Guided Surgery.

PF 3.5–PF 4.5
L 6.5–L 12.5

Instructions for use THM61144

Version 004_AA, Issue date 08/20

THOMMEN Medical

Content

1. At a glance

These instructions apply to all guided surgery PF 3.5–PF 4.5/L 6.5–L 12.5 specific instruments as listed on page 4/5 in this document and/or shown.

⚠ Only use original Thommen Medical drills with a guiding cylinder ∅ 4.8 mm in combination with original guide sleeves ∅ 4.8 mm.

For more information on guided surgery of other platforms and lengths, please refer to the VECTOdrill ™ pilot drilling solution at www.ifu-tm.com/THM61141.
For more information on the standard surgical procedure including the use of standard instruments, visit www.ifu-tm.com/THM61141. For more information on the Thommen 3.0 Implant System, visit www.ifu-tm.com/THM61146.

Intended use

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.

Restrictions of use

See General restrictions of use (see p. 14).

Cleaning, disinfection and sterilization

⚠ **Warning:**
Prepare the cassette and instruments before their first use.

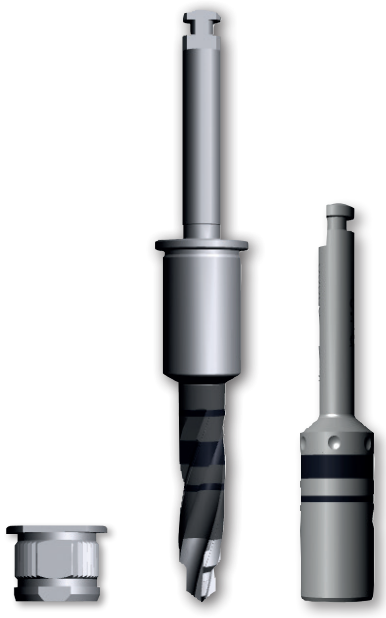
Single-use products:
All products, which are supplied in a non-sterile state, must be sterilized before first use, unless stated otherwise. If prosthetic components have not been reprocessed, no cleaning and disinfection is necessary.
Multiple-use products:
All multiple-use products must be cleaned,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

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

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

Storage

The cassette (Art. No. 1.04.020) must be protected from exposure to strong light or high heat during storage.



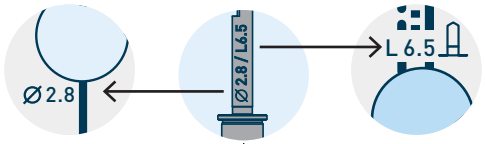
2. Cassette and instruments for guided surgery

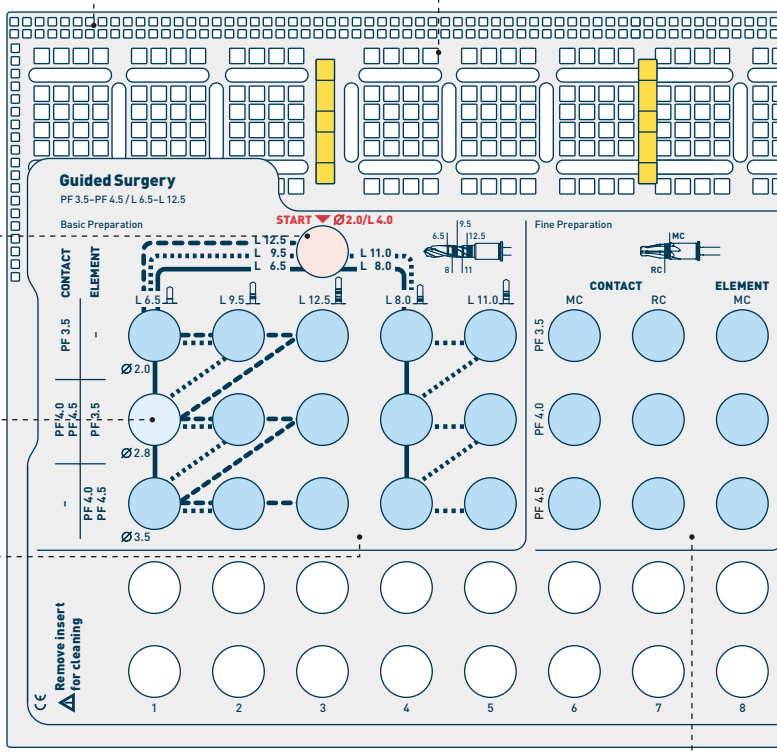
ELEMENT & CONTACT PF 3.5–PF 4.5 / L 6.5–L 12.5, ALL COLLAR HEIGHTS

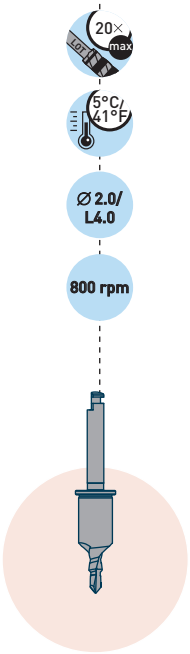
Cassette for guided surgery 1.04.020

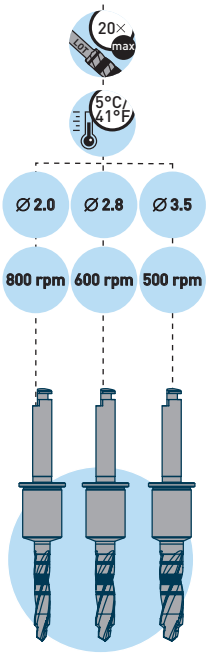
Warning:
Special slots are provided for loading the cassette with instruments. Pay attention to the dental shaft and graphic template.

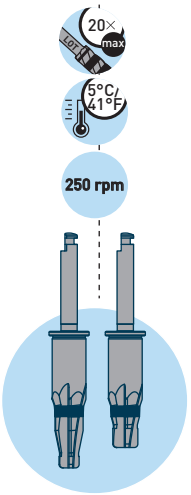
Example:











Basic preparation
Initial drill, guided

Stainless steel

	L 4.0
Length mm	28.5
Ø **2.0**	3.04.110

Basic preparation
VECTOdrill™pilot drill and drill, guided

Stainless steel

	L 6.5	L 9.5	L 12.5	L 8.0	L 11.0
Length mm	31.5	34.5	37.5	33.0	36.0
Ø **2.0**	3.04.111	3.04.113	3.04.115	3.04.112	3.04.114
Ø **2.8**	3.04.121	3.04.123	3.04.125	3.04.122	3.04.124
Ø **3.5**	3.04.131	3.04.133	3.04.135	3.04.132	3.04.134

Fine preparation
profile drill, guided

Stainless steel

	CONTACT MC	CONTACT RC	ELEMENT MC
Length mm	34.0	32.5	30.5
Ø **3.5**	3.04.171	3.04.161	3.04.151
Ø **4.0**	3.04.172	3.04.162	3.04.152
Ø **4.5**	3.04.173	3.04.163	3.04.153

MONO torque ratchet*

Titanium alloy

	3.03.160

MONO guide key*

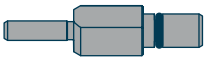
Stainless steel

	3.03.203

Guide sleeve

Stainless steel

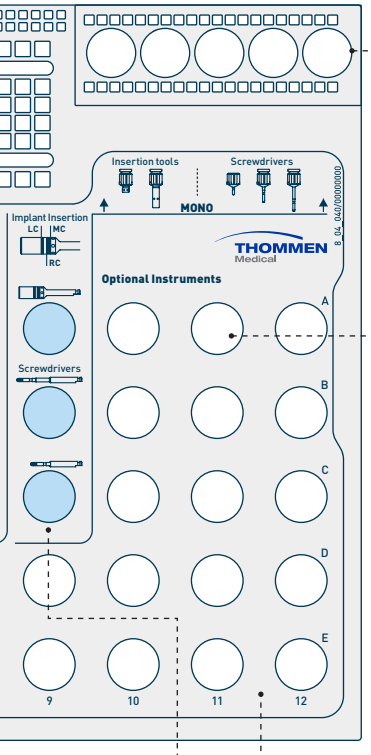
Length mm	5.0
∅ **4.8**	3.04.080 Q4

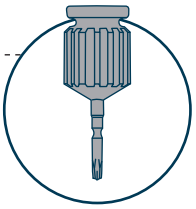


Seating instrument for guide sleeve

Stainless steel

∅ **4.8**	3.04.100





Optional instruments*

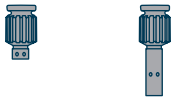
In addition to the clearly designated slots, additional slots are available for other instruments.

* Standard instruments (see www.ifu-tm.com/THM61141 and www.ifu-tm.com/THM31111)

MONO insertion device*

Stainless steel/PEEK

3.03.162	3.03.163	



MONO screwdriver*

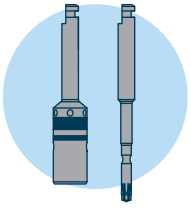
Stainless steel/PEEK

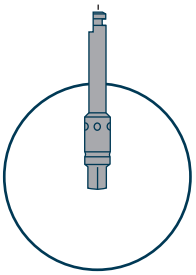
3.03.165	3.03.166	3.03.167

Max. 20 use cycles (operation, cleaning, sterilization) for cutting instruments. Further use cycles no longer guarantee the function of the product.

Cooling during drilling, approx. 5° C/ 41 °F.

15 rpm





Implant insertion adapter, guided

Stainless steel

	Adapter, guided	Screwdriver short	Screwdriver extra short
Length mm	25.5	22.0	17.0
	3.04.090	3.03.501	3.03.500

Adapter for contra angle, one-piece

Stainless steel

	∅ 3.5	∅ 4.0	∅ 4.5-6.0
Length mm			
24.0	3.03.248	3.03.251	3.03.241

3. Planning and preparation

Drilling template preparation

Before the operation, the drilling template must be checked for correct function (correct fit, stability, space) in the patient's mouth. The alignment of the guide sleeves must correspond to the preoperative planning. The respective manufacturer of the drilling template guarantees the compatibility of Thommen Medical guide sleeves with the drilling template. See p. 11 for assembly of the sleeves.

Planning software: You can find information on the compatible planning software solutions at www.thommenmedical.com

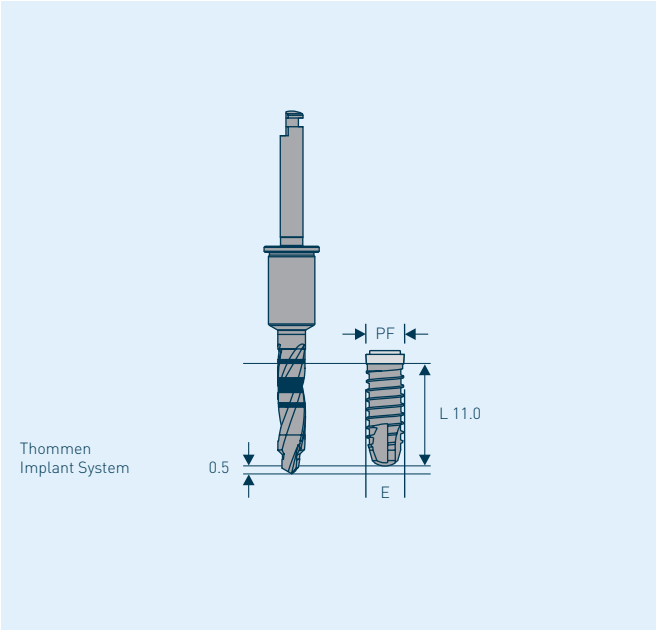
Drilling

⚠ **Warning:**
All VECTOdrill™ drills are 0.5 mm longer apically than the specified length of the respective Thommen Medical 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.

Note: If the guided surgery cannot be performed as planned, the guided instruments are also suitable for the standard procedure:

- Use the depth marks for depth control as shown on the graphic insert
- Start with the VECTOdrill ™ pilot drill, guided; do not use the initial drill, guided
- Sequential processing with VECTOdrill ™ drills and pilot drills, guided, if necessary
- Use the adapter, guided for implant insertion

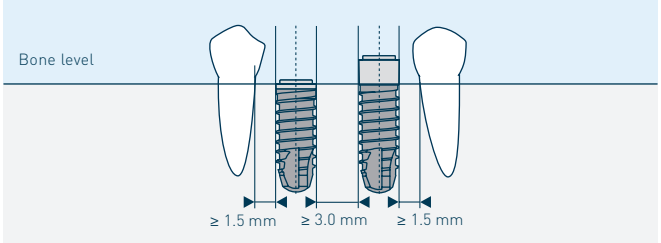
⚠ **Warning:**
Check the drilling depth of the implant bed after the first pilot drill step using the respective laser markings on the drill or using the depth gauge.



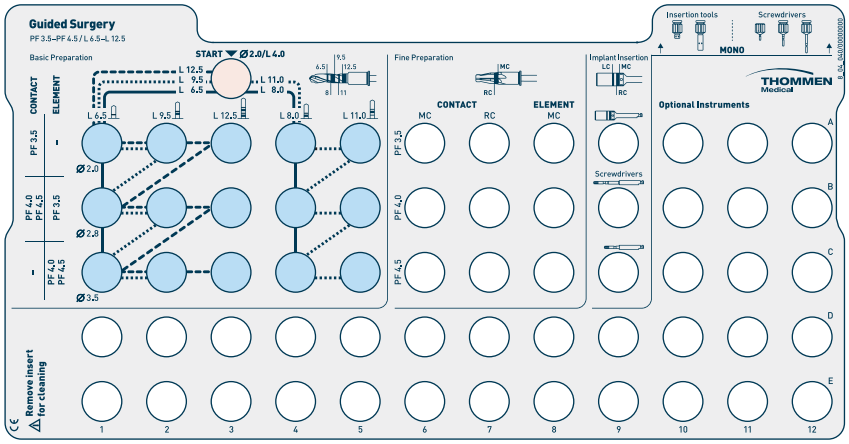
Anatomical structures

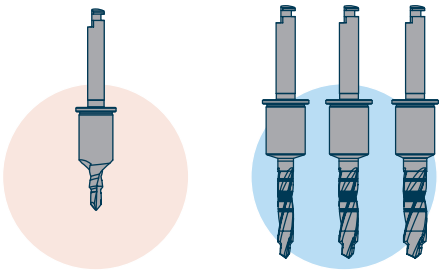
The mesiodistal position of the implants can be easily estimated by using a periodontal probe placed vestibularly or determined with a gauge. The required minimum gap width for the sleeve and minimum height for the instruments must be considered.

In case of tight spaces or guided pilot drilling, use the guide sleeve for VECTOdrill™ Pilot Drill ∅ 2.0 (Art. No. 3.03.141).



4. Basic preparation (VECTOdrill™)

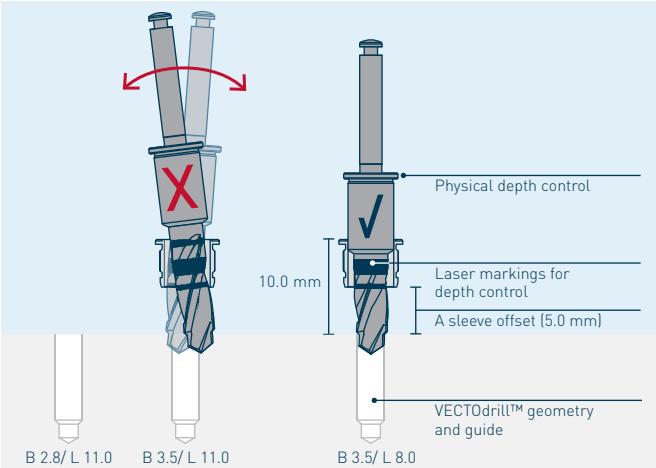




Double-guide principle

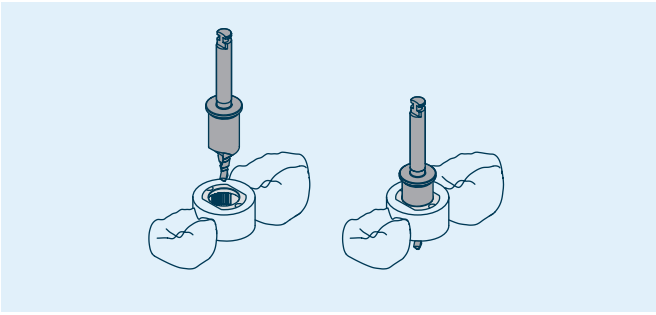
All VECTOdrill™ drills feature a stepped guide tip corresponding to the diameter of the preceding drill. This axis guidance prevents slippage of the drill and ensures a precisely shaped implant bed.

Warning:
No drilling sequences may be skipped to ensure the double-guide principle.



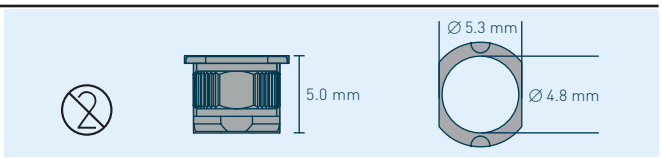
Drilling

Warning:
All holes must be drilled while constantly cooling the exterior with physiological, sterile, cooled saline solution (approx. 5°C/41°F). Recommended rotation speeds must be adhered to to avoid overheating the bone tissue and possible instrument fractures. Lateral forces must be avoided to prevent retention of the guide sleeve in the drilling template. Do not start drilling until the drill is positioned on the bone. Ensure continuous rotation of the drill during extraction.

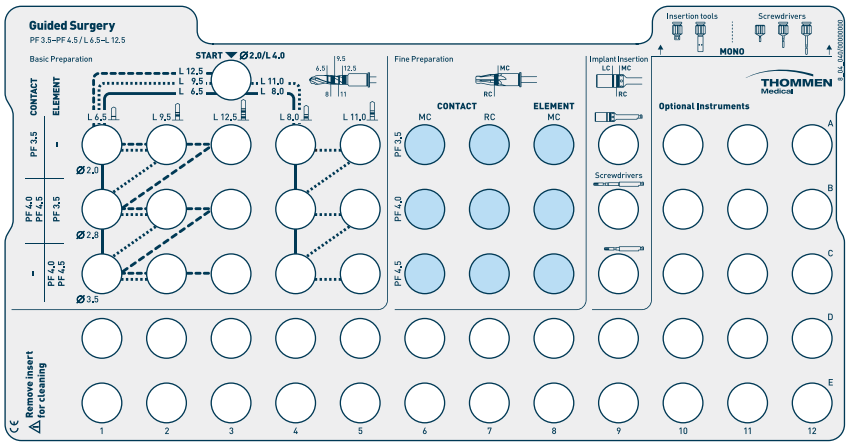


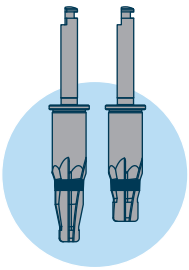
Guide sleeve

Warning:
The guide sleeves are intended only for single use. Multiple use does not guarantee correct functioning of the sleeve.



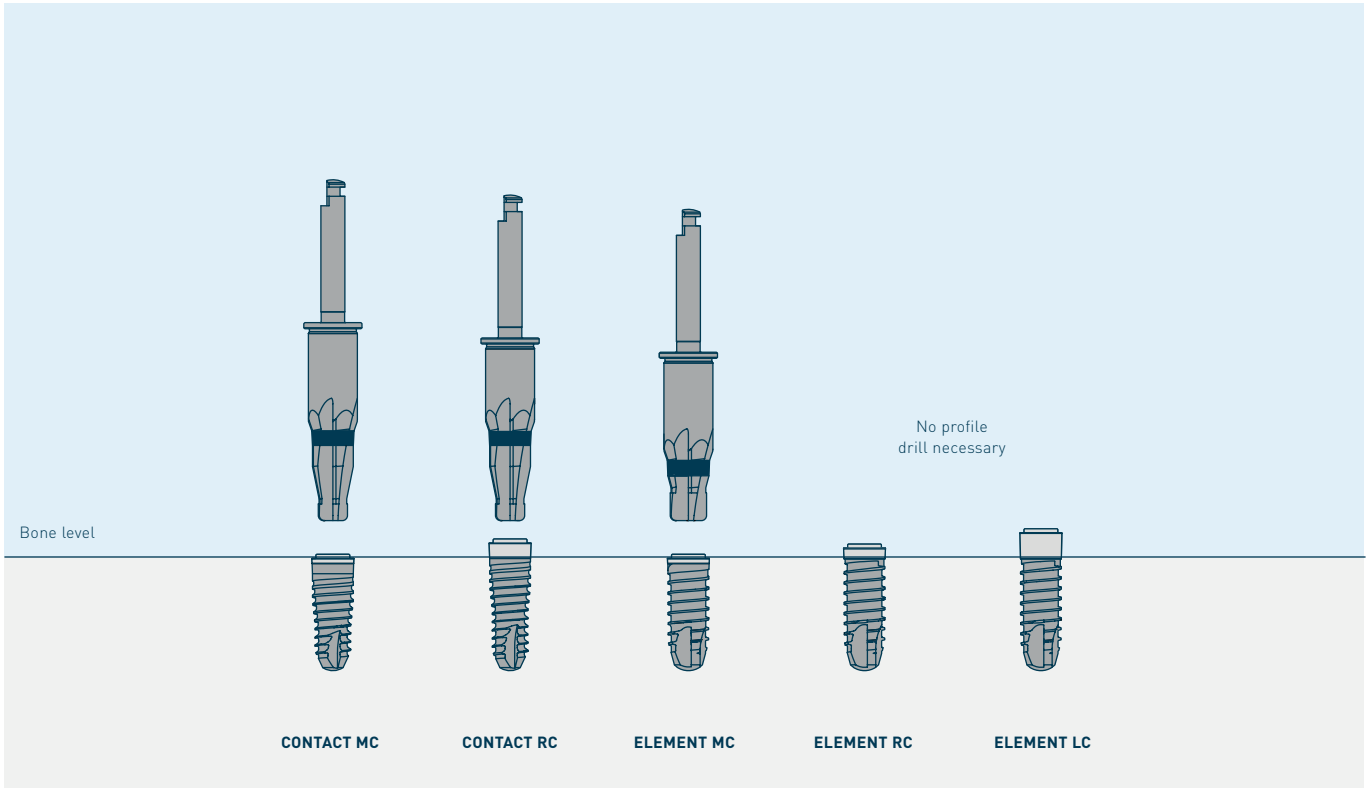
5. Fine preparation (profile drill)



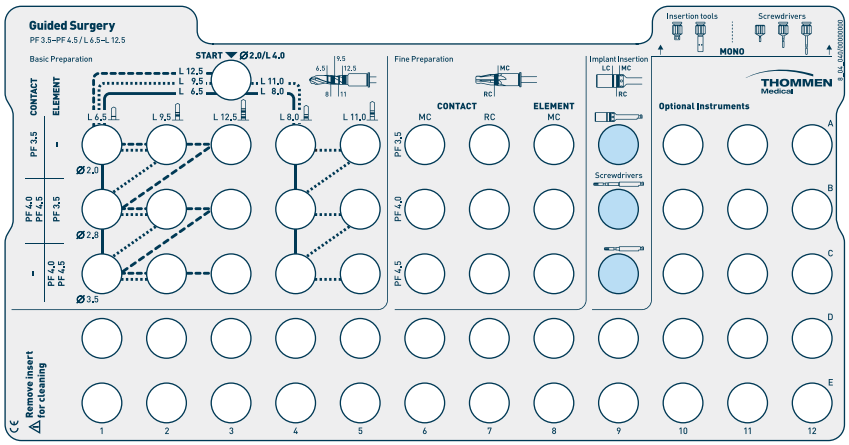


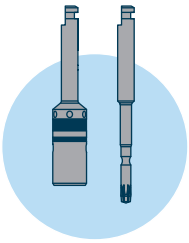
Selecting the profile drill

The profile drill is selected according to implant type and platform size as specified on the graphic insert.



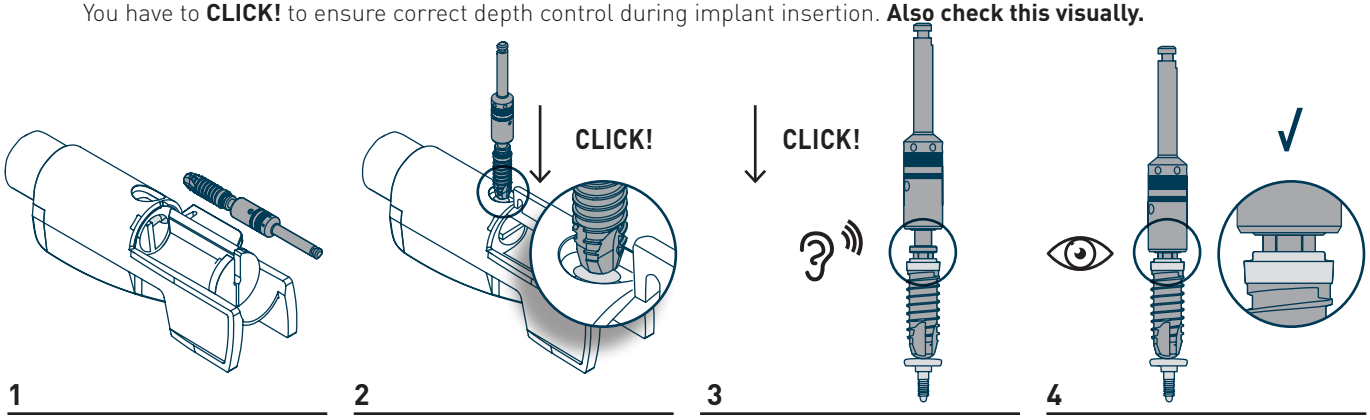
6. Implant insertion





Take up the implant and engage for implant insertion

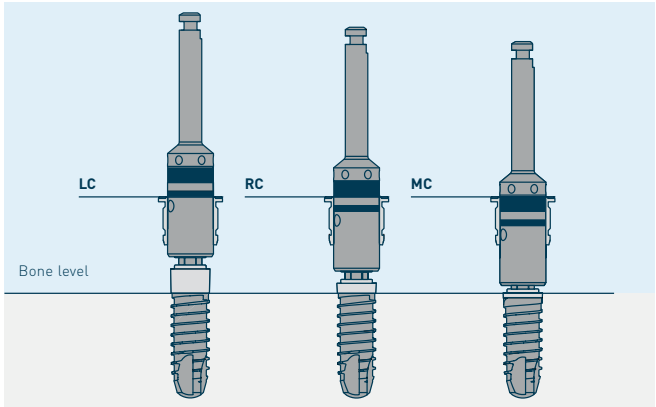
⚠ **Warning:**
You have to **CLICK!** to ensure correct depth control during implant insertion. **Also check this visually.**



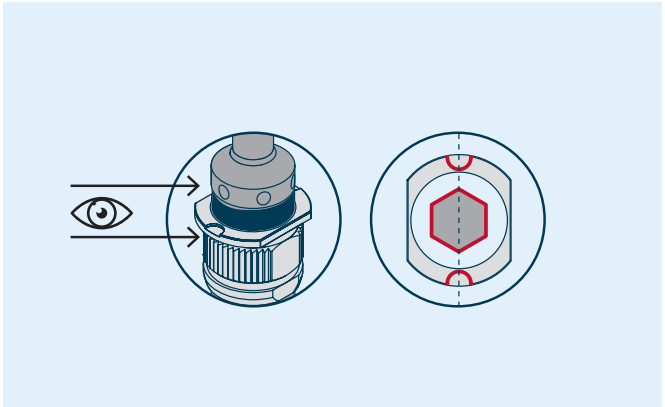
1 2 3 4

Use the same procedure for the standard implant packaging.

Implant insertion: Visual depth control

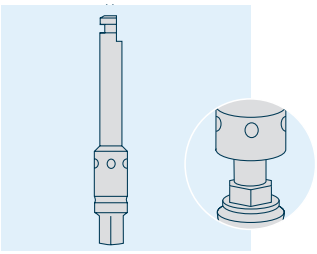


Rotation index: Implant alignment



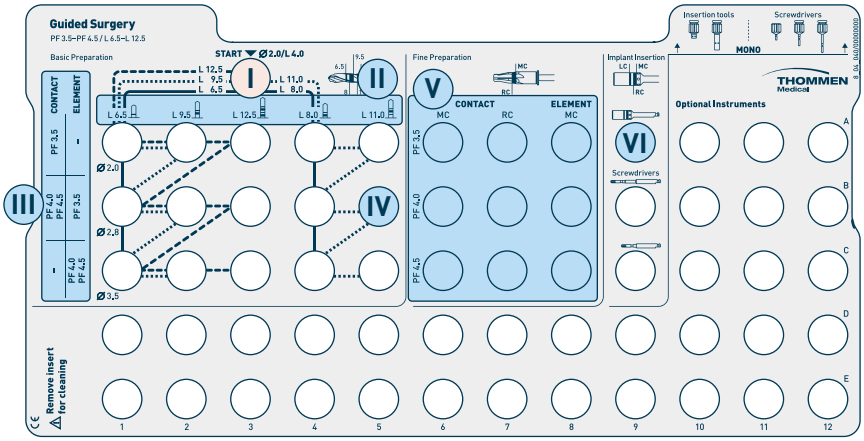
Adapter for handpiece, one-piece

The one-piece adapter for hand piece engages directly into the implant hexagon. It can be used after initially positioning the implant in the bone after the insertion aid has been removed.



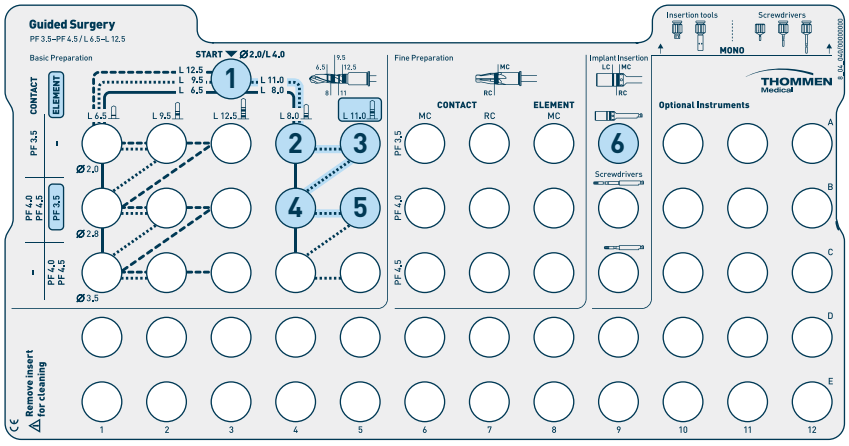
7. Drilling sequence

General information



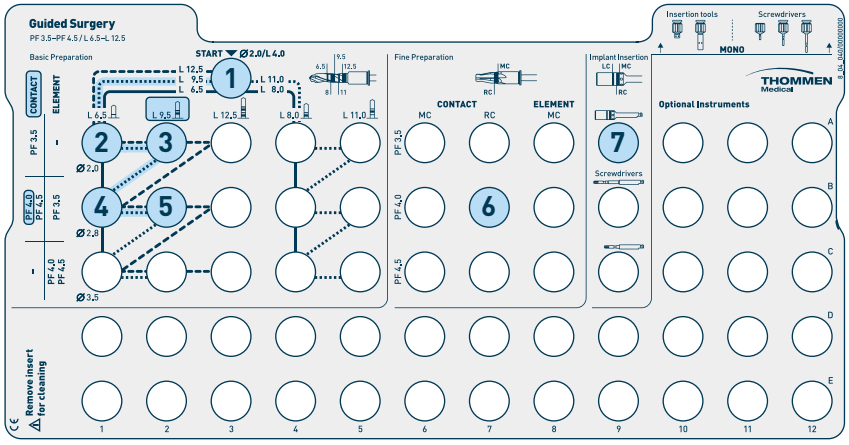
- I Always start with the initial drill
- II Select the length
- III Select the implant type and PF
- IV Identify the last VECTOdrill™ drill and follow the lines on the graphic insert
- V Use a profile drill, if necessary
- VI Use the adapter for implant insertion

Example 1, ELEMENT RC , PF 3.5/ L 11.0



ELEMENT RC: No profile drill required
(See p. 8).

Example 2, CONTACT RC, PF 4.0 / L 9.5



8. Assembly of the guide sleeve

Reprocessing

The guide sleeve is suitable for the sterilization procedure described in the processing instructions (www.ifu-tm.com/THM61131).

⚠ **Warning:**
Process the drilling template before use in accordance with the manufacturer's instructions. Make sure that the guide sleeves are securely and correctly fixed in the drilling template before use.

Drilling templates

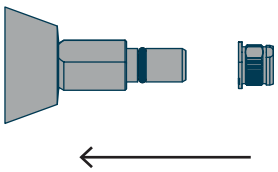
The diameter of printed sleeve cavities may vary depending on the 3D printing system used. If diameter corrections are necessary, you can refer to the design settings, if available. You can find recommended printing systems at www.thommenmedical.com.

⚠ **Warning:**
The seating instrument MUST be used for assembly of the sleeve and functional testing. The seating instrument is intended for multiple use. The product must be replaced as soon as it shows signs of wear and tear and/or damage.

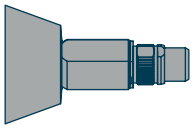
Handle for dental technicians	3.03.250

Seating instrument for guide sleeves	∅ 4.8 mm	3.04.100

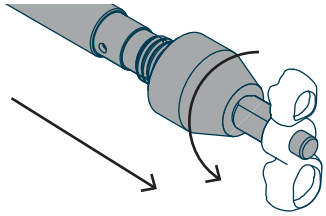
Guide sleeves	∅ 4.8 mm/L 5.0 mm	3.04.080 Q4



1

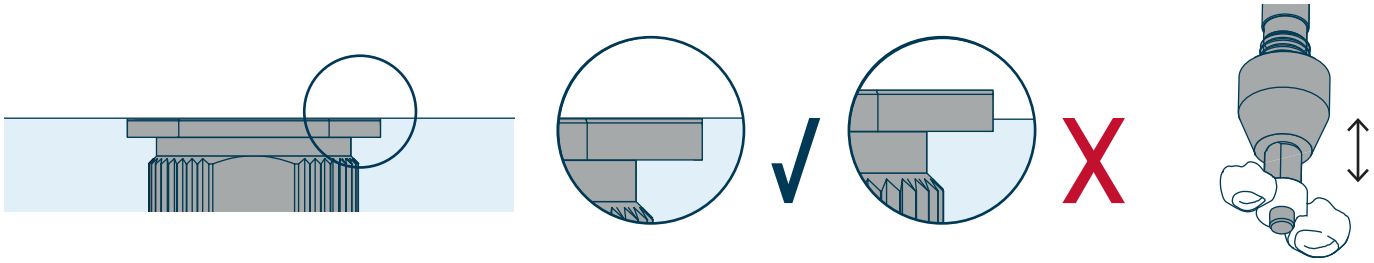


2



3

Functional testing



⚠ **Warning:**

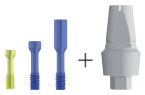
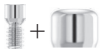
- The sleeve must be seated securely
- The seating instrument must fit and slide
- The sleeve edge must be correctly positioned vertically

9. Important

Precautionary measures

⚠
- Process the cassette and instruments before first use.
- You can find processing instructions at www.ifu-tm.com/THM61131.
- Max. 20 use cycles (operation, cleaning, sterilization) for cutting instruments. Further use cycles no longer guarantee the function of the product.
- Special slots are provided for loading the cassette with instruments. Pay attention to the dental shaft and graphic template.
  Process the drilling template before use in accordance with the manufacturer's instructions.
  Make sure that the guide sleeves are securely and correctly fixed in the drilling template before use.
- Defective or worn instruments must be replaced before the operation.
- Due to the function and construction of the drills, all VECTOdrill drills are 0.5 mm longer apically than the specified length of the respective Thommen Medical 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.
  Only use original Thommen Medical drills with a guiding cylinder B 4.8 mm in combination with original guide sleeves ∅ 4.8 mm.
- Do not start drilling until the drill is positioned on the bone. Ensure continuous rotation of the drill during extraction.
- Recommended rotation speeds must be adhered to in order to avoid overheating the bone tissue and possible instrument fractures.
- All holes must be drilled while constantly cooling the exterior with physiological, sterile, cooled saline solution (approx. 5°C/41°F). Regularly remove the bone chips to ensure ideal drilling performance.
- Check the drilling depth of the implant bed after the first pilot drill step using the respective laser markings on the drill or using the depth gauge.
  However, when implants are placed in extremely hard bone (such as, for example, in the case of a strongly atrophied edentulous mandible), thread-tapping can be indicated. You can find information on this at www.ifu-tm.com/THM61141.
- You have to CLICK! to ensure correct depth control during implant insertion. Also check this visually.
- The guide sleeves are intended only for single use. Multiple use does not guarantee correct functioning of the sleeve.
- The seating instrument MUST be used for assembly of the sleeve and functional testing. The seating instrument is intended for multiple use. The product must be replaced as soon as it shows signs of wear and tear and/or damage
- Functional testing: The sleeve must be fixed, the seating instrument must fit and slide and the sleeve edge must be correctly positioned vertically.

10. Torque values

ABUTMENT/SCREW	TORQUE VALUES IN Ncm				
	10	15	20	25	30
Healing cap Gingiva former 	PF 3.0 PF 3.5 PF 4.0 PF 4.5 PF 5.0 PF 6.0				
Abutment screws 		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 Novaloc® 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, 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 always be used for permanent insertion of the supraconstruction in the mouth.

11. General notes

THOMMEN IMPLANT SYSTEM

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

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

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

NEW HANDLING

New design – the application has not been changed.

NEW DESIGN

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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