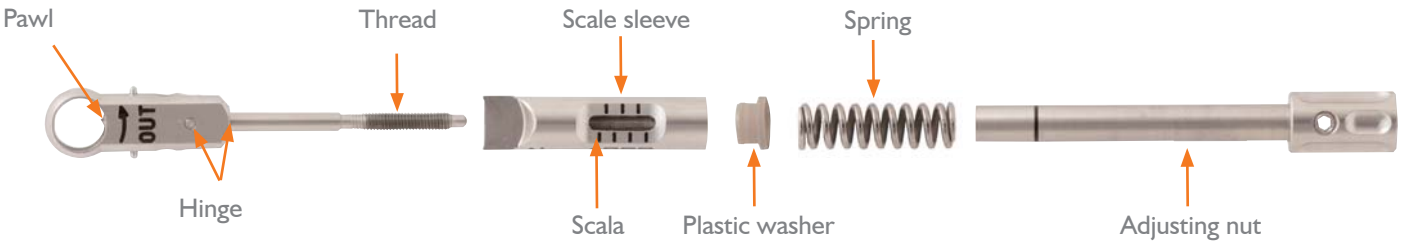
When using the torque ratchet, it is essential to pay attention to the desired direction (screwing in / unscrewing):

The pressure point for exact torque release is located only on the handle of the adjusting nut (see arrow). The torque ratchet is only released with the touch of a finger. The handle should not be touched with thumb and index finger. When the set torque is reached, the scale sleeve bends around the axis in the ratchet head. The release is audible and perceptible. When the handle is released, the torque ratchet returns to its initial position.

Note:
After triggering the torque, do not continue pressing as this could damage the prosthetic components.

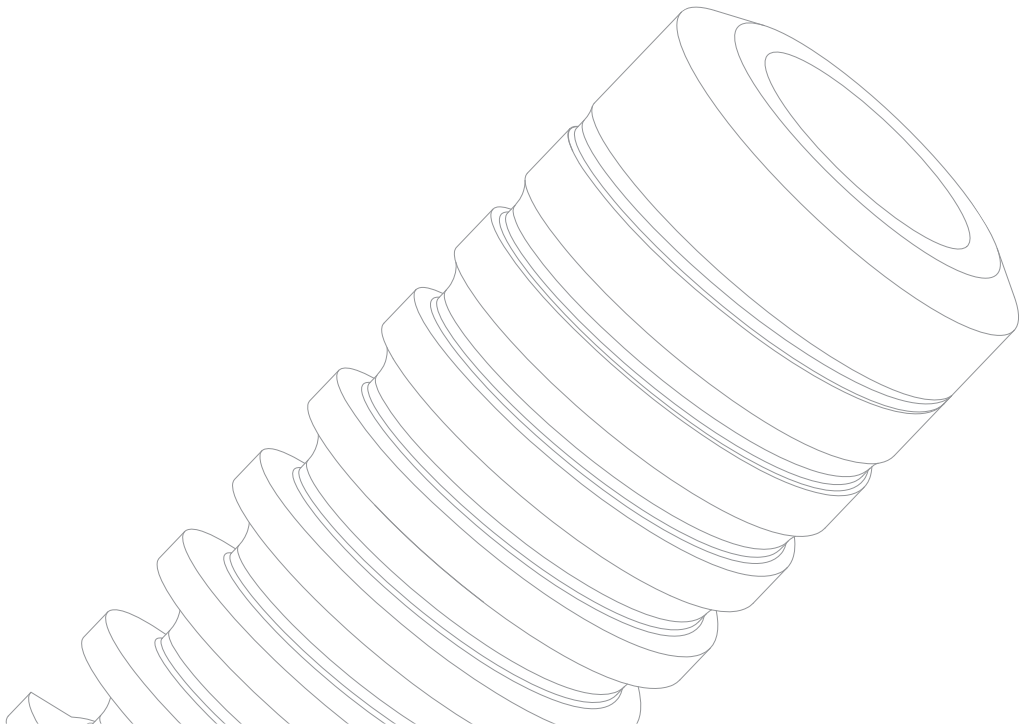
Preparation

To clean the torque ratchet, it must be completely dismantled into its individual parts. For this purpose, the adjusting nut is completely unscrewed.



The plastic washer does not need to be removed, but can be pulled out if necessary. After cleaning, the washer must be pressed in again, as a loss affects the accuracy of the torque ratchet.
The torque ratchet is now completely disassembled and can be cleaned and disinfected according to validated reprocessing instructions.

After cleaning and disinfection, the torque ratchet can be assembled and finally sterilized.



GENERAL SAFETY ADVICE

The application of the MyPlant II implant system is intended for trained personnel. The concrete application is decided by the clinician and depending on the indication. Implants may only be inserted by dentists and physicians who are well versed in dental implantology including diagnosis, pre-operative planning, surgical techniques and prosthetic restoration. Touching the enossal part of the implant by the user is to be avoided. The instruments are adapted to the diameter variant of an implant. Care should be taken to use only matched items. Please observe the corresponding color coding. The respective user decides solely, and on his/her own responsibility, on the concrete application and respective design of implant system, the corresponding prosthetic restoration and thus the detailed application of the product, depending on the presenting situation (indication). Methodical errors in application can lead to a loss of the implants as well as cause considerable damage to the peri-implant bone substance. Note: Appropriate options for information and training for physicians, dentists and dental technicians are offered by Hager & Meisinger GmbH. The technical application advice concerning our products is given verbally, in writing, by means of electronic media or through demonstrations. The basis is the state-of-the-art in science and technology as it is known to us at the time of placing on the market. It does not release the user from the obligation to personally test the product for its indication-related suitability and to provide further training in the field of dentoalveolar surgery/implantology.

Only system-intrinsic components and instruments may be used for treatment. The use of components not belonging to the system as well as any type of modification may impair the function of the implant system (problems of fit, reduced duration as well as damage of the implant up to fracture) and precludes any guarantee or replacement by the manufacturer. This applies in particular to other application procedures that have not been recommended. System faults by mistaking tools and implants are to be minimized. Therefore, color coding and/or labeling should be observed. The processing and application of MyPlant II products is solely subject to the responsibility of the user. Any liability for such caused damages is excluded. Technical advice on the application of our products is verbal, in writing, via electronic media or demonstrations. This is based on state-of-the-art science and technology as known to us at the time of going to market. It does not absolve the user from the duty of personally checking the product for its indication-relevant suitability and training in the field of dento-alveolar surgery/implantology. Thermal damage from rotary tools in the jawbone is to be avoided (user training, working at low speeds, intermittent and sufficient cooling).

Rotating instruments are subject to wear. For this reason, the instruments need to be checked before any use. The option and responsibility of multiple use of a product and the frequency of application is solely the decision and own responsibility of the treating clinician based on the application in each case and the possible wear of the products. If in doubt, the products should always be sorted out early and replaced.

You will find all important application instructions for the use and reprocessing of the preparation instruments in the current version of the “General Application and Safety Instructions for MEISINGER Products in the Medical Field” and under “Instructions for the reprocessing (cleaning, disinfection and sterilization) of medical products from Hager & Meisinger GmbH” on our website www.meisinger.de. You will find the indications and contraindications including the important application instructions and implantation steps under Application and Safety Instructions for the myplant two Implant System from Hager & Meisinger GmbH.

AVAILABILITY

Some of the myplant two products given in this documentation may not be available in all countries. Detailed information is available upon request from myplant GmbH.

CAUTION

In addition to the warnings given in this document, the myplant two products are to be secured against aspiration when used intraorally. Please observe the appropriate instructions for use as well as the manual for surgical and prosthetic procedures.

VALIDITY

The publication of this document voids all previous versions.

DOCUMENTATION

Further information on the myplant two products is available from your myplant two contact partner.

REGULATORY REQUIREMENTS

Since 1888 Meisinger has produced high-quality medical products. The quality management system of a company that manufactures medical devices must meet special requirements. These particularly high requirements are defined by ISO 13485 and are met by our company with great care. A MDSAP certificate according to ISO 13485:2016 confirms compliance with the requirements of international authorities in the USA (FDA), Canada (Health Canada), Australia (TGR), Japan (MHLW) and Brazil (ANVISA). All medical devices that you purchase from us as a customer comply with all applicable requirements of the Medical Device Directive 93/42/EEC. The certification of our company is carried out by an independent Notified Body and is carried out according to standard specifications. Current certificates can be found on our homepage www.meisinger.de

KEY TO THE SYMBOLS

Manufacturer

REF — Item number

LOT — Lot number

Rx only — U.S. federal law restricts this device to sale by or on the order of a dental professional.

Follow the instruction for use

STERILE R — Sterilized by radiation

Use by

Single use only

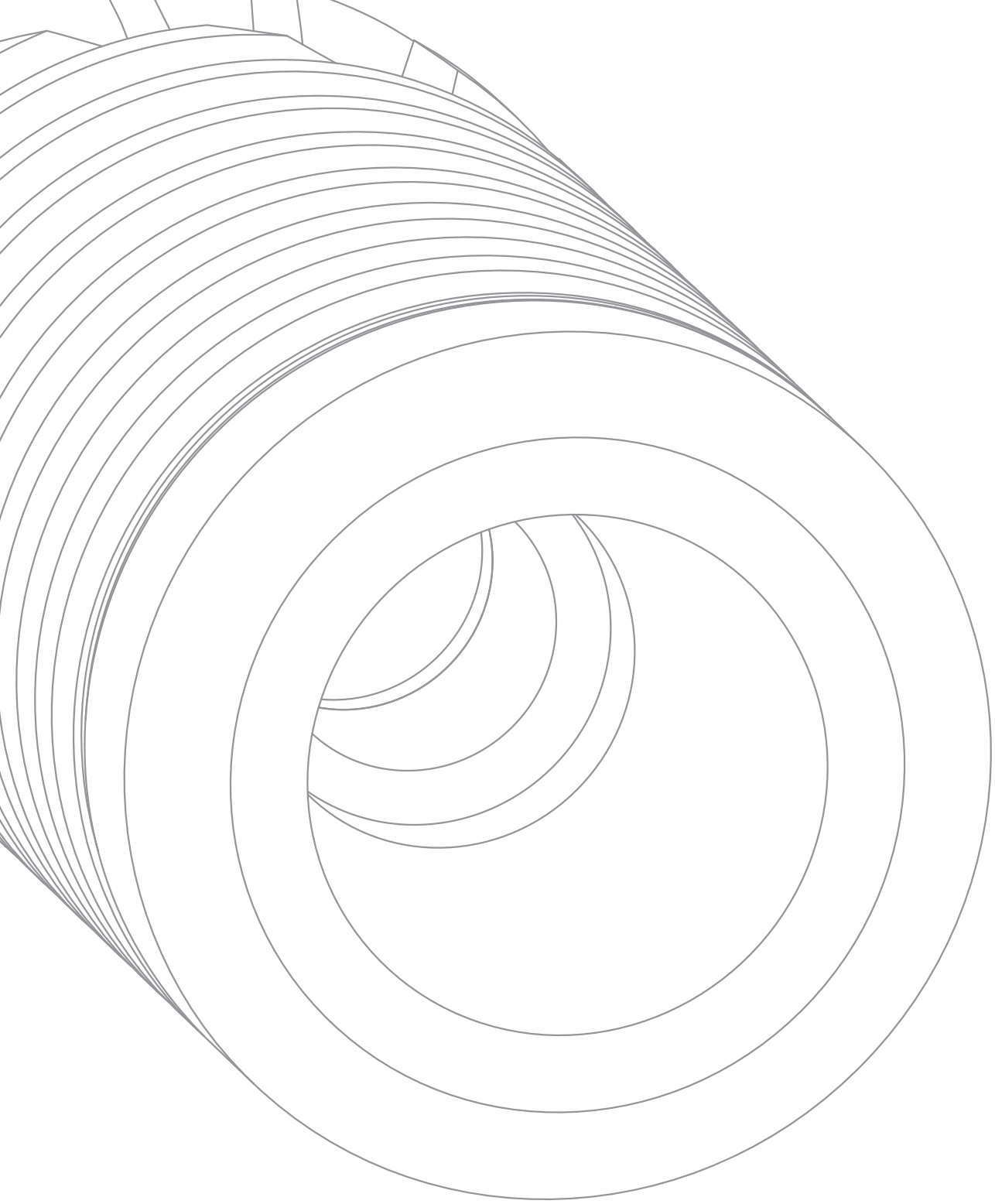
Do not use if the packaging is damaged

Keep away from sunlight

Attention, observe accompanying documents

NON STERILE — Non-sterile

Notes:



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