

*mej*plant^{two}



SURGICAL
MANUAL

Meisinger since 1888

TWO-PHASE TITANIUM IMPLANT BY

Meisinger

The concept of a two-phase titanium implant with a special expansion thread and self-locking cone as an abutment connection was developed by Prof. Dr. Georg-Hubertus Nentwig and Dr.-Ing. Walter Moser over 30 years ago and brought to clinical maturity. Creating a design that offered high primary stability, minimum construction height, and deep platform switching in addition to a micro-movement free and bacteria-proof implant abutment connection soon proved to be superior components in terms of achievable bone and soft tissue stability, and thus providing exceptional long-term success.

The two-phase titanium implant has currently been taken one step further with the MyPlant II system. Together with Hager & Meisinger GmbH, the MyPlant II system is a state-of-the-art design for use in implant therapy.

As a German company with a long tradition and international positioning, Hager & Meisinger is the ideal partner for ensuring the highest quality standards in dentistry in both production and customer service.



Georg-Hubertus Nentwig

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



*my*plant **two**

Made in Germany. Made by

Meisinger since 1888

CONTENT

I. THE MYPLANT II SYSTEM

The Implant	2
The Cone Connection	3
Integrated Biology	4
The MyPlant II Implant Range	5
Subcrestal Placement	6

II. INDICATIONS AND CONTRAINDICATIONS

Indications and Contraindications	7-8
-----------------------------------	-----

III. SURGICAL PROCEDURE

MyPlant II Instruments	9
Surgical Kit	10-11
Preparation for Implant Surgery	12
Smoothing of the Alveolar Ridge	12
Initial Drilling	12
Pilot Drilling	13
Parallel Gauge	13
Preparation of the Implant Bed – Tri-Spade Drills	14-15
Conical Preparation of the Implant Bed	16
Bone Condensation	17
Pretapping the Implant Thread	17
Unpacking of the Implant	18
Insertion of the Implant	18-19
Disengaging the Insertion Instrument	20

IV. POSTOPERATIVE RESTORATION

Prosthetics Concept	21-22
The Healing Phase	23
Subgingival Healing	24-25
Transgingival Healing	26
Temporary Immediate Restoration	27-28
Impression Taking Techniques	29-30

V. APPENDIX

Implants	31
Indications at a Glance	32-33
Surgical Instruments	34-35
Storage, Care and Reprocessing of MyPlant II instruments	35-36
Handling of the Ratchet	37-38
Sterilization of the Ratchet	39
Product Overview	40-41
Recommended Torques for the MyPlant II Prosthetics	42
General Safety Advice	43
Guidelines	44

I. THE MYPLANT II SYSTEM

The MyPlant II 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. It has been optimized with regard to achievable primary stability and mechanical safety under functional loading. The prosthetic restoration has been simplified and revised conceptually.

THE IMPLANT

The cervical section is of cylindrical design to avoid tension in the cortical bone. The depth of thread increases in apical direction with an arch-shaped curve of the thread shanks, thus achieving favorable biomechanical load induction into the bone.

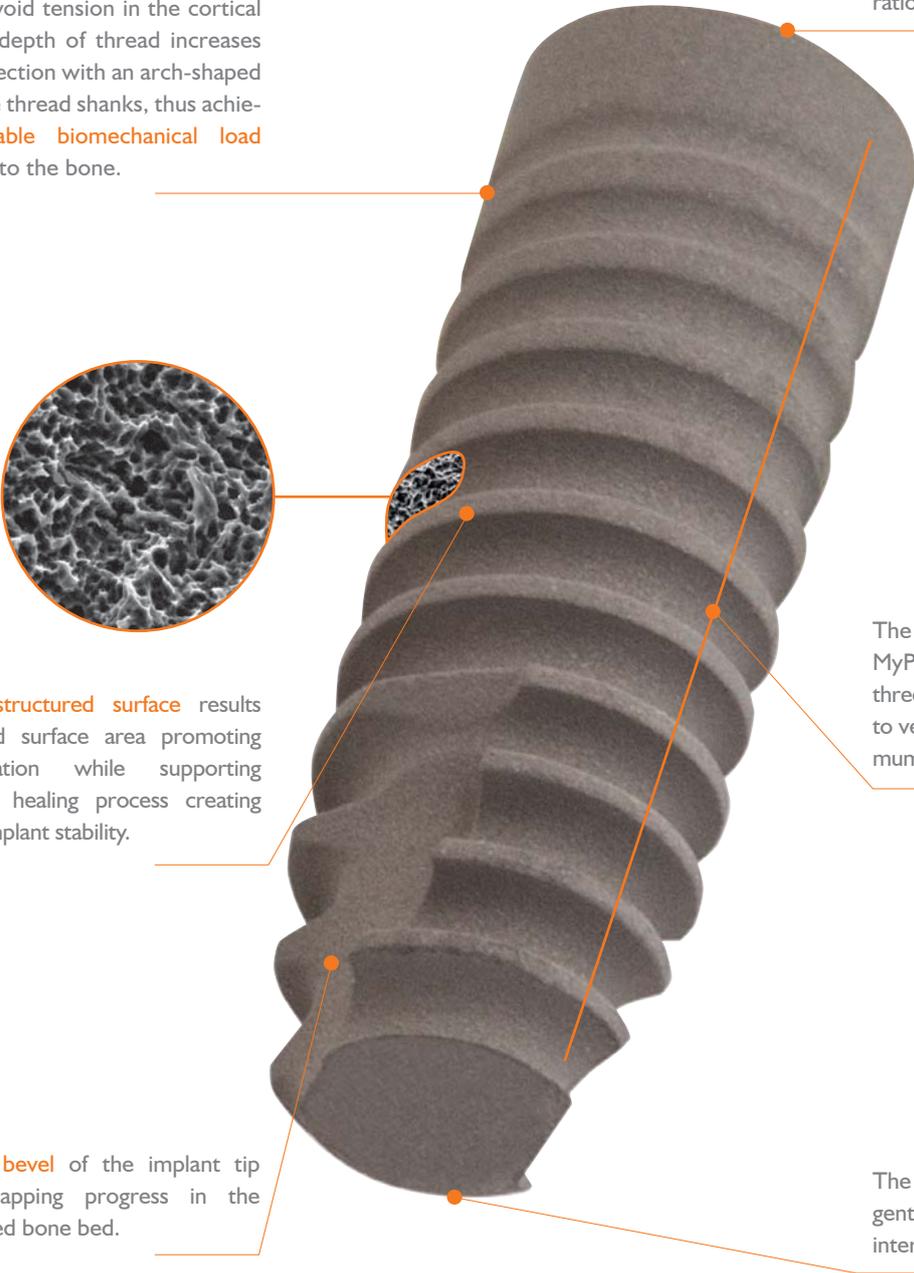
The microstructured surface results in increased surface area promoting osseointegration while supporting the natural healing process creating increased implant stability.

The apical bevel of the implant tip enhances tapping progress in the compromised bone bed.

Where adequate vertical bone volume exists, the MyPlant II implant can be inserted subcrestally by approximately 1 mm promoting stable bony incorporation supporting soft tissue.

The progressive thread design of the MyPlant II implants, supported by the three-stage preparation technique, lead to very high primary stability with maximum bone-implant contact.

The rounded implant tip promotes gentle lifting of the sinus membrane for internal sinus floor lifts.

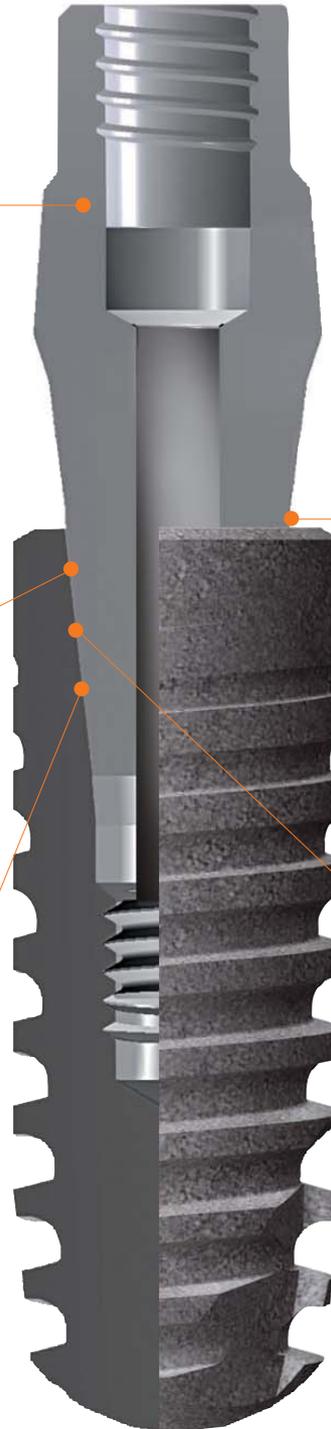


THE CONE CONNECTION

The standard dimensioning of the cone connection in the MyPlant II implant system makes it uncomplicated to use and facilitates the choice of prosthetic components. Despite different implant diameters this allows „ONE prosthesis for ALL“.

The non-indexed cone connection allows free positioning as well as simple parallel alignment of angled abutments.

The self-locking internal cone connection can be oriented freely, is absolutely rotation-stable and also seals practically bacteria-proof. Micro-movement between the implant and prosthetic abutments is reliably avoided.



The broad circular implant shoulder results in deep platform switching and provides an increased support surface for the bone in subcrestal implant insertion.

The reinforced and extended inner cone leads to greater fatigue strength and a high level of mechanical loading. Compared with most other implant systems, the abutment only needs to be fixated at 15 Ncm.

INTEGRATED BIOLOGY

THREAD DESIGN

The progressive thread design of the MyPlant II implants, supported by the three-stage preparation technique, leads to very high primary stability with maximum bone-implant contact. The cervical section is of cylindrical design to avoid tension in the cortical bone. The depth of thread increases in apical direction with an arch-shaped curve of the thread shanks, thus achieving favorable biomechanical load induction into the bone.

The apically enlarging thread area allows good anchorage in different bone quality and generates a load distribution during chewing which helps to maintain the bone structure. Vertical and lateral forces are primarily deflected to the elastic cancellous bone relieving the cortical bone. Stress concentration in the emergence area of the implant, as is the case with screw-retained implants with a consistent thread, is thus avoided. The preparation technique and the special design are matched perfectly to the natural bone structure and result in high primary stability with maximum bone-implant contact even when bone strength is compromised.

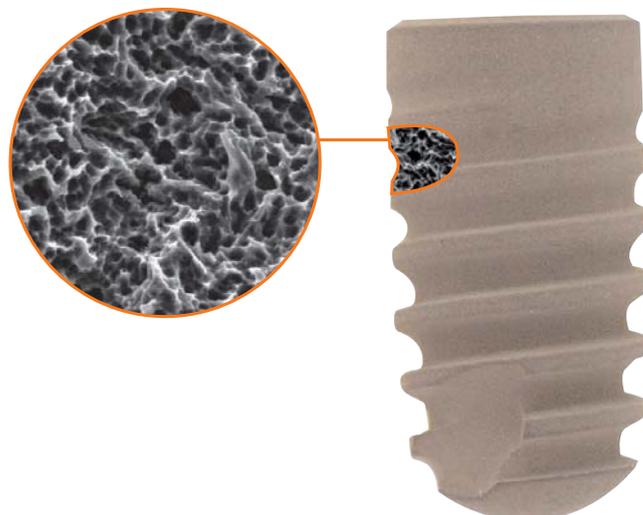


THE IMPLANT SURFACE

During the manufacturing process, the MyPlant II implants are surface-treated in compliance with validated processes.

During the process, the enossal surface of the implants is blasted with corundum and creates a macro-roughness of the titanium surface. This is followed by acid etching resulting in a micro-roughness of the implant surface.

The microstructured surface and the resulting increase in surface area promote the ongrowth of bone, supporting the natural healing process and resulting in a stable implant-bone connection. Compared to many other systems, this surface treatment is also performed on the front face of the implants. As a result, the MyPlant II implants can be positioned approximately 1 mm subcrestally if sufficient vertical bone is available. This procedure reduces the burden during healing and provides for a more stable integration into the bone and better support of the peri-implant soft tissue in the long term.



THE MYPLANT II IMPLANT RANGE

The Meisinger MyPlant II 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 safe healing.

Grade 4 pure titanium demonstrates a perfect combination of ductility and strength. It offers excellent corrosion resistance and does not contain toxic constituents. Owing to its outstanding properties, Grade 4 pure titanium has been successfully employed as a material for implantology and medical technology in general for over 25 years.

The MyPlant II implant is available in three diameters and five different lengths. The MyPlant II system delivers the proper size implant for all dental implant indications.

The MyPlant II coding system and corresponding instruments for the complete implant procedure allow for fast and safe identification of the various implant components. The coordinated letter and color coding provides a simple step-by-step procedural approach.

COLOR CODE

	Red	Endosseous Implant Diameter 3.5 mm
	Orange	Endosseous Implant Diameter 4.0 mm
	Yellow	Endosseous Implant Diameter 4.5 mm

The designation of the implant includes a capital letter which codes the diameter of the implant, (same as the color). The following number designates the length of the implant in millimeters.

Ø [mm]	L [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



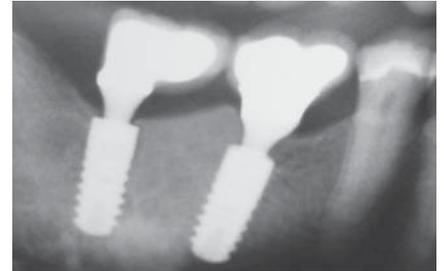
ADDITIONAL IMPLANT DIAMETER 4.0 MM

The 4.0 mm implant diameter permits risk-free restorations in regions subject to considerable mastication due to the increased mechanical stability without the need for additional augmentation.

SUBCRESTAL PLACEMENT

Compared to most implant systems, the MyPlant II implant is suitable for subcrestal placement and should be inserted approximately 1mm below the crest. As a consequence, the crestal bone can grow over the implant shoulder up to the abutment diameter, which benefits increased implant stability and biological support of the peri-implant soft tissue. To avoid complete overgrowth of the implant with bone during subgingival healing, the original pack includes a cover screw which extends over the implant by 1 mm.

Note: Subcrestal placement must be taken into consideration when selecting the length of the implant. The appropriate X-ray templates are to be used for the orthopantomograph in this case.

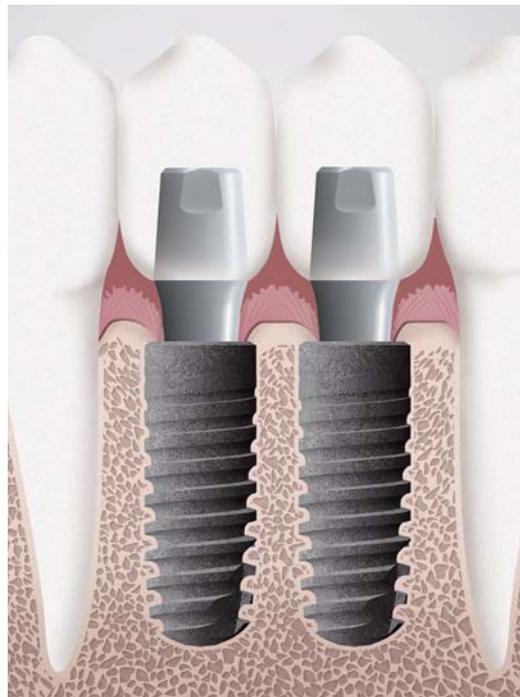


© Prof. Dr. med. dent. Georg-Hubertus Nentwig

If equicrestal healing is desired or indicated (for example, if the implant can be stabilized primarily in the cortical bone), then the separately available flush cover screw can be used.

SOFT TISSUE SUPPORT

With narrowly spaced implants, the broader implant shoulder of the MyPlant II allows for sufficient approximal space which is crucial for establishing a stable soft tissue cuff between implants.



II. 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.

INDICATIONS AND CONTRAINDICATIONS

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 II implants.

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

SPECIAL CONTRAINDICATION FOR IMPLANTS WITH 6.6 MM LENGTH

A one-off procedure may not be performed with implants of 6.6 mm length as sufficient anchorage in the bone is not given. The risk of implant loss is increased for single tooth restorations with implants of 6.6 mm length as well as for free-end bridges.

More information on indications and contraindications for the individual implants can be found in the corresponding instructions for use. These can also be found on our website at www.meisinger.de.

III. SURGICAL PROCEDURE

MYPLANT II INSTRUMENTS

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.

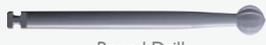
A systemized surgical technique for the preparation of the implant bed was developed to provide **Enhanced Primary Stability (EPS)**. This technique provides options for immediate restorations in all bone densities. Based on the measured torque and bone density, the implant bed can be prepared in three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

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.

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. (More information you'll find on page 35)

	Ø 3.5 mm	Ø 4.0 mm	Ø 4.5 mm
Smoothing of the Alveolar Ridge	 Round Drill 0RB01		
Initial Drilling	 Initial Bur 0IB01		
Pilot Drilling Ø 2.0 mm	 Twist Drill 0SB01		
1. Expansion of the implant bed Ø 2.4 mm for A, M & B Implants	 Tri-Spade Drill A 0AT01 0AT02 0AT03		
2. Expansion of the implant bed Ø 2.9 mm for M & B Implants	 Tri-Spade Drill M 0MT01 0MT02 0MT03		
3. Expansion of the implant bed Ø 3.3 mm for B Implants	 Tri-Spade Drill B 0BT01 0BT02 0BT03		
Conical Expansion of the implant bed	 Conical Reamer A 0AKA01 0AKA02 0AKA03 0AKA04	 Conical Reamer M 0MKA01 0MKA02 0MKA03 0MKA04	 Conical Reamer B 0BKA01 0BKA02 0BKA03 0BKA04
Pretapping the Implant Thread	 Tap A 0AGS01	 Tap M 0MGS04	 Tap B 0BGS02
Implant Insertion	 Implant A 0A3566 0A3580 0A3595 0A3511 0A3514	 Implant M 0M4066 0M4080 0M4095 0M4011 0M4014	 Implant B 0B4566 0B4580 0B4595 0B4511 0B4514

SURGICAL KIT

All instruments for surgical use are available in the MyPlant II Surgical Kit. This allows for particularly structured and user-friendly storage and the color coding of the instruments facilitates their use during implant surgery.

1. Torque Indicator
Order No. ZDMA1

2. Ratchet
Order No. ZRA01

3. Open-End Wrench
Order No. ZGS01

4. 2x Positioning Key
Order No. ZPS01

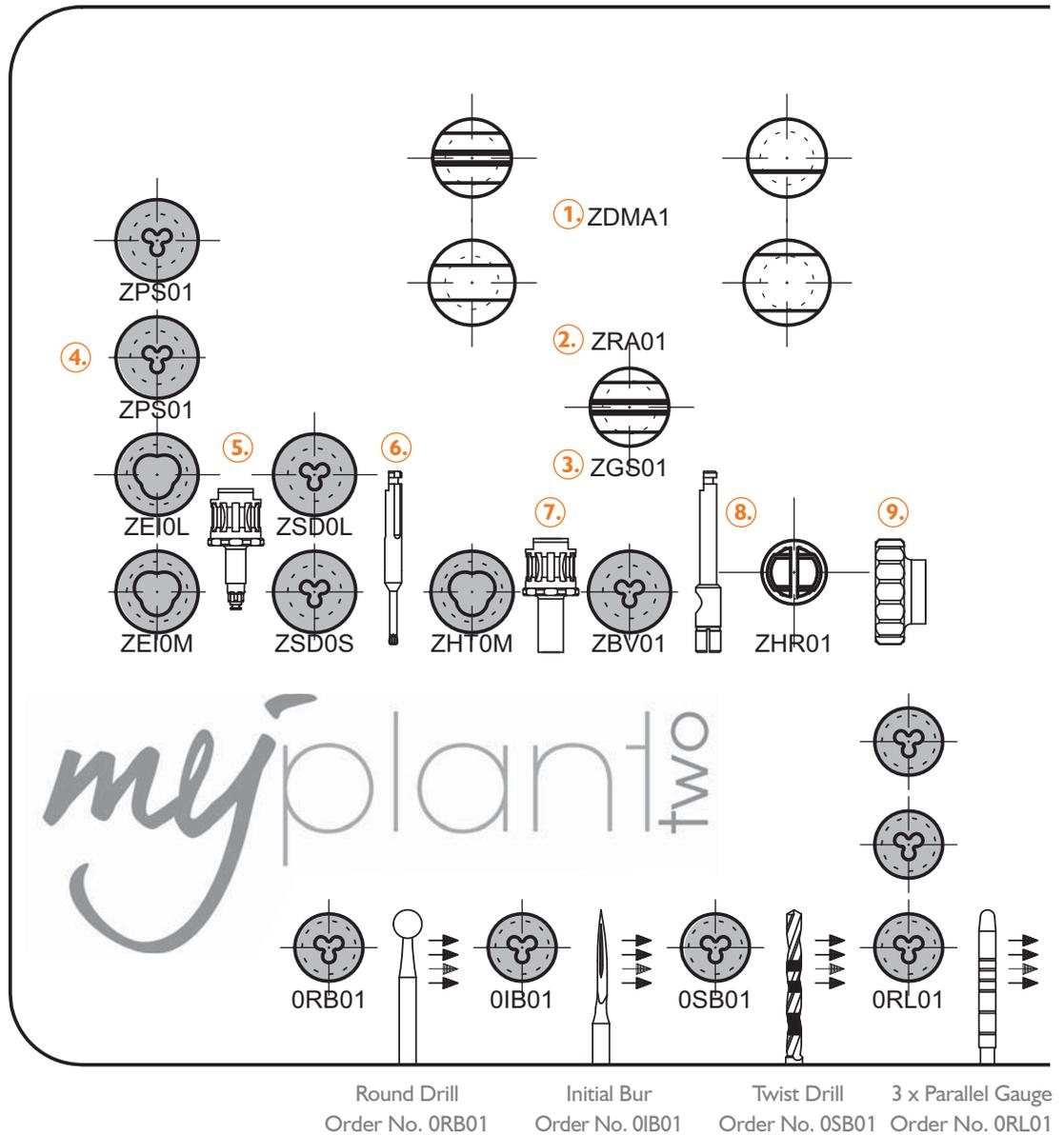
5. Seating Instrument
Order No. ZE10M + ZE10L

6. Screw Driver
Order No. ZSD0S + ZSD0L

7. High Torque Adapter
Order No. ZHT0M

8. Drill Extension
Order No. ZBV01

9. Handwheel
Order No. ZHR01



Round Drill
Order No. ORB01

Initial Bur
Order No. 0IB01

Twist Drill
Order No. 0SB01

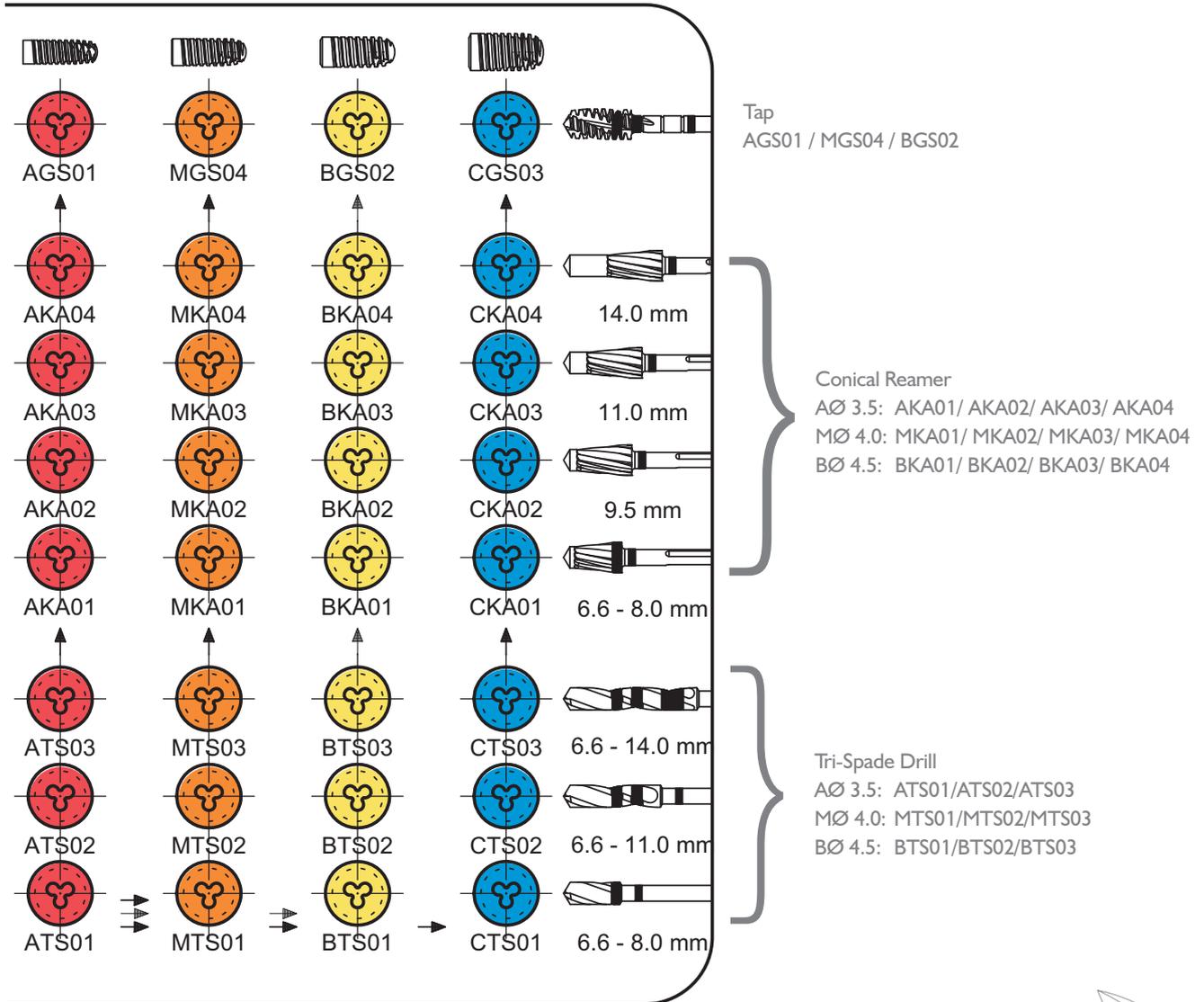
3 x Parallel Gauge
Order No. 0RL01

Instruments for
Implant Diameter
Ø 3.5 mm

Instruments for
Implant Diameter
Ø 4.0 mm

Instruments for
Implant Diameter
Ø 4.5 mm

The Implant Diameter
Ø 5.5 mm is currently
being planned



PREPARATION FOR IMPLANT SURGERY

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.



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.

SMOOTHING OF THE ALVEOLAR RIDGE

Local irregularities can be smoothed carefully using the 0RB01 round bur contained in the surgical kit.

Max. Speed: 30.000 min⁻¹

Note:

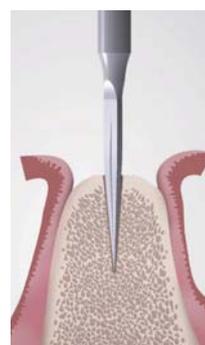
The performed vertical reduction of the alveolar ridge must be taken into consideration when selecting the length of the implant!



INITIAL DRILLING

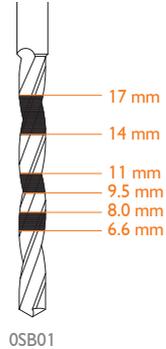
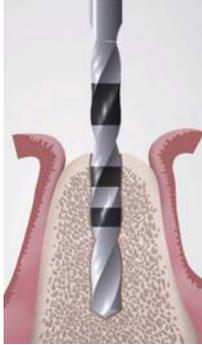
The initial drill (01B01) is used to mark the implantation site. A suitable orientation template helps in the exact transfer of the prosthetically defined implant position. The axis of the implant can then be pre-drilled and the bone quality judged by the penetration resistance.

Max. Speed: 1.000 min⁻¹



PILOT DRILLING

Final alignment and depth of the implant is performed with the aid of a twist drill \varnothing 2.0 mm. For gentle preparation of the implant bed, drilling should be performed intermittently at a maximum speed of 800 min^{-1} 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.

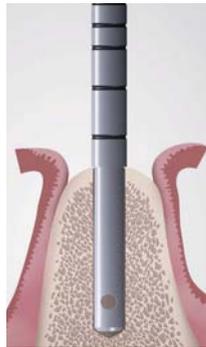


Note:

If subcrestal positioning of the implant is planned, the corresponding marking lines are placed approximately 1 mm below bone level.

PARALLEL GAUGE

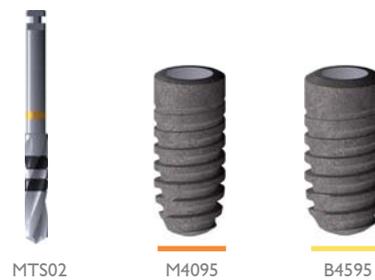
The parallel gauge is a combination instrument. The slim end of the parallel gauge is used after pilot drilling to check the correct orientation of the implant axis and to have a visual aid for aligning further implants.



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 \varnothing 2.4 mm. When using an A implant with a diameter of \varnothing 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 \varnothing 2.9 mm. When using a M implant with a diameter of \varnothing 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 \varnothing 3.3 mm. After using the Tri-spade drill B, the parallel-walled preparation is completed after this step.

Note:
If subcrestal positioning of the implant is planned, the corresponding marking lines are placed approximately 1 mm below bone level.

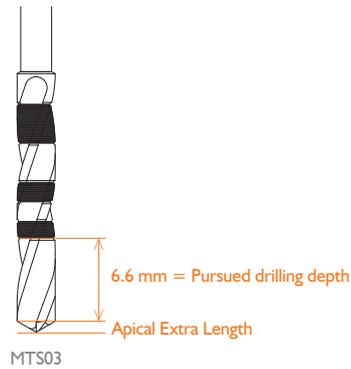


For gentle preparation, drilling should be performed intermittently at a speed of approximately 800 min^{-1} and with moderate force. It should be ensured that the instruments are cooled adequately and that no bone chips adhere to the cutting edges of the drill tips.

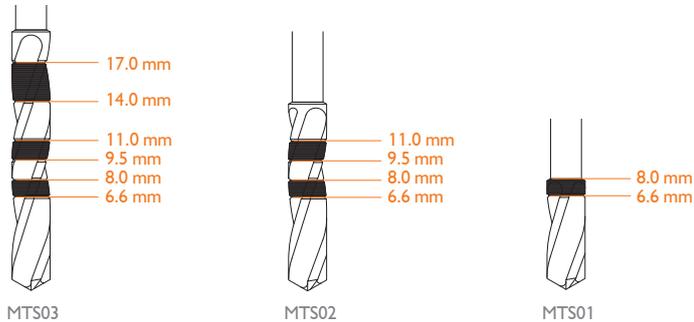
APICAL EXTRA LENGTHS

Note: Due to the function and design of the Tri-Spade drills, the effective drilling depth during preparation is always somewhat greater than the desired implant length. This extra additional apical 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

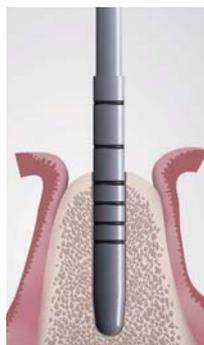


EXPLANATION OF LASER MARKS



PARALLEL GAUGE

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



Application with Handpiece or Angled Handpiece

Place the conical reamer into the handpiece or angled handpiece. Insert the conical reamer into the prepared cavity and perform the preparation with a clockwise setting and without applying major force. (Information regarding the handling on p.37f.)

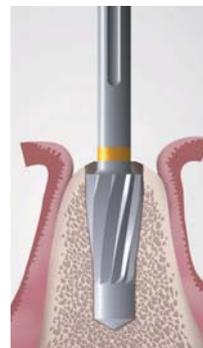
Manual Application with the Ratchet

Attach the conical reamer to the ratchet adapter. Then mount the ratchet on the ratchet adapter. Now insert the conical reamer into the prepared cavity and perform the preparation with a clockwise setting and without applying major force.

The maximum speed is 50 min⁻¹. A torque of 50 Ncm may not be exceeded.

Note:

The conical reamers also act as „measuring implants“ as they correspond to the final position of the implant.



As the tip of the instrument is not serrated, the implant bed cannot be deepened. The edge of the working part of the conical reamer should lie marginally below the bone level at the end of the preparation. Prior to extraction, the conical reamer should be turned to the left by a single rotation.

BONE CONDENSATION

In order to achieve sufficient primary stability for a bone quality of D3-D4, the conical reamer can also be used as a bone condenser.

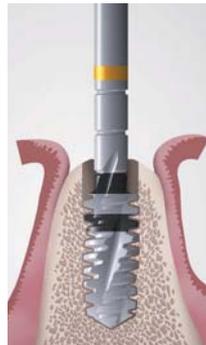
To do this, the conical reamer has to be used anti-clockwise with the handpiece or angled handpiece or manually with the ratchet. This will lead to slight condensation of the bone and increased primary stability of the implant.

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. Close attention is to be paid to the depth marking of the instrument during the entire preparation. 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.



UNPACKING OF THE IMPLANT

All MyPlant II 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.



1 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.

2 Place the seating instrument on the insertion guide so that there is a clamped fit between the insertion guide and seating instrument.

3 Slightly compress the implant retaining bracket and remove the implant.

INSERTION OF THE IMPLANT

IMPLANT INSERTION

The MyPlant II implants are inserted manually using the hand wheel and ratchet. In case of subcrestal insertion, the auxiliary lines at millimeter intervals on the insertion guide are to be observed.

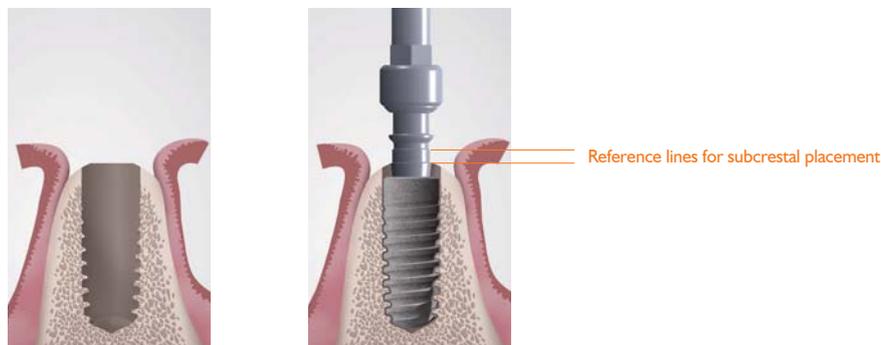
With the aid of the insertion guide and the hand wheel, the implant is inserted manually into the implant bed by approximately two thirds. Final positioning is performed manually with the ratchet. The torque in the final position is determined and documented with the torque indicator.

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 min^{-1} 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 II implants. It is important for the inserted implant to be primary stable to allow subsequent successful osseointegration.

Should the maximum torque of 50 Ncm be reached before the implant is in its final position, then the implant should be removed and the implant preparation checked and, if required the implant site should be re-tapped and the implant inserted again.



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.

DISENGAGING THE INSERTION INSTRUMENT



To disengage the insertion unit after insertion, first secure the insertion guide against rotation with the retaining key. Then disengage the screw anti-clockwise using the insertion instrument. It should be noted that the disengagement torque of the screw increases again after a few rotations when the insertion guide is lifted vertically from the implant. The entire insertion guide can then be removed from the implant.

In case of inclined alveolar ridges in oro-vestibular direction, the implant should be aligned according to the lowest level of the bone profile. After removal of the insertion instrument, the supplied cover screw with a height of 1 mm is to be inserted and any excess protrusion of bone should be reduced using the round bur.



Whether immediate restoration is possible or subgingival or transgingival healing is required depends on the achieved final torque.

REASSEMBLY OF THE INSERTION INSTRUMENT FOR CORRECTION OF THE INSERTION DEPTH

If subsequent correction of the insertion depth is necessary after removing the insertion guide, the insertion guide can again be placed on the implant and screw-retained. To do this, place the insertion instrument on the insertion guide so that there is a clamped fit between the insertion guide and insertion instrument. The insertion guide can now be screw-retained again in the implant. Using the open-ended wrench is not necessary here. After correcting the implant position, the insertion guide is removed as already described.

IV. POSTOPERATIVE RESTORATION

PROSTHETICS CONCEPT

The MyPlant II system offers a new philosophy in terms of prosthetic restoration. In normal restorations, the abutments only serve the purpose of retention and are not involved in shaping the emergence profile. This is solely designed by the base of the prosthetic restoration.

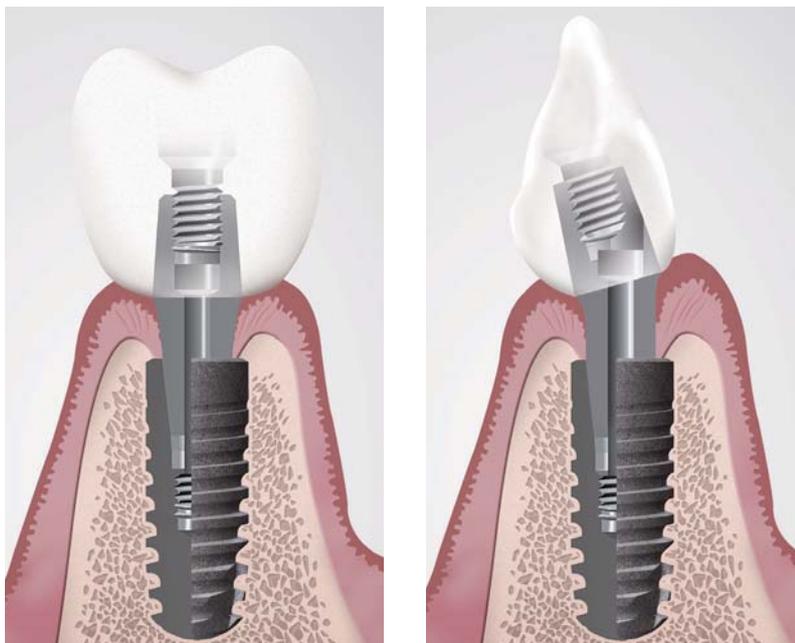
Note:
Already mounted Abutments can be removed and replaced at any time by a loosening screw.



The following requirements are important:

- The lower margin of the abutment lies below the level of the mucosa
- Mounting of the superstructure should be as cement-free as possible as excess cement would prove difficult to remove

To enable cement-free mounting, all MyPlant II abutments, both straight and angled, are equipped with occlusal screw channels.



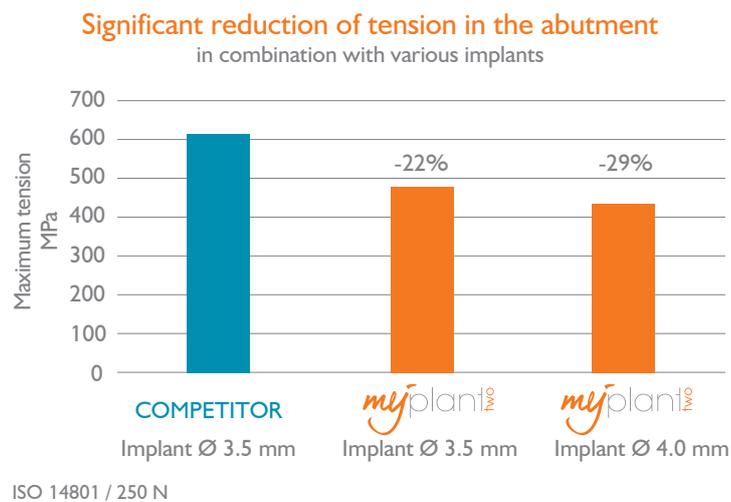
Alternatively, a friction-fixed retention of the superstructure is possible with precise fitted casts or veneered secondary caps fabricated using CAD/CAM technology.

Another possible conventional procedure is the individual technical dental fabrication of abutments with bonding bases.

Pre-fabricated retention elements are also available. For more information, please see the Meisinger MyPlant II product catalogue.

HIGHLY RESILIENT ABUTMENT-IMPLANT CONNECTION

Design changes were able to significantly improve the mechanical resilience of the MyPlant II system. Strengthening and extending the inner cone led to increased fatigue strength of the abutment without reducing the fatigue strength of the implant. The strengthened and extended inner cone results in a highly resilient connection between the abutment and the implant.



NON-INDEXED CONE CONNECTION

The non-indexed cone connection allows free positioning as well as simple parallel alignment of angled abutments.

FREE COMBINABILITY

The design of the MyPlant II implants and abutments allows for „ONE prosthesis for ALL“ implant diameters. This free combinability of the MyPlant II prosthetic components leads to a reduction in the prosthetic portfolio size. The implants are selected according to the available bone volume. As a result, the focus can be placed exclusively on the prosthetic requirements when selecting the abutment.

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

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

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 > 30-35 Ncm

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

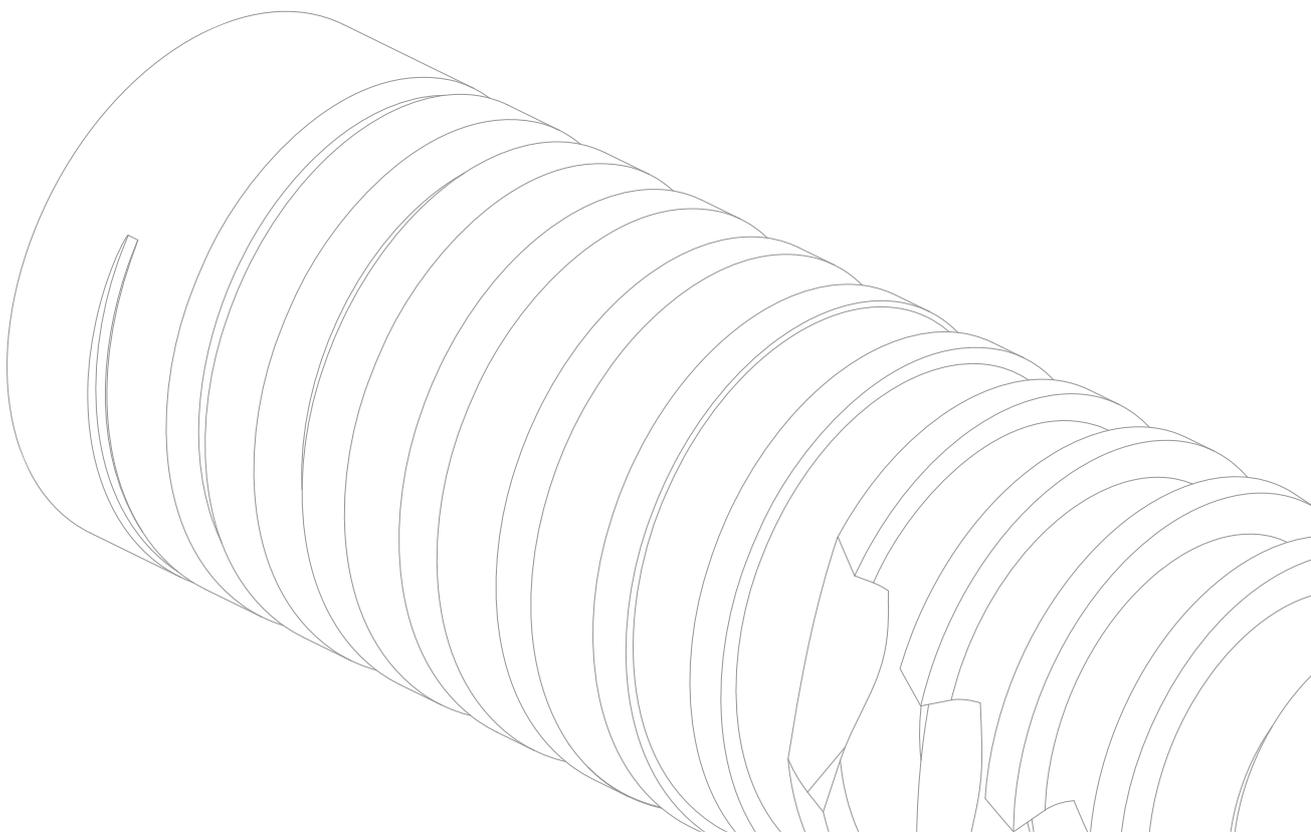
In subgingival healing, the implant heals under a closed mucoperiosteal flap. A second surgical procedure is always necessary to remove the cover screw, to shape the gingiva in a second and third step and to provide an abutment.

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 into the implant. The fit is designed such, that the cover screw is attached securely to the screw driver and assures safe handling.

Note:

Should a different cover screw be selected, it should be noted that this is supplied non-sterile and needs to be sterilized before use.



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 forced apart slightly and the cover screw removed with a screwdriver.



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 makes a 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.



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.



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. 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.



Note:

The procedure for an immediate restoration follows the same workflow.

After adaptation of the healing cap, the crown shape is replaced with a light-curing or self-curing 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 temporary restoration should not be used for longer than 6 months.



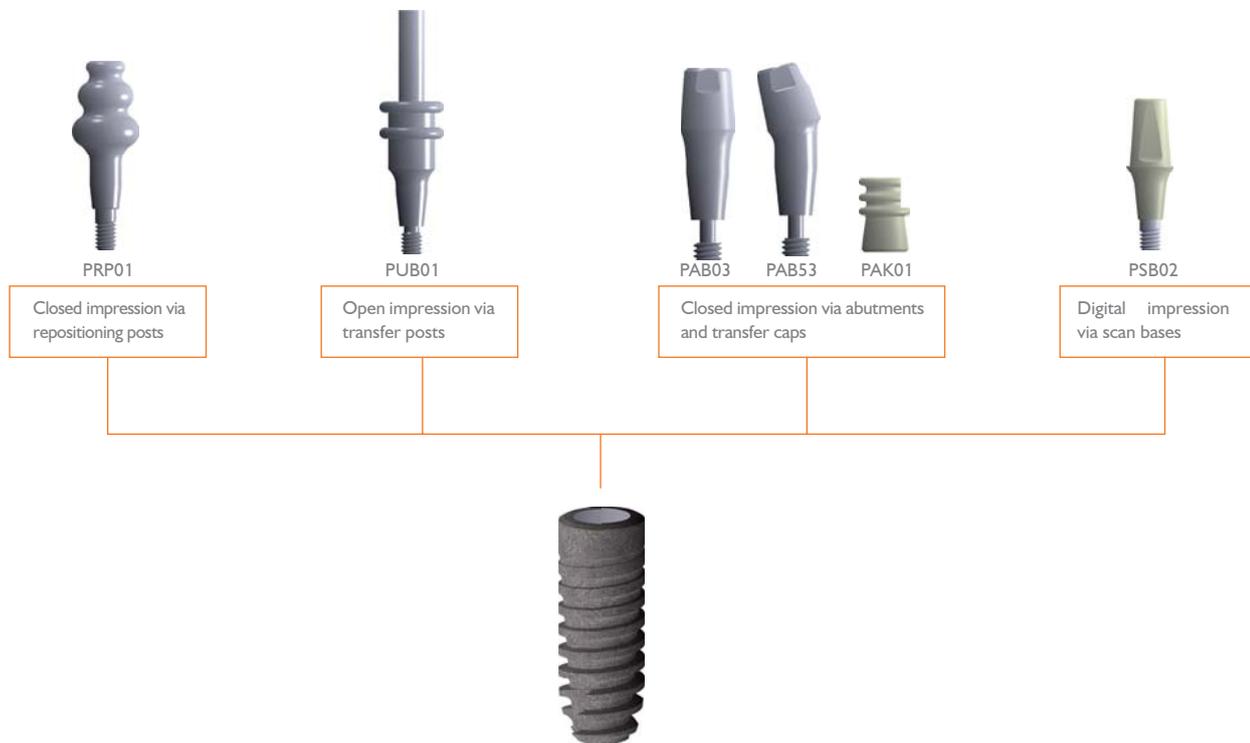
LAB-FABRICATED TEMPORARY RESTORATION

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 TECHNIQUES

The MyPlant II implant system offers four different variants of impression taking.

This includes the open and closed tray technique, impression taken via abutment level and impressions taken by scanning with scan bases.



CLOSED 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 repositioning post is subsequently screw-retained in the implant and screwed hand-tight. 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.



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. Any trapping of the gingiva should be avoided.

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.



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 VIA ABUTMENTS

After the control of the abutment position and dimensioning with respect to parallelism and subgingival crown margin (emergence profile, esthetics), the corresponding transfer cap is mounted on the abutment and pressed down firmly. 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 chairside fabricated temporary restoration.

Note:

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



IMPRESSION VIA SCAN BASES

After selecting the bonding base / titanium base to be used, the corresponding scan base is hand-tightened in the implant. The digital impression is taken with the aid of an intraoral scanner.

V. APPENDIX

IMPLANTS

The Hager & Meisinger GmbH MyPlant II implants 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.



INDICATIONS AT A GLANCE

IMPLANTS

MyPlant II	Length	Anterior tooth	Canine	Premolars	Molars
Ø 3.5	 6.6 mm	✓*	✓*	✓*	✓*
	 8.0 mm	✓	✓	✓	✓
	 9.5 mm	✓	✓	✓	✓
	 11.0 mm	✓	✓	✓	✓
	 14.0 mm	✓	✓	✓	✓
Ø 4.0	 6.6 mm	✓*	✓*	✓*	✓*
	 8.0 mm	✓	✓	✓	✓
	 9.5 mm	✓	✓	✓	✓
	 11.0 mm	✓	✓	✓	✓
	 14.0 mm	✓	✓	✓	✓
Ø 4.5	 6.6 mm	✓*	✓*	✓*	✓*
	 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 suitable for the following indications until appropriate clinical studies are available:

- In edentulous jaws: as auxiliary implant/supporting implant for implant-supported bar constructions

PROSTHETICS

MyPlant II	Length	Single	Bridge	Telescope	Ball Anchor
Ø 3.5	 6.6 mm	✓*	✓	✓*	✓*
	 8.0 mm	✓	✓	✓	✓
	 9.5 mm	✓	✓	✓	✓
	 11.0 mm	✓	✓	✓	✓
	 14.0 mm	✓	✓	✓	✓
Ø 4.0	 6.6 mm	✓*	✓	✓*	✓*
	 8.0 mm	✓	✓	✓	✓
	 9.5 mm	✓	✓	✓	✓
	 11.0 mm	✓	✓	✓	✓
	 14.0 mm	✓	✓	✓	✓
Ø 4.5	 6.6 mm	✓*	✓	✓*	✓*
	 8.0 mm	✓	✓	✓	✓
	 9.5 mm	✓	✓	✓	✓
	 11.0 mm	✓	✓	✓	✓
	 14.0 mm	✓	✓	✓	✓

or splinted bridges.

- Partially edentulous jaws: as auxiliary implant/supporting implant in connection with longer implants splinted to a superstructure.

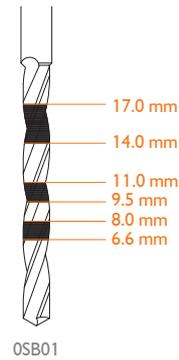
Important: attention should be paid to the load distribution of the prosthetic.

SURGICAL INSTRUMENTS

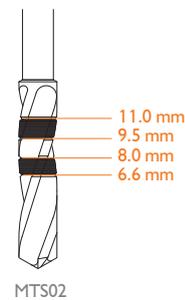
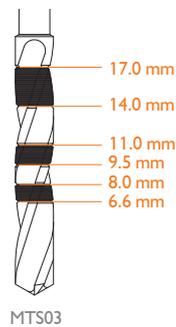
The instrument tray of the MyPlant II implant system is to be checked for completeness and functionality before use. An adequate stock of implants and sterile replacement instruments should always be available. The instruments must be disassembled completely for sterilization. All instruments and materials used must be sterile. The sterilized instruments must be removed with forceps or with sterile gloves. This is the only way to avoid contamination of the operating field.

EXPLANATION OF LASER MARKS

TWIST DRILL OSB01



TRI-SPADE DRILLS

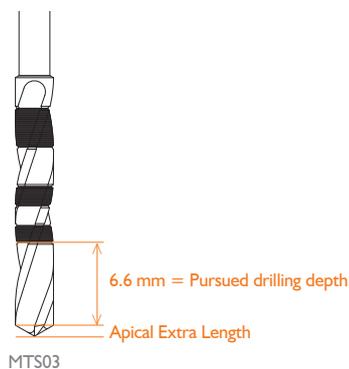


APICAL EXTRA LENGTHS OF TRI-SPADE DRILLS

Due to the function and design of the Tri-Spade drill, the effective drilling depth during preparation is always somewhat greater than the desired implant length. This extra additional apical length must already be taken into account during the planning phase.

APICAL EXTRA LENGTHS

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



STORAGE, CARE AND REPROCESSING OF MYPLANT II 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.

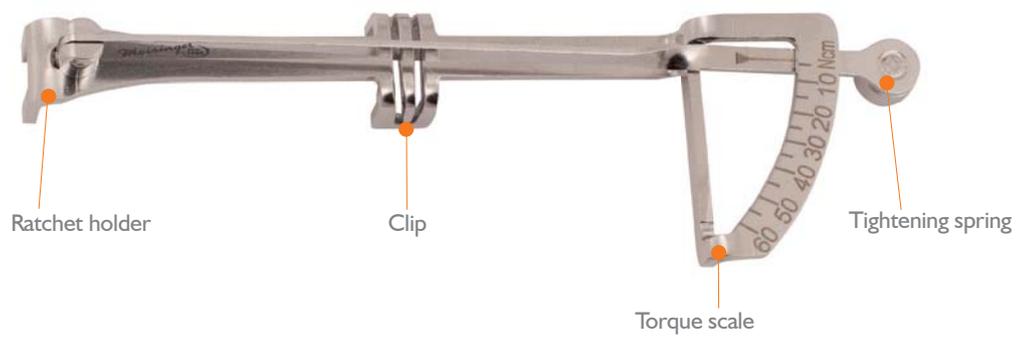
Rotating instruments are subject to wear. For this reason, the instruments need to be checked before any use. The option and responsibility of multiple use of a product and the frequency of application is solely the decision and own responsibility of the treating clinician based on the application in 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

RATCHET

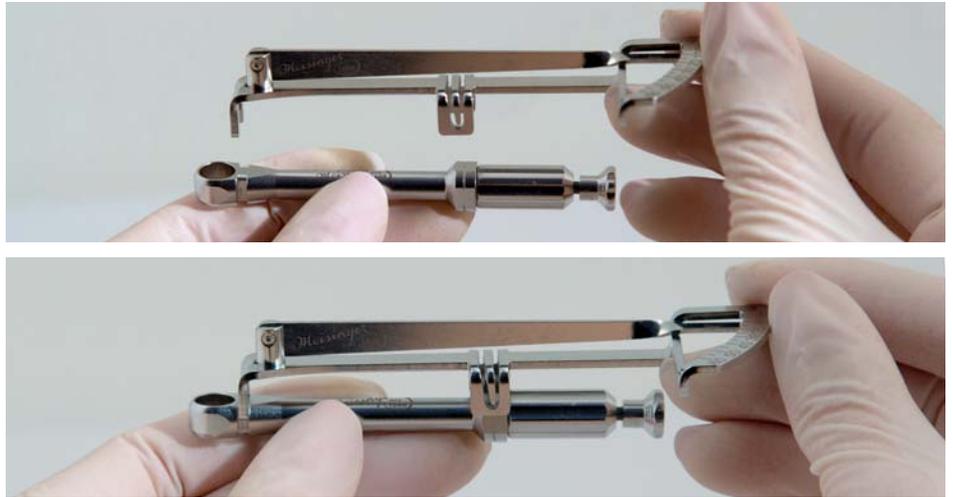


TORQUE INDICATOR



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.



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 disassembly nut of the ratchet must be disengaged completely 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.

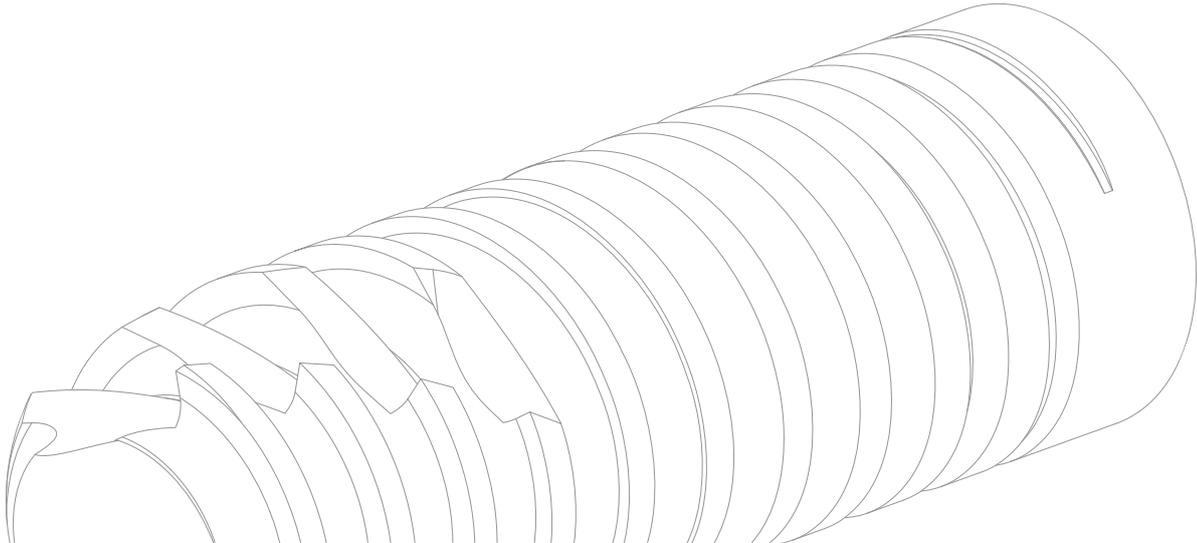


ASSEMBLY

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.

PRODUCT OVERVIEW

	Ø 3.5 mm	Ø 4.0 mm	Ø 4.5 mm
Smoothing of the Alveolar Ridge	 <p>Round Drill ORB01</p>		
Initial Drilling	 <p>Initial Bur 0IB01</p>		
Pilot Drilling Ø 2.0 mm	 <p>Twist Drill OSB01</p>		
1. Expansion of the implant bed Ø 2.4 mm for A, M & B Implants	 <p>Tri-Spade Drill A ATS01 ATS02 ATS03</p>		
2. Expansion of the implant bed Ø 2.9 mm for M & B Implants	 <p>Tri-Spade Drill M MTS01 MTS02 MTS03</p>		
3. Expansion of the implant bed Ø 3.3 mm for B Implants	 <p>Tri-Spade Drill B BTS01 BTS02 BTS03</p>		
Conical Expansion of the implant bed	 <p>Conical Reamer A AKA01 AKA02 AKA03 AKA04</p>	 <p>Conical Reamer M MKA01 MKA02 MKA03 MKA04</p>	 <p>Conical Reamer B BKA01 BKA02 BKA03 BKA04</p>
Pretapping the Implant Thread	 <p>Tap A AGS01</p>	 <p>Tap M MGS04</p>	 <p>Tap B BGS02</p>
Implant Insertion	 <p>Implant A A3566 A3580 A3595 A3511 A3514</p>	 <p>Implant M M4066 M4080 M4095 M4011 M4014</p>	 <p>Implant B B4566 B4580 B4595 B4511 B4514</p>



	Ø 3.5 mm	Ø 4.0 mm			Ø 4.5 mm	
Implants	 <p>Implant A A3566 A3580 A3595 A3511 A3514</p>	 <p>Implant M M4066 M4080 M4095 M4011 M4014</p>			 <p>Implant B B4566 B4580 B4595 B4511 B4514</p>	
	 Cover Screw PVS00 PVS01 PVS02					
	 Healing Abutment PGF15 PGF30 PGF45					
Restoration with	Abutments				Ball Anchor	Titanium Base
	 Trial Abutment 0° PAP01 PAP02 PAP03 PAP04	 Trial Abutment 15° PAP51 PAP52 PAP53 PAP54	 Transfer Post PUP01 PUP02	 Repositioning Post PRP01 PRP02	 Ball Anchor PKA01 PKA02	 Scan Base PSB01 PSB02 PSB03
	 Abutment 0° PAB01 PAB02 PAB03 PAB04	 Abutment 15° PAB51 PAB52 PAB53 PAB54				
Practice	 Transfer Cap PAK01 PAK02					
	 Laboratory Analog (one-piece) 0° PLA04 PLA06	 Laboratory Analog (one-piece) 15° PLA54 PLA56	 Implant Analog PLI01		 Laboratory Analog Ball Anchor PLAK1	 Titanium Base PTB01 PTB02 PTB03
			 Abutment 0° PAB01 PAB02 PAB03 PAB04	 Abutment 15° PAB51 PAB52 PAB53 PAB54	 Matrix Ball Anchor PMAK1 PMAK2 PMAK3	
	 Wax-Up Coping PMK01 PMK02 PMK03 PMK04					
Laboratory	 Occlusal Screw POS01					

RECOMMENDED TORQUES FOR THE MYPLANT II PROSTHETICS

	Product	Torque
	Cover Screw	tangible
	Healing Abutment	
	Transfer Post	
	Repositioning Post	
	Scan Base	
	Occlusal Screw	10 Ncm
	Abutment	15 Ncm
	Titanium Base	
	Ball Anchor	25 Ncm

Note: The images are examples only.

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.

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 labelling 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).

All items which can fall out of place must be secured against aspiration and swallowing when used intraorally to exclude any injury to the patient.

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).

Lacking primary stability may also be caused by improper preparation of the implant bed and/or poor bone quality. In this case, the loose implant should be removed and replaced by a larger one.

Due to their reduced surface, implants of 6.6 mm length may only be used as additional implants to support implant-supported restorations. They are not suited as single tooth restorations and should only be used splinted.

GUIDELINES

All MyPlant II items are to be used according to the instructions for use provided by the manufacturer. The use of components not belonging to the system as well as any type of modification may impair the function of the MyPlant II implant system and precludes any guarantee or replacement by Hager & Meisinger GmbH. 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 labelling should be observed. The processing and application of MyPlant II products takes place outside our control and 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, its indication-relevant suitability and training in the field of dento-alveolar surgery/ implantology.

AVAILABILITY

Some of the MyPlant II products given in this documentation may not be available in all countries. Detailed information is available upon request from Hager & Meisinger GmbH.

CAUTION

In addition to the warnings given in this document, the MyPlant II 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

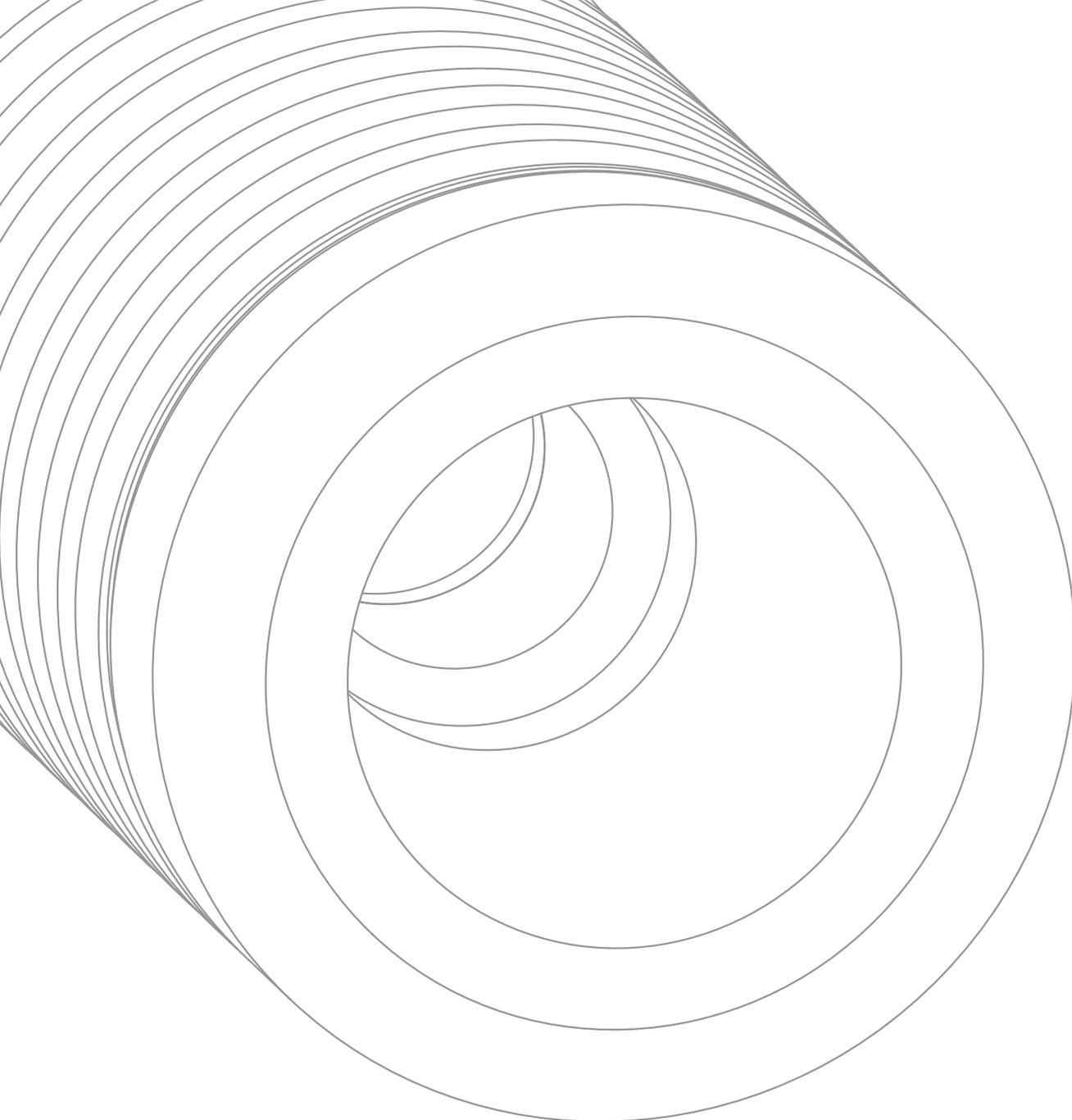
The publication of this document voids all previous versions.

DOCUMENTATION

Further information on the MyPlant II products is available from your MyPlant II contact partner.

REGULATORY REQUIREMENTS

Since 1888, Meisinger has stood for high quality medical devices. The company is certified for quality management according to ISO 9001. The quality management system of a company which manufactures medical devices must meet specific special requirements. These extremely high requirements are defined in ISO 13485 and meticulously complied with by Hager & Meisinger GmbH. All medical devices which are purchased from Hager & Meisinger GmbH comply with all requirements of the Medical Device Directive 93/42/EEC which applies to these products. Hager & Meisinger GmbH is certified by an independent appointed body and certification is performed according to the specifications of standards.



Hager & Meisinger GmbH | Hansemannstr. 10 | 41468 Neuss | Germany
Phone: +49 2131 2012-0 | Fax: +49 2131 2012-222 | E-Mail: info@meisinger.de | Internet: www.meisinger.de

CE 0044

Meisinger USA, L.L.C. | 10200 E. Easter Avenue | Centennial, Colorado 80112 | USA
Phone: +1 (303) 268-5400 | Toll free: +1 (866) 634-7464 | Fax: +1 (303) 268-5407 | E-Mail: info@meisingerusa.com | Internet: www.meisingerusa.com