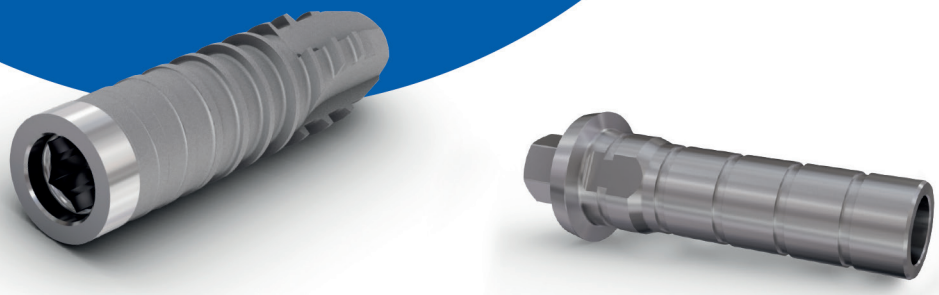
The Thommen 3.0 Implant System.

Surgical and prosthetic procedure

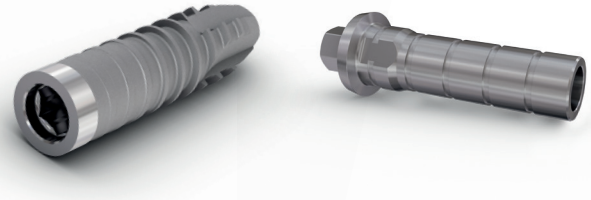
Instructions for use THM61146



Version 005_AA, Issue date 10/20

THOMMEN Medical

Content

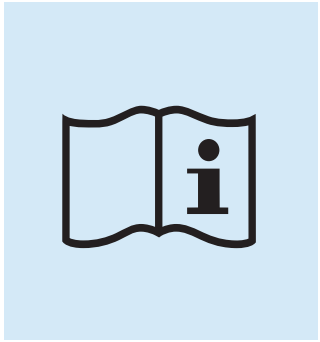


1. System description and specifications

PRINCIPLES

The Thommen 3.0 Implant System comprises the diameter-reduced implant SPI® ELEMENT RC INICELL® PF 3.0, the VARIOunite abutment PF 3.0 (used as a temporary filling or final restoration) and the associated instruments.

For the sake of simplification, the SPI® ELEMENT RC INICELL® PF 3.0 is referred to in this document as ELEMENT PF 3.0.



Note: The implants are part of an overall scheme and may only be used with the intended original components and instruments in accordance with the manufacturer's instructions. The use of non-system parts may compromise the performance of the implants and abutments and lead to failures.

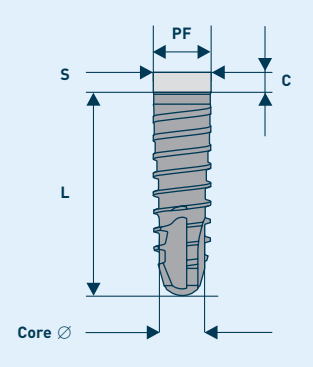
The use of the product is the responsibility of the user and, as such, is beyond the control of Thommen Medical AG. Thommen Medical AG refuses to accept any responsibility or liability for any damage caused hereby.

You can find information below on the intended use, indication, contraindication, clinical use as well as the clinical restrictions of use for the implants. Training by a specialist experienced in the use of this system is recommended

Availability
Not all products mentioned below are available in all countries. Please consult your country's sales representative.

IMPLANT SPECIFICATIONS

The clinically relevant properties of the ELEMENT PF 3.0 are defined as follows and listed on the packaging (see p. 6):



PF = platform
Refers to the implant-abutment connection, which constitutes the connection geometry to the abutment. The platform diameter is a key parameter for the selection of the prosthetic components. The platform diameter for the ELEMENT PF 3.0 is identified on the packaging by color-coding (brown).

C = collar
The collar height refers to the absolute height of the machined collar. The ELEMENT PF 3.0 is only available with a collar height of 1 mm (RC, regular collar).

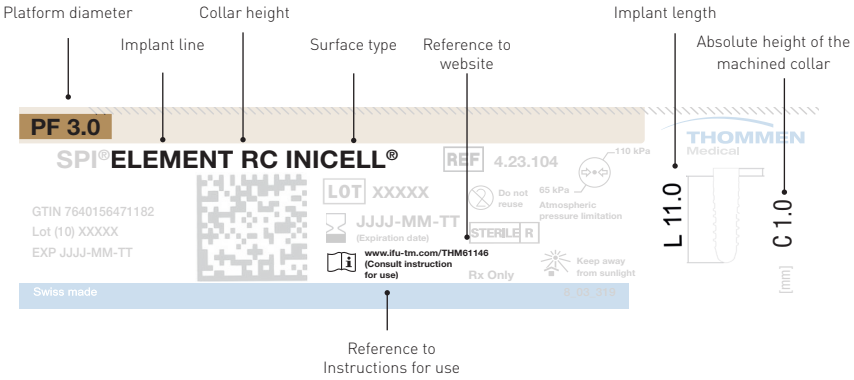
S = shoulder
Refers to the coronal level of the implant. The shoulder diameter corresponds to the platform diameter.

L = endosseous length
The endosseous length of the implant determines the profile drill that must be used for implant bed preparation.

Core ∅ = core diameter
Central diameter of the implant minus the thread height, which corresponds to the diameter of the drill hole.

LABELING

The most important specifications are given on the outer packaging of the product for easier orientation:



In addition to these important specifications, the label also includes a web address that links to these instructions for use in electronic form: www.ifu-tm.com/THM61146.

IMPLANT MATERIAL AND SURFACE

The ELEMENT PF 3.0 is made of pure titanium (grade 4) in accordance with ASTM F 67 / ISO 5832- 2.

The surface of the endosseous portion of the implant is sandblasted and acid-etched.

INICELL® is produced during the conditioning process, whereby the APLIQUIQ® cartridge must be pushed in and the applicator shaken at least five (5) times The effect of INICELL® lasts after conditioning during the treatment time of the patient.

MATERIAL OF ABUTMENT AND AUXILARY PARTS

Components	Material	Intended use	Reusable
VARIOunite abutment for PF 3.0, crown	Titanium alloy	As a provisional or final restoration	No
VARIOunite burn-out cap	POM	Auxiliary parts	No
Abutment screw	Titanium alloy		No

STERILITY AND STORAGE OF IMPLANT/NSTRUMENTS

- **Sterilization method**
  Gamma radiation of at least 25 kilogray (kGy) is used to sterilize the ELEMENT PF 3.0 implant and all other components in the sterile pack.

- **Guarantee of sterility/resterilization**
  If ELEMENT PF 3.0 implants are removed from damaged packaging or from packaging that was opened but the implant was not immediately removed, the sterility can no longer be guaranteed and, consequently, the implants must no longer be used. Implants may not be resterilized.

  Implants which have passed their expiry date must not be used or resterilized under any circumstances. The manufacturer does not accept any liability for resterilized implants.

  This also applies to profile drills and pilot drills for single use of the implant system.

  Implants must be stored in their original protective pack at room temperature, and protected from direct sunlight.

STERILITY AND STORAGE OF ABUTMENT

Single-use products:
All products, which are supplied in a non-sterile state, must be sterilized before first use, unless stated otherwise. If prosthetic components have not been reprocessed, no cleaning and disinfection is necessary.
Multiple-use products:
All multiple-use products must be cleaned, disinfected and sterilized before the first use. An effective cleaning and disinfection are absolutely necessary requirements for an efficient sterilization for re-use.
Steam sterilization is recommended:

- Fractionated vacuum process with at least 3 vacuum steps (with adequate product drying)
- A steam sterilizer compliant with DIN EN 13060 / DIN EN 285 or ANSI AAMI ST79
- According to EN ISO 17665 validated performance assessment
- Maximum sterilization temperature 138°C (280°F), (plus tolerance in compliance with DIN EN ISO 17665)

Sterilization time, i.e. exposure time at the sterilization temperature, is at least 4 minutes at 132°C (270°F) or 18 minutes at 134°C (273°F) for prion inactivation (not relevant for USA).
For further instructions on the sterilization of prosthetic components, please refer to the valid Thommen Medical processing instructions (www.ifu-tm.com/THM61131).

VARIOunite burn-out caps must be protected from exposure to strong light or high heat during storage.

MRI SAFETY INFORMATION

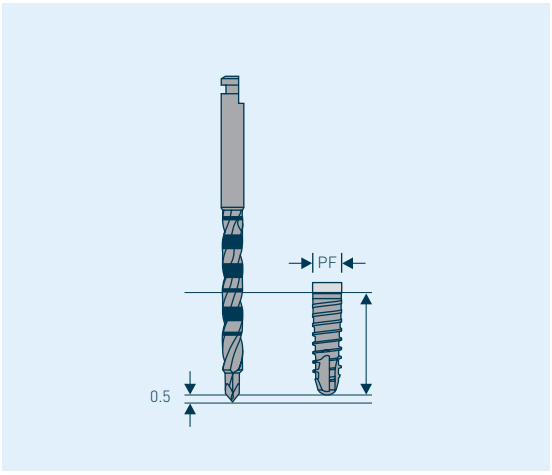
The ELEMENT PF 3.0 has not been evaluated for safety and compatibility in the MR environment. Thommen Medical products have not been tested for heating or migration in the MR environment. The safety of ELEMENT PF 3.0 implants and the abutments in the magnetic resonance environment is, therefore, unknown. Magnetic resonance tomographic examinations of patients, who have been treated with Thommen Medical products, may result in patient injuries.

2. Treatment planning

PRINCIPLES

A carefully conducted treatment plan is of utmost importance for the success of an implant-supported restoration.

Comprehensive preoperative diagnostics is essential, based on the intended prosthetic solution and taking the biological conditions into account. It provides key information for the surgical procedure, as well as any necessary preparatory and accompanying measures.



Due to system requirements, all drills for the Thommen Medical implant system are 0.5 mm longer than the actual insertion depth of the implants. This 0.5 mm must be added to the calculated safety margin.

The creation of optimal bone and soft tissue conditions - whether it is a preventative measure for bone preservation after tooth extraction or for bone augmentation - is an important element of multidisciplinary treatment planning. Thommen Medical offers a comprehensive selection of biomaterials for the regenerative treatment of tissue and bone defects.

Furthermore, gathering comprehensive patient information and the clarification of patients' expectations are essential.

It is the responsibility of the implant specialist to refresh and acquire new mandatory medical knowledge and technical skills through training and continuing education.

Thommen Medical offers courses and educational events for training in surgery and prosthetics.

INDICATION, CLINICAL USE AND GENERAL CONTRAINDICATIONS

Intended use
Thommen Medical implants are used in the upper and lower jaw for implant-borne reconstructions.

Indication
Thommen Medical implants are inserted into partially edentulous upper and lower jaws in order to restore chewing function.

Contraindications
Implantation is contraindicated under the following conditions:
- insufficient bone volume or poor bone quality, which cannot guarantee a stable fit for the implant (primary stability) - acute or chronic infectious diseases
- subacute chronic osteitis of the jaws. Diseases which cause microvascular disorders.
- systemic diseases
- poor general health of patient
- addictions (abuse of alcohol, tobacco, drugs)
- inadequate oral hygiene as well as poorly motivated, uncooperative patients
- titanium allergy

Note: Take account of all generally applicable contraindications in implant dentistry. Poor periodontal conditions must be remedied before implantation.

Clinical use
The ELEMENT PF 3.0 must only be used to replace the lateral incisors of the upper jaw and the central and lateral incisors of the lower jaw.

The ELEMENT PF 3.0 is suitable for use in one-stage or two-stage surgical techniques for the restoration of chewing function. The ELEMENT PF 3.0 is suitable for immediate implantation and restoration in case of replacement of individual teeth; prerequisites are good primary stability and appropriate occlusal loading.

The ELEMENT PF 3.0 should only be used if the distance to the neighboring teeth does not allow a larger diameter.

Clinical restrictions of use
The ELEMENT PF 3.0 must only be used for single tooth replacement of lateral incisors of the upper jaw and the central and lateral incisors of the lower jaw.

General restrictions of use, see Page 46.

POSSIBLE COMPLICATIONS

Intraoperative

- Inadequate preoperative planning and / or non-observance of the surgical technique may cause complications and implant failure.
- Failure to recognize or take account of the physical or psychological preconditions listed as contraindications may cause complications and implant failure.

Postoperative

If the implant or abutment is loaded beyond its functional capacity, excessive bone loss or breakage of implant or restoration may occur.

Clinicians must monitor patients at regular intervals to determine any possible periimplant loss of bone, changes to the implant's response to percussion, or radiologic changes to the bone-to-implant contact along the length of the implant. If the implant has mobility or greater than 50% peri-implant bone loss, the implant should be evaluated for possible removal.

Note: Patients should avoid exposing their bodies to strenuous physical activity after surgery.

Despite high success rates for dental implants, the possibility of failure can never be eliminated. The causes of such failures often cannot be determined, are specific to each case or patient-related. They should be documented and reported to the manufacturer.

SELECTION OF IDEAL IMPLANT DIAMETER, LENGTH AND POSITIONING

X-rays

X-ray images provide information about vertical bone volume, and the relation of adjacent dental structures to the planned insertion site and about the thickness of the soft tissue structures. Therefore, they provide important clues in determining the optimal diameter, length and positioning of implants. To determine the magnification factor or the scale of the X-ray image, the X-ray reference sphere ∅ 5.0 mm (Art. No. 3.03.140) can be incorporated into an individual X-ray template.

After taking the X-ray images, the respective magnification factor or scale can be determined as follows:

- By scale comparison of the X-ray reference sphere in the patient's X-ray image with the reference sphere in the X-ray template for Thommen implants (measuring and comparison templates with various distortion factors).
- By measuring the size of the X-ray reference sphere in the X-ray image and calculating the magnification factor.

Art. no.	Article
Fo_20d184.00	X-ray template for SPI® ELEMENT

The X-ray templates for the Thommen Implant System are for guidance purposes only in determining the implant parameters and positioning. In critical regions more extensive examinations (e.g. DVT) may be required.

Note: Due to their function and construction, all drills are 0.5 mm longer apically than the specified length of the corresponding Thommen implants. To avoid complications, this , must be taken into account when selecting and positioning the implant, particularly in proximity to anatomical structures.

Mesiodistal position
The gaps between the adjacent natural tooth root and the implant shoulder at bone level should be at least 1.5 mm.

⚠ **Warning:** Check when planning whether the profile drill and adapter for hand piece fit easily into the tooth gap, taking the intended implant position and angulation into account. If use of a bone contouring instrument is intended, also check that the bone contouring instrument can be guided properly.

The mesiodistal position of the implants can be easily estimated by using a periodontal probe placed vestibularly or determined with a gauge.

Alveolar ridge width (buccolingual position)
To enable a sufficient supply of blood to the peri-implant bone, a minimum vestibular and oral bone lamella of a thickness of at least 1.0 mm should be ensured around the endosseous collar region of the implant, though more is ideal. Strong dimension in the vestibular lamella is a requirement for good bone healing and an aesthetic restoration, especially in the anterior region. Missing bone width in the vestibular region can be compensated to a certain degree by strong palatal positioning of the implant. However, too strong palatal positioning should be avoided in the anterior region, otherwise the restoration proves to be very difficult or prone to compromise, especially with thin gingival morphology.

Vertical position and soft tissue situation
An important part of preoperative planning is estimating the attachment height of neighboring teeth and measuring soft tissue characteristics (in particular the thickness and mobility of soft tissue.

The implant shoulder of the ELEMENT PF 3.0 implant with a collar height of 1.0 mm (RC, Regular Collar) allows supracrestal as well as subcrestal positioning.

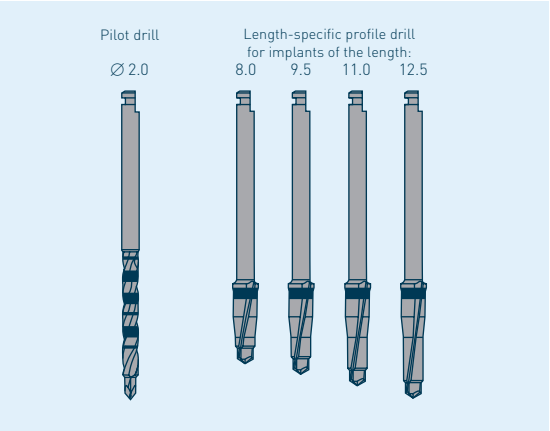
3. Implant bed preparation

ESSENTIALS

The implant bed preparation for Thommen implants using the drills for the Thommen implant system reduces the number of instruments needed to a minimum.

Any implant bed preparation for the ELEMENT PF 3.0 starts by using the VECTOdrill™pilot drill to accurately define the drilling axis and drilling depth. The drilling depth and drilling axis of the implant bed can be checked using the depth gauge, diameter 2.0 mm (see page 36).

The ELEMENT PF 3.0 requires a specific drill protocol. Preparation using a profile drill follows use of the VECTOdrill pilot drill. The length-specific profile drill must be used to prepare the conical areas of the implant bed. The corresponding length of the ELEMENT PF 3.0 can only be set after this.



PF 3.0	Speed rpm
2.0 pilot drill	800
Length-specific profile drill	400

Overview of the drilling protocol
All holes must be drilled by exerting gentle pressure intermittently while constantly cooling the exterior with physiological, sterile, cooled saline solution (approx. 5°C/41°F). Recommended rotation speeds must be adhered to in order to avoid overheating the bone tissue and possible instrument fractures.

Regularly remove the bone chips to ensure ideal drilling performance.

Secure the products used in the oral cavity against aspiration. Complete clinical and X-ray documentation is recommended.

⚠ **Warning:** The ELEMENT PF 3.0 must not be screwed in deeper than intended, measured or predrilled. Implants that were not correctly screwed in or were implanted in an implant bed that was not prepared using the designated profile drill may exert pressure on the bone. This can compromise osseointegration or result in a bone fracture

IMPLANT BED PREPARATION FOR THE ELEMENT PF 3.0

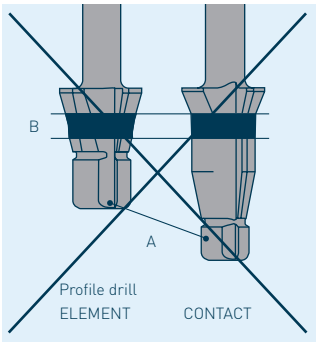
Pilot drilling
First, prepare the drill hole with the VECTOdrill ∅ 2.0 mm pilot drill. The pilot drilling defines the crestal implant position, angulation and drilling depth. We recommend using the VECTOdrill pilot drill ∅ 2.0 mm, length 40.0 mm (for single use Art. No. 3.03.611Q4; reusable Art. No. 3.03.730) to avoid obstructions caused by neighboring teeth. For the digital workflow, pay attention to the differing length specifications of your software.

The smaller diameter drill tip of the pilot drill secures the drilling position and prevents drill chatter. Center marking with the round burr is not required.

Guide the pilot drill using a maximum of 800 rpm by exerting slight axial pressure intermittently and while constantly cooling the exterior with physiological, sterile, cooled saline solution (approx. 5°C/41°F) until the required depth is reached. The pilot drills permit easy correction of the axis. Always perform lateral drilling corrections with the pilot drill carefully and with the drill turning.

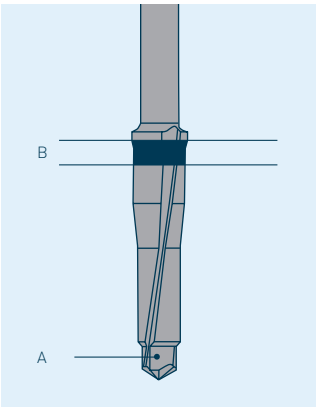
Using the profile drill
After the pilot drilling, preparation must be finalized using length-specific profile drills for the ELEMENT PF 3.0 (see page 14).

Note: Profile drills are only intended for use for the ELEMENT PF 3.0. Neither the CONTACT profile drill nor the ELEMENT profile drill may be used, as they are intended for larger implant diameters.



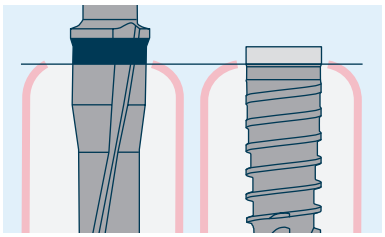
All profile drills of the ELEMENT PF 3.0 feature a tapered tip which corresponds to the diameter of the preceding drill (A). This permits the profile drill to be accurately aligned in the pre-drilled hole and thus offers optimum safety to the user while shaping the coronal implant bed.

All profile drills feature the same 1.5 mm depth marking (black band «B»).

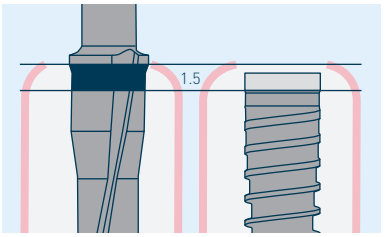


With the ELEMENT PF 3.0, preparation corresponds to the lower edge of the depth mark of the standard protocol, i.e. the implant is placed in a supracrestal location so that the machined collar is positioned in the soft tissue.

Preparation to the upper edge of the black band means that the implant shoulder is positioned 0.5 mm subcrestally. If the implant shall be positioned subcrestally, implant bed preparation that is correspondingly deeper must also be carried out using the VECTOdrill pilot drill and profile drill.



Supracrestal positioning



Subcrestal positioning

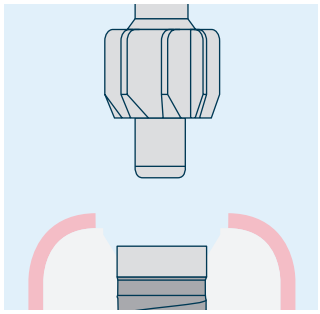
Guide the profile drill ELEMENT PF 3.0 using a maximum of 400 rpm by exerting slight axial pressure intermittently and while constantly colling the exterior with physiological, sterile, cooled saline solution (approx. 5°C/41°F) until the necessary depth is reached.

Using the last profile drill completes the implant bed preparation and the implant can be positioned immediately.

Note: Profile drills are intended for single use and are sterile packed. When using the surgical cassette, additional sterile instruments for single use may be placed into the designated instrument holders of the surgical cassette only after sterilization (see page 33).

Bone contouring instrument for PF 3.0

The bone contouring instrument, reusable, stainless steel, are supplied in a non-sterile condition and must be processed prior to first use. They may be processed a maximum of 20 times. For processing in accordance with the cutting instruments for standard use, see THM61131.



If bone prevents insertion of the prosthetic components, the bone contouring instrument for PF 3.0 (Art. No. 3.03.658) can be used to prepare the contour of the bone without damaging the implant. Adequate space can thus be created to accurately fit impression caps and abutments. The bone contouring instrument can be used manually with the short MONO insertion device or under power. If you use the contra angle, we recommend cooling at a maximum rotational speed of 200 rpm.

4. Implantation

ESSENTIALS

Only open the protective packaging (cardboard box) prior to implantation.

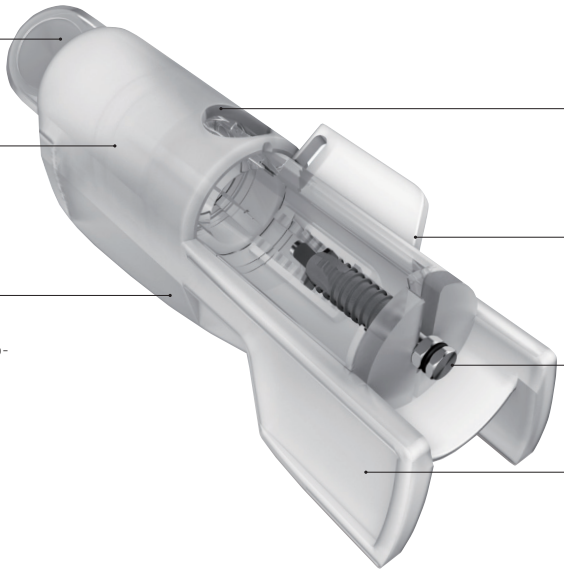
Sterility
Thommen implants are sterile and are double-packed. Inspect the sterile packaging for damage before opening. Damage to the sterile packaging (blister) may compromise the sterility of the products contained. Sterility is also not guaranteed if the implants are not used immediately once the package is opened.

The corresponding aseptic regulations must be complied with when removing the applicator from the sterile packaging and when removing the implant from the applicator.

Documentation/Traceability:
The manufacturer recommends complete clinical, radiologic, photographic and statistical documentation. Implant traceability must be guaranteed.

Note: Use adhesive labels enclosed in the protective pack for the documentation in the respective patient's medical records (art. no./lot. no.). This simplifies identification of the implant type and implant dimensions for later prosthetic restoration.

APLIQUIQ® – Optimal functionality thanks to the unique design.



Cartridge
The cartridge contains the conditioning agent and is sealed with a foil seal.

Body
The body is the central part of APLIQUIQ and protects the dry mounted implant during transport and conditioning.

Reservoir
The integrated reservoir catches the liquid after the conditioning process and prevents spillage.

Healing cap
The healing cap is securely positioned in the rotating lid and can only be removed in the half-open position of the lid.

Lid
The rotating lid offers access to the implant and covers access to the reservoir when fully open.

Implant
Implants are attached to the practical insertion aid.

Winglets
When the winglets are pressed together the clamping force on the insertion aid is released and the implant can be removed easily.

reddot design award
winner 2011

INICELL®/APLIQUIQ®

Surface conditioning is performed chairside immediately before implantation using the APLIQUIQ conditioning system. Remove the APLIQUIQ container from the sterile packaging and activate by pressing the liquid-filled cartridge.

⚠ **Warning:** The conditioning agent is an irritant, do not ingest (contains 0.05 M NaOH). Avoid contact with eyes, in case of eye contact rinse immediately with plenty of water while keeping eyelids open and seek medical attention. If swallowed, dilute with copious amounts of water.

Hold the applicator vertically with the cartridge upwards and shake vigorously at least 5 times. This is the only way to produce the superhydrophilic INICELLsurface.

Afterwards hold APLIQUIQ horizontally and allow the conditioning agent to flow into the integrated reservoir.

Ensure that the implant is entirely conditioned and wet.

After conditioning, the effect of INICELL lasts during the patient's treatment time. The liquid must not be used any further.

REMOVING THE IMPLANT FROM THE APLIQUIQ CONTAINER

After conditioning, remove the rubber cap on the rear of the applicator. Place the applicator horizontally on a firm surface.

Rotate the lid to an unobstructed view of the implant and the insertion aid.

Note: Only use the adapter for the handpiece PF 3.0 for the ELEMENT PF 3.0.

Place the adapter for the handpiece PF 3.0 on the insertion device as far as it will go (for manual use, the MONO insertion device, short can be installed on the adapter).

Press the lateral wings on the applicator together, so that a gap in the implant holder opens. Carefully remove the implant from the implant holder without turning it.

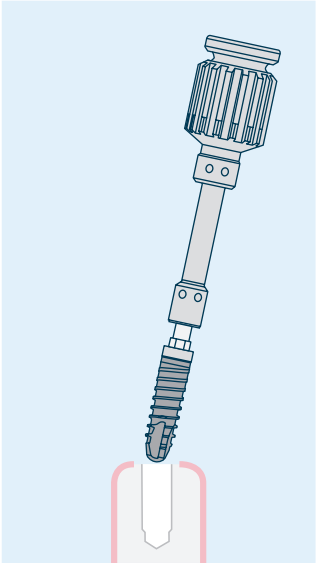
MANUAL IMPLANT INSERTION

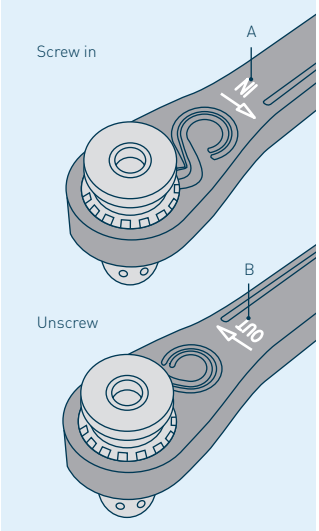
For manual implant insertion of the ELEMENT PF 3.0 using the MONO torque ratchet, the adapter for the handpiece PF 3.0 must be installed on the MONO insertion device short,.

Insert the implant into the prepared implant bed. Manually screw in the implant to the point where the implant is seated firmly in the bone.

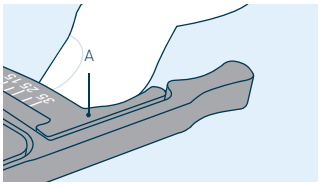
Afterwards continue working with the MONO torque ratchet. Push the torque ratchet as far as it will go onto the MONO screwdriver.

Do not force the ratchet onto the insertion device. The torque ratchet should simply slide over the ratchet body of the MONO instrument. If this is not the case, the parts are not aligned correctly and must be realigned accordingly and checked for damage.

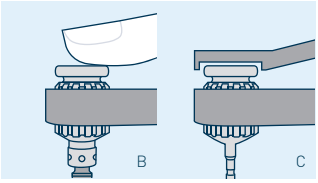




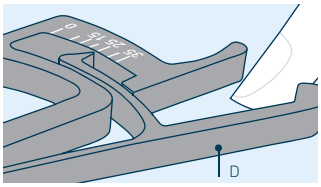
The torque ratchet is labeled on one side with “IN” (A), and on the other side with “OUT” (B). The arrow on the ratchet indicates the direction for tightening or loosening. For tightening, place the torque ratchet on the ratchet body in such a way that the side marked “IN” points upward. For unscrewing, the word “OUT” points upward.



Screw in the ELEMENT PF 3.0 with slow movements of the ratchet. To screw in, guide the ratchet on the rigid arm (A) as shown in the picture.



The ratchet can be guided either with the finger on the finger rest (B) or the guide key (C).



To display the torque exerted, the flexible section of the ratchet, the bending rod (D), can be used.

MECHANICAL IMPLANT INSERTION

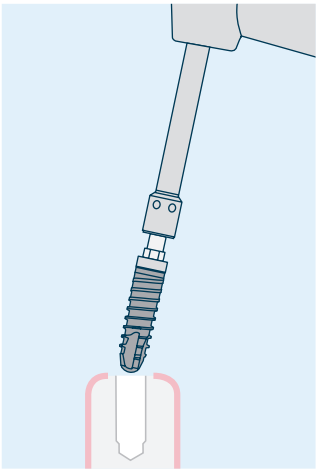
The adapter for hand piece PF 3.0 is provided for mechanical implant insertion.

Note: Only supported contra angles must be used for mechanical insertion. impressions.

Push the contra angle with adapter for he contra angle PF 3.0 on the insertion device as far as it will go.

While screwing in the implant under power, always exert a slight axial pressure on the handpiece. This ensures that the insertion aid completely engages with the internal hexagon of the implant and the insertion aid can be removed without any problems after implantation.

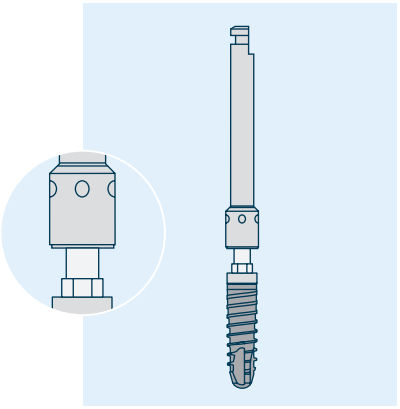
The maximum rotation speed is 15 rpm



Alignment of the internal hexagon
The internal hexagon needs to be perfectly aligned if impression and prosthetic components are to be used.

On instruments for insertion of implants, six circular dots can be seen. These dots are used for the alignment of the implant, marking the position of the corners of the internal hexagon.

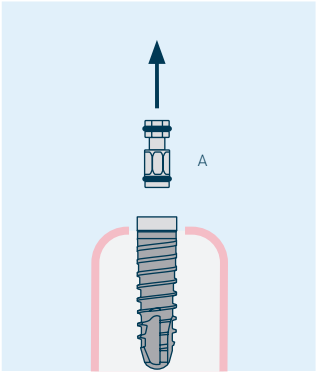
One of these dots must be aligned strictly in a labial direction.



REMOVING THE INSERTION AID

Take the insertion aid (A) out of the implant in an axial direction.

Note: If there is high insertion torque after screwing in the implant with the adapter, make a short counter-movement (counter-clockwise). This facilitates removing the insertion aid.

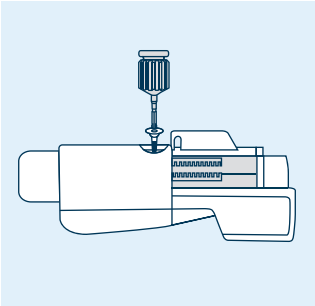


INSERTION OF HEALING CAP (GINGIVA FORMER)/ USE OF MONO SCREWDRIVER

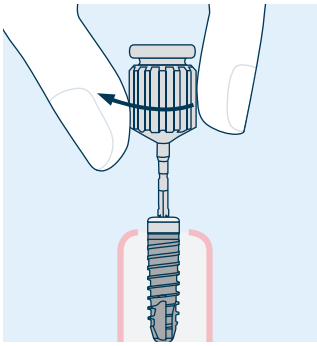
Healing caps seal the implant during subgingival healing of the implant. Gingiva formers are used for transgingival healing. Before sealing the ELEMENT PF 3.0 implant, the interior of the implant needs to be clean and free of blood.

The fit of the implant-abutment connection can be considerably impaired if any additional material (such as, e.g. bone substitute material) is introduced between the implant and the healing cap, gingiva former or abutment. The correct seating of all prosthetic parts must be precisely checked, especially when using very viscous pastes. Ensure that small items are not aspirated.

Twist the cover of the APLIQUIQ container to expose the healing cap. The flat, rounded design enables better adaptation of the flap of mucous membrane in case of thin soft tissue conditions.



Engage the healing cap with a MONO screwdriver by exerting slight axial pressure.



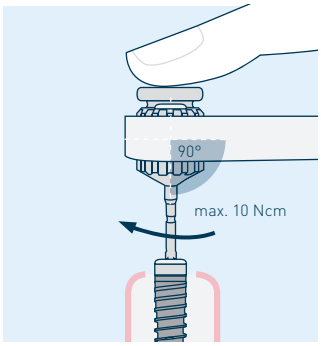
Always avoid non-axial forces on the screwdriver.

Screw in the healing cap (or, if required, the gingiva former) by hand until it is in slight contact with the implant shoulder.

Note: Tightening by hand with the MONO screwdriver can subject the healing cap/gingiva former to such a high torque that it can be damaged.

The tightening torque must not exceed the screw-in torque of the implant and may be max. 10 Ncm.

For final tightening, push the torque ratchet as far as it will go onto the MONO screwdriver and tighten while checking the torque.



Healing caps or gingiva formers must not be subjected to any stress loading during the entire healing phase and, therefore, must be kept entirely out of occlusion.

gingiva formers are not supplied in a sterile state; unless directed otherwise, steam sterilization of the gingiva former is recommended:

- fractionated vacuum process with at least 3 vacuum steps (with adequate product drying)
- a steam sterilizer compliant with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- Maximum sterilization temperature 138 °C (280 °F; plus tolerance in compliance with DIN EN ISO 17665)

Sterilization time, i.e. exposure time at the sterilization temperature, is at least 4 minutes at 132 °C (270 °F) or 18 minutes at 134 °C (273 °F) for prion inactivation (not relevant for USA).

HEALING PHASE

Thommen implants are approved for immediate implantation and restoration if adequate primary stability can be achieved (see indications and contraindications, page 10 onwards).

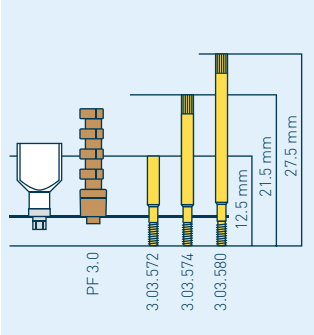
We recommend a healing phase of at least 12 weeks for ELEMENT PF 3.0 implants.

The healing time is the same for the upper and lower jaw.

In situations where the sandblasted and acid-etched surface is not completely in contact with the bone, or where bone augmentation measures are necessary, a healing phase in accordance with the situation must be planned.

An radiographic check is recommended after a healing phase of 3– 12 weeks before starting the prosthetic restoration.

Note: The bone contouring instrument for PF 3.0 (Art. No: 3.03.658) should be used during exposure in order to remove interfering sections of bone (see page 16).



CONVENTIONAL IMPRESSION TAKING

The prosthetic restoration with the VARIOunite abutment requires taking an impression at the implant level. As impression coping for conventional impression taking, the impression coping for an open-tray technique is provided for multiple use (titanium). Where occlusal space is limited, the impression coping can be shortened. However, at least one retention ring must be retained.

The screws for impression coping platform 3.5 must be used (Art. No. 3.03.572, 3.03.574 or 3.03.580).

Note: After shortening the impression coping, break off the resulting rough or sharp edges at the separation site using a suitable sander/polisher. Worn or damaged impression coping or scan abutments may no longer be used.

The forceps (Art. No. 332.10.20) can be used especially in tight spaces or in the molar region to position the impression coping more easily in the internal hexagon of the implant.

Information on taking conventional impressions can be found online at:
www.ifu-tm.com/THM61127

DIGITAL IMPRESSION TAKING

The Thommen scan abutment (Art. No. 3.03.774) can be used for taking digital impressions. This can be used either intraorally or for scanning from the master cast.

The screws for impression coping PF 3.5 must be used (Art. No. 3.03.572).

Information on taking digital impressions can be found online at:
www.ifu-tm.com/THM61143

FABRICATING THE LABORATORY MODEL

Implant analogs are available for VARIOunite abutments. These can be used for conventional or digital processes.

Information on producing digital models can be found online at:
www.ifu-tm.com/THM61143

CAD LIBRARIES

Thommen Medical can provide libraries for dental CAD-software. The libraries used must be aligned between the users (e.g.: dentist, dental technician, milling center). Conventionally, it is the final link in the value creation chain which administers the final configuration of the library and distributes this to the upstream users. If the basic libraries have not been included when the CAD-software was installed, they can be downloaded from the Thommen Medical website. For this, please visit: www.thommenmedical.com

If no library is available for the CAD system in use, please contact your local sales representative or country's sales representative.

5. Gingiva shaping and temporary restoration

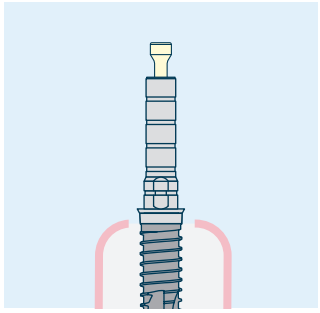
Gingiva formers are used in the transgingival healing phase and also for shaping the soft tissue. Thommen Medical provides standardized gingiva formers made of titanium (grade 4) in three different heights (3.2; 4.5; 7.0 mm) for the ELEMENT PF 3.0.

See p. 22 f for information on how to use gingiva formers and MONO screwdrivers.

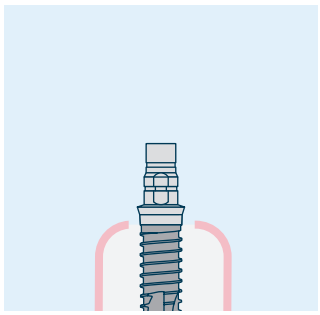
The VARIOunite abutment PF 3.0 is a modifiable bonding base and is suitable for temporary restorations until the definitive restoration is inserted. The abutment is also suitable as a basis for individual soft-tissue conditioning. A provisional restoration can be carried out chairside by the dentist or in the laboratory. VARIOunite abutments are intended for single use.

The same requirements apply to indication, clinical uses, restrictions of use and modification as described in the "Definitive restoration section, below.

CONVENTIONAL FABRICATION OF TEMPORARY RESTORATIONS

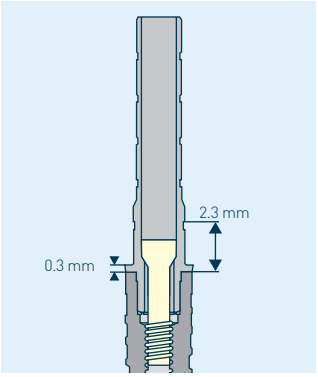


1. Fix the VARIOunite abutment PF 3.0 on the implant using the abutment screw (Art. No. 4.03.500). Make sure that the rotation surface is aligned in a mesio-distal direction.

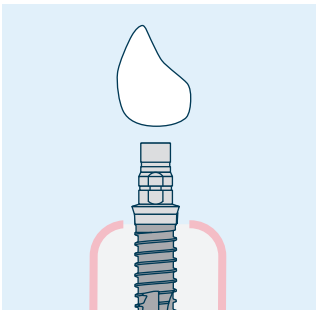


2. If the height of the abutment prevents maximum intercuspidation, the cylindrical part must be shortened. Occlusal contact of the antagonistic structures with the abutment must be avoided.

Shortening the abutment:
The implant analog (3.03.098) is fixed in the handle for dental technicians (3.03.250). Afterward, the VARIOunite abutment PF 3.0 is fixed on the implant analog using the abutment screw (Art. No. 4.03.500) and shortened to the required length using a cutting disk. VARIOunite abutments can be shortened to the first retention ring at the maximum. Do not go below the minimum height of 2.3 mm, measured from the implant shoulder. A minimum construction height of 4.0 mm (2nd retention groove from the implant shoulder) must be maintained for zirconium oxide restorations. Reducing the wall thickness and grinding the abutment collar is not permitted.

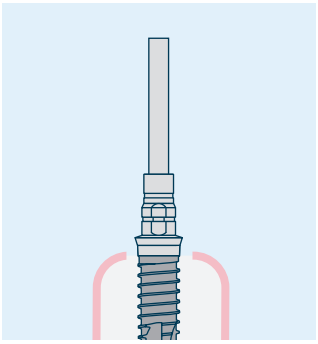


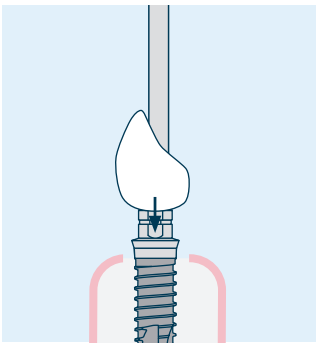
3. The temporary restoration can be fabricated using a prefabricated plastic denture tooth, silicone key, a crown form prefabricated in the laboratory or using prefabricated crown forms.



4. The abutment screw can be replaced with the laboratory cylindrical pin (Art. No. 2.03.450 Q5) before the plastic material is processed. The use of the laboratory cylindrical pin facilitates better handling and prevents the liquid plastic material from flowing into the screw channel while the plastic veneering material is being processed.

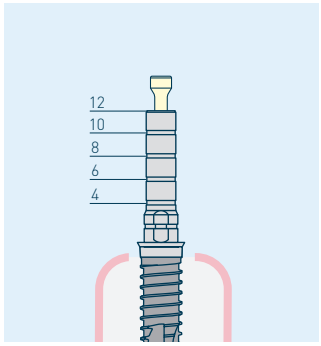
   To reduce the forces acting on the abutment, the prefabricated temporary restoration must be out of occlusion.



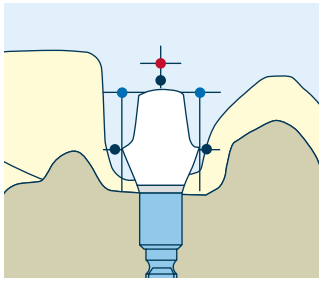


DIGITAL FABRICATION OF TEMPORARY RESTORATIONS

See Steps 1 and 2 under "Fabricating the provisional restoration conventionally".



3. The virtual cylinder height of the abutment is selected in the CAD library according to Step 1.



Computer-assisted fabrication of superstructures depends on the CAD/CAM system used. The corresponding procedures must be taken from the user documentation of the system supplier.

Step 4, see under "Fabricating the temporary restoration conventionally".

DEFINITIVE ATTACHMENT OF THE FINISHED TEMPORARY RESTORATION

The implant and prosthetic components must not show any signs of damage or contamination before the components are inserted and attached. Additionally, make sure that the implant shoulder is free of all overhanging soft tissue.

New abutment screws must always be used for the definitive insertion (Art. No: 4.03.500 . The VARIOunite Abutment PF 3.0 is fixed on the ELEMENT PF 3.0 using a tightening torque of 15 Ncm.

The screw channel is sealed with a suitable material.

6. Final restoration

INDICATION

Thommen Medical VARIOunite Abutments PF 3.0 are only used in conjunction with the ELEMENT PF 3.0 and are for fabrication of provisional and final crowns in the anterior upper and lower jaw (upper lateral incisors, lower anterior teeth without the canine teeth).

CLINICAL USE

The VARIOunite Abutment PF 3.0 is a modifiable bonding base and is used for screw-retained single crowns.

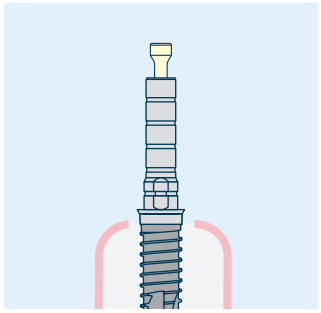
The abutment is also suitable for bonding metal or CAD/CAM fabricated zirconium restorations. The VARIOunite abutment PF 3.0 is supplied with the abutment screw (VARIOunite abutment set). Suitable composite adhesives are recommended for bonding. VARIOunite abutments are intended for single use.

The VARIOunite PF 3.0 abutment is made from a titanium alloy (Ti-6Al-7Nb in accordance with DIN/ISO 5832-11/ASTM F1295).

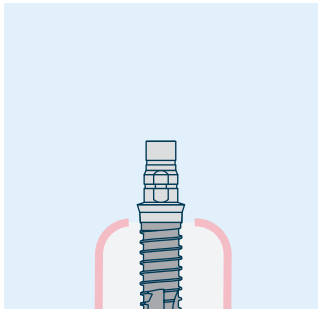
RESTRICTIONS FOR USE

See the general instructions of use (page 46).

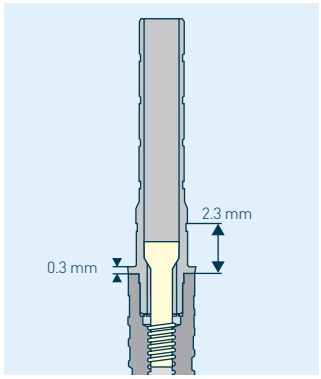
CONVENTIONAL FABRICATION OF DEFINITIVE RESTORATIONS



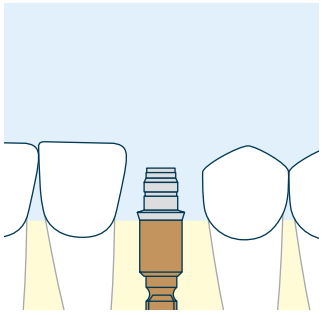
1. Screw the VARIOunite abutment PF 3.0 onto the implant analog using the abutment screw (Art. No. 4.03.500). Pay attention to the alignment of the abutment when fitting it.



2. If the height of the abutment prevents maximum intercuspidation, the cylindrical part or screw channel must be shortened. Occlusal contact of the antagonistic structures with the abutment must be avoided.



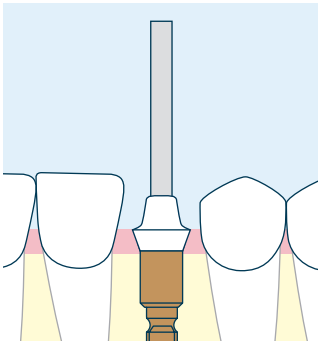
VARIOunite abutments can be shortened at the very most to the upper edge of the lowest retention ring. Do not go below the minimum height of 2.3 mm, measured from the implant shoulder. Reducing the wall thickness and grinding the abutment collar (0.3 mm) is not permitted.



3. Place the VARIOunite plastic caps PF 3.0 on the abutments and shorten to the corresponding length. The plastic caps have a rotation lock. Move the cap onto its final position by exerting slight pressure. The burn-out plastic caps are not suitable for use as plastic temporary restorations.

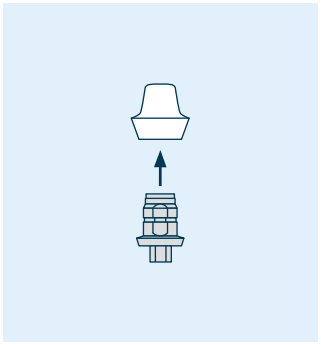
⚠ **Warning:** The plastic caps from the PF 3.5 are marked with easily visible grooves with the exception of the PF 3.0 platform that does not have any grooves.

4. Fabricate the crown framework on the plastic caps. By using the laboratory cylindrical pin (Art. No. 2.03.450 Q5), no residual wax can get into the screw channel. The total wall thickness must be at least 0.3 mm. During the burn-out process, the applied wax provides an expansion zone for the plastic. Insufficient coverage of the cap with wax can cause the investment mold to fracture in the oven during warming due to expansion of the plastic material. After attaching the sprues and runner bar, unscrew and remove the screw.



5. After attaching the sprues/runner bar, remove the wax construction incl. abutment from the analog or model at the same time. The abutment must be removed completely from the wax construction. The fabricated framework can then be embedded and cast as usual.

   Sprues should, as far as possible, be attached in line with the flow direction in order to prevent the investment material in the screw channel from fracturing.



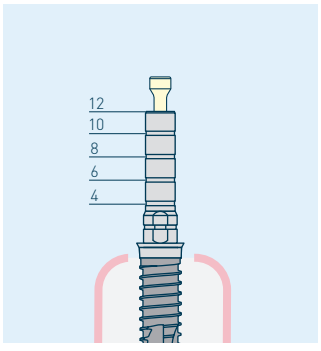
6. Adapt the cast crown framework after divesting and subsequent cleaning off the model on the VARIOunite abutment PF 3.0. Be careful of the rotation lock.

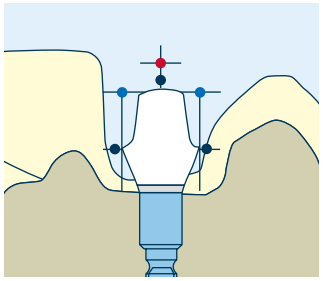
   Note: Do not subject the VARIOunite abutment to a high heat stress! VARIOunite abutments must be removed from the framework construction before each burn-out process.

DIGITAL FABRICATION OF THE DEFINITIVE RESTORATION

See Steps 1 and 2 under "Fabricating the definitive restoration conventionally".

3. The virtual cylinder height of the abutment is selected in the CAD library in correspondence with the defined groove from Step 1.

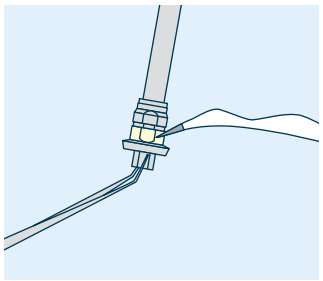




4. Computer-assisted fabrication of superstructures depends on the CAD/CAM system used. The corresponding procedures must be taken from the user documentation of the system supplier.

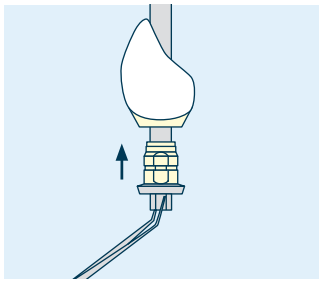
BONDING THE VARIOUNITE ABUTMENT PF 3.0 TO THE FINISHED

VENEERED CROWN



1. Sand blast the bonding surface of the VARIOunite PF 3.0 abutment using 50 µm aluminum oxide and max. 2 bar pressure, and clean thoroughly (free of grease). Cover the marginal area with suitable material before the blasting process.

2. Mix and apply the bonding agent (PANAVIA™F 2.0 from Kuraray or ReliyX Unicem™ from 3M) in accordance with the manufacturer's instructions. The bonding agent absolutely must be in a soft condition during the following processes.



3. Finally, position the construction in the analog on the model. Check that the crown is fully and correctly seated. Remove the laboratory cylindrical pins, insert the abutment screw (or laboratory screw) and tighten firmly. Let the cement cure, remove any remaining cement residues and then finish the crown.

   Bonded constructions are no longer sterilizable.

DEFINITIVE ATTACHMENT OF THE FINISHED DEFINITIVE RESTORATIONS

1. Remove the gingiva former or temporary crown from the implant. Clean the inner configuration of the implant thoroughly. Position crowns on the implants and check that these are correctly seated. Make sure that no soft tissue is trapped.

2. New abutment screws must always be used for the definitive insertion (Art. No. 4.03.500). The VARIOunite Abutment PF 3.0 is fixed on the ELEMENT PF 3.0 using a tightening torque of 15 Ncm.

3. Fill the screw channel with a removable material. Then seal with a suitable composite material.

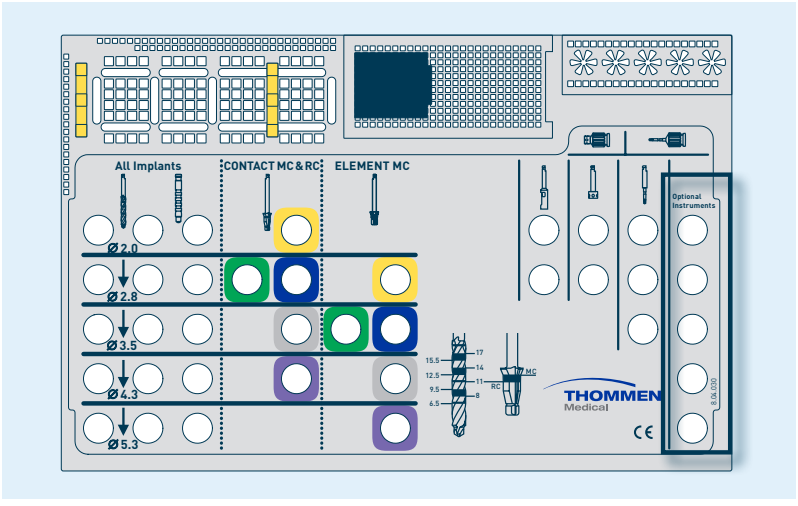
7. Instruments and techniques – good to know.

GENERAL INFORMATION

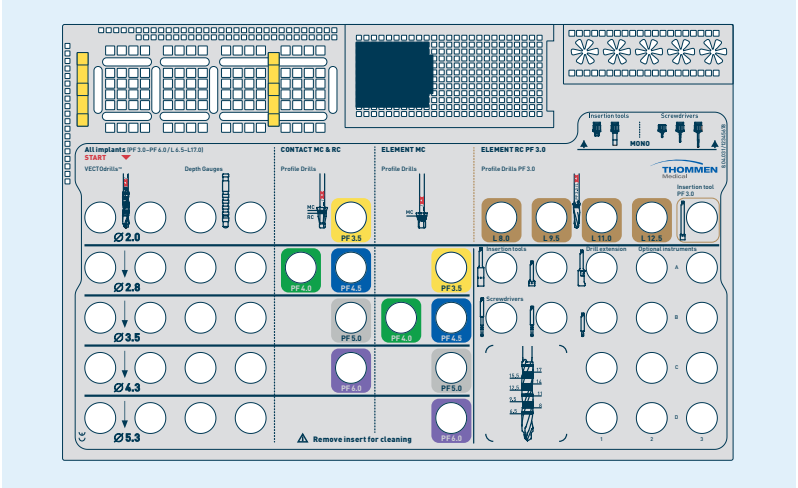
When using the surgical cassette, additional sterile instruments for single use may be placed into the cassette only after sterilization. Sterile instruments must be loaded under sterile conditions (sterile assistant) and care must be taken to ensure that instruments already in the cassette are not contaminated through this process.

SURGICAL CASSETTE FOR MECHANICAL CLEANING

The surgical cassettes for mechanical cleaning (Art. No. 1.03.030, first and second generation, play a pivotal role in the processing of Thommen instruments and their prosthetic components for multiple use. Information on use of the surgical cassettes for mechanical cleaning can be found in the processing instructions at (www.ifu-tm.com/THM61131). In the surgical cassette for mechanical cleaning (Art. No. 1.03.030) of the second generation (from 2018), designated spaces are provided for the profile drill and adapter for hand piece PF 3.0.



Surgical cassette for mechanical cleaning (Art. No.1.03.030) first generation



Surgical cassette for mechanical cleaning (Art. No. 1.03.030) second generation (from 2018)

Note: Profile drills, bone contouring instruments and adapters for hand piece PF 3.0 do not have designated places in the surgical cassette for mechanical cleaning, first generation (Art. No. 1.03.030). However, they may be placed in the instrument holders of the surgical cassette for "optional instruments".

SURGICAL CASSETTE FOR MANUAL CLEANING (PLASTIC)

The surgical cassette made of plastic (Art. No: 1.03.016) is only for the use and sterilization of the Thommen implant system surgical instruments.

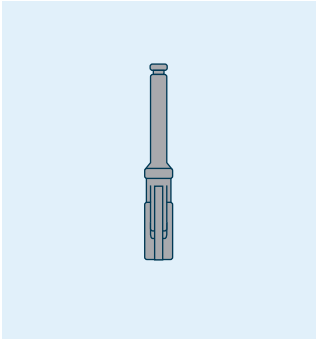
Mechanical cleaning of instruments or prosthetic components is only permitted for surgical cassettes for mechanical cleaning (Art. No: 1.03.030, first and second generation).

DRILL EXTENSION

Every VECTOdrill drill can be extended by 16.0 mm with the drill extension. Greater differences between drills and the mechanical drive can be bridged, especially with single tooth gaps or when using drill guides.

Only the narrow drill extension (Art: No. 3.03.231) with the external diameter of 3.7 mm may be used for the ELEMENT PF 3.0. The drill extension must not be used for the insertion of any implant.

You can find information on the processing of this product in the Thommen Medical processing instructions (www.ifu-tm.com/THM61131).



VECTOdrill™ PILOT DRILL MADE OF STEEL FOR SINGLE AND MULTIPLE USE

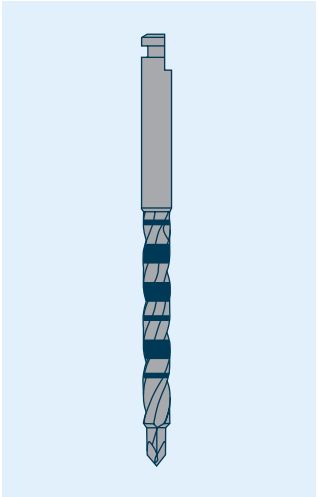
VECTOdrill pilot drills ∅ 2.0 mm for single and multiple use must be used to prepare the implant bed for ELEMENT PF 3.0.

VECTOdrill pilot drills are available in a length of 40.0 mm.

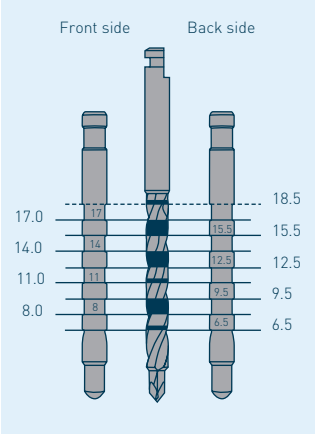
VECTOdrill pilot drills for single use are made of stainless steel and are delivered in a sterile package. This guarantees optimal protection against cross-infections and ensures high cutting properties. Product with the note "not reusable" marked on the packaging must not be reused under any circumstances (see notes on this from page 41 onwards).

The VECTOdrill pilot drills for multiple use are made from stainless steel and have a greater resistance to wear than the VECTOdrill drill for single use. Otherwise, they have the same geometry, are available in the same lengths as the VECTOdrill drill for single use and are used according to the same procedure as all other VECTOdrill drills. The drills for multiple use are supplied in a non-sterile condition and must be processed before first use. They may be processed a maximum of 10 times.

You can find information on the processing of this product in the Thommen Medical processing instructions (www.ifu-tm.com/THM61131).



DEPTH GAUGE



The depth gauge may be used after using the pilot drill ∅ for the ELEMENT PF 3.0.

The upper and lower edge of the notches on the depth gauge designate the drilling depths. The distance from edge to edge is always 1.5 mm and matches the depth marks on the VECTOdrill twist drills.

Check the drilling depth on the front or back of the depth gauge. The notches make it easier to read the drilling depth on the X-ray image.

You can find information on the processing of this product in the Thommen Medical processing instructions (www.ifu-tm.com/THM61131).

MONO TORQUE RATCHET

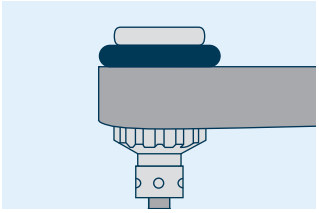
The MONO torque ratchet is manufactured from a solid billet of high-strength, titanium alloy and has the following advantages:

- can be used in surgery and prosthetics
- exceptional stability and longevity with consistent precision
- no parts to disassemble for cleaning or sterilization
- no maintenance

Step by step instructions on MONO torque ratchet use are described on pages 20 (Manual implant insertion) and 22/23 (Use of screwdriver).

Before using the torque ratchet ensure that the indicator on the bending arm is pointed exactly to "0" on the scale under no load. If this is not the case, the bending arm might be damaged and torque values will no longer be displayed correctly. In this case, the torque ratchet must no longer be used. The accurate indication of torque values is critical to the long-term success of screw-retained components.

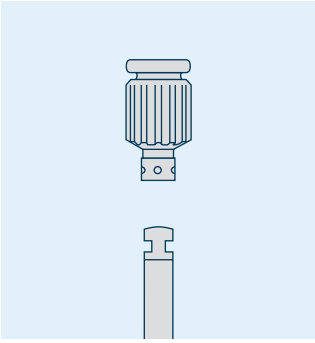
To achieve additional safety when using MONO instruments, the MONO circlip can be optionally used. This circlip is intended for multiple use, however, it must be replaced if its function starts to be compromised or signs of wear appear (cracks, brittleness).



Components, which are not intended for use with the MONO torque ratchet, must not be used with it in any circumstances. Incorrect use can damage the torque ratchet.

You can find information on the processing of this product in the Thommen Medical processing instructions (www.ifu-tm.com/THM61131).

MONO INSERTION DEVICE

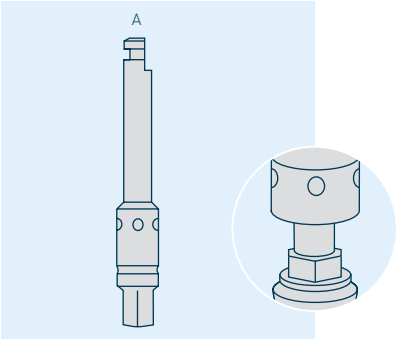


The MONO insertion device, short, is designed for the manual insertion and removal of ELEMENT PF 3.0 implants using the adapter for hand piece, one-piece.

Any instrument with a dental latch can, thus, be used with the MONO torque ratchet. The MONO torque ratchet can thus also be used with other systems.

You can find information on the processing of this product in the Thommen Medical processing instructions (www.ifu-tm.com/THM61131).

ADAPTER FOR CONTRA ANGLE, ONE-PIECE



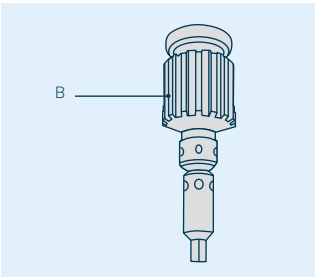
Use the one-piece adapter for the contra angle PF 3.5 (Art. No. 3.03.248) with the ELEMENT PF 3.0.

The one-piece adapter for handpiece (A) engages directly with the internal hexagon of the implant and thus allows for direct, precise transfer of the forces applied. It can be used after initially positioning of the implant, after the insertion aid has been removed.

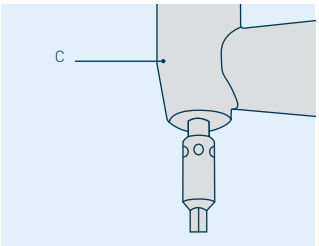
The following manipulations are possible:
- correction of the vertical implant position
- alignment of the implant hexagon

Subsequent corrections to the position can impair the primary stability of the implant.

The adapter for hand piece features six dots in a circle that indicate the corners of the internal hexagon and are used to align the implant and thus the superstructure. See page 21 for details.



The adapter for the contra angle can be used either manually with the MONO insertion device, short (B), or by mechanical means with a supported contra angle (C).



You can find information on the processing of this product in the Thommen Medical processing instructions (www.ifu-tm.com/THM61131).

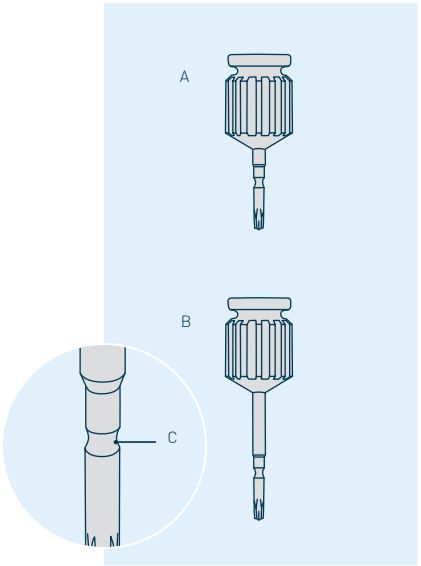
MONO SCREWDRIVER

MONO screwdrivers can be used to screw in and tighten all healing caps, gingiva formers and screws of the ELEMENT PF 3.0 implant system.

MONO screwdrivers are available in two lengths for the ELEMENT PF 3.0 implant. The screwdrivers, short (A) and long (B), are equipped with a finger rest for optimal guidance.

All screwdrivers have a 4-lobe screw head configuration which securely holds the corresponding Thommen implant system components and provides optimal torque transfer. Avoid exerting any non-axial pressure on the screwdriver. All screwdrivers feature a predetermined breaking point (C). If excess torque is applied the screwdriver will fracture at this point. If screws, healing caps and gingiva formers are tightened too firmly, the special instruments from the service set must be used.

You can find information on the processing of this product in the Thommen Medical processing instructions (www.ifu-tm.com/THM61131).



SERVICE SET FOR REMOVAL OF OVERLY TIGHTENED OR FRACTURED SCREWS

To remove overly tightened abutment screws which can neither be removed with the MONO screwdriver nor with the screwdriver for contra angle, Thommen Medical offers a service set for PF 3.5.

Note: The abutment screw can be fractured due to excessive force, such as in an accident. Abutment screws typically fracture directly below the head, or at the transition from the shaft to the thread. In this case, if the fractured part of the screw is flush with, or projects above the implant, loosen or unscrew the remaining part of the screw using ultrasound and/or a suitable instrument (e.g. forceps).

Contact your Thommen Medical representative for further details.

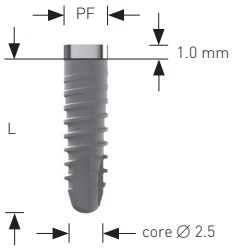
EXPLANATION

We recommend the implant removal instrument CC 3.0, Art. 37473, from Nobel Biocare for the ELEMENT PF 3.0 with the appropriate surgical torque ratchet, Art. 28839.

8. Overview and appendices

PRODUCT OVERVIEW

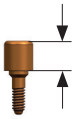
Rotation locked
Rotation unlocked



ELEMENT implant RC INICELL® PF 3.0, incl. healing cap, titanium

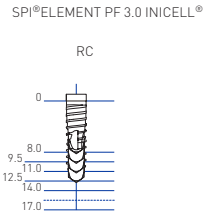
Length	core ∅ 2.5 mm
8.0 mm	**4.23.102**
9.5 mm	**4.23.103**
11.0 mm	**4.23.104**
12.5 mm	**4.23.105**

Healing caps for SPI®ELEMENT are included as standard in the delivery (component of the APLIQUIQ).



Gingiva former for PF 3.0, 4-lobe, titanium

Height	
3.2 mm	**4.03.538**
4.5 mm	**4.03.548**
7.0 mm	**4.03.558**



X-ray template, for planning with two-dimensional X-ray devices

for the ELEMENT implant RC **Fo_20d184.00**

X-ray reference sphere, stainless steel

∅	
5.0 mm	**3.03.140**

VECTOdrill™ pilot drill, reusable, stainless steel

		Pilot drill
Length		∅ 2.0 mm
40.0 mm	long	**3.03.730**

VECTOdrill™ Pilot drill, single use, sterile packed, stainless steel, 4 per pack (Q4)

		Pilot drill
Length		∅ 2.0 mm
40.0 mm	long	**3.03.611 Q4**

Bone contouring instrument for PF 3.0, reusable, stainless steel

Length	
29.0 mm	**3.03.658**

VECTOdrill™ depth gauge titanium

Length	∅ 2.0 mm
27.5 mm	**3.03.630**

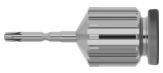
ELEMENT profile drill for PF 3.0, single use, sterile packed, stainless steel

for implants of lengths	8.0 mm	9.5 mm	11.0 mm	12.5 mm
	3.03.740	**3.03.741**	**3.03.742**	**3.03.743**

MONO insertion device, stainless steel/PEEK

	short
Length	15.4 mm
	3.03.162

latch-type instruments can be utilized with the MONO insertion device, short



MONO screw driver, 4-lobe, stainless steel/PEEK

	short	long
Length	22.2 mm	28.2 mm
Shaft length	10.3 mm	16.3 mm
	3.03.166	**3.03.167**

Drill extension, stainless steel

Length	External ∅	
26.0 mm	3.7 mm	**3.03.231**

Adapter for hand piece PF 3.0, stainless steel

Length	
28.0 mm	**3.03.238**

Screwdriver for hand piece, 4-lobe, stainless steel

	short	long	extra long
Length	22.0 mm	28.0 mm	38.0 mm
Shaft length	8.0 mm	14.5 mm	24.5 mm
	3.03.501	**3.03.502**	**3.03.503**

All latch-type instruments can be utilized with the MONO insertion device, short, with the MONO torque ratchet

MONO torque ratchet, titanium alloy

Length	
110.0 mm	**3.03.160**

MONO circlip, viton, 2 per pack (Q2)

2.03.170 Q2

Rotation locked
Rotation unlocked

Adapter for hand piece, one-piece, stainless steel

Length	
24.0 mm	**3.03.248**

VARIOunite abutment PF 3.0 for crown, incl. abutment screw, titanium alloy

Height	
12.0 mm	**1.04.138**

VARIOunite burn-out plastic cap, PF 3.0, POM

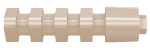
Height	
11.8 mm	**2.03.848**

Laboratory cylindrical pin, PTFE, 5 per pack (Q5)

Length	
70.0 mm	**2.03.450 Q5**

Impression coping PF 3.0 for open tray technique, reusable, retentive, screw-retained, titanium

	External ∅ 3.3 mm
cylindrical, height 16.0 mm	**3.04.028**



Screw for impression copings, reusable, 4-lobe, stainless steel

Length		
12.5 mm	extra short	**3.03.572**
21.5 mm	long	**3.03.574**
27.5 mm	extra long	**3.03.580**

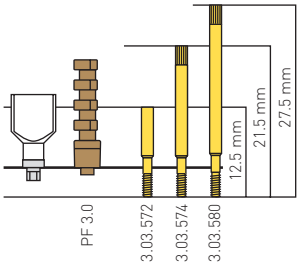
Rotation locked
Rotation unlocked

digital

Scan abutment, stainless steel, coated, PF 3.0

3.03.774

Selection of appropriate screw length:



digital

Implant analogs for CAD/CAM, titanium alloy

Length	
11.0 mm	**3.03.084**

Implant analogs for CAD/CAM are used if a digital impression is taken using an intraoral scanner.

Insertion device for implant analog for CAD/CAM, stainless steel

Length	
36.0 mm	**3.03.158**

Implant analog PF 3.0, titanium

Length	
14.0 mm	**3.03.098**

Abutment screw, 4-lobe, titanium alloy

Length	
5.8 mm	**4.03.500**

Surgical cassette, for mechanical cleaning, stainless steel/aluminum

Length × width × height	
274.8 × 176.0 × 63.6 mm	**1.03.030**

Instrument holder, for surgical cassettes, stainless steel/PEEK

Consisting of 2 holders	Size S	**8.03.090 Q2**
Consisting of 1 holder	Size M	**8.03.091**

Size S is compatible with the surgical cassette for guided surgery 1.04.020 and sizes S and M are compatible with the surgical cassette 1.03.030.

Container for surgical cassette, incl. identification plate
Thommen Medical, aluminum alloy

Length × width × height	
312.0 × 189.0 × 83.0 mm	**ER510.080E**

Single-use paper filter, 100 per pack

Length × width	
118.0 × 235.0 mm	**ER802.000N**

Permanent filter, 1200 sterilization cycles, PTFE

Length × width	
95.0 × 215.0 mm	**ER802.020**

ER802.000N and ER802.020 are compatible with Container ER510.080E.

9. General notes

THOMMEN IMPLANT SYSTEM

THOMMEN Medical

Manufacturer: Thommen Medical AG
Neckarsulmstrasse 28
2540 Grenchen, Switzerland
www.thommenmedical.com

LOT	Batch code
	Use by date
	Date of manufacture
STERILE R	Sterilized using irradiation
EC REP	Authorized representative
	Temperature limitation
	Do not re-use
NON STERILE	Non-sterile
	Caution
REF	Article number
CE	Conformity symbol as specified by EU Directive MDD 93/42/EEC
	Consult instructions for use
STERILIZE	Do not resterilize
	Do not use if package is damaged
	Atmospheric pressure limitation
	Manufacturer
	Keep away from sunlight
Rx Only	May only be sold to and prescribed by physicians (USA)
MD	Medical device
UDI	Single product code

COLORED WARNING STICKER
Application was changed – follow the directions in the corresponding instructions for use.

NEW HANDLING

New design – the application has not been changed.

NEW DESIGN

PRODUCT INFORMATION The information in this document describes the application of the Thommen Medical implant system. This information is available in electronic form online at: www.ifu-tm.com. The responsible country representative or distributor for Thommen Medical AG is available to provide technical advice.

COLOR CODE Each implant platform diameter has a color code, which can be found on all implant packagings, on the impression items and on most diameter-specific instruments.

TRACEABILITY
In order to ensure the traceability of the implantable products as well as the manufacturer, product type and product dimensions for a later prosthetic re-restoration, each product package comes with three patient labels. These labels should be used in the practice for documentation and for the implant passport.

Brown	=	PF 3.0
Yellow	=	PF 3.5
Green	=	PF 4.0
Blue	=	PF 4.5
Grey	=	PF 5.0
Purple	=	PF 6.0

AVAILABILITY Not all of the Thommen Medical products mentioned in these instructions for use are available in all countries. The responsible country representative or distributor of Thommen Medical AG informs about availability of Thommen Medical products for the country in question.

GENERAL RESTRICTIONS OF USE Restorations with cantilevers to individual implants are not recommended. Individual restorations with angled abutments should not be used in regions with high mechanical stress. For implants with a small diameter (PF 3.0 and 3.5), the prosthetic restoration should be constructed in such a way that large bending moment does not occur.

CONTRAINDICATION The Thommen Medical products may not be used on patients who are known to have allergies to the corresponding materials.

POSSIBLE COMPLICATIONS A stressed loading of the implant or abutment over and above its functional capacity can lead to excessive bone loss or fracture of the implant or restoration. The clinician must supervise the occlusion and functional loading of the prosthetic supraconstruction very carefully.

SIDE EFFECTS The patient should be informed about the possible side effects, interactions, precautionary measures and complications associated with Thommen Medical products.
Potential complications can occur immediately after insertion of dental implants:
Temporary symptoms: swelling, difficulties with speaking, gum inflammations, pain.
Longer lasting symptoms: chronic pain connected with the dental implant, localized or systemic infections, dysesthesia, loss of alveolar ridge (upper and lower jaw), oroantral or oronasal fistulas, irreversible damage to neighboring teeth, esthetic problems, nerve damage, hyperplasia.

WARNINGS All Thommen Medical products that come into effect inside the oral cavity must be protected against aspiration. Thommen Medical products have not been tested for safety and compatibility in an MR environment. Thommen Medical products have not been tested for heating or migration in the MR environment. The safety of Thommen Medical products in the MR environment is unknown. Magnetic resonance tomographic examinations of patients, who have been treated with Thommen Medical products, may result in patient injuries.

RESPONSIBILITY/LIABILITY As a part of an overall scheme, Thommen Medical products may be used only with the related original components and instruments in accordance with the instructions for use provided by Thommen Medical. The use of non-system parts may compromise the performance of Thommen Medical products and lead to failures. Users must have appropriate knowledge and information about the handling of Thommen Medical products in order to use the products safely and correctly. The user is obliged to use the Thommen Medical products according to the instructions for use and to check whether the product is suitable for the individual patient situation. The use of Thommen Medical products is the responsibility of the user, as such, beyond the control of Thommen Medical AG. We refuse to accept any responsibility or liability for any damage due to incorrect utilization of the product. Products labeled «Do not re-use» may not be refurbished and/or reused. The refurbishment and/or reuse of these products can affect their function (e.g. fitting and/ or cutting properties) as well as their safe use (e.g. risk of infection, disease transmission, fading of the laser or color marks, corrosion). Detailed information about the possible consequences, which may result from incorrect use, is available from the responsible country representative or distributor of Thommen Medical AG. All serious incidents which have occurred in connection with the product must be reported to the manufacturer and the competent authority of the Member State, in which the user is resident.

GUARANTEE The comprehensive guarantees can be found in the country-specific guarantee leaflets.

TRANSPORT AND STORAGE Please note the specifications on the labels and instructions for use regarding transportation, storage and handling. If the packaging is damaged, the products must not be used; a visual inspection is necessary. Under no circumstances may Thommen Medical products be used beyond the expiry date, as proper functioning or sterility of sterile packaged products cannot be guaranteed by the manufacturer.

APPLICATION The following descriptions are not intended as comprehensive for the. immediate use of the Thommen Medical Implant System. Training by a specialist experienced in the use of this system is recommended

GUARANTEE OF STERILITY In general, products of the Thommen Implant System supplied in sterile packaging must not be re-sterilized Sterile-packed products, whose packaging is damaged, must not be used under any circumstances. Sterile-supplied products, which have not been used for the surgical operation, whose packaging has been opened are considered as having been used and must not be used thereafter. In the event of resterilization, proper function and the sterility cannot be guaranteed by the manufacturer. The products intended for single use must never be reprocessed, sterilized or reused and must be disposed of safely and properly after use in compliance with all applicable legal and regulatory requirements. Reusable products must be reprocessed according to the instructions for use and, if used on patients, sterilized. They must be checked for their integrity before each use. Any damage (for example, scratches, cracks, nicks, dents), as well as bent parts, means that they must not be used any longer. The number of reprocessing cycles is limited and must be monitored. If the number of cycles is exceeded, proper function and sterility of the product are not guaranteed by the manufacturer anymore.

DISPOSALIn the case of cutting products, there is always a risk of injury, therefore the products must be disposed of safely and properly after use, observing all applicable legal and regulatory requirements. For products and their accessories, which have been used on a patient, there is a risk of an infection. Our products are designed and produced so that they can be disposed of safely and correctly after use in compliance with all valid legal and regulatory requirements.

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