Surgical procedure.

The Thommen Implant System PF 3.5-6.0

Instructions for use THM61141

Version 009_AA, Issue date 09/22

THOMMEN Medical

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ELEMENT and CONTACT (detachable)

1. At a glance

This surgical procedure relates to all Thommen Medical implants including the associated instruments PF 3.5-PF 6.0.

The SPI®ELEMENT implant and SPI®ELEMENT INICELL® and the SPI®CONTACT implant and SPI®CONTACT INICELL® are called implants in this document for the sake of simplicity.

You can find more information on the intended purpose, indications, contraindications, restrictions of use, clinical use, healing phases and material relating to ELEMENT/CONTACT INICELL® APLIQUIQ® implants in the instructions for use THM61112, «www.ifu-tm.com/THM61112».

You can find more information on the intended purpose, indications, contraindications, restrictions of use, clinical use, healing phases and material relating to ELEMENT/CONTACT implants in the instructions for use THM61113, «www.ifu-tm.com/THM61113».

You can find more information on the Thommen 3.0 Implant System in the instructions for use THM61146, «www.ifu-tm.com/THM61146».

Intended purpose

Thommen Medical instruments are used in combination with the Thommen Medical Dental Implant System in the upper and lower jaw for implant-borne tooth replacement.

Restriction of use for sterile products

The VECTOdrill™ twist drills as well as the ELEMENT/CONTACT profile drills are intended for single use. The sterility period for the VECTOdrill™ twist drills is thus 7 years which is the same as the ELEMENT/CONTACT profile drills.

Indication

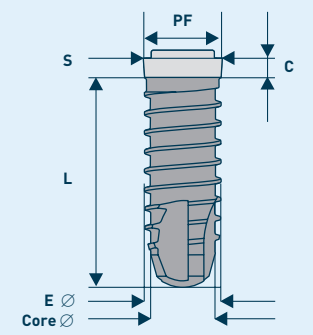
Thommen Medical instruments are used in combination with the Thommen Medical Dental Implant System in partially edentulous/edentulous upper and lower jaw for restoration of masticatory function.

Contraindication

Thommen Medical instruments are used exclusively in combination with the Thommen Medical Dental Implant System and are thus subject to the contraindications for implants. See www.ifu-tm.com/THM61112 and www.ifu-tm.com/THM61113.

2. 5 Implant specifications

Nomenclature



The clinically relevant properties of Thommen implants are defined as follows:

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 (see next page).

C = collar
Collar height – refers to the absolute height of the machined collar. At 0.5 mm the collar of the MC implant (Minimized Collar) is shorter than the Regular Collar (RC). The LC implant (Long Collar) at 2.5 mm has the longest collar.

S = shoulder
Refers to the coronal level of the implant. For MC implants it is the level that is positioned crestally. The shoulder diameter corresponds to the platform diameter.

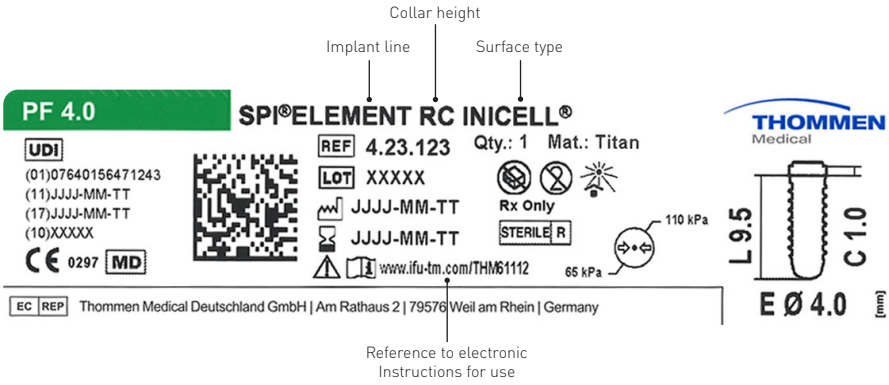
L = endosseous length
Length of the implant without collar (except for MC implants, in which the collar height is included in the total length L). The length L thus always corresponds to the endosseous insertion depth (drilling depth) when preparing the implant bed.

E ∅ = endosseous diameter
Refers to the largest external diameter of the implant thread (in the parallel-walled part of the implant).

Core ∅ = core diameter
The core diameter corresponds to the drill diameter.

Labeling

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



You can find the electronic instructions for use at: www.ifu-tm.com. Enter the corresponding 5-digit THM number of the product for this. For example: «www.ifu-tm.com/THM61112» for the ELEMENT RC INICELL® implant shown on the label.

Color coding

For easy identification, each platform diameter of the Thommen Implant System has a specific color:

PF 3.5	PF 4.0	PF 4.5	PF 5.0	PF 6.0
Yellow	Green	Blue	Grey	Violet

All implant packages have a color-coded label. This simplifies logistics and prevents mistakes. To the extent that there is a clear assignment to a platform, all the labels of impression copings and secondary components can also be easily identified by the platform-specific color.

Healing caps, gingiva formers and impression copings are color-coded.

3. Treatment planning

Essentials

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.

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 is crucial.

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

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

X-ray templates are available for planning, using 2-dimensional X-ray images (see Fo_20d184 and Fo_20d185). (see p. 9)

Sterility

Sterilization method

All Thommen implants as well as all sterile packaged cutting instruments are sterilized with at least 25 Kilogray (kGy) of gamma irradiation.

Clinical use

Implant lines

Thommen offers two implant lines. The parallel-walled ELEMENT implant as a universal implant and the conical-cylindrical CONTACT implant.

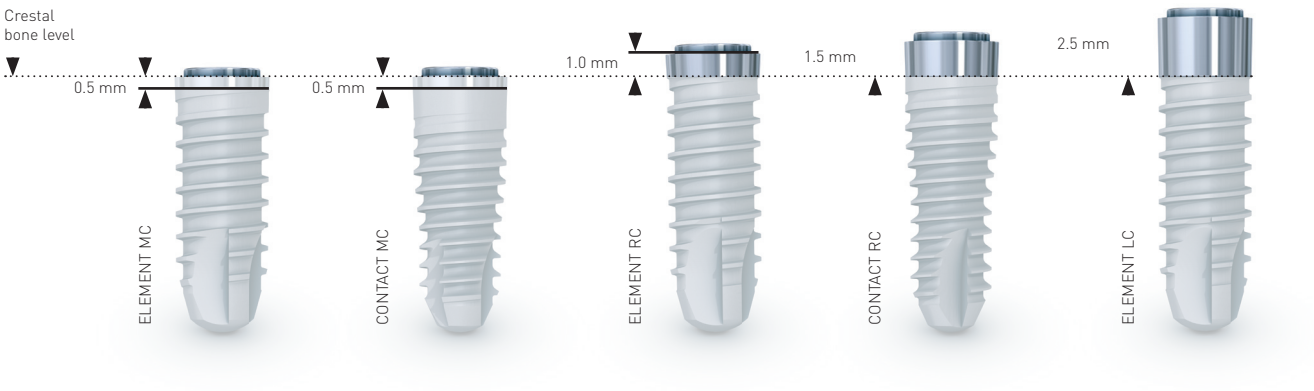
Due to its conical-cylindrical design, the CONTACT implant is indicated for:

- immediate or delayed placement in extraction sockets.
- special anatomical situations such as converging roots or alveolar ridge concavities.

ELEMENT and CONTACT collar heights

ELEMENT and CONTACT implant lines are offered with various collar heights.

ELEMENT and CONTACT implants with a collar height of 0.5 mm (MC, Minimized Collar) are designed for crestal positioning. Implants with a greater collar height (RC, Regular Collar) should be placed supracrestally. The ELEMENT LC implant (LC, Long Collar) is designed for transgingival positioning.



Selection of ideal implant diameter, positioning and length

X-rays

X-ray images provide information about vertical bone volume, and the relation of adjacent dental structures to the planned insertion site. 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.

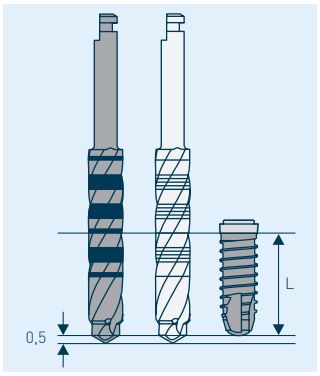
⚠ **Important:** Small parts which are used in the oral cavity must be secured against aspiration.

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	X-ray templates for ELEMENT MC, RC and LC implants
Fo_20d185	X-ray templates for CONTACT MC and RC implants

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



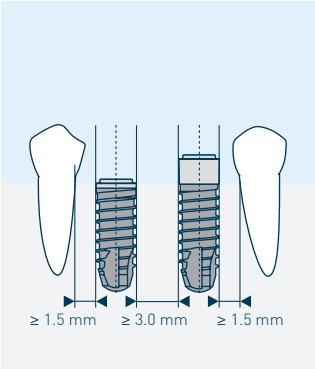
⚠ **Important:** Due to the function and construction of the drills, all VECTOdrill™ twist drills are 0.5 mm longer apically than the specified length of the respective Thommen implants. In order to avoid complications, this must be taken into account when choosing and positioning of the implant, particularly in proximity to anatomical structures.

DVT or CT-based planning
There are various planning systems, which contain data on the Thommen Implant System, for planning based on 3D X-ray procedures.

The current list can be found on the Thommen Medical website under the heading "Planning software".

Thommen supports guided surgery (see p. 25).

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



As a rule of thumb: distance from the adjacent tooth = half the platform diameter (measured from the center of the implant) + at least 1.5 mm.

The minimum required gap width for inserting an implant can be determined correspondingly as the platform diameter of the implant + 3 mm.

The minimum distance between two implants at bone level should be 3 mm.

As a rule of thumb: Distance from the adjacent implant (measured from the center of the implant) = half the platform diameter (implant 1) + half the platform diameter (implant 2) + at least 3 mm.

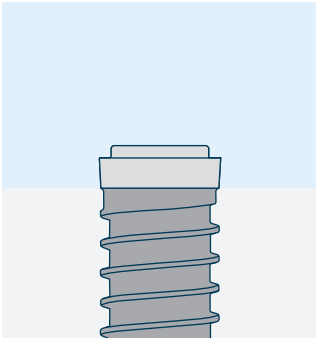
The mesiodistal position of the implants can be easily estimated by using a periodontal probe placed vestibularly or determined with a gauge.

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 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.

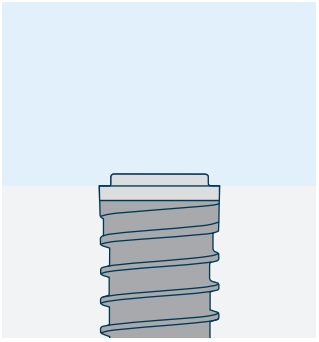
Vertical position and soft tissue situation
An important part of preoperative planning is estimating the attachment height of adjacent teeth and measuring soft tissue characteristics (in particular the thickness and mobility of soft tissue). The vertical position of the implant and the length of the machined implant collar can be defined in conjunction with the selected prosthetic restoration and the X-ray diagnostic results.

Thommen Medical offers implant lines with different collar heights in order to satisfy varying clinical situations.

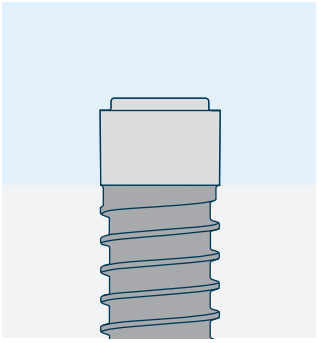
The regular collar heights (RC) allow for the biological situation resulting from the supracrestal position in standard situations.



The minimum collar height (MC) is suitable for situations, in which for esthetic reasons a crestal placement is more favorable, (e.g. such as low soft tissue volume, thin gingival biotype, situations after bone augmentation and low vertical jaw relation).



In an edentulous jaw an uneven progression of gingival height often necessitates a longer collar height. LC implants are ideally suited for transgingival use in restorations with hybrid prosthetics.



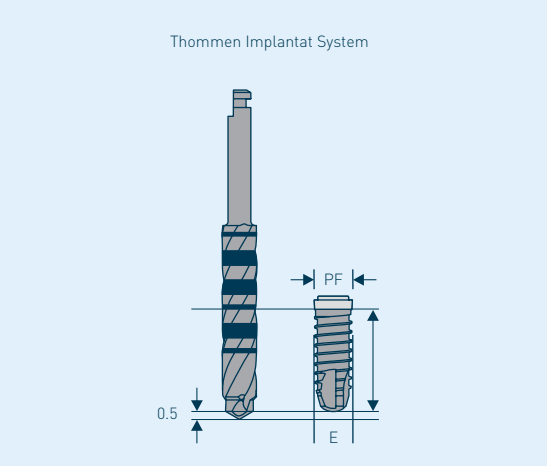
⚠ **Important:** The conical-cylindrical shape of the CONTACT implant requires a particularly careful adherence to the surgical technique. In essence, the CONTACT implant must never be inserted deeper than planned, measured and predrilled.

4. Implant bed preparation

Essentials

The implant bed preparation for Thommen implants using VECTOdrill™ drills reduces the number of instruments needed to a minimum. Surgery time can be further reduced by careful preparation, arrangement of the required surgical instruments and suture material. This can have positive effects on postoperative healing.

Any implant bed preparation for Thommen Implant System implants starts by using the VECTOdrill™pilot drill to accurately define the drilling axis and drilling depth. This is followed by sequential preparation with
the VECTOdrill™ step drills (see pages 31– 33 for product details). All VECTOdrill™ twist drills feature a tapered tip which corresponds to the diameter of the preceding drill. This axis guidance prevents slippage of the drill and ensures a precisely shaped implant bed.



⚠ **Important:** Due to function and design requirements, all Thommen Implant System drills are 0.5 mm longer than the actual insertion depth of the implants.

When using ELEMENT implants, a final profile drilling is only required with the crestal placement of ELEMENT MC implants (see chapter «Implant bed preparation for the ELEMENT implant line», p. 13). When using CONTACT implants, profile drilling is always required (see p. 14).

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. The rotation speeds to be used are subject to the respective drill size: with ascending drill diameter the rotation speed reduces (see back cover page).

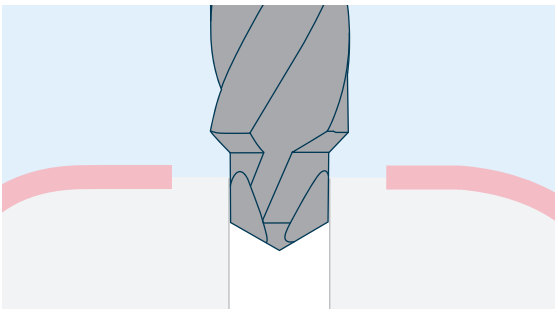
Regularly remove the bone chips to ensure ideal drilling performance.

Check the drilling depth and drilling axis of the implant bed
at each drilling step with the corresponding depth gauge (see p. 33).

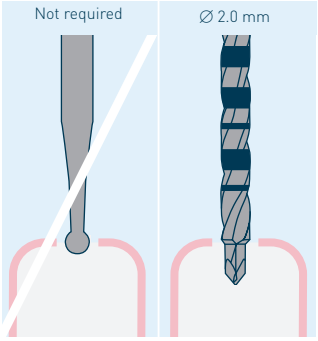
Secure the products used in the oral cavity against aspiration.

Complete clinical and X-ray documentation is recommended.

The operational sequences shown below refer to implantation in medium to hard bones. See chapter "Implant bed preparation in extremely hard bone" for implantations in very hard bone, p. 29.



Pilot drilling

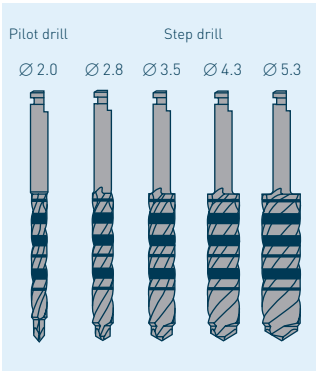


First, prepare the drill hole with the VECTOdrill™ ∅ 2.0 mm pilot drill. This drill hole has special significance since it defines the drilling depth and drilling axis.

The small/narrow drill bit 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 at a maximum of 800 rpm while exerting slight axial pressure until the required depth is reached. Pilot drills, unlike other twist drills, have the attribute of also cutting laterally and thus allow for easy axis corrections. Always perform lateral drilling corrections with the pilot drill carefully and with the drill turning. See (also) page 25 for guided pilot drilling.

Implant bed preparation for the ELEMENT implant line



The sequential use of VECTOdrill™ twist drills is presented in the following overview (see also the appendix with the ELEMENT and CONTACT drilling protocols on the back cover). Using the last VECTOdrill™ twist drill completes the implant bed preparation for RC and LC implants and the implant can be placed immediately.

The implant shoulder of MC implants must be positioned crestally. When using ELEMENT MC, be certain to use a profile drill in every case when preparing the implant bed to prevent the implant from exerting pressure on the crestal bone edge. The use of the ELEMENT profile drill is described in the chapter "Profile drill" (see p. 14).

Overview of ELEMENT drilling protocol

PF 3.5 endosseous ∅ 3.5 mm	PF 4.0 endosseous ∅ 4.0 mm	PF 4.5 endosseous ∅ 4.2 mm	PF 5.0 endosseous ∅ 5.0 mm	PF 6.0 endosseous ∅ 6.0 mm	Speed rpm
2.0 pilot drill	**2.0** pilot drill	**2.0** pilot drill	**2.0** pilot drill	**2.0** pilot drill	800
2.8 VECTOdrill™	**2.8** VECTOdrill™	**2.8** VECTOdrill™	**2.8** VECTOdrill™	**2.8** VECTOdrill™	600
	3.5 VECTOdrill™	**3.5** VECTOdrill™	**3.5** VECTOdrill™	**3.5** VECTOdrill™	500
			4.3 VECTOdrill™	**4.3** VECTOdrill™	400
				5.3 VECTOdrill™	300
3.5/3.5 ELEMENT Profile drill *	**4.0/4.0** ELEMENT Profile drill *	**4.2/4.5** ELEMENT Profile drill *	**5.0/5.0** ELEMENT Profile drill *	**6.0/6.0** ELEMENT Profile drill *	250-300

* only with ELEMENT MC and in very hard bone

Implant bed preparation for the CONTACT implant line

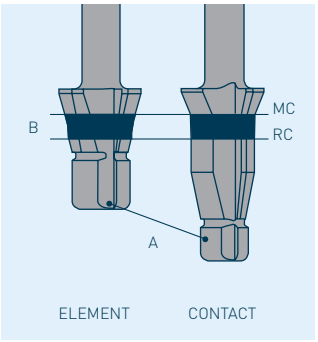
The sequential use of VECTOdrill™ twist drills is presented in the following overview (see appendix). When using CONTACT implants, profile drilling is always required.

Overview of CONTACT drilling protocol

PF 3.5 endosseous ∅ 2.7 mm	PF 4.0 endosseous ∅ 3.5 mm	PF 4.5 endosseous ∅ 3.5 mm	PF 5.0 endosseous ∅ 4.2 mm	PF 6.0 endosseous ∅ 5.0 mm	Speed rpm
2.0 pilot drill	**2.0** pilot drill	**2.0** pilot drill	**2.0** pilot drill	**2.0** pilot drill	800
	2.8 VECTOdrill™	**2.8** VECTOdrill™	**2.8** VECTOdrill™	**2.8** VECTOdrill™	600
			3.5 VECTOdrill™	**3.5** VECTOdrill™	500
				4.3 VECTOdrill™	400
2.7/3.5 CONTACT Profile drill	**3.5/4.0** CONTACT Profile drill	**3.5/4.5** CONTACT Profile drill	**4.2/5.0** CONTACT Profile drill	**5.0/6.0** CONTACT Profile drill	250-300

Profile drill: Use WITH implants of varied collar heights

Due to the varying implant design of ELEMENT and CONTACT, there is a corresponding profile drill for each implant line.



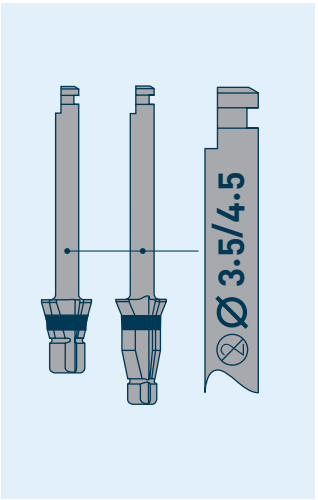
The profile drills feature an integrated guide tip (A) that corresponds to the diameter of the preceding drill hole with the VECTOdrill™ twist drill. This permits the profile drill to be accurately aligned in the pre-drilled hole and thus offers optimum safety to the user while shaping the coronal implant bed.

All profile drills feature the same 1.5 mm depth marking (black band «B»). This height matches the depth markings of the VECTOdrill™ twist drills and depth gauges.

With ELEMENT MC and CONTACT MC, preparation as far as the top edge of the depth marking follows the standard protocol.

Preparation to the bottom edge of the depth marking follows the standard protocol for all CONTACT RC implants.

The standard protocols for using the profile drill, including the maximum speed to be used, are shown in the respective overviews (see appendix). If the insertion depth of ELEMENT RC or CONTACT RC is increased, the profile drill has to be used in every case. For further special instructions on this procedure, see chapter "Implant bed preparation in extremely hard bone", p. 29.



The first number on the shaft corresponds with the endosseous diameter, while the second number corresponds with the implant platform (PF)

⚠ **Important:** The profile drills are for single use and are supplied in sterile packaging. Sterile instruments for single use may be placed into the designated instrument holders of the surgical cassette only after sterilization. Load sterile instruments/prosthetic components under sterile conditions (sterile assistant) and ensure that instruments in the cassette are not contaminated through this.

5. Implantation

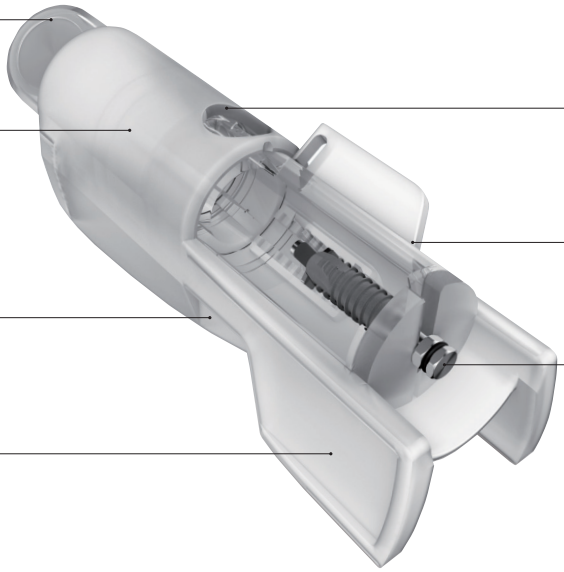
Essentials

In order to ensure the traceability of the implants as well as to relay the pertinent information of manufacturer, implant type and implant dimensions also for a later prosthetic re-restoration, each implant package comes with three patient labels. These labels should be used in the practice for documentation and for the patient passport. Fill in the implant ID card as shown in: www.ifu-tm.com/THM61154 and give the completed implant ID card to the patient. The Summary of Safety and Clinical Performance for the products listed in these instructions for use is available in the Download Center at: www.thommenmedical.com. If anything is unclear, please contact the responsible member of the field sales force.

Thommen implants are sterile and are double-packed. Remove the implant in the sterile packaging and protective packaging from the cardboard box and check for damage. Sterility is not guaranteed if implants are removed from damaged packaging or if implants are not used immediately after opening the packaging.

Follow the directions for aseptic working when removing the implant container out of the sterile packaging and the implant from the implant container.

APLIQUIQ®



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.

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

Healing cap
The healing cap can be removed in the half-open position of the lid.

Lid
The rotating lid offers access to the implant and healing cap.

Implant
Implants are mounted on the insertion aid.

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Surface conditioning with APLIQUIQ®

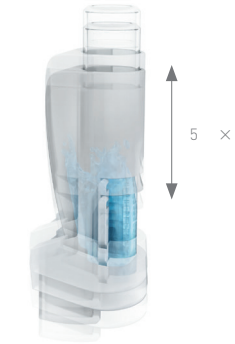
Conditioning is performed immediately before implantation using the APLIQUIQ® conditioning system. Remove the APLIQUIQ® container from the sterile packaging and activate by pressing the liquid-filled cartridge.

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

Afterwards hold APLIQUIQ® horizontally and allow the conditioning agent to

flow into the integrated reservoir.

The effect of INICELL® lasts after conditioning during the treatment time of the patient. The liquid must not be used any further.



Removing the implant from the APLIQUIQ® container

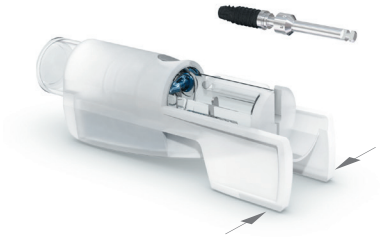
After conditioning, remove the rubber cap on the rear of the applicator in the direction of the arrow. Place the applicator horizontally on a firm surface.

Rotate the lid to an unobstructed view of the implant and the insertion aid. Ensure that the implant is entirely conditioned and wet.

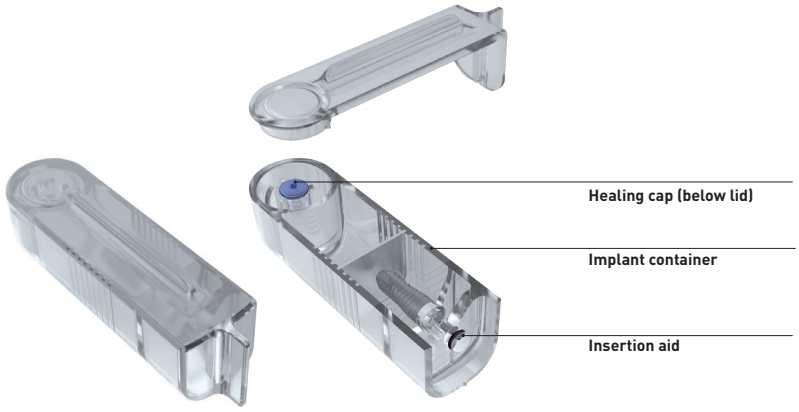
Attach the MONO insertion device or the adapter for hand piece to the insertion aid. Press the lateral wings on the applicator together, so that a gap in the implant holder opens. Carefully remove the implant from the implant holder without turning it.

The implant can be inserted manually (using the MONO insertion device) or mechanically (with the adapter for hand piece) (see p. 19– 20).

For implants that are not packaged in APLIQIQ,® proceed similarly and remove using the MONO insertion device or the adapter for the hand piece (see explanations below).

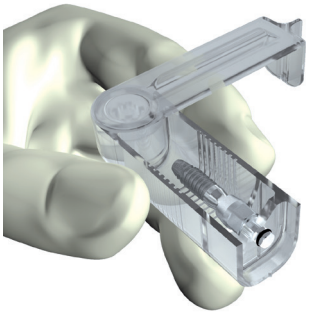


Standard packaging for implants



Remove the implant from the standard packaging

Hold implant container as shown. Swivel the lid until resistance is felt.



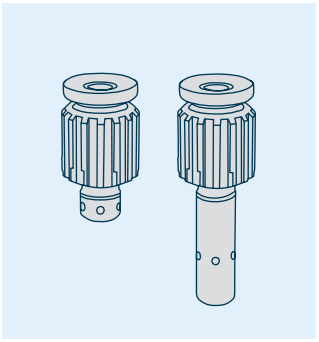
Place the insertion device on the insertion aid and carefully remove the implant from the implant container without rotating the implant.

Manual implant insertion

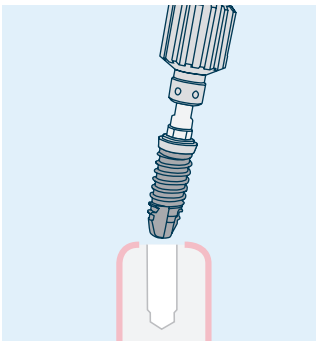
Two insertion tools are available for the manual implant insertion of Thommen implants using the MONO torque ratchet: the MONO insertion device, short, and the MONO insertion device, long.

Both instruments feature an internal hexagon for accepting the pre-mounted insertion aid on the implant.

Without the insertion aid (due to being unsterile or lost), work can be done with the adapter for handpiece, one-piece (see p. 36).



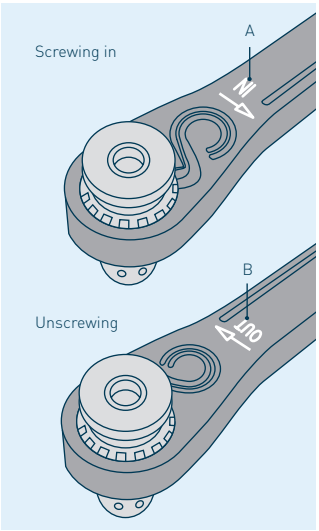
Insert the implant into the prepared implant bed. Manually screw in the implant with the MONO insertion device to the point where the implant is seated firmly in the bone.



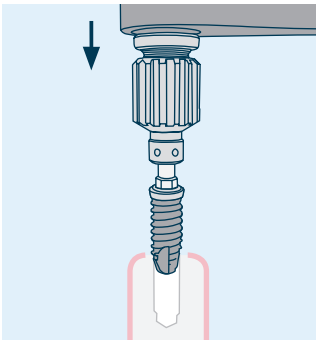
Afterwards continue working with the MONO torque ratchet.

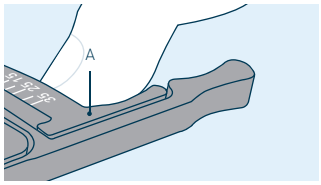
Do not force the ratchet onto the insertion device. The torque ratchet should simply slide over the ratchet body of the MONO instrument. If this is not the case, the parts are not aligned correctly and must be realigned accordingly and checked for damage.

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 insertion or tightening, place the torque ratchet on the ratchet body in such a way that the side marked "IN" points upward, and so that the word "OUT" points upward for unscrewing.

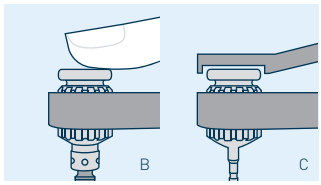


See Page 34 for further information on using the torque ratchet. To achieve additional safety when using MONO instruments, the MONO circlip can be optionally used.

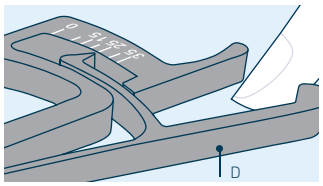




Screw in the implant with slow movements of the ratchet. To screw in, guide the ratchet on the rigid arm (A) as shown in the picture.

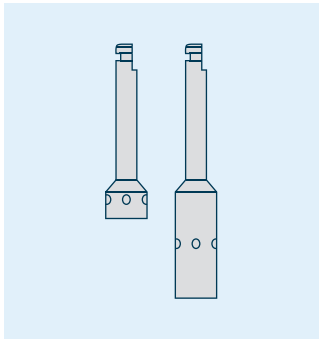


The ratchet can be guided either with the finger on the finger rest (B) or the guide key (C).



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

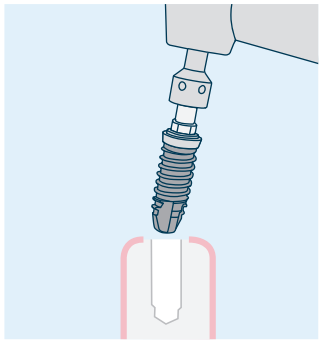
Mechanical implant insertion



To mechanically insert the implant, the handpiece adapter comes in two lengths.

⚠ **Important:** Only supported handpieces must be used for mechanical insertion under power.

Push the handpiece with inserted handpiece adapter over the insertion aid until it stops against the APLIQUIQ® implant container.



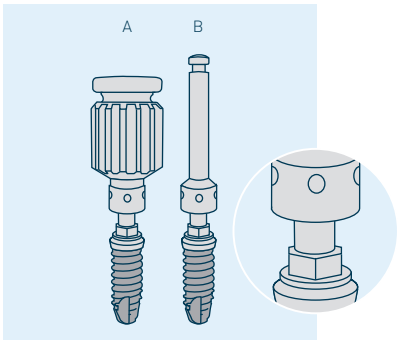
While screwing in the implant under power, always exert a slight axial pressure on the handpiece. This ensures that the insertion aid completely engages with the internal hexagon of the implant and the insertion aid can be removed without any problems after implantation.

The maximum rotation speed is 15 rpm

Alignment of the internal hexagon

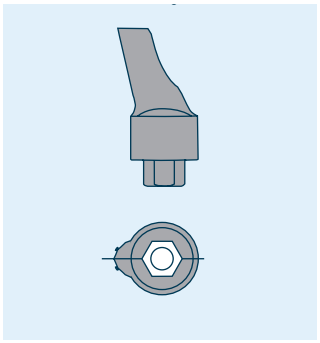
The internal hexagon needs to be perfectly aligned if angled abutments (e.g. SPI®EASY or SPI®VARIO) are to be used in the prosthetic restoration.

The devices for screwing in the implants – MONO insertion device (A), Adapter for handpiece (B) and Adapter for handpiece (one-piece) – are marked with six dots. These dots are used for the alignment of the implant, marking the position of the corners of the internal hexagon and thus the superstructure.



To ensure adequate access to the abutment screw channel, we recommend aligning one of the points strictly in a labial direction.

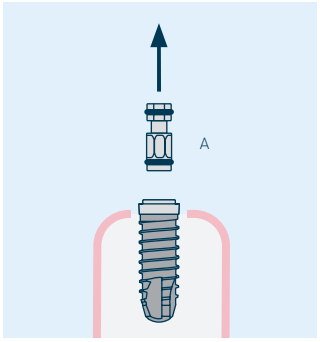
See the instructions for use for the respective abutments.



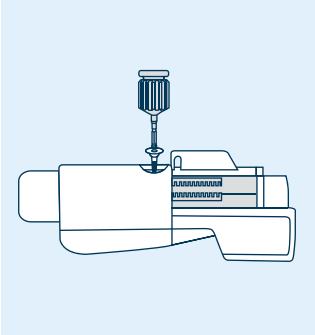
Removing the insertion aid

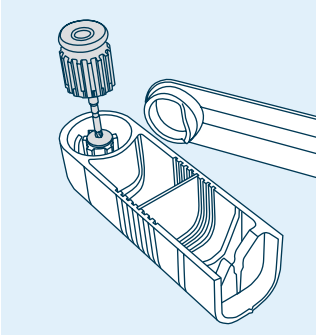
Take the insertion aid (A) out of the implant in an axial direction.

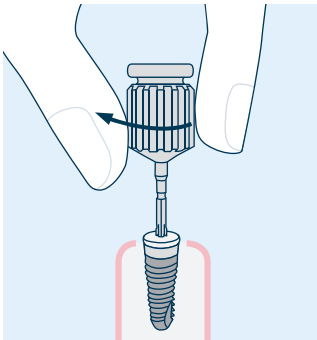
⚠ **Important:** If there is high insertion torque after screwing in the implant with the adapter, make a short counter-movement (counter-clockwise). This facilitates removing the insertion aid.

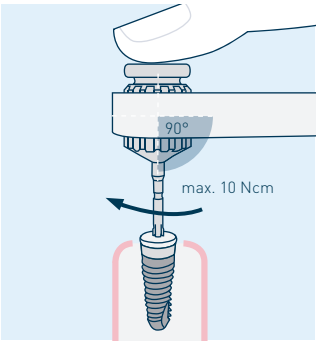


Insertion of healing cap (gingiva former)/ use of MONO screwdriver









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

Removing the healing cap from the standard packaging: support both hands on a firm surface and remove the lid of the implant container by continuing to turn it beyond the point of resistance (do not fold down). Then place the screwdriver directly onto the healing cap and transfer to the implant.

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.

⚠ **Important:** Tightening by hand with the MONO screwdriver can subject the healing cap/gingiva former to such a high torque that it can be damaged. Thus for final tightening only use the torque ratchet with the indicated maximum torque (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.

A list of all torque values can be found on page 42. The overview of torque values is on the Thommen Medical website and can be downloaded at www.ifu-tm.com/THM61122 and can also be ordered separately in English (Fo_22d123).

Gingiva formers must not have any occlusal contact.

Shaping of the gingiva

Thommen offers standardized titanium gingiva formers in various heights (see p. 37). Furthermore, the emergence profile can be shaped with customizable/individualizable gingiva formers (see p. 38).

Provisional and final restorations

The implant can be provisionalized in a variety of ways. SPI®VARIOunite and SPI®VARIOtemp abutments are thus available for provisional restorations.

Single-tooth implants can also be temporarily restored with the customizable gingiva former (see p. 38).

Thommen Medical offers a comprehensive range of abutments for the final restoration using the Thommen Implant System. An overview of abutments can be found in the product catalogue «www.ifu-tm.com/THM31111».

See the corresponding instructions for use for more detailed information on using the abutments.

The information can also be found on the Thommen website:
www.thommenmedical.com

6. Instruments and techniques – good to know!

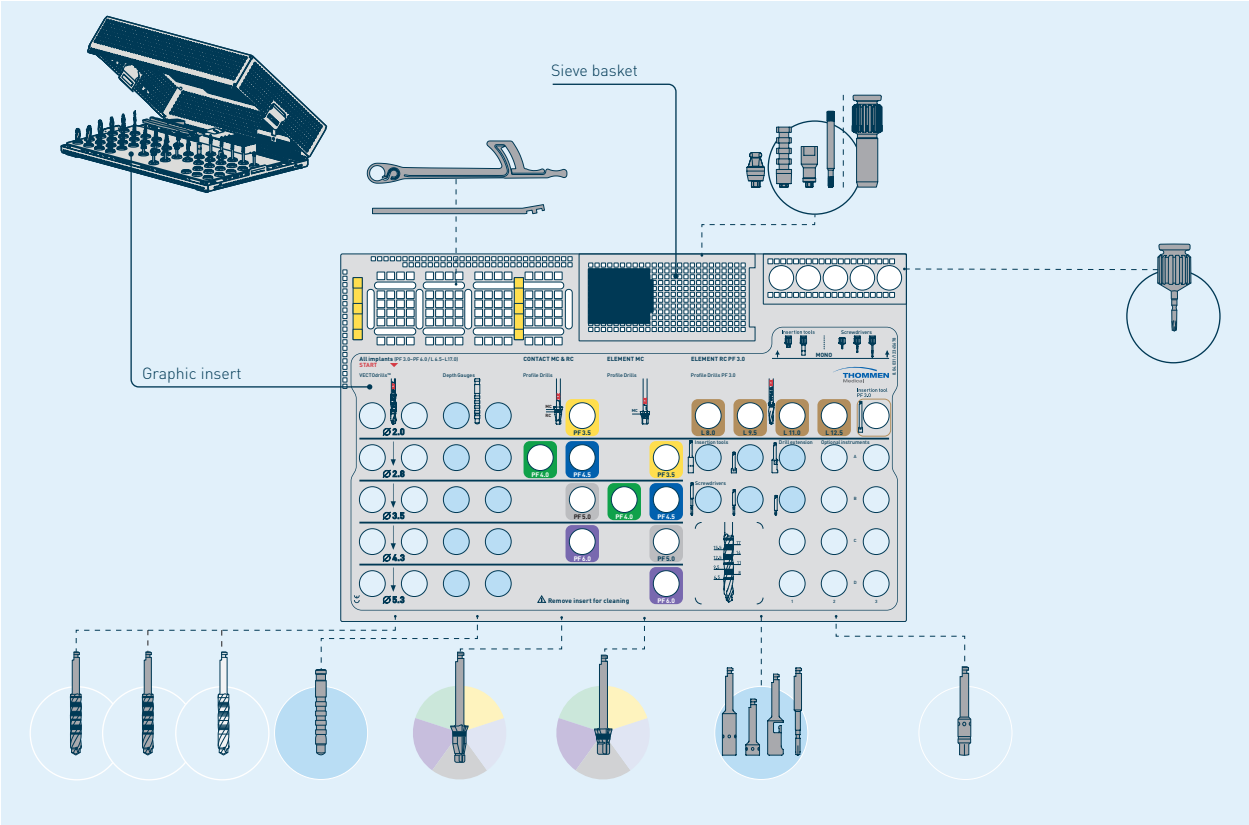
Surgical cassette for mechanical cleaning

The surgical cassettes for mechanical cleaning (art. no. 1.03.030 - generation 01 and 02) play a pivotal role in the processing of Thommen instruments and prosthetic components for multiple use.

Instruments and prosthetic components (for multiple use) may be cleaned and sterilized according to validated processes.

The graphic insert guides the user through the required surgical sequence for implant bed preparation for all Thommen implant lines.

The instruments for implant bed preparation are arranged according to the drilling sequences and marked by pictograms. This facilitates the sorting of the instrument set and ensures the set is complete.



Surgical cassette for mechanical cleaning. Art. no. 1.03.030 generation 02.

You can find information on the use of the surgical cassette for mechanical cleaning in the processing instructions THM61131, «www.ifu-tm.com/THM61131».

The previous version of the surgical cassette (art. no. 1.03.030 – generation 01) Its use is described in the instructions for use THM61131 – Version 001, «www.ifu-tm.com/THM61131».

Other surgical cassettes (e.g. plastic) are used only for use and sterilization of the Thommen implant system surgical instruments. Mechanical cleaning of instruments or prosthetic components is not possible with these cassettes.

Guided surgery

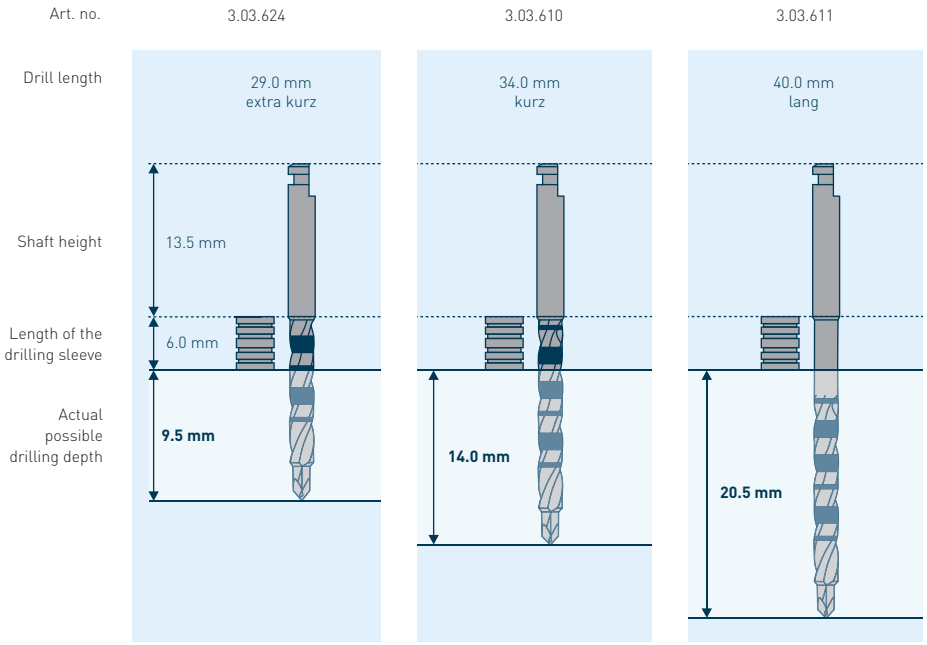
There are various planning systems, which contain data on the Thommen Implant System, for planning based on 3D X-ray procedures. You can find information at www.thommenmedical.com under the heading "Digital Solutions".

Thommen supports guided surgery both with a pilot solution and a guided surgery kit for fully guided surgery, including implant insertion.

Thommen Medical recommends using drill guides with the "Open Flap Technique".

Guided pilot drilling
To define the drilling depth, the guide sleeve can be used in combination with the ∅ 2.0 mm VECTOdrill™ pilot drill as a stop. The guide sleeve must be accurately positioned in the drill guide, taking into account the vertical distance between the guide sleeve and the bone.

The following table provides guidance on which drilling depths are achieved with the respective pilot drill by using the guide sleeve (art. no. 3.03.141).

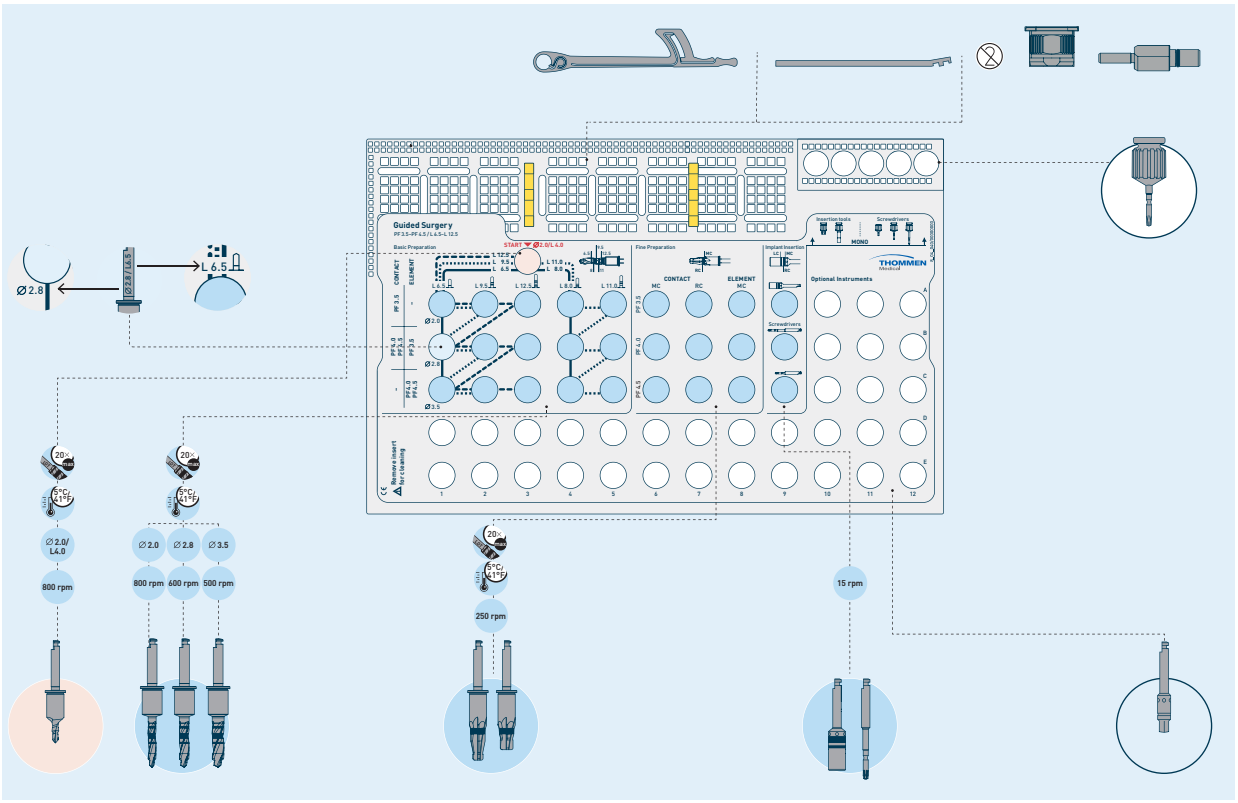


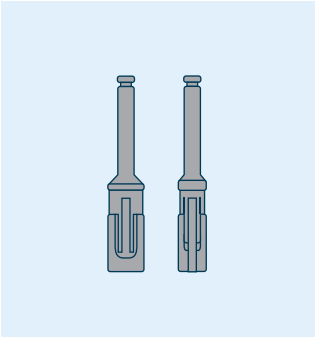
Alternative solution

The StecoGuide double-sleeve system (steco system technik GmbH & Co. KG, Hamburg, www.steco.de) enables guided drilling sequences up to the VECTOdrill™ twist drill ∅ 3.5 mm. You can find further information at www.thommenmedical.com under the heading "Digital Solutions".

Fully guided surgery
The guided surgery system is available for PF 3.5 to 4.5 / L 6.5 to 12.5 for all implant lines. The guided surgery cassette (art. no. 1.04.020) must be used with the associated guided instruments for the guided surgery system.

You can find more information on fully guided surgery at:
«www.ifu-tm.com/THM61144».





Drill extension

Every VECTOdrill™ twist drill and thread tap 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.
The drill extensions come in two sizes:

- for PF 3.5 and PF 4.0: exterior ∅ 3.7 mm
- for PF 4.0 and greater exterior ∅ 5.0 mm

You can find information on the processing of this product in the processing instructions THM61131, «www.ifu-tm.com/THM61131».

⚠ **Important:** The drill extension must not be used for insertion of any implant.

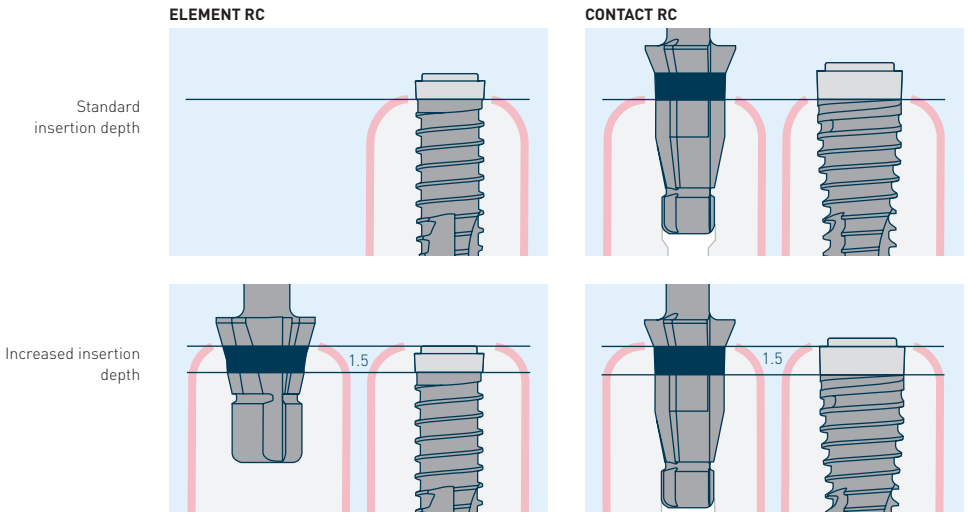
Extending insertion depth for RC implants

In special clinical situations, implants which are designed for supracrestal use need to have deeper vertical placement. Two key points must be considered:

⚠ **Important:**

- All prior holes have to be drilled 1.5 mm deeper.
- The implant bed must be shaped in the area of the implant shoulder with the respective profile drill (this pertains also to ELEMENT implants). Drill to the upper edge of the depth marking (see p. 15).

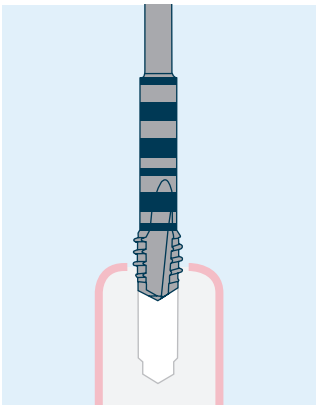
MC implants are more suitable for use at bone level.



Implant bed preparation in extremely hard bone

All Thommen implants are self-tapping. This substantially simplifies the standard procedure of implant bed preparation since thread tapping is not normally required. Clinical experience and *in-vitro* tests with these implants demonstrate that high primary stability can be ensured by this approach.

However, when implants are placed in extremely hard bone (such as, for example, in the case of a strongly atrophied edentulous jaw), thread-tapping can be indicated.



The thread is tapped after drilling the final hole for the intended endosseous implant diameter and, if necessary, prior to use of the profile drill.

To prepare the implant bed, insert the thread tap and its guide into the prepared implant bed. Ensure that the thread tap is screwed exactly in the axis of the hole, as otherwise the implant bed will widen and primary stability will be reduced. Do not exert any axial force in tapping the thread.

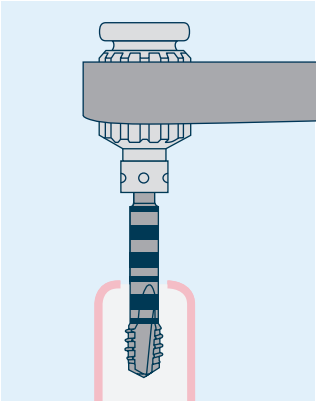
Tap the thread to the same depth as the implant bed prepared with the drill (depth marking).

⚠ **Important:** Be sure not to screw the thread tap deeper into the site. If the thread tap is screwed in deeper, it will damage or tear the threads in the bone. It is recommended to tap the final thread towards the intended implant insertion depth very slowly.

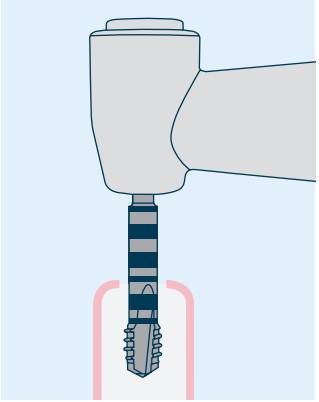
Never remove the thread tap and screw it back in again. Separate out blunt or damaged thread taps or replace after a maximum of 20 applications.

The thread tap is made of stainless steel and is meant for multiple use. Please find detailed notes on care and and also information on the processing this product in the processing instructions THM61131, «www.ifu-tm.com/THM61131».

The dental latch allows both the thread tap to be used manually with the MONO insertion device, short, and to be used under power.



Manual operation
Insert the thread tap with the short MONO insertion device into the hole and then tap the thread uisng the MONO torque ratchet with slow, clockwise turns.



Mechanical operation
Employ supported handpieces for mechanical operation. The maximum rotation speed is 20 rpm

⚠ **Important:** To unscrew the thread tap, set the drill or hand piece to rotate counter-clockwise. Slowly unscrew the thread tap and within the axis, as otherwise the implant bed will widen and primary stability will be reduced.

Implant insertion after using the thread tap

If the implant bed was prepared using a thread tap, work slowly and without pressure when placing the implant, especially when making the first turns, so that you can check precisely if the implant is engaged with the pre-cut thread. A rise in torque indicates that the implant has not engaged with the pre-cut thread. In this case, unscrew the implant and screw it back in.

VECTOdrill™ twist drill, stainless steel, for single use

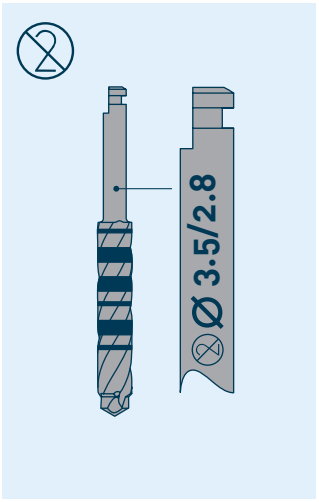
The VECTOdrill™ twist drills for single use are made of stainless steel and are delivered in a sterile package.

See pages 13 and 28 for notes on usage, especially for the clinically relevant specification of the drill lengths.

VECTOdrill™ twist drills, stainless steel, for single use come in the lengths: 29.0 mm, 34.0 mm, and 40.0 mm.

VECTOdrill™ twist drills for single use must not be re-used under any circumstances (see page 43 Guarantee of sterility).

The numbers on the shaft correspond with the single use symbol, drill diameter and the previous drill diameter.



VECTOdrill™ twist drill made of steel for multiple use

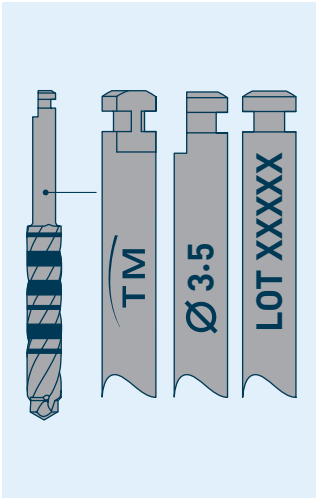
The VECTOdrill™ twist drills for multiple use are made from stainless steel and have a greater resistance to wear than the VECTOdrill twist drill for single use. Otherwise, they have the same geometry and are available in the same lengths as the VECTOdrill™ twist drill for single use.

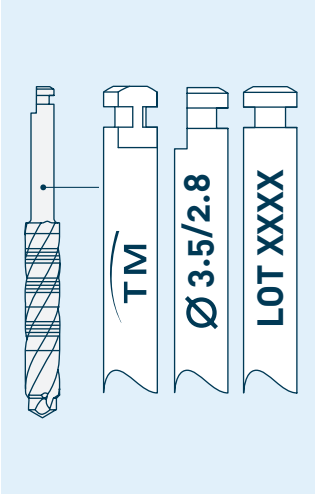
The VECTOdrill™ twist drills, stainless steel, for multiple use are supplied in a non-sterile condition and must be processed prior to first use.

They may be processed a maximum of 20 times. You can find information on the processing of this product in the processing instructions THM61131, «www.ifu-tm.com/THM61131».

See pages 13 and 28 for notes on usage, especially for the clinically relevant specification of the drill lengths. The drills come in the lengths: 29.0 mm, 34.0 mm, and 40.0 mm.

The numbers on the shaft correspond with the company logo, drill diameter and the LOT number.





VECTOdrill™ twist drill, ceramic, for multiple use

VECTOdrill™ ceramic twist drills are made from the high-grade composite ceramic ATZ (alumina toughened zirconia). Ceramic drills feature good cutting properties due to a high initial sharpness which is maintained throughout multiple applications and provide good biocompatibility. They do not corrode and can be re-sterilized.

Ceramic is more brittle than metal, and thus more susceptible to fracture. This means that the following points must be observed when using the drills:

- Do not stop the drill in the bone, but ensure continuous rotation even for removal.
- Do not make any corrections from the drilled axis or exert lateral pressure on the drill.
- Damaged or blunt drills must be disposed of.

⚠ **Important:** VECTOdrill™ ceramic drills must not be stored in disinfection cabinets with ultraviolet radiation, or otherwise be exposed to strong ultraviolet radiation, as this can lead to discoloration of the surface.

The ceramic drills have the identical VECTOdrill™ guide tip design as the stainless steel drills and are used according to the same surgical procedure.

Use of ceramic drills together with guide sleeves is not recommended.

The drills are supplied in non-sterile condition and must be processed prior to first use.

They may be processed a maximum of 20 times. You can find information on the processing of this product in the processing instructions THM61131, «www.ifu-tm.com/THM61131».

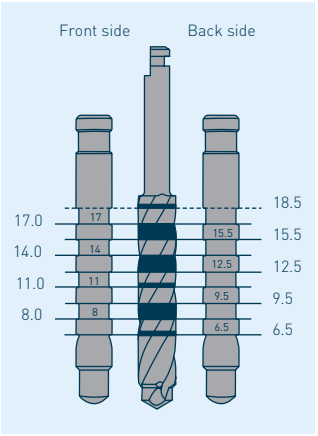
The numbers on the shaft correspond with the company logo, drill diameter/previous drill diameter and the LOT number.

Depth gauge

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 processing instructions THM61131, «www.ifu-tm.com/THM61131».

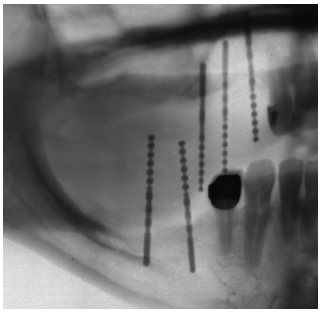


Pilot drilling with narrower diameter drills

The twist drill and depth gauge with ∅ 1.5 mm can be used in clinical cases where adjacent structures necessitate additional precautionary measures and precision.

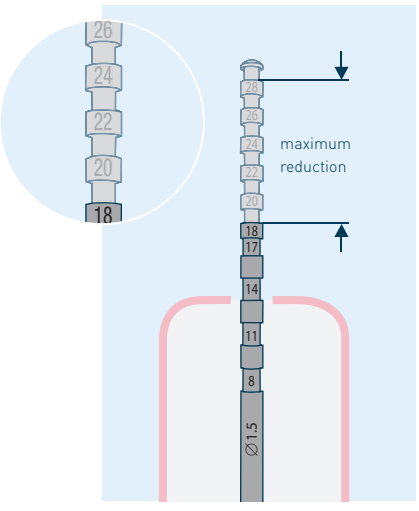
For these critical situations we recommend an intraoperative X-ray image with the depth gauge inserted. The notches which are present on the depth gauge are visible in the X-ray image and allow the drilling depth to be read.

The depth gauge must not be allowed to come into contact with antagonistic structures, since it could pierce adjacent anatomical structures (mandibular canal, sinus floor, nasal floor, floor of the mouth).



Case image used with kind permission of Dr. med. Dr. med. dent. Roland R. Schmoker, Bern, Switzerland

The depth gauge ∅ 1.5 mm not only serves for measuring the drilling depth, but can also be used to estimate available occlusal space and the later alignment of the implant. For this purpose it is possible to individually shorten the coronal area of the depth gauge by intervals of 1 mm up to a length of 18 mm.



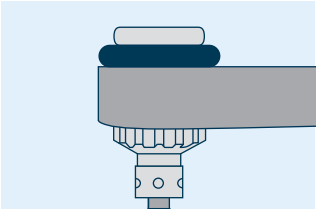
MONO torque ratchet

The MONO torque ratchet is manufactured from a solid billet of high-strength, titanium alloy and features 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 19 (Manual implant insertion) and 22 (use of MONO 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).

⚠ **Important:** The MONO circlip must be protected from exposure to strong light or high heat during storage.

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 processing instructions THM61131, «www.ifu-tm.com/THM61131».

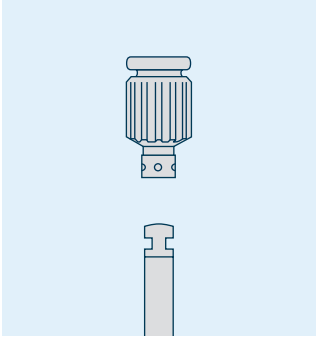
reddot design award
winner 2007 – best of the best

MONO insertion device, short, with integrated dental latch

The MONO insertion devices are designed for manual insertion and removal of Thommen implants. Implants can be optimally aligned for the prosthetic restoration thanks to the marked corners on the outer surface of the internal hexagon.

The insertion device, short (A), features an integrated dental latch for use with latch-type dental instruments. 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 processing instructions THM61131, «www.ifu-tm.com/THM61131».



MONO screwdriver

MONO screwdrivers can be used to place and tighten all healing caps, gingiva formers and screws of the Thommen Implant System.

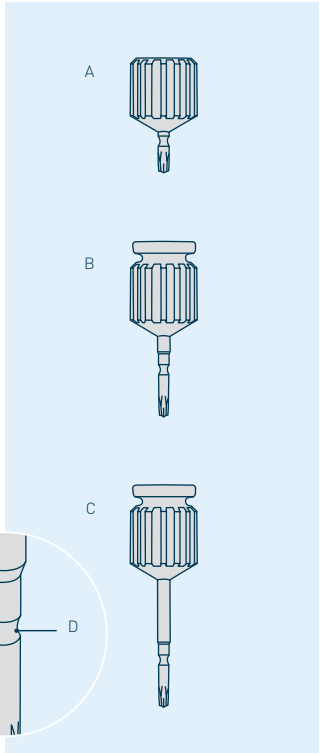
MONO screwdrivers come in three lengths. The short (B) and long (C) screwdrivers are equipped with a fingerplate for optimal guidance. The screwdriver, extra short (A), has no fingerplate in order to minimize its height so that the screwdriver can also be inserted into narrow occlusal spaces.

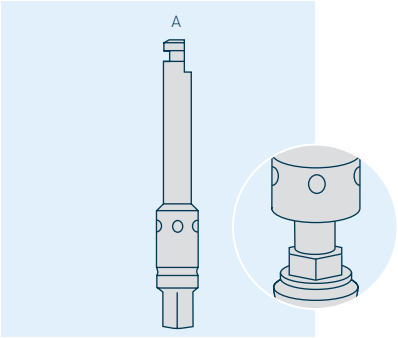
All screwdrivers have a 4-lobe screw head design which securely holds all Thommen Implant System components and provides optimum torque transfer. Avoid exerting any non-axial pressure on the screwdriver.

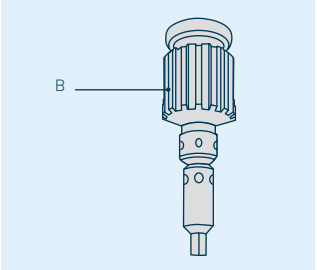
All screwdrivers feature a predetermined breaking point (D). If excess torque is applied the screwdriver will fracture at this point. Always observe the tightening torques as given in the overview for a successful outcome (see p. 42).

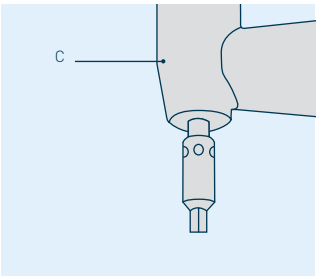
If screws, healing caps and gingiva formers are tightened too firmly, the special instruments from the service set must be used to prevent the breakage of instruments for which this task was not designed (see p. 40).

You can find information on the processing of this product in the processing instructions THM61131, «www.ifu-tm.com/THM61131».









Adapter for handpiece, one-piece

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 the implant in the bone after the insertion aid has been removed.

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

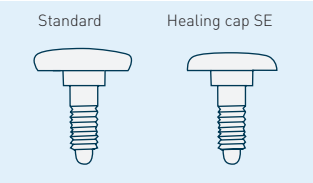
Subsequent corrections to the position can impair the primary stability of the implant.

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

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

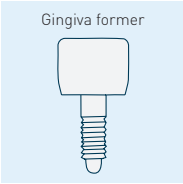
You can find information on the processing of this product in the processing instructions THM61131, «www.ifu-tm.com/THM61131».

Healing caps and gingiva formers



In addition to the healing cap in the implant container, Thommen Medical also offers healing caps separately which because of their rounded edges enable a better adaption of the mucosal flap particularly in thin soft tissue conditions (healing cap SE, smooth edge).

Gingiva former

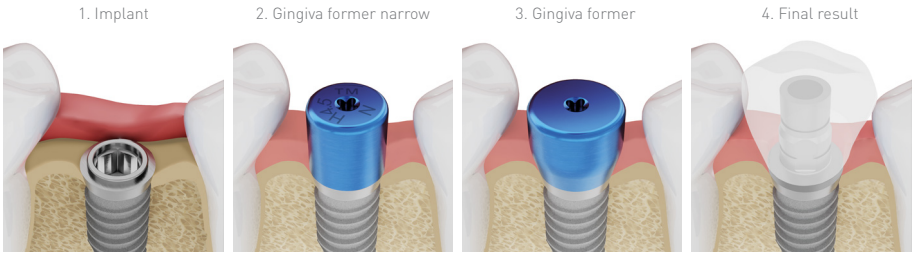


The gingiva former allows the shaping of the peri-implant soft tissue for all implant platforms. Five different heights (2.0/3.2/4.5/5.7 and 7.0 mm) ensure optimal soft tissue conditioning.

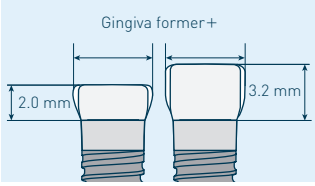
Gingiva former narrow

The gingiva former narrow should be used in combination with the gingiva former in a two-stage procedure. Five different heights (2.0/3.2/4.5/5.7 and 7.0 mm) ensure optimal soft tissue conditioning for all implant platforms.

After inserting the implant (Fig. 1), the gingiva former narrow is inserted (Fig. 2). After the healing phase or during the 2nd session, the narrow gingiva former is replaced by the standard gingiva former (Fig. 3) in order to exert a graduated compression and to prepare the soft tissue for the subsequent final restoration (Fig. 4).



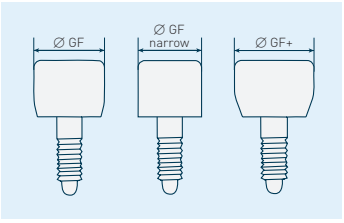
Note:
In order to guarantee an accurate and unobstructed fit of the abutment, the bone contouring instrument must be used for implants in a crestal or subcrestal position.



Gingiva former +

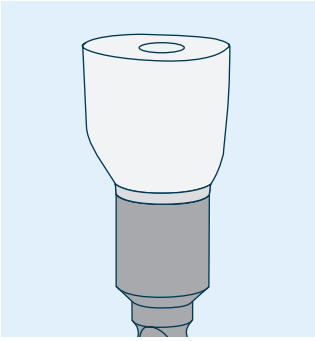
The gingiva former+ is available for PF 3.5 and features a slightly larger outer diameter (4.5 mm instead of 4.0 mm) compared to the standard gingiva former. The gingiva former+ is available in the heights of 2 mm and 3.2 mm and is ideally used for shaping the gingiva in edentulous patients and in combination with the SPI®ELEMENT LC implant. The gingiva former is ideally used in a partially edentulous jaw. Due to the larger outer diameter, the gingiva former+ should not be used if teeth are positioned closely together. Healing caps and gingiva formers are sold separately and are non-sterile, and must be sterilized prior to use.

For information on sterilizing this product, please go to the gingiva former customizable. THM61116, «www.ifu-tm.com/THM61116».



Overview of gingiva former (GF) diameters

	PF 3.5			PF 4.0		PF 4.5		PF 5.0		PF 6.0	
Height	∅ GF	∅ GF narrow	∅ GF+	∅ GF	∅ GF narrow	∅ GF	∅ GF narrow	∅ GF	∅ GF narrow	∅ GF	∅ GF narrow
2.0 mm	4.0 mm	3.6 mm	4.5 mm	4.6 mm	4.1 mm	5.1 mm	4.6 mm	5.6 mm	5.1 mm	6.6 mm	6.1 mm
3.2 mm	4.0 mm	3.6 mm	4.5 mm	5.0 mm	4.1 mm	5.5 mm	4.6 mm	6.0 mm	5.1 mm	7.0 mm	6.1 mm
4.5 mm	4.0 mm	3.6 mm		5.0 mm	4.1 mm	5.5 mm	4.6 mm	6.0 mm	5.1 mm	7.0 mm	6.1 mm
5.7 mm	4.0 mm	3.6 mm		5.0 mm	4.1 mm	5.5 mm	4.6 mm	6.0 mm	5.1 mm	7.0 mm	6.1 mm
7.0 mm	4.0 mm	3.6 mm		5.0 mm	4.1 mm	5.5 mm	4.6 mm	6.0 mm	5.1 mm	7.0 mm	6.1 mm



Gingiva former, customizable

The customizable gingiva former, made of polymethyl methacrylate (PMMA), enables the emergence profile for the final single-tooth crown to be individually shaped during the healing phase. It can be used immediately after implantation or at the time of re-exposure, if a non-load bearing, short-term temporary restoration is required.

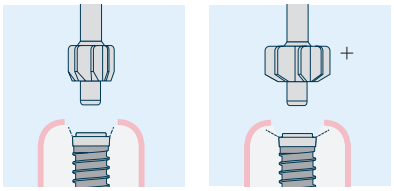
The customizable gingiva former may remain in the mouth for a maximum of 30 days.

The customizable gingiva former can be used in several ways:

- as a gingiva former, shortened to gingival level
- as a provisional abutment for a cement-retained temporary crown
- as a directly veneered, temporary screw-retained single-tooth replacement

Customizable gingiva formers must only be used for single-tooth restorations. You can find further information in the instructions for use THM 61125, «www.ifu-tm.com/THM61125».

Bone contouring instrument and bone contouring instrument+



In order to ensure a precise and unobstructed fit of the abutment, the contour of the bone can easily be prepared using the bone contouring instrument without damaging the implant.

By using the bone contouring instrument+ excess bone at implants placed in a strongly angled position is removed from around angled VARIOmulti abutments.

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. You can find information on the processing of this product in the processing instructions THM61131, «www.ifu-tm.com/THM61131».

⚠ **Important:** The bone contouring instrument+ must not be used to prepare bone for other abutments as this instrument is larger than the standard bone contouring instrument and would remove too much bone.

The interior of the implant needs to be fully accessible. Position the guide pin of the bone contouring instrument into the implant, ensuring that the axis of the contouring instrument is aligned with the implant axis.

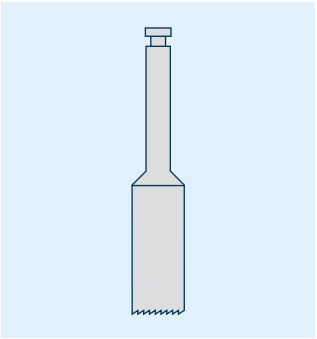
Rotate the instrument clockwise to remove the bone around the implant platform.

The bone contouring instrument can be used manually with the short MONO insertion device or under power. If you use the contra-angle handpiece, we recommend cooling at a maximum rotational speed of 200 rpm.

The interfering bone is removed as soon as the bone contouring instrument touches the implant. Before taking the subsequent impression or before placing any prosthetic components, clean and dry the interior configuration of the implant thoroughly.

You can find information on the processing of this product in the processing instructions THM61131, «www.ifu-tm.com/THM61131».

Mucosa punch



Indication/area of application
The mucosa punch is used to perforate the soft tissue when placing an implant (flapless technique) or for exposing a previously placed implant.

The mucosa punch should only be used when:
- The existing anatomical conditions are well understood.
- There is sufficient width of the alveolar ridge and masticatory mucosa.

The mucosa punch is made of stainless steel and is indicated for multiple use. A sharp and undamaged mucosa punch is essential for a precise cut in soft tissue. Check the mucosa punch for correct functioning after each use. Damaged and blunt instruments must not be used. The mucosa punch features a dental latch for manual or mechanical operation. The diameter of the mucosa punch must match the platform diameter of the planned or placed implant platform. Only use the mucosa punch under sterile conditions.

You can find information on the processing of this product in the processing instructions THM61131, «www.ifu-tm.com/THM61131».

Manual operation
Manual use is especially recommended for exposing a placed implant. It provides more tactile control and reduces the risk of damaging the healing cap. Always carefully evaluate the position of the implant before use.

Use the mucosa punch manually with the MONO insertion device, short. Open the soft tissue as far as the alveolar ridge with an oscillating movement and while applying light axial pressure.

Mechanical operation
For mechanical operation, use a handpiece with a low rotational speed (approximately 20 rpm).

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 hand piece, Thommen Medical offers a service set that is specific to the screw type and platform diameter.

⚠ **Important:** The abutment screw/transversal 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.

Explantation

If explantation of an implant with the adapter for handpiece, one-piece, is impossible, explantation drills and corresponding guiding cylinders are available for all types of implant and platform diameters (see Product Catalogue).

Contact your Thommen Medical representative for further details.

7. Thommen Service

Long-term provision of components of the Thommen implant system

The Thommen Implant System evolved from the Ha-Ti system which has been in use and clinically documented since 1986. In the further development of the implant system, care has been taken to ensure that the new components are compatible with the existing connection geometry. Therefore, all prosthetic components can be provided for all Thommen Medical and Ha-Ti implants from 1986 onwards.

Guarantee

The comprehensive guarantees for implants, abutments and instruments can be found in the country-specific guarantee leaflets.

See also the information at: www.thommenmedical.com

Training and education

Thommen Medical offers courses and educational events for training in surgery and prosthetics. Contact your Thommen Medical representative for details of any current programs.

See also the information at: www.thommenmedical.com

Customer service

Your main contact is your field sales representative. The instructions for use for our products can be found in electronic format on the Thommen Medical website or at the website www.ifu-tm.com. A THM number is listed on the product label. This links to the website www.ifu-tm.com and refers to the instructions for use for the corresponding product.

See also the information at: www.thommenmedical.com

Scientific documentation

Thommen Medical invests in research and development. The goal of these endeavors is to scientifically confirm and document the successful use of Thommen Medical products with preclinical and clinical trials. A comprehensive summary of the studies on the Thommen Implant System can be found on the Thommen Medical website.

8. Torque value chart

Torque values

Abutment/screw	Torque values in Ncm				
	10	15	20	25	30
Healing cap Gingiva former Gingiva former narrow 	PF 3.0 PF 3.5 PF 4.0 PF 4.5 PF 5.0 PF 6.0				
Abutment screw 		PF 3.0 PF 3.5		PF 4.0 PF 4.5 PF 5.0 PF 6.0	
Dynamic abutment screw 		PF 3.5		PF 4.0 PF 4.5 PF 5.0	
Abutment screw in combination with ART Abutment 		PF 3.5	PF 4.0 PF 4.5 PF 5.0		
VARIOmulti abutment 		PF 3.5		PF 4.0 PF 4.5 PF 5.0 PF 6.0	
VARIOmulti protective cap 	PF 3.5 PF 4.0 PF 4.5 PF 5.0 PF 6.0				
Occlusal screw (VARIOmulti, VARIO 17°, bar)  Occlusal closure screw, for CAD/CAM bar		PF 3.5 PF 4.0 PF 4.5 PF 5.0 PF 6.0			
Retentive anchor 				PF 4.0 PF 4.5 PF 5.0	
ZEST® LOCATOR® abutment 			PF 3.5		PF 4.0 PF 4.5 PF 5.0 PF 6.0
ZEST® LOCATOR® abutment and collar for VARIOmulti 			PF 4.0 PF 4.5 PF 5.0 PF 6.0		

New abutment screws must be used for permanent insertion of the restoration in the mouth.

Product list

Article number	Description	Material	single use	Sterile	UDI-DI
3.03.610Q4	VECTOdrill™ pilot drill ∅ 2.0 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156476606
3.03.611Q4	VECTOdrill™ pilot drill ∅ 2.0 mm, long, L 40.0 mm	Stainless steel	Yes	Yes	07640156474787
3.03.612Q4	VECTOdrill™ twist drill ∅ 2.8 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156474770
3.03.613Q4	VECTOdrill™ twist drill ∅ 2.8 mm, long, L 40.0 mm	Stainless steel	Yes	Yes	07640156474763
3.03.614Q4	VECTOdrill™ twist drill ∅ 3.5 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156474756
3.03.615Q4	VECTOdrill™ twist drill ∅ 3.5 mm, long, L 40.0 mm	Stainless steel	Yes	Yes	07640156474749
3.03.616Q4	VECTOdrill™ twist drill ∅ 4.3 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156474732
3.03.617Q4	VECTOdrill™ twist drill ∅ 4.3 mm, long, L 40.0 mm	Stainless steel	Yes	Yes	07640156474725
3.03.618Q4	VECTOdrill™ twist drill ∅ 5.3 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156472653
3.03.624Q4	VECTOdrill™ pilot drill ∅ 2.0 mm, extra short, L 29.0 mm, for implant L 6.5-14.0 mm	Stainless steel	Yes	Yes	07640156474718
3.03.625Q4	VECTOdrill™ twist drill ∅ 2.8 mm, extra short, L 29.0 mm, for implant L 6.5-14.0 mm	Stainless steel	Yes	Yes	07640156474701
3.03.626Q4	VECTOdrill™ twist drill ∅ 3.5 mm, extra short, L 29.0 mm, for implant L 6.5-14.0 mm	Stainless steel	Yes	Yes	07640156474695
3.03.627Q4	VECTOdrill™ twist drill ∅ 4.3 mm, extra short, L 29.0 mm, for implant L 6.5 14.0 mm	Stainless steel	Yes	Yes	07640156474688
3.03.628Q4	VECTOdrill™ twist drill ∅ 5.3 mm, extra short, L 29.0 mm, for implant L 6.5-14.0 mm	Stainless steel	Yes	Yes	07640156472660
3.03.710	VECTOdrill™ pilot drill ∅ 2.0 mm, L 29.0 mm, for implant L 6.5-14.0 mm	Stainless steel	No	No	07640156477269
3.03.712	VECTOdrill™ twist drill ∅ 2.8 mm, L 29.0 mm, for implant L 6.5-14.0 mm	Stainless steel	No	No	07640156477276
3.03.714	VECTOdrill™ twist drill ∅ 3.5 mm, L 29.0 mm, for implant L 6.5-14.0 mm	Stainless steel	No	No	07640156477283
3.03.716	VECTOdrill™ twist drill ∅ 4.3 mm, L 29.0 mm, for implant L 6.5-14.0 mm	Stainless steel	No	No	07640156477290
3.03.718	VECTOdrill™ twist drill ∅ 5.3 mm, L 29.0 mm, for implant L 6.5-14.0 mm	Stainless steel	No	No	07640156477306
3.03.720	VECTOdrill™ pilot drill ∅ 2.0 mm, short, L 34.0 mm	Stainless steel	No	No	07640156477313
3.03.722	VECTOdrill™ twist drill ∅ 2.8 mm, short, L 34.0 mm	Stainless steel	No	No	07640156477320
3.03.724	VECTOdrill™ twist drill ∅ 3.5 mm, short, L 34.0 mm	Stainless steel	No	No	07640156477337
3.03.726	VECTOdrill™ twist drill ∅ 4.3 mm, short, L 34.0 mm	Stainless steel	No	No	07640156477344
3.03.728	VECTOdrill™ twist drill ∅ 5.3 mm, short, L 34.0 mm	Stainless steel	No	No	07640156477351
3.03.730	VECTOdrill™ pilot drill ∅ 2.0 mm, long, L 40.0 mm	Stainless steel	No	No	07640156477368
3.03.734	VECTOdrill™ twist drill ∅ 3.5 mm, long, L 40.0 mm	Stainless steel	No	No	07640156477382
3.03.736	VECTOdrill™ twist drill ∅ 4.3 mm, long, L 40.0 mm	Stainless steel	No	No	07640156477399
3.03.660	VECTOdrill™ ceramic pilot drill ∅ 2.0 mm, L 29.0 mm, for implant L 6.5-14.0 mm	Ceramic	No	No	07640156474459
3.03.662	VECTOdrill™ ceramic twist drill ∅ 2.8 mm, L 29.0 mm, for implant L 6.5-14.0 mm	Ceramic	No	No	07640156474435
3.03.664	VECTOdrill™ ceramic twist drill ∅ 3.5 mm, L 29.0 mm, for implant. L 6.5-14.0 mm	Ceramic	No	No	07640156474411
3.03.666	VECTOdrill™ ceramic twist drill ∅ 4.3 mm, L 29.0 mm, for implant L 6.5-14.0 mm	Ceramic	No	No	07640156474398
3.03.668	VECTOdrill™ ceramic twist drill ∅ 5.3 mm, L 29.0 mm, for implant L 6.5-14.0 mm	Ceramic	No	No	07640156472646

Product list

Article number	Description	Material	single use	Sterile	UDI-DI
3.03.661	VECTOdrill™ ceramic pilot drill ∅ 2.0 mm, short, L 34.0 mm	Ceramic	No	No	07640156474442
3.03.663	VECTOdrill™ ceramic twist drill ∅ 2.8 mm, short, L 34.0 mm	Ceramic	No	No	07640156474428
3.03.665	VECTOdrill™ ceramic twist drill ∅ 3.5 mm, short, L 34.0 mm	Ceramic	No	No	07640156474404
3.03.667	VECTOdrill™ ceramic twist drill ∅ 4.3 mm, short, L 34.0 mm	Ceramic	No	No	07640156474381
3.03.669	VECTOdrill™ ceramic twist drill ∅ 5.3 mm, short, L 34.0 mm	Ceramic	No	No	07640156472639
3.03.140	X-ray reference sphere, ∅ 5.0 mm	Stainless steel	No	No	07640156475388
3.03.141Q4	Guiding sleeve for VECTOdrill™ pilot drill, internal ∅ 2.0 mm, L 6.0 mm	Stainless steel	Yes	No	07640156475371
3.03.640Q4	CONTACT profile drill, 2.7/3.5 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156474633
3.03.641Q4	CONTACT profile drill, 2.7/3.5 mm, extra short, L 29.0 mm	Stainless steel	Yes	Yes	07640156474626
3.03.642Q4	CONTACT profile drill, 3.5/4.5 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156474619
3.03.643Q4	CONTACT profile drill, 3.5/4.5 mm, extra short, L 29.0 mm	Stainless steel	Yes	Yes	07640156474602
3.03.644Q4	CONTACT profile drill, 4.2/5.0 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156474596
3.03.645Q4	CONTACT profile drill, 4.2/5.0 mm, extra short, L 29.0 mm	Stainless steel	Yes	Yes	07640156474589
3.03.646Q4	CONTACT profile drill, 5.0/6.0 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156474572
3.03.647Q4	CONTACT profile drill, 5.0/6.0 mm, extra short, L 29.0 mm	Stainless steel	Yes	Yes	07640156474565
3.03.648Q4	CONTACT profile drill, 3.5/4.0 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156474558
3.03.649Q4	CONTACT profile drill, 3.5/4.0 mm, extra short, L 29.0 mm	Stainless steel	Yes	Yes	07640156474541
3.03.651Q4	ELEMENT profile drill, 3.5/3.5 mm, extra short, L 29.0 mm	Stainless steel	Yes	Yes	07640156474527
3.03.653Q4	ELEMENT profile drill, 4.2/4.5 mm, extra short, L 29.0 mm	Stainless steel	Yes	Yes	07640156474503
3.03.655Q4	ELEMENT profile drill, 5.0/5.0 mm, extra short, L 29.0 mm	Stainless steel	Yes	Yes	07640156474480
3.03.657Q4	ELEMENT profile drill, 4.0/4.0 mm, extra short, L 29.0 mm	Stainless steel	Yes	Yes	07640156474466
3.03.659Q4	ELEMENT profile drill, 6.0/6.0 mm, extra short, L 29.0 mm	Stainless steel	Yes	Yes	07640156472592
3.03.690Q4	Drill ∅ 1.5 mm, short, L 34.0 mm	Stainless steel	Yes	Yes	07640156474282
3.03.790	Drill ∅ 1.5 mm, short, L 34.0 mm	Stainless steel	No	No	07640156477412
3.03.630	VECTOdrill™ depth gauge ∅ 2.0 mm, L 27.5 mm	Titanium	No	No	07640156474671
3.03.632	VECTOdrill™ depth gauge ∅ 2.8 mm, L 27.5 mm	Titanium	No	No	07640156474664
3.03.634	VECTOdrill™ depth gauge ∅ 3.5 mm, L 27.5 mm	Titanium	No	No	07640156474657
3.03.636	VECTOdrill™ depth gauge ∅ 4.3 mm, L 27.5 mm	Titanium	No	No	07640156474640
3.03.638	VECTOdrill™ depth gauge ∅ 5.3 mm, L 27.5 mm	Titanium	No	No	07640156472615
3.03.692	Depth gauge ∅ 1.5 mm, customizable length, L 30.5 mm	Titanium	No	No	07640156474275
3.03.680	Thread tap, endosseous ∅ 3.5 mm, L 34.0 mm	Stainless steel	No	No	07640156474329
3.03.682	Thread tap, endosseous ∅ 4.0 mm, L 34.0 mm	Stainless steel	No	No	07640156474312
3.03.684	Thread tap, endosseous ∅ 4.2 mm, L 34.0 mm	Stainless steel	No	No	07640156474305
3.03.686	Thread tap, endosseous ∅ 5.0 mm, L 34.0 mm	Stainless steel	No	No	07640156474299
3.03.688	Thread tap, endosseous ∅ 6.0 mm, L 34.0 mm	Stainless steel	No	No	07640156472622
3.03.671	Bone contouring instrument for PF 3.5, L 29.0 mm	Stainless steel	No	No	07640156474374
3.03.673	Bone contouring instrument for PF 4.0, L 29.0 mm	Stainless steel	No	No	07640156474367
3.03.675	Bone contouring instrument for PF 4.5, L 29.0 mm	Stainless steel	No	No	07640156474350
3.03.677	Bone contouring instrument for PF 5.0, L 29.0 mm	Stainless steel	No	No	07640156474343
3.03.679	Bone contouring instrument for PF ∅ 6.0 mm, L 29.0 mm	Stainless steel	No	No	07640156474336
3.03.670	Bone contouring instrument+ for PF 3.5, L 29.0 mm	Stainless steel	No	No	07640156478105
3.03.672	Bone contouring instrument+ for PF 4.0, L 29.0 mm	Stainless steel	No	No	07640156478112

Article number	Description	Material	single use	Sterile	UDI-DI
3.03.674	Bone contouring instrument+ for PF 4.5, L 29.0 mm	Stainless steel	No	No	07640156478129
3.03.676	Bone contouring instrument+ for PF 5.0, L 29.0 mm	Stainless steel	No	No	07640156478136
3.03.231	Drill extension for PF 3.5 - 4,0, external ∅ 3.7 mm, L 26.0 mm	Stainless steel	No	No	07640156475326
3.03.230	Drill extension for PF 4.0 - 6,0, external ∅ 5.0 mm, L 26.0 mm	Stainless steel	No	No	07640156475333
3.03.315	Mucosa punch, for PF 3.5, L 27.0 mm	Stainless steel	No	No	07640156475135
3.03.316	Mucosa punch, for PF 4.0, L 27.0 mm	Stainless steel	No	No	07640156475128
3.03.320	Mucosa punch, for PF 4.5, L 27.0 mm	Stainless steel	No	No	07640156475098
3.03.317	Mucosa punch, for PF 5.0, L 27.0 mm	Stainless steel	No	No	07640156475111
3.03.318	Mucosa punch, for PF 6.0, L 27.0 mm	Stainless steel	No	No	07640156475104
3.03.248	Adapter for hand piece, one-piece, for PF 3.0 - 3.5, L 24.0 mm	Stainless steel	No	No	07640156475296
3.03.251	Adapter for hand piece, one-piece, for PF 4.0, L 24.0 mm	Stainless steel	No	No	07640156475265
3.03.241	Adapter for hand piece, one-piece, for PF 4.5 - 6.0, L 24.0 mm	Stainless steel	No	No	07640156475302
3.03.240	Adapter for hand piece, ∅ 4.4 mm, L 18.0 mm	Stainless steel	No	No	07640156475319
3.03.249	Adapter for hand piece, long, ∅ 4.4 mm, L 28.0 mm	Stainless steel	No	No	07640156475289
3.03.500	Screwdriver for hand piece (4-lobe), extra short, L 17.0 mm	Stainless steel	No	No	07640156474954
3.03.501	Screwdriver for hand piece (4-lobe), short, L 22.0 mm	Stainless steel	No	No	07640156474947
3.03.502	Screwdriver for hand piece (4-lobe), long, L 28.0 mm	Stainless steel	No	No	07640156474930
3.03.503	Screwdriver for hand piece (4-lobe), extra long, L 38.0 mm	Stainless steel	No	No	07640156477566
3.03.160	MONO torque ratchet, L 110.0 mm	Stainless steel	No	No	07640156471823
3.03.203	MONO guide key, L 94.7	Titanium	No	No	07640156472677
2.03.170Q2	MONO circlip	Viton	No	No	07640156471847
3.03.162	MONO insertion device, short, ∅ 8.5 mm, L 15.4 mm	Stainless steel/PEEK	No	No	07640156471816
3.03.163	MONO insertion device, long, ∅ 8.5 mm, L 25.8 mm	Stainless steel/PEEK	No	No	07640156471809
3.03.165	MONO screwdriver, extra short (4-lobe), ∅ 8.5 mm, L 14.5 mm	Stainless steel/PEEK	No	No	07640156471793
3.03.166	MONO screwdriver, short (4-lobe), ∅ 8.5 mm, L 22.2 mm	Stainless steel/PEEK	No	No	07640156471786
3.03.167	MONO screwdriver, long (4-lobe), ∅ 8.5 mm, L 28.2 mm	Stainless steel/PEEK	No	No	07640156471779
4.03.515	Healing cap SE (4-lobe), PF 3.5	Titanium	Yes	No	07640156471960
4.03.516	Healing cap SE (4-lobe), PF 4.5	Titanium	Yes	No	07640156471953
4.03.517	Healing cap SE (4-lobe), PF 5.0	Titanium	Yes	No	07640156471946
4.03.518	Healing cap SE (4-lobe), PF 6.0	Titanium	Yes	No	07640156471939
4.03.519	Healing cap SE (4-lobe), PF 4.0	Titanium	Yes	No	07640156471922
4.03.520	Gingiva former (4-lobe), PF 3.5, H 2.0 mm	Titanium	Yes	No	07640156473612
4.03.524	Gingiva former (4-lobe), PF 4.0, H 2.0 mm	Titanium	Yes	No	07640156473575
4.03.521	Gingiva former (4-lobe), PF 4.5, H 2.0 mm	Titanium	Yes	No	07640156473605
4.03.522	Gingiva former (4-lobe), PF 5.0, H 2.0 mm	Titanium	Yes	No	07640156473599
4.03.523	Gingiva former (4-lobe), PF 6.0, H 2.0 mm	Titanium	Yes	No	07640156473582

Product list

Article number	Description	Material	single use	Sterile	UDI-DI
4.03.538	Gingiva former (4-lobe), PF 3.0, H 3.2 mm	Titanium	Yes	No	07640156478587
4.03.530	Gingiva former (4-lobe), PF 3.5, H 3.2 mm	Titanium	Yes	No	07640156473568
4.03.534	Gingiva former (4-lobe), PF 4.0, H 3.2 mm	Titanium	Yes	No	07640156473520
4.03.531	Gingiva former (4-lobe), PF 4.5, H 3.2 mm	Titanium	Yes	No	07640156473551
4.03.532	Gingiva former (4-lobe), PF 5.0, H 3.2 mm	Titanium	Yes	No	07640156473544
4.03.533	Gingiva former (4-lobe), PF 6.0, H 3.2 mm	Titanium	Yes	No	07640156473537
4.03.548	Gingiva former (4-lobe), PF 3.0, H 4.5 mm	Titanium	Yes	No	07640156478594
4.03.540	Gingiva former (4-lobe), PF 3.5, H 4.5 mm	Titanium	Yes	No	07640156473513
4.03.544	Gingiva former (4-lobe), PF 4.0, H 4.5 mm	Titanium	Yes	No	07640156473476
4.03.541	Gingiva former (4-lobe), PF 4.5, H 4.5 mm	Titanium	Yes	No	07640156473506
4.03.542	Gingiva former (4-lobe), PF 5.0, H 4.5 mm	Titanium	Yes	No	07640156473490
4.03.543	Gingiva former (4-lobe), PF 6.0, H 4.5 mm	Titanium	Yes	No	07640156473483
4.03.560	Gingiva former (4-lobe), PF 3.5, H 5.7 mm	Titanium	Yes	No	07640182642044
4.03.564	Gingiva former (4-lobe), PF 4.0, H 5.7 mm	Titanium	Yes	No	07640182642082
4.03.561	Gingiva former (4-lobe), PF 4.5, H 5.7 mm	Titanium	Yes	No	07640182642051
4.03.562	Gingiva former (4-lobe), PF 5.0, H 5.7 mm	Titanium	Yes	No	07640182642068
4.03.563	Gingiva former (4-lobe), PF 6.0, H 5.7 mm	Titanium	Yes	No	07640182642075
4.03.558	Gingiva former (4-lobe), PF 3.0, H 7.0 mm	Titanium	Yes	No	07640156478600
4.03.550	Gingiva former (4-lobe), PF 3.5, H 7.0 mm	Titanium	Yes	No	07640156473469
4.03.554	Gingiva former (4-lobe), PF 4.0, H 7.0 mm	Titanium	Yes	No	07640156473421
4.03.551	Gingiva former (4-lobe), PF 4.5, H 7.0 mm	Titanium	Yes	No	07640156473452
4.03.552	Gingiva former (4-lobe), PF 5.0, H 7.0 mm	Titanium	Yes	No	07640156473445
4.03.553	Gingiva former (4-lobe), PF 6.0, H 7.0 mm	Titanium	Yes	No	07640156473438
4.03.570	Gingiva former, customizable, PF 3.5, H 7.5 mm	Titanium/ PMMA	Yes	No	07640156473414
4.03.571	Gingiva former, customizable, PF 4.0, H 7.5 mm	Titanium/ PMMA	Yes	No	07640156473407
4.03.572	Gingiva former, customizable, PF 4.5, H 7.5 mm	Titanium/ PMMA	Yes	No	07640156473391
4.03.573	Gingiva former, customizable, PF 5.0, H 7.5 mm	Titanium/ PMMA	Yes	No	07640156473384
4.03.574	Gingiva former, customizable, PF 6.0, H 7.5 mm	Titanium/ PMMA	Yes	No	07640156473377
4.03.525	Gingiva former+, PF 3.5, H 5.7 mm	Titanium	Yes	No	07640156471915
4.03.535	Gingiva former+, PF 3.5, H 5.7 mm	Titanium	Yes	No	07640156471908
4.04.310	Gingiva former narrow, PF 3.5, H 2.0 mm	Titanium	Yes	No	07640182642099
4.04.311	Gingiva former narrow, PF 4.0, H 2.0 mm	Titanium	Yes	No	07640182642105
4.04.312	Gingiva former narrow, PF 4.5, H 2.0 mm	Titanium	Yes	No	07640182642112
4.04.313	Gingiva former narrow, PF 5.0, H 2.0 mm	Titanium	Yes	No	07640182642129
4.04.314	Gingiva former narrow, PF 6.0, H 2.0 mm	Titanium	Yes	No	07640182642136
4.04.320	Gingiva former narrow, PF 3.5, H 3.2 mm	Titanium	Yes	No	07640182642143
4.04.321	Gingiva former narrow, PF 4.0, H 3.2 mm	Titanium	Yes	No	07640182642150
4.04.322	Gingiva former narrow, PF 4.5, H 3.2 mm	Titanium	Yes	No	07640182642167

Article number	Description	Material	single use	Sterile	UDI-DI
4.04.323	Gingiva former narrow, PF 5.0, H 3.2 mm	Titanium	Yes	No	07640182642174
4.04.324	Gingiva former narrow, PF 6.0, H 3.2 mm	Titanium	Yes	No	07640182642181
4.04.330	Gingiva former narrow, PF 3.5, H 4.5 mm	Titanium	Yes	No	07640182642198
4.04.331	Gingiva former narrow, PF 4.0, H 4.5 mm	Titanium	Yes	No	07640182642204
4.04.332	Gingiva former narrow, PF 4.5, H 4.5 mm	Titanium	Yes	No	07640182642211
4.04.333	Gingiva former narrow, PF 5.0, H 4.5 mm	Titanium	Yes	No	07640182642228
4.04.334	Gingiva former narrow, PF 6.0, H 4.5 mm	Titanium	Yes	No	07640182642235
4.04.340	Gingiva former narrow, PF 3.5, H 5.7 mm	Titanium	Yes	No	07640182642242
4.04.341	Gingiva former narrow, PF 4.0, H 5.7 mm	Titanium	Yes	No	07640182642259
4.04.342	Gingiva former narrow, PF 4.5, H 5.7 mm	Titanium	Yes	No	07640182642266
4.04.343	Gingiva former narrow, PF 5.0, H 5.7 mm	Titanium	Yes	No	07640182642273
4.04.344	Gingiva former narrow, PF 6.0, H 5.7 mm	Titanium	Yes	No	07640182642280
4.04.350	Gingiva former narrow, PF 3.5, H 7.0 mm	Titanium	Yes	No	07640182642297
4.04.351	Gingiva former narrow, PF 4.0, H 7.0 mm	Titanium	Yes	No	07640182642303
4.04.352	Gingiva former narrow, PF 4.5, H 7.0 mm	Titanium	Yes	No	07640182642310
4.04.353	Gingiva former narrow, PF 5.0, H 7.0 mm	Titanium	Yes	No	07640182642327
4.04.354	Gingiva former narrow, PF 6.0, H 7.0 mm	Titanium	Yes	No	07640182642334

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
	Simple sterile barrier system
	Simple sterile barrier system with protective packaging on the inside
21	No more than 20 processing cycles
EC REP	EU authorized representative
	Temperature limitation
	Do not re-use
NON STERILE	Non-sterile
	Caution
REF	Article number
CE 0297	Conformity mark according to Directive MDD 93/42/EEC or Regulation (EU) 2017/745 MDR (see corresponding declaration of conformity)
	Consult instructions for use
	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 also 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 for Thommen Medical AG can provide information about availability of Thommen Medical products for the country in question.

GENERAL RESTRICTIONS OF USE Reconstructions 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 a 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. Possible additional side effect: Implant loss.

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 user's local competent authority.

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.

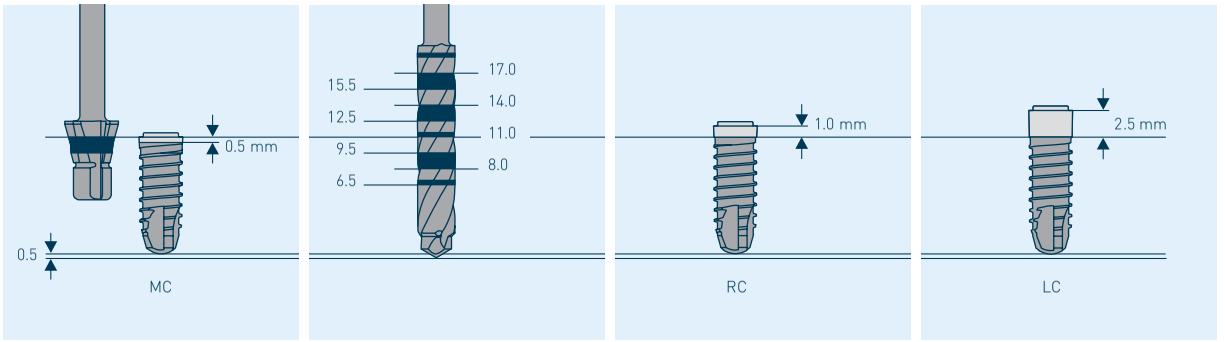
DISPOSAL In the case of cutting products, there is always a risk of injury, therefore the products must be disposed of safely and properly after use, observing all applicable legal and regulatory requirements. For products and their accessories, which have been used on a patient, there is a risk of an 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.

VALIDITY Thommen Medical AG. All previous versions lose their validity with the publication of this instruction for use.

OVERVIEW OF ELEMENT DRILLING PROTOCOL

PF 3.5 endosseous ∅ 3.5 mm	**PF 4.0** endosseous ∅ 4.0 mm	**PF 4.5** endosseous ∅ 4.2 mm	**PF 5.0** endosseous ∅ 5.0 mm	**PF 6.0** endosseous ∅ 6.0 mm	**Speed** rpm
2.0 pilot drill	**2.0** pilot drill	**2.0** pilot drill	**2.0** pilot drill	**2.0** pilot drill	800
2.8 VECTOdrill™	**2.8** VECTOdrill™	**2.8** VECTOdrill™	**2.8** VECTOdrill™	**2.8** VECTOdrill™	600
	3.5 VECTOdrill™	**3.5** VECTOdrill™	**3.5** VECTOdrill™	**3.5** VECTOdrill™	500
			4.3 VECTOdrill™	**4.3** VECTOdrill™	400
				5.3 VECTOdrill™	300
3.5/3.5 ELEMENT Profile drill*	**4.0/4.0** ELEMENT Profile drill*	**4.2/4.5** ELEMENT Profile drill*	**5.0/5.0** ELEMENT Profile drill*	**6.0/6.0** ELEMENT Profile drill*	250-300

Optional	**Speed** rpm
mech. implant insertion	**15**
Thread tap	**20**
Bone contouring instrument	**200**



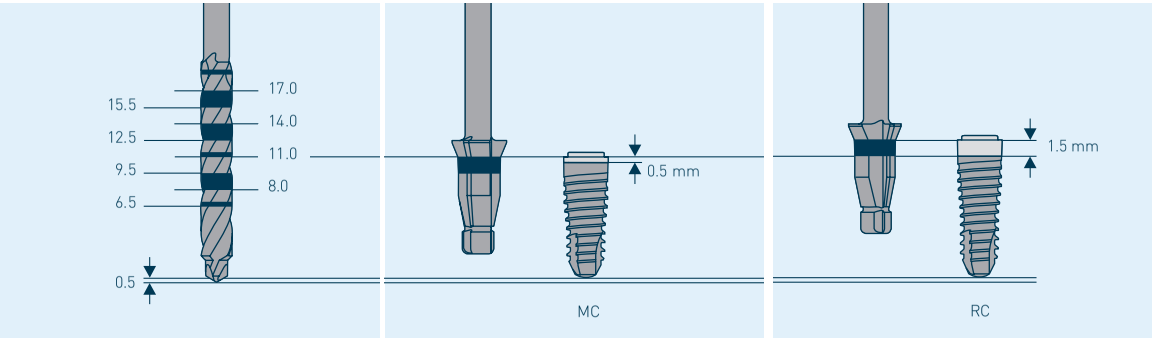
* only for ELEMENT MC

THOMMEN Medical

OVERVIEW OF CONTACT DRILLING PROTOCOL

PF 3.5 endosseous ∅ 2.7 mm	**PF 4.0** endosseous ∅ 3.5 mm	**PF 4.5** endosseous ∅ 3.5 mm	**PF 5.0** endosseous ∅ 4.2 mm	**PF 6.0** endosseous ∅ 5.0 mm	**Speed** rpm
2.0 pilot drill	**2.0** pilot drill	**2.0** pilot drill	**2.0** pilot drill	**2.0** pilot drill	800
	2.8 VECTOdrill™	**2.8** VECTOdrill™	**2.8** VECTOdrill™	**2.8** VECTOdrill™	600
			3.5 VECTOdrill™	**3.5** VECTOdrill™	500
				4.3 VECTOdrill™	400
2.7/3.5 CONTACT Profile drill	**3.5/4.0** CONTACT Profile drill	**3.5/4.5** CONTACT Profile drill	**4.2/5.0** CONTACT Profile drill	**5.0/6.0** CONTACT Profile drill	250-300

Optional	**Speed** rpm
mech. implant insertion	**15**
Thread tap	**20**
Bone contouring instrument	**200**



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