SPI®VARIOmulti

Multi-unit occlusal screw-retained bridge restorations. Prosthetic procedure

Instructions for use and technical description THM61118

Version 010_AA, issue date 2025-02

THOMMEN Medical

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Instructions for use

These instructions for use refer to the Thommen Medical SPI®-VARIOmulti prosthetic components. See the technical description for detailed step-by-step instructions.

1.1 Product description

The prosthetic components of the Thommen Medical Dental Implant System are part of an overall concept and may only be used with the original components in accordance with the instructions for use and technical description provided.

Material

The materials for the individual products are to be found in the product list in Section 1.21.

The exact material composition of the implantable devices is as follows:

Titanium (grade 4)

Chemical components	**Composition in % (mass/mass)**
Total residual materials (Fe, O, C, N, H)	Max. 1.05
Pure titanium grade 4*	Residual
*ASTM F 67/ISO 5832–2	

Titanium aluminum-6 niobium-7 alloy (TAN)

Chemical components	**Composition in % (mass/mass)**
Niobium (Nb)	7
Aluminum (Al)	6
Residual materials (Ta, Fe, O, H, N, C) in total	Max. 1.09
Titanium (Ti)	Residual

Gold alloy

Chemical components	**Composition in % (mass/mass)**
Gold (Au)	60
Platinum (Pt)	24
Palladium (Pd)	15
Iridium (Ir)	1

1.2 Intended purpose

Thommen Medical prosthetic components are to be used in conjunction with the Thommen Medical dental implant system in the maxillary and mandibular jawbone for implant-supported dentures.

1.3 Indication

Thommen Medical prosthetic components are used in conjunction with the Thommen Medical Dental implant system in the partially/fully edentulous maxil-lary and mandibular arch to restore the chewing function.

1.4 Expected clinical benefit

Thommen Medical products help restore masticatory function.

1.5 Patient target group and intended user

These products are intended for the treatment of edentulous or partially edentulous patients for whom there is no contra-indication. Patients with incomplete growth of the lower or upper jaw are excluded from this treatment. Dentists must have appropriate knowledge of the field of implantology and information on the handling of Thommen Medical products in order to use the products safely and correctly. These users are 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.

1.6 Contra-indications

Hypersensitivity to the chemical components listed in Section 1.1 "Material".

1.7 Warnings and precautionary measures

Patients must be informed about contra-indications, warnings, precautionary measures, side effects and possible complications. They must also be informed about the MRI compatibility of the products used.

- Thommen Medical products may only be used with the associated original components in accordance with the accompanying documentation provided by Thommen Medical.
- Thommen Medical recommends always keeping spare products in stock and carrying out thorough preoperative planning in order to avoid complications.
- Failure to identify or comply with the contra-indications may cause implant failure.
- Inadequate preoperative planning and / or non-observance of the surgical technique, e.g. bone contouring, may cause complications and implant failure.
- Under no circumstances may Thommen Medical products be used beyond the expiry date, as proper functioning or sterility of the products cannot be guaranteed by the manufacturer.
- Products with damaged packaging must not be used under any circumstances. Damaged packaging can cause product contamination and/or impair the proper functioning of the product.

- Inspect the components carefully before each use. Never use damaged, deformed, corroded or discolored components.
- The instructions for use of other manufacturers whose materials are used for processing the prosthetic framework (e.g. cement, polymer or zirconium) must be observed.
- There is always a risk of injury from products with sharp edges.
- Restorations with cantilevers are not recommended.
- On implants with a reduced diameter (PF 3.5), the prosthetic restoration should be constructed in such a way that large torque does not occur.
- All Thommen Medical products which are used in the oral cavity must be protected against aspiration. Inhalation of products can restrict the ability to breathe and cause a foreign body reaction.
- Unless otherwise stated, all products are intended for single use. In the event of reuse, the general safety and performance of the products cannot be guaranteed. Cross-infection can potentially occur.
- Unless expressly stated in the instructions for use or the technical description, prosthetic components may not be modified.
- Sandblasting of prosthetic components in the neck area, in the screw channel or in the area of the mechanical connections is not permitted.
- Prosthetic components that are bonded to the superstructure (cement) must not be steam sterilized.
- Prosthetic components made of titanium must not be exposed to high heat (firing process).
- Prosthetic components can be used in occlusion if the implant is fully osseointegrated or has sufficient primary stability. The healing time required for complete osseointegration can vary considerably; it is patient-specific and depends on the treatment in question. The decision as to when the implant can be loaded is the sole responsibility of the user.
- Clean the internal implant connection before inserting the prosthetic components.

Information on MRI safety (magnetic resonance imaging)

These products are made from a metal material which can be affected by the magnetic fields of an MRI system. For further information, please refer to the instructions for use and the MRI safety information (THM61157) www.ifu-tm.com/THM61157. The patient must be informed about the MRI compatibility of the Thommen Medical products used.

1.8 Residual risks and undesirable side-effects

The clinical outcome of dental treatment is subject to various factors. The following possible residual risks and undesirable side-effects are associated with the products, and these must be communicated to the patient in this context:

- Ingestion/aspiration of products
- Injury to hard and soft tissue
- Hypersensitivity reactions
- Problems with biting/chewing/speaking
- Local pain and/or inflammation
- Local or systemic infection
- Inflammation of the mucous membrane (e.g. peri-implant mucositis)
- Loss, fracture or removal of the implant, prosthetic component or dental prosthesis
- Additional treatment in the dental practice

1.9 Restrictions of use

The implants restrictions of use must be strictly observed.

Single-tooth restorations:
Single-tooth restorations on SPI®VARIOmulti are not permitted.

Partially edentulous lower and upper jaw:
Restorations with SPI®VARIOmulti must be placed on at least three implants.

Edentulous lower and upper jaw:
Implants of the PF 3.5 platform that are restored with angulated VARIOmulti abutments in the posterior region must be splinted to implants with a larger platform.

1.10 Compatibility information

Each platform (PF) has a color code which can be found on all implant and abutment packs, on the impression items and on most diameter-specific instruments.

Yellow	=	PF 3.5
Green	=	PF 4.0
Blue	=	PF 4.5
Gray	=	PF 5.0
Purple	=	PF 6.0

For information on the Thommen Medical implant system, see:

www.ifu-tm.com/THM61112
www.ifu-tm.com/THM61113
www.ifu-tm.com/THM61141

1.11 Cleaning and disinfection

All products that are delivered in a non-sterile state must be processed in accordance with the instructions at www.ifu-tm.com/THM61131.

1.12 Sterility

The sterile products have a shelf-life of five years from the date of manufacture. 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 resterilized and used thereafter.

1.13 Further information

Since the launch of the new European Database for Medical Devices (EUDAMED), the summary of safety and clinical performance (SSCP) can be accessed on the EUDAMED website at: https://ec.europa.eu/tools/eudamed. The report is available on request.

1.14 Storage

Store the products in their original packaging in a dry place at room temperature and protected from direct sunlight. Improper storage can impair essential material properties and design features and result in functional failure.

1.15 Disposal

These products should be disposed of in an environmentally friendly way and in compliance with local laws and regulatory requirements. Hazardous waste including contaminated products or sharp objects should be disposed of in appropriate containers that correspond with the specific technical requirements.

1.16 Notes

Three patient labels are enclosed in each product package.
Users must have appropriate knowledge and information about the handling of Thommen Medical products in order to use the products safely and correctly.
The use of Thommen Medical products is the responsibility of the user.
The product must be used in accordance with the instructions for use and in each individual case the user must check whether the product is suitable for the patient's individual situation.
All serious incidents which have occurred in connection with the product must be reported to the manufacturer and to the local competent authority in the country where the user is resident.

1.17 Validity

All previous versions lose their validity with the publication of these instructions for use.

1.18 Availability

Not all Thommen Medical products mentioned in these instructions for use are available in all countries. The responsible country representative or distributor for Thommen Medical Ltd can provide information about availability of Thommen Medical products for the country in question.

1.19 Warranty

The comprehensive warranty services can be found in the country-specific warranty brochures in the download center at www.thommenmedical.com.

1.20 Symbols

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

LOT Batch code

Use by date

Date of manufacture

STERILE R Sterilized using irradiation

Single sterile barrier system

Single sterile barrier system with protective packaging inside

Not more than 20 processing cycles

EC REP European representative

Temperature limitation

Do not re-use

Non-sterile

Attention

REF Article number

CE 0297 Manufacturer's declaration that the product complies with the applicable EU legislation

Consult instructions for use or consult electronic instructions for use

Do not resterilize

Do not use if package is damaged and consult instructions for use

Atmospheric pressure limitation

Importer

Distributor

Keep away from sunlight

Rx only May only be sold to and prescribed by physicians (USA)

MD Medical device

UDI Unique device identifier

Sterile indicator – red means it has passed through a source of radiation

1.21 Product list

Art. No./REF	Description	Material	Single use	Sterile	UDI-DI
1.04.850	VARIOmulti titanium base for CAD/CAM, H 4.5 mm including occlusal screw	Titanium/ TAN	Yes	No	07640182641627
1.04.851	VARIOmulti titanium base for CAD/CAM set, shortenable H 9.0 mm, including occlusal screw	Titanium/ TAN	Yes	No	07640182641634
2.03.450Q5	Laboratory cylindrical pin, PF 3.5, L 70.0 mm	PTFE	Yes	No	07640156476163
2.03.600	VARIOmulti gold cap, incl. burn-out plastic cylinder, ∅ 4.8 mm, H 4.2/13.5 mm	Gold alloy/ POM	Yes	No	07640156476149
2.03.601Q2	VARIOmulti plastic cap, burn-out, ∅ 4.8 mm, H 13.5 mm	POM	Yes	No	07640156476132
3.03.083	VARIOmulti analog for CAD/CAM, L 13.2 mm	Titanium	No	No	07640182641672
3.03.157	Insertion device for VARIOmulti analog for CAD/CAM	Stainless steel	No	No	07640182641689
3.03.420	VARIO/VARIOmulti reamer for base, for VARIO PF 3.5 – 4.0 and VARIOmulti ∅ 4.8 mm, L 16.0 mm	Hard metal	No	No	07640156475012
3.03.424	VARIO guide pin for VARIOmulti reamer and VARIO PF 3.5, L 15.0 mm	Stainless steel	No	No	07640156474978
3.03.430	Gauge for reamer for screw channel	Stainless steel	No	No	07640156472288
3.03.437	Reamer for screw channel for VARIOmulti, L 40.0 mm	Stainless steel	No	No	07640156472257
3.03.521	Positioning handle for angled VARIO and VARIOmulti abutments, L 25.0 mm	Stainless steel	No	No	07640156474923
3.03.598Q4	Fabrication screw for VARIOmulti temporary cap	Stainless steel	Yes	No	07640156477771
3.03.780	VARIOmulti scan abutment, H 8.0 mm	Titanium	No	No	07640182641641
3.03.781	VARIOmulti scan abutment, short, H 5.0 mm	Titanium	No	No	07640182641665
3.03.800	VARIOmulti analog ∅ 4.8 mm, H 21.2 mm	Stainless steel	Yes	No	07640156474169
3.03.801	VARIOmulti impression coping, ∅ 5.3 mm, H 18.0 mm	Aluminum	Yes	No	07640156474152
3.03.803	VARIOmulti temporary cap, incl. fabrication screw, ∅ 5.0 mm, H 18.0 mm	Titanium, stainless steel	Yes	No	07640156478099
3.03.804	VARIOmulti temporary cap, ∅ 5.2, H 15.0 mm, incl. fabrication screw	Titanium, stainless steel	Yes	No	07640182642426
3.04.805	VARIOmulti impression coping, ∅ 5.3 mm, H 18.0 mm	Titanium	No	No	07640182642419
4.03.500	Abutment screw (4-lobe) for PF 3.5, L 5.8 mm	TAN	Yes	No	07640156473704
4.03.501	Abutment screw (4-lobe) for PF 4.0 - 6.0, L 7.2 mm	TAN	Yes	No	07640156471830
4.03.507	Occlusal screw (4-lobe), L 3.5 mm	TAN	Yes	No	07640156473674
4.03.800	VARIOmulti protective cap, incl. occlusal screw, ∅ 5.3 mm, H 4.2 mm	Titanium/ TAN	Yes	No	07640156472974
4.03.801	VARIOmulti protective cap ∅ 5.3 mm, H 4.5 mm	Titanium	Yes	No	07640182642433
4.03.300S	VARIOmulti abutment 17°, PF 3.5/4.8 mm, h 1.6 mm, sterile	Titanium	Yes	Yes	07640182644345
4.03.301S	VARIOmulti abutment 17°, PF 4.0/4.8 mm, h 1.6 mm, sterile	Titanium	Yes	Yes	07640182644352
4.03.302S	VARIOmulti abutment 17°, PF 4.5/4.8 mm, h 1.6 mm, sterile	Titanium	Yes	Yes	07640182644369
4.03.303S	VARIOmulti abutment 17°, PF 5.0/4.8 mm, h 1.6 mm, sterile	Titanium	Yes	Yes	07640182644376
4.03.304S	VARIOmulti abutment 17°, PF 6.0/4.8 mm, h 1.6 mm, sterile	Titanium	Yes	Yes	07640182644383
4.03.305S	VARIOmulti abutment 30°, PF 3.5/4.8 mm, h 1.2 mm, sterile	Titanium	Yes	Yes	07640182644390
4.03.306S	VARIOmulti abutment 30°, PF 4.0/4.8 mm, h 1.2 mm, sterile	Titanium	Yes	Yes	07640182644406
4.03.307S	VARIOmulti abutment 30°, PF 4.5/4.8 mm, h 1.2 mm, sterile	Titanium	Yes	Yes	07640182644413
4.03.308S	VARIOmulti abutment 30°, PF 5.0/4.8 mm, h 1.2 mm, sterile	Titanium	Yes	Yes	07640182644420

Art. No./REF	Description	Material	Single use	Sterile	UDI-DI
4.03.309S	VARIOmulti abutment 30°, PF 6.0/4.8 mm, h 1.2 mm, sterile	Titanium	Yes	Yes	07640182644437
4.03.310S	VARIOmulti abutment 17°, PF 3.5/4.8 mm, h 2.5 mm, sterile	Titanium	Yes	Yes	07640182644444
4.03.311S	VARIOmulti abutment 17°, PF 4.0/4.8 mm, h 2.5 mm, sterile	Titanium	Yes	Yes	07640182644451
4.03.312S	VARIOmulti abutment 17°, PF 4.5/4.8 mm, h 2.5 mm, sterile	Titanium	Yes	Yes	07640182644468
4.03.313S	VARIOmulti abutment 17°, PF 5.0/4.8 mm, h 2.5 mm, sterile	Titanium	Yes	Yes	07640182644475
4.03.315S	VARIOmulti abutment 30°, PF 3.5/4.8 mm, h 2.5 mm, sterile	Titanium	Yes	Yes	07640182644482
4.03.316S	VARIOmulti abutment 30°, PF 4.0/4.8 mm, h 2.5 mm, sterile	Titanium	Yes	Yes	07640182644499
4.03.317S	VARIOmulti abutment 30°, PF 4.5/4.8 mm, h 2.5 mm, sterile	Titanium	Yes	Yes	07640182644505
4.03.318S	VARIOmulti abutment 30°, PF 5.0/4.8 mm, h 2.5 mm, sterile	Titanium	Yes	Yes	07640182644512
4.03.600S	VARIOmulti abutment, PF 3.5/4.8 mm, h 0.8 mm, sterile	Titanium	Yes	Yes	07640182644215
4.03.601S	VARIOmulti abutment, PF 4.0/4.8 mm, h 0.8 mm, sterile	Titanium	Yes	Yes	07640182644222
4.03.602S	VARIOmulti abutment, PF 4.5/4.8 mm, h 0.8 mm, sterile	Titanium	Yes	Yes	07640182644239
4.03.603S	VARIOmulti abutment, PF 5.0/4.8 mm, h 0.8 mm, sterile	Titanium	Yes	Yes	07640182644246
4.03.604S	VARIOmulti abutment, PF 6.0/4.8 mm, h 1.5 mm, sterile	Titanium	Yes	Yes	07640182644253
4.03.605S	VARIOmulti abutment, PF 3.5/4.8 mm, h 2.0 mm, sterile	Titanium	Yes	Yes	07640182644260
4.03.606S	VARIOmulti abutment, PF 4.0/4.8 mm, h 2.0 mm, sterile	Titanium	Yes	Yes	07640182644277
4.03.607S	VARIOmulti abutment, PF 4.5/4.8 mm, h 2.0 mm, sterile	Titanium	Yes	Yes	07640182644284
4.03.608S	VARIOmulti abutment, PF 5.0/4.8 mm, h 2.0 mm, sterile	Titanium	Yes	Yes	07640182644291
4.03.610S	VARIOmulti abutment, PF 3.5/4.8 mm, h 3.0 mm, sterile	Titanium	Yes	Yes	07640182644307
4.03.611S	VARIOmulti abutment, PF 4.0/4.8 mm, h 3.0 mm, sterile	Titanium	Yes	Yes	07640182644314
4.03.612S	VARIOmulti abutment, PF 4.5/4.8 mm, h 3.0 mm, sterile	Titanium	Yes	Yes	07640182644321
4.03.613S	VARIOmulti abutment, PF 5.0/4.8 mm, h 3.0 mm, sterile	Titanium	Yes	Yes	07640182644338
4.03.600	VARIOmulti abutment, with handle, PF 3.5/4.8 mm, shoulder height 0.8 mm	Titanium	Yes	No	07640156473360
4.03.601	VARIOmulti abutment, with handle, PF 4.0/4.8 mm, shoulder height 0.8 mm	Titanium	Yes	No	07640156473353
4.03.602	VARIOmulti abutment, with handle, PF 4.5/4.8 mm, shoulder height 0.8 mm	Titanium	Yes	No	07640156473346
4.03.603	VARIOmulti abutment, with handle, PF 5.0/4.8 mm, shoulder height 0.8 mm	Titanium	Yes	No	07640156473339
4.03.604	VARIOmulti abutment, with handle, PF 6.0/4.8 mm, shoulder height 1.5 mm	Titanium	Yes	No	07640156472165
4.03.605	VARIOmulti abutment, with handle, PF 3.5/4.8 mm, shoulder height 2.0 mm	Titanium	Yes	No	07640156473322
4.03.606	VARIOmulti abutment, with handle, PF 4.0/4.8 mm, shoulder height 2.0 mm	Titanium	Yes	No	07640156473315
4.03.607	VARIOmulti abutment, with handle, PF 4.5/4.8 mm, shoulder height 2.0 mm	Titanium	Yes	No	07640156473308
4.03.608	VARIOmulti abutment, with handle, PF 5.0/4.8 mm, shoulder height 2.0 mm	Titanium	Yes	No	07640156473292
4.03.610	VARIOmulti abutment, with handle, PF 3.5/4.8 mm, shoulder height 3.0 mm	Titanium	Yes	No	07640156473285
4.03.611	VARIOmulti abutment, with handle, PF 4.0/4.8 mm, shoulder height 3.0 mm	Titanium	Yes	No	07640156473278
4.03.612	VARIOmulti abutment, with handle, PF 4.5/4.8 mm, shoulder height 3.0 mm	Titanium	Yes	No	07640156473261
4.03.613	VARIOmulti abutment, with handle, PF 5.0/4.8 mm, shoulder height 3.0 mm	Titanium	Yes	No	07640156473254
4.03.680	VARIOmulti abutment 17°, PF 3.5/4.8 mm, shoulder height 2.7 mm	Titanium	Yes	No	07640156473247
4.03.681	VARIOmulti abutment 17°, PF 4.0/4.8 mm, shoulder height 2.7 mm	Titanium	Yes	No	07640156473230
4.03.682	VARIOmulti abutment 17°, PF 4.5/4.8 mm, shoulder height 2.7 mm	Titanium	Yes	No	07640156473223
4.03.683	VARIOmulti abutment 17°, PF 5.0/4.8 mm, shoulder height 2.7 mm	Titanium	Yes	No	07640156472158
4.03.684	VARIOmulti abutment 17°, PF 6.0/4.8 mm, shoulder height 2.7 mm	Titanium	Yes	No	07640156472141
4.03.685	VARIOmulti abutment 30°, PF 3.5/4.8 mm, shoulder height 3.3 mm	Titanium	Yes	No	07640156472523
4.03.686	VARIOmulti abutment 30°, PF 4.0/4.8 mm, shoulder height 3.3 mm	Titanium	Yes	No	07640156472516
4.03.687	VARIOmulti abutment 30°, PF 4.5/4.8 mm, shoulder height 3.3 mm	Titanium	Yes	No	07640156472509
4.03.688	VARIOmulti abutment 30°, PF 5.0/4.8 mm, shoulder height 3.3 mm	Titanium	Yes	No	07640156472134
4.03.689	VARIOmulti abutment 30°, PF 6.0/4.8 mm, shoulder height 3.3 mm	Titanium	Yes	No	07640156472127

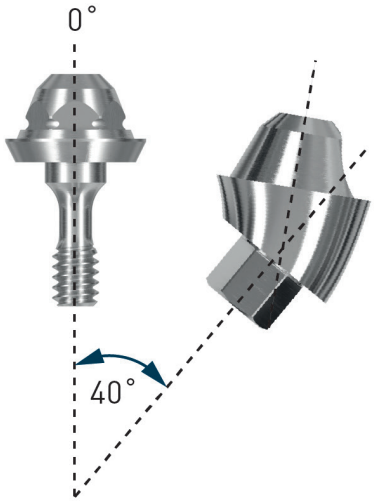
Technical description

2 SPI®VARIOmulti

2.1 General information

This technical description applies to the Thommen Medical prosthetic components of the SPI®VARIOmulti product line, including all other products intended for use in combination with this product line. This accompanying documentation contains important information for users which, together with the instructions for use, contribute to ensuring that the products are used safely and effectively.

SPI®VARIOmulti is suited for multi-unit, screw-retained bridge restorations on at least three implants. Depending on the number and position of implants, implant divergences of up to 40° can be compensated.



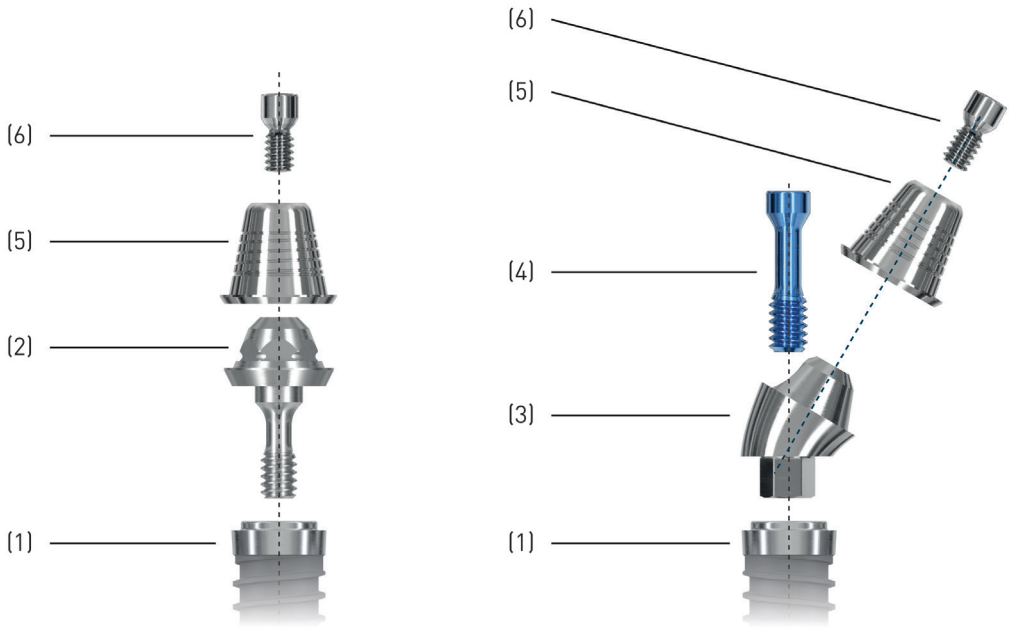
For details of the identifying elements (geometries, dimensions) of the individual products, see the product catalog (www.ifu-tm.com/THM31111).

2.2 Overview

The Thommen Medical SPI®VARIOmulti product line comprises various prosthetic components. VARIOmulti abutments are only compatible with Thommen Medical implants[1] with the interfaces PF 3.5, PF 4.0, PF 4.5, PF 5.0 and PF 6.0.

VARIOmulti abutments are available in two types. The straight type, the VARIOmulti abutment[2], is one-piece and has a screw stump for attachment to the implant. The angled type, the VARIOmulti abutment, angled[3], is in two parts and is fixed with a separate prosthetic screw, the abutment screw[4]. The angle is either 17° or 30°.

The abutments are available in different neck heights, allowing the prosthetic interface with a diameter of 4.8 mm to be positioned accessibly in the soft tissue. This means that all further treatment steps, such as the impression and the temporary and final prosthetic restoration, can be carried out at abutment level. The tertiary parts[5] intended for the prosthetic restoration, which are sometimes also referred to as caps due to their geometric shape, are attached to the abutment either with an internal screw stump or separate screws, e.g. with an occlusal screw[6].



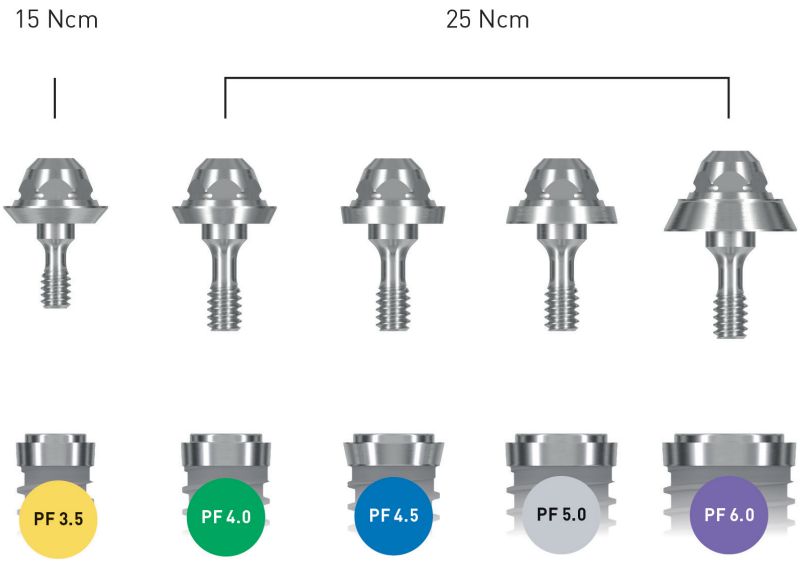
Example: VARIOmulti abutment (left) and VARIOmulti angled 30° (right) incl. associated products.

⚠ **Warning/precautionary measure:** Thommen Medical products may only be used with the associated original components in accordance with the accompanying documentation provided by Thommen Medical.

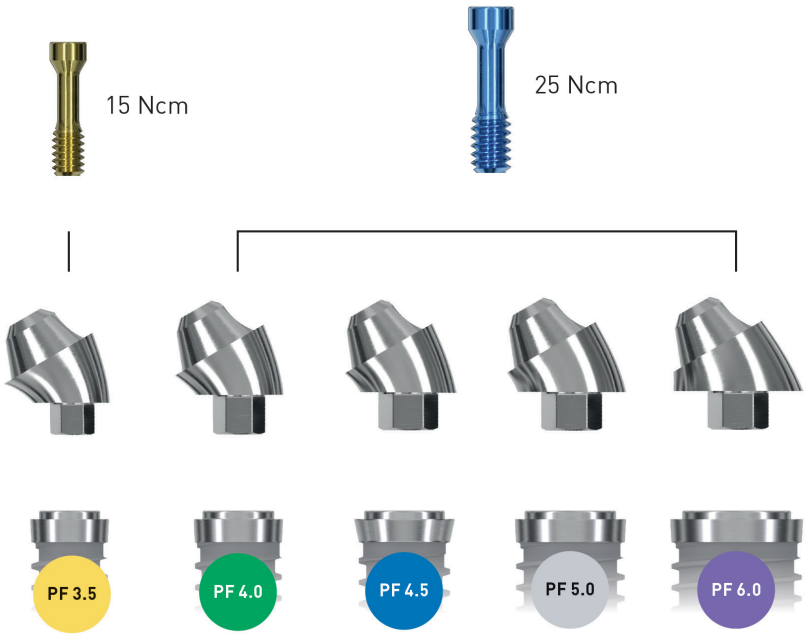
2.3 The implant-abutment connection

Information on the EVERGUARD® implant-abutment connection is to be found in the technical description under "Surgical procedure" (www.ifu-tm.com/THM61141)

Connection overview for VARIOmulti abutment

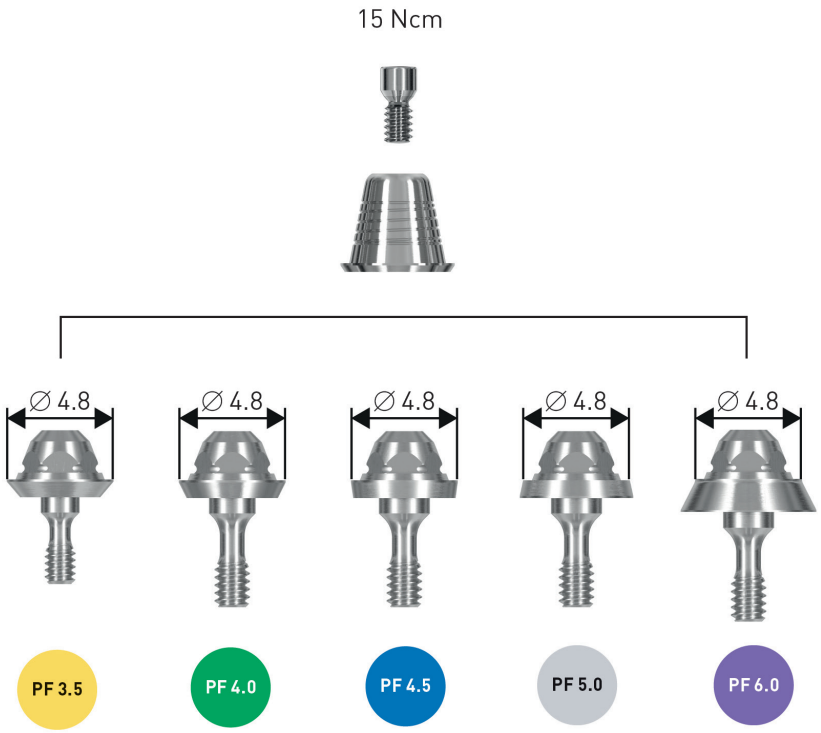


Connection overview for VARIOmulti abutment, angled

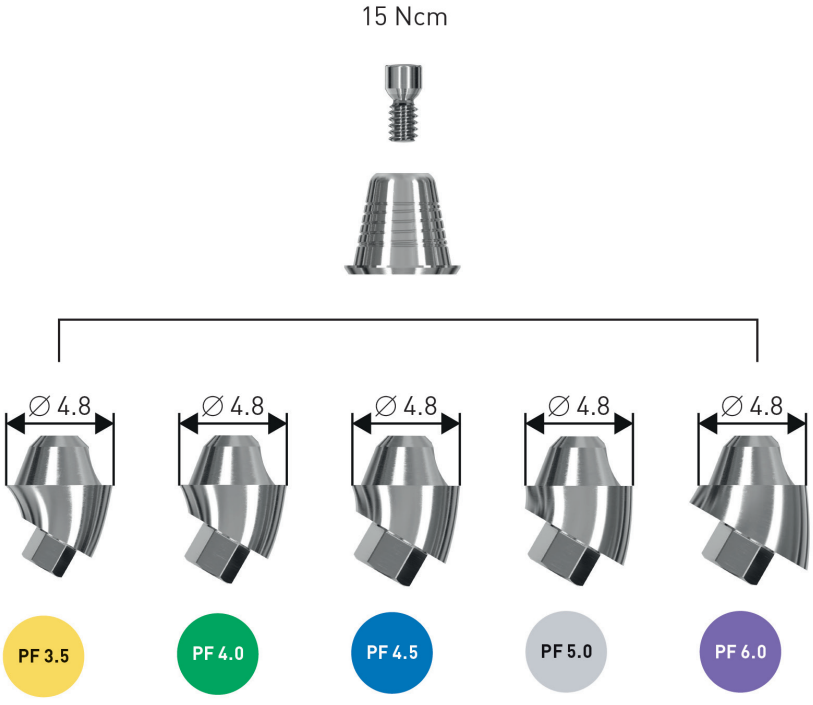


2.4 The prosthetic connection

Connection overview for VARIOmulti abutment

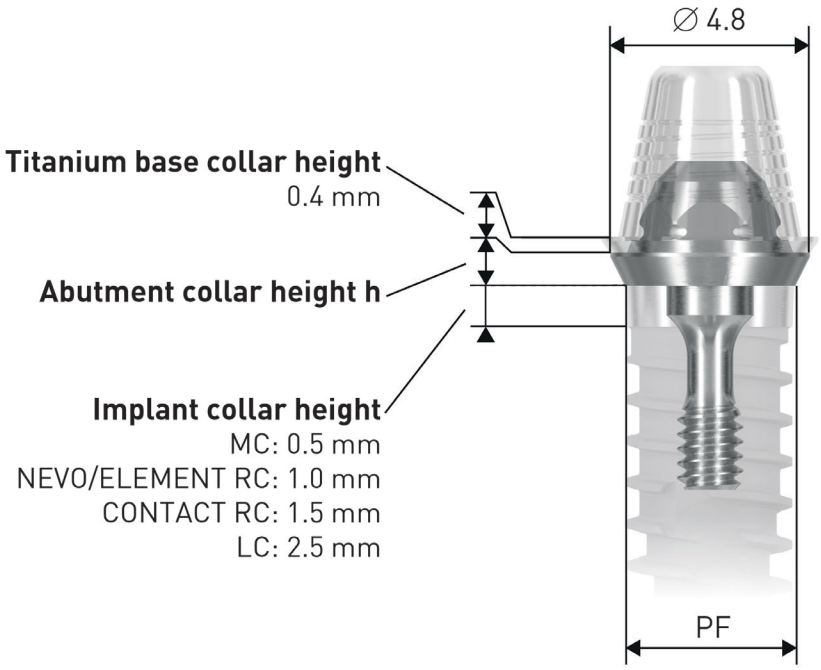


Connection overview for VARIOmulti abutment, angled



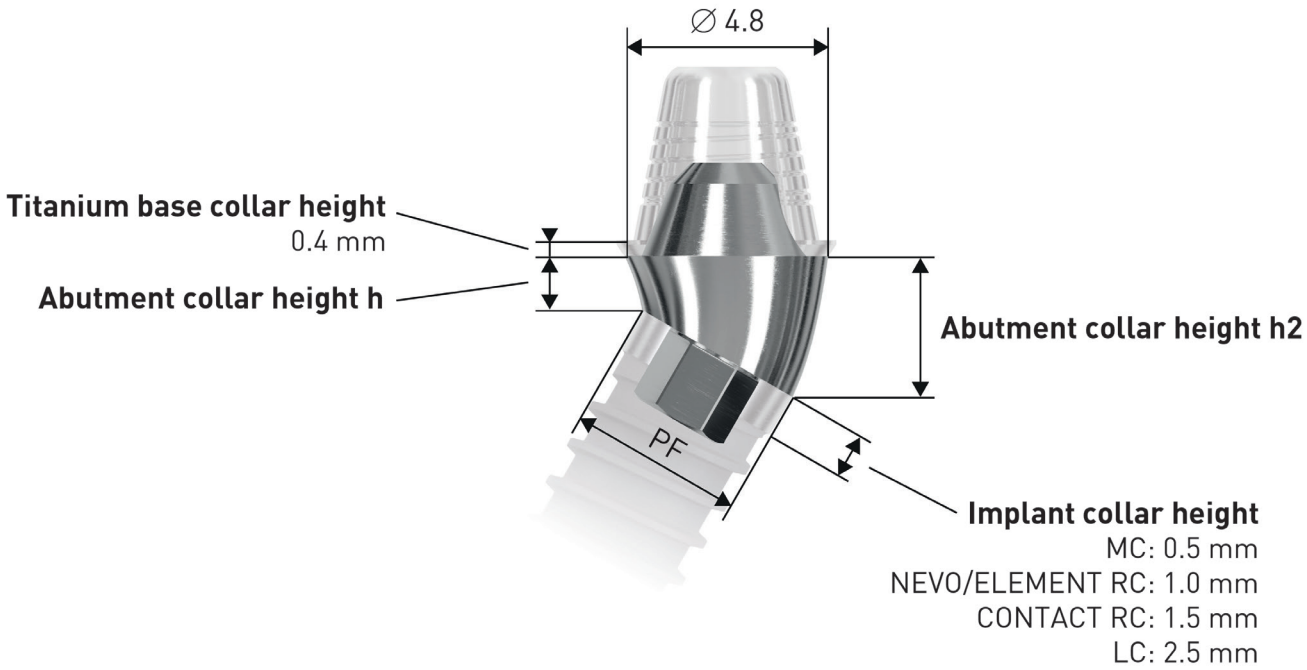
3 Overview of variants

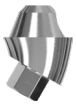
3.1 VARIOmulti abutment



Abutment neck height h (mm)	PF 3.5	PF 4.0	PF 4.5	PF 5.0	PF 6.0
0.8	 4.03.600S	 4.03.601S	 4.03.602S	 4.03.603S	
1.5					 4.03.604S
2.0	 4.03.605S	 4.03.606S	 4.03.607S	 4.03.608S	
3.0	 4.03.610S	 4.03.611S	 4.03.612S	 4.03.613S	
Torque	15 Ncm	25 Ncm			

3.2 VARIOmulti abutment, angled



Angle	Abutment neck height: h, h2 (mm)	PF 3.5	PF 4.0	PF 4.5	PF 5.0	PF 6.0
17°	h: 1.6 h2: 3	 4.03.300S	 4.03.301S	 4.03.302S	 4.03.303S	 4.03.304S
	h: 2.5 h2: 4	 4.03.310S	 4.03.311S	 4.03.312S	 4.03.313S	
30°	h: 1.2 h2: 3.5	 4.03.305S	 4.03.306S	 4.03.307S	 4.03.308S	 4.03.309S
	h: 2.5 h2: 4.5	 4.03.315S	 4.03.316S	 4.03.317S	 4.03.318S	
	Abutment screw					
	Torque	15 Ncm	25 Ncm			

4 Components and accessories

4.1 Cleaning, disinfection and sterilization

Non-sterile packaged disposable products:
Non-sterile packaged products that are removed directly from the packaging and used in the sterile work area only need to be sterilized.

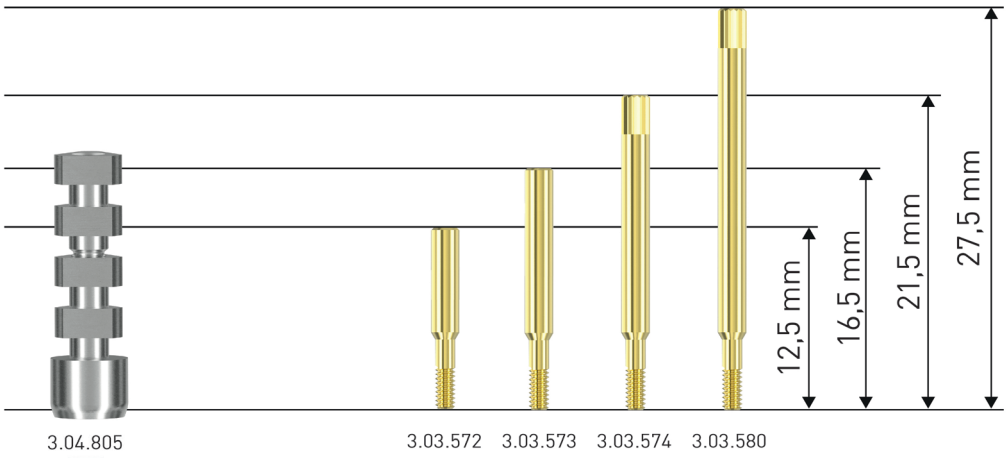
Non-sterile packaged products that are further processed in the sterile working area before use (e.g. trial fitting on the model) must be cleaned/disinfected and sterilized.

For a description of the processing procedure, see www.ifu-tm.com/THM61131.

Non-sterile packaged, reusable products:
All reusable products must be cleaned, disinfected and sterilized before first use.

For a description of the processing procedure, see www.ifu-tm.com/THM61131.

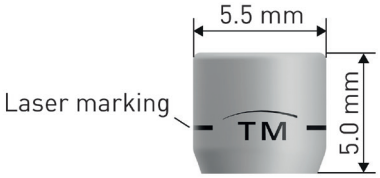
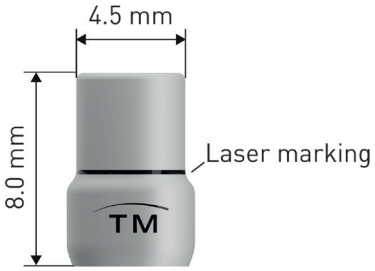
4.2 Impression coping and scan abutment

	VARIOmulti impression coping	**Screws for impression coping**
Dimensions		
Application	Torque: hand-tight	
Use	Multiple use	
Material	Titanium	Stainless steel
Delivery status	Non-sterile	

⚠ **Warnings/precautionary measures:**
- After shortening the VARIOmulti impression coping, break off any rough or sharp edges at the separation site using a suitable sander/polisher.
- Visually inspect the product for wear on the connection geometry.

The **Thommen Medical VARIOmulti scan abutments** are used to transfer the position and orientation of VARIOmulti abutments during digital impression taking, either on the master cast or intraorally. A coating spray is not required.

Two variants are available for digital impression taking at abutment level:

	VARIOmulti scan abutment, short	**VARIOmulti scan abutment, long**
Dimensions	 3.03.781	 3.03.780
Application	– For intraoral scans without adjacent teeth, if the laser marking is visible above the gingiva. – Torque: hand-tight.	– For laboratory scans. – For intraoral scans with adjacent teeth. – Torque: hand-tight.
Use	Multiple use (max. 20 times) (21)	
Material	Titanium	
Delivery status	Non-sterile	

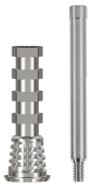
⚠ **Warnings/precautionary measures:**
– Modification of the VARIOmulti scan abutment is not permitted. The scan abutments must be processed and sterilized before intraoral use. They may be processed a maximum of 20 times.
– Visually inspect the product for wear on the connection geometry and on the scan area.

For general information on processing, see: www.ifu-tm.com/THM61131.

4.3 Laboratory analog

	VARIOmulti analog for stone models	**VARIOmulti analog for CAD/CAM for printed models**
	 3.03.800	 3.03.083
Diameter (mm)	4.8	
Length (mm)	21.2	13.2
Use	Single use ⊗	Multiple use
Material	Stainless steel	Titanium
Delivery condition	Non-sterile	
Accessories		**Insertion device for VARIOmulti analog for CAD/CAM**  3.03.157 Multiple use Length: 35.8 mm

4.4 Protective cap and components for the temporary restoration

	VARIOmulti protective cap	**VARIOmulti temporary cap, incl. fabrication screw**
	 4.03.801	 3.03.804
Diameter (mm)	5.3	5.2
Height (mm)	4.5	15
Application	Torque: 10 Ncm	Torque fabrication screw: hand-tight Torque occlusal screw: 15 Ncm
Use	Single use	
Material	Titanium	Cap: Titanium Screw: Stainless steel
Delivery condition	Non-sterile	

⚠ **Warnings/precautionary measures:**

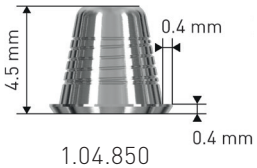
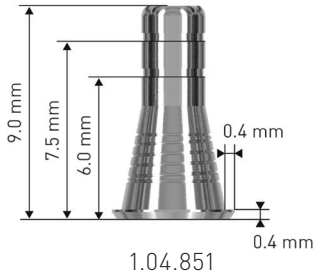
- The temporary cap must not be steam sterilized in a polymerized state.
- The temporary cap must not be sandblasted in the region of the connection geometry and screw channel. Precautionary measure: The VARIOmulti analog can be used to protect the connection geometry when processing the temporary cap.
- Shrinkage of the curing polymer can cause the abutment interface of the temporary cap to shift its position. Precautionary measure: In order to minimize such displacements, it is recommended to apply the polymer over the entire area and as close as possible to the abutment interface.
- Follow the instructions for use for the liquid polymer. Make sure that no polymer enters the wound area, if applicable. Precautionary measure: Using a rubber dam can reduce contamination of the wound area.

4.5 Components for the final restoration

Reconstruction using the casting technique:

	VARIOmulti gold cap	**VARIOmulti burn-out plastic cap**
	 2.03.600	2.03.601Q2
Diameter (mm)	4.8	
Height	4.2/13.5	13.5
Use	Single use	
Material	NOA/burn-out plastic	Plastic

Reconstruction using CAD/CAM:

	Occlusal screw	**VARIOmulti titanium base for CAD/CAM**	**VARIOmulti titanium base for CAD/CAM, shortenable**
Dimensions	 4.03.507 Length: 3.5 mm	 1.04.850	 1.04.851
Application	Torque: 15 Ncm	⚠ **Warning/precautionary measure:** Modification of the VARIOmulti titanium base for CAD/CAM is not permitted	shortening only possible up to the retention groove, height 6.0 mm
Use	Single use		
Material	Titanium alloy	Titanium	

⚠ **Warning/precautionary measure:** The wall thickness or the neck area of the two titanium bases must not be modified.

LOCATOR® abutment and collar for VARIOmulti (not for PF 3.5)	 8909-2
Torque	20 Ncm

For information on abutments and instruments in the ZEST system, see: www.zestdent.com/knowledge-hub/library

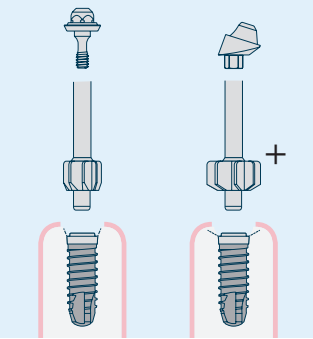
5 Instruments

5.1 Bone contouring instruments

⚠ **Warning/precautionary measure:** In order to guarantee an accurate and unobstructed fit of the abutment, a bone contouring instrument should be used for implants in a crestal or subcrestal position.

To facilitate an accurate fit of the prosthesis, the contour of the bone can be prepared with the bone contouring instrument without damaging the connection geometry of the implant.

The bone contouring instrument+ has been specifically developed for the removal of excess bone around angled VARIOmulti abutments. The bone contouring instrument+ is larger than the existing bone contouring instrument because a sufficient amount of bone must be removed from around implants positioned at an acute angle which are provided with angled VARIOmulti abutments.



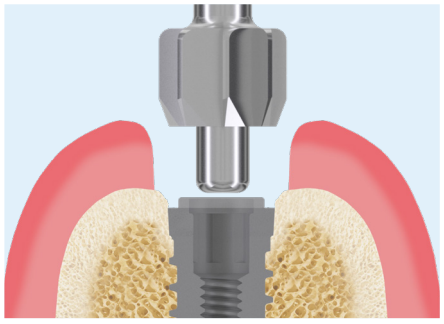
⚠ **Warning/precautionary measure:** Because of the larger size of the bone contouring instrument+, it must be used exclusively with implants that are then restored with a angeled VARIOmulti abutment.

Bone contouring instruments

	3.03.671	3.03.670	3.03.673	3.03.672	3.03.675	3.03.674	3.03.677	3.03.676	3.03.679
PF	3.5		4.0		4.5		5.0		6.0
Use	Multiple (max. 20 times (21))								
Material	Stainless steel								
Length (mm)	29								
External diameters	4.3	7	5.1	7.2	5.6	7.2	6.1	7.2	7.1

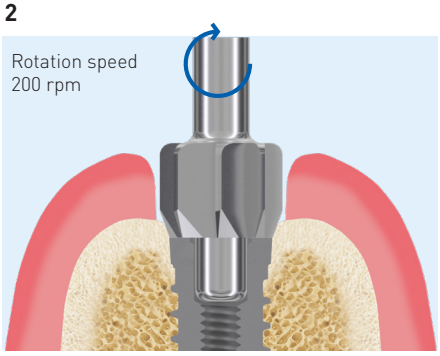
Application

1



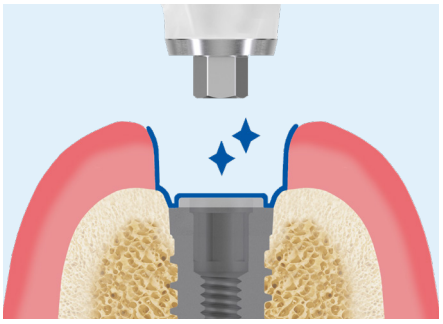
1. The connection geometry needs to be fully accessible. Position the guide pin of the bone contouring instrument, ensuring that the axis of the contouring instrument is aligned with the implant axis.

2



2. Turning it clockwise removes the bone from 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 rotation speed of 200 rpm.

3



3. The clearance for the passive seat of the prosthesis is established as soon as the bone contouring instrument sits on the implant. Before inserting the prosthetic components, the connection geometry must be cleaned thoroughly and dried.

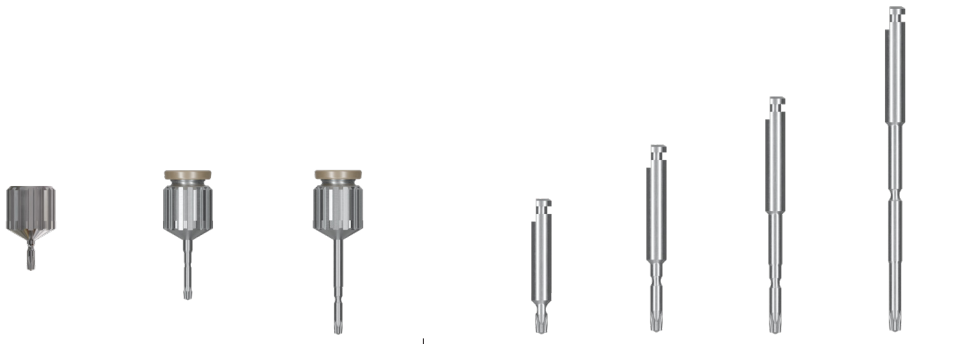
5.2 Insertion devices

3.03.162 3.03.163

3.03.240 3.03.249

Name	MONO insertion device		Adapter for handpiece	
Use	Multiple		Multiple	
Material	Stainless steel/PEEK		Stainless steel	
Length (mm)	Short 15.4	Long 25.8	Short 18.0	Long 28.0
Use	Manual insertion and removal of implants		Mechanical insertion and removal of implants	
Special features	Standard size for all PFs		Standard size for all PFs For use with the MONO insertion device or a supported handpiece	

Screwdrivers



	3.03.165	3.03.166	3.03.167	3.03.500	3.03.501	3.03.502	3.03.503
Name	**MONO screwdriver**			**Screwdriver for handpiece**			
Use	Multiple			Multiple			
Material	Stainless steel (also finger plate made of PEEK for short and long)			Stainless steel			
Length (mm)	Extra short 14.5	Short 22.2	Long 28.2	Extra short 17.0	Short 22.0	Long 28.0	Extra long 38.0
Use	Manual insertion and tightening of all healing caps, gingiva formers and screws			Mechanical insertion and tightening of all healing caps, gingiva formers and screws			
Special features	Integrated breaking point for the prevention of excess torques						

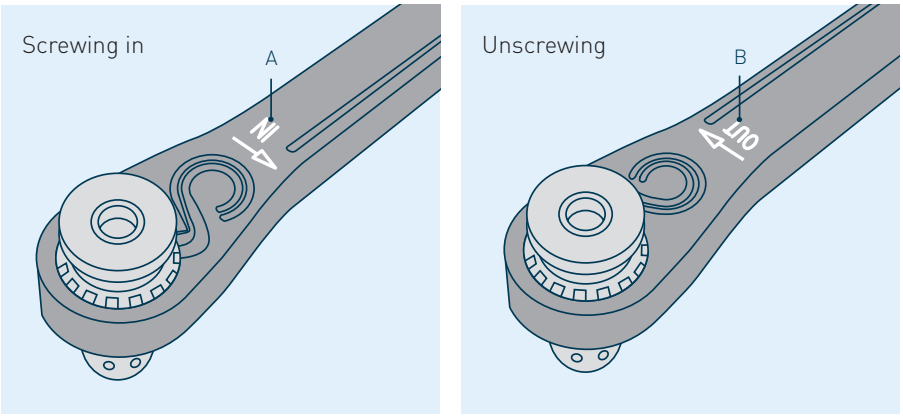
MONO torque ratchet

⚠ **Warning/precautionary measure:** The MONO torque ratchet may only be used in combination with MONO insertion devices and MONO screwdrivers.

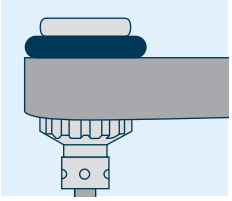
The one-piece MONO torque ratchet is made of titanium alloy and features the following advantages:

– can be used in surgery and prosthetics
– no parts to disassemble for cleaning or sterilization
– no need for maintenance

The torque ratchet is marked on both sides: one side with «IN» (A) and the other side with «OUT» (B). The arrows shown on each side indicate in which direction the ratchet must be turned. For screwing in, place the ratchet on the ratchet body in such a way that the side marked "IN" points upward. For unscrewing, the word "OUT" points upward.



To achieve additional safety when using MONO torque ratchet, the MONO circlip can be optionally used. This is intended for multiple use and should be checked for functionality before each use.



⚠ **Warning/precautionary measure:** The MONO circlip must be protected from exposure to strong light or high heat.

5.3 Reamers

	VARIOmulti reamer for base	**VARIO guide pin for VARIOmulti reamer**	**Gauge for reamer for screw channel**	**Reamer for screw channel for VARIOmulti**
	 3.03.420	 3.03.424	 3.03.430	 3.03.437 Use with MONO insertion instrument (3.03.162 oder 3.03.163).
Dimensions (mm)	16.0	15.0	–	40.0
Use	Multiple use			

6. Prosthetic procedure

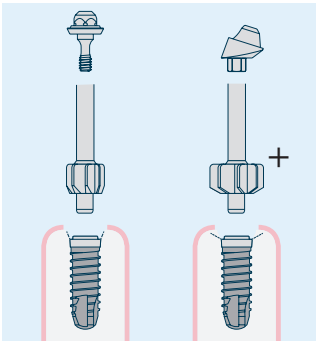
6.1 Preparation

Note: If you have an older version or generation of the products, please refer to the information in the older technical descriptions at www.ifu-tm.com/THM61118. An overview of the versions can be found in Section 7.

⚠ **Warning/precautionary measure:** Thommen Medical recommends always keeping spare products in stock and carrying out thorough preoperative planning in order to avoid complications.

Preparation for VARIOmulti abutment straight and angled:

1) Bone contouring
If the bone prevents the insertion of the abutments, the contour of the bone can be prepared using the bone contouring instrument in order to create room for the precise fit of the abutment.



The regular bone contouring instrument should be used for preparing VARIOmulti abutments (straight) and the bone contouring instrument+ should be used for the VARIOmulti abutments angled.

The bone contouring instrument can either 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.
See Section 5.1 for further information on using the bone contouring instrument.

2) Cleaning the interface

⚠ **Warning/precautionary measure:** The implant interface must be cleaned thoroughly before the abutment is inserted.

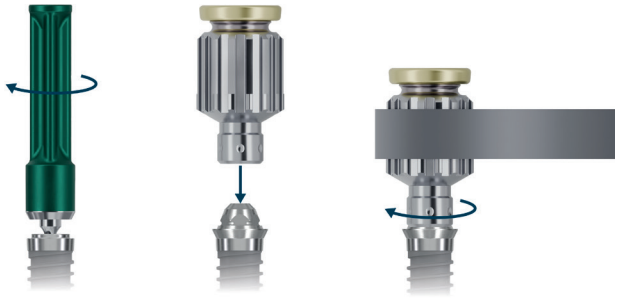
6.2 Inserting the abutment

Inserting the VARIOmulti abutment

Insertion
- Screw the abutment with the handle onto the implant and remove the handle.

Tightening
- Tighten the abutment to the recommended torque with the MONO torque ratchet and the insertion device or with the adapter for handpiece:

15 Ncm for PF 3.5
25 Ncm for PF 4.0-6.0



Inserting VARIOmulti angled (17° and 30°)

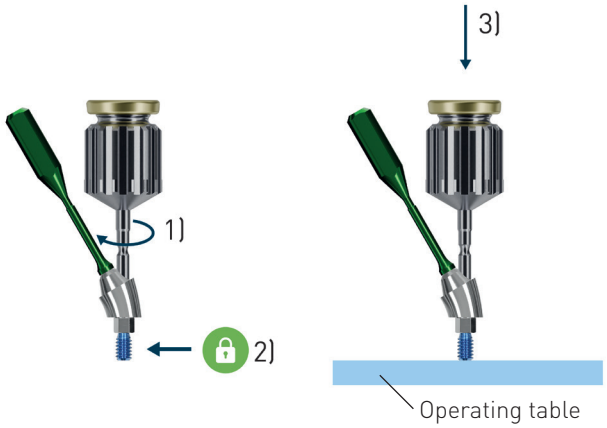
Preparation
- Screw the abutment screw into the abutment [1] until the screw stub protrudes from the underside [2].

Note: The screw is now secured against falling out.

Insertion
- Press the screwdriver firmly onto the screw [3], screw the abutment onto the implant and unscrew the handle.

Tightening
- Tighten the screw to the recommended torque:

15 Ncm for PF 3.5
25 Ncm for PF 4.0-6.0



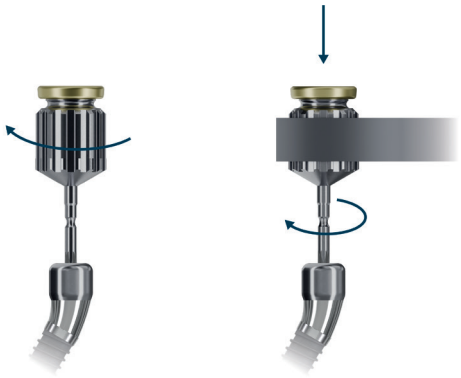
⚠ **Warning/precautionary measure:** Modification of the VARIOmulti abutments is not permitted.

6.3 Temporary restoration

VARIOmulti protective cap

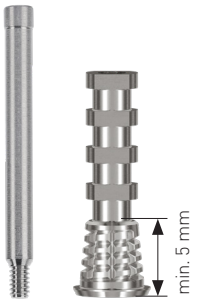
– Tighten the protective cap with a maximum tightening torque of 10 Ncm.

Note: The protective cap must not be subjected to any stress loading.



VARIOmulti temporary cap

- **Application area:** These caps are designed for the fabrication of temporary plastic tooth replacements and can be shortened to **5 mm** if required.
- **Adhesion:** In order to improve adhesion, **sandblasting** with 50 µm aluminum oxide and a maximum air pressure of 2 bar is recommended.
- **Protection of the geometry:** During processing, the screw channel and the connection geometry must be protected, ideally with the **fabrication screw** (included in the scope of delivery).



Notes:

- **Not suitable for permanent integration.**
- Isolate with **Vaseline** before modeling.
- Torque: **hand-tight**

For the integration of temporary tooth replacements:
- **Use new occlusal screws**.
- **Torque: 15 Ncm.**
- **Cover screw openings** with removable materials (e.g. Teflon or gutta-percha) and then seal with **composite**.

⚠ **Warnings/precautionary measures:**

– The temporary cap must not be steam sterilized in a polymerized state.

– The temporary cap must not be sandblasted in the region of the connection geometry and screw channel.
Precautionary measure: The VARIOmulti analog can be used to protect the connection geometry when processing the temporary cap.

– Shrinkage of the curing polymer can cause the abutment interface of the temporary cap to shift its position.
Precautionary measure: In order to minimize such displacements, it is recommended to apply the polymer over the entire area and as close as possible to the abutment interface.

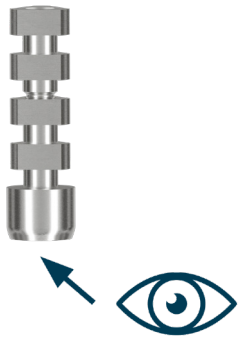
– Follow the instructions for use for the liquid polymer. Make sure that no polymer enters the wound area, if applicable.
Precautionary measure: Using a rubber dam can reduce contamination of the wound area.

6.4 Conventional impression taking for final tooth replacement

The impression is taken with an open impression tray at **abutment level**.

Check before insertion

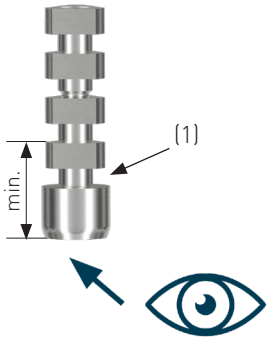
⚠ **Warning/precautionary measure:** Visually inspect the product for wear on the connection geometry.

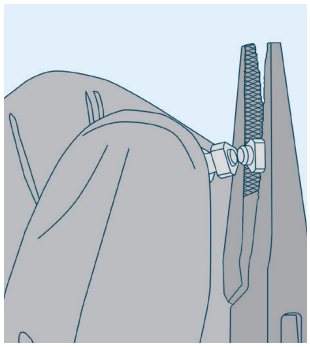


Selecting the height of the impression coping

- The impression coping can be shortened, the last retention ring [1] must be retained.
- **To shorten:** Break the predetermined breaking point with pliers.

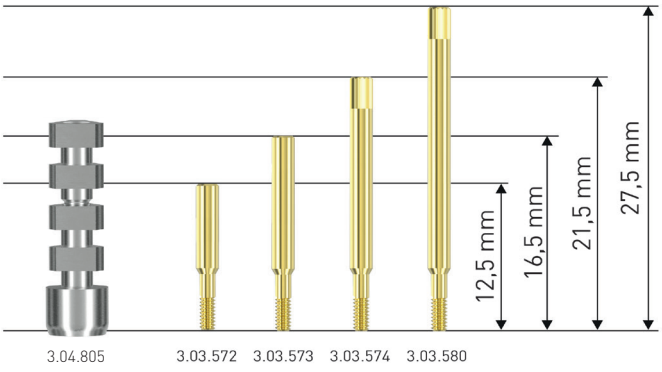
⚠ **Warning/precautionary measure:** After shortening the VARIOmulti impression coping, break off any rough or sharp edges at the separation site using a suitable sander/polisher.





Select screw length

- Determine the impression screw length based on the tray height or the available space in the mouth.



Position the impression coping

- Clean the connection geometry of the abutment and remove any overhanging soft tissue.
- The analogs are attached to the VARIOmulti impression copings using the yellow screws for PF 3.5 **manually and without applying strong torque**.
- Check the fit using an x-ray if necessary.

Impression taking

- Use elastomeric impression material (polyvinylsiloxane or polyether rubber). **Do not use alginates or hydrocolloids.**
- Once the material has set: Loosen the screw and remove the impression. The impression cap remains in the impression material.

6.5 Digital impression taking for final tooth replacement

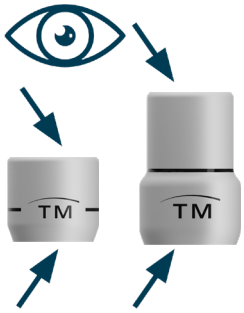
The digital impression is taken at **abutment level.**

Libraries for CAD software

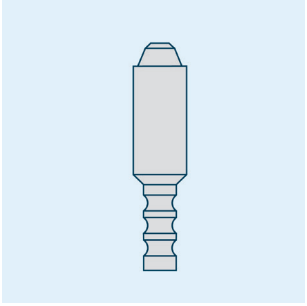
Thommen Medical provides **CAD libraries**. The libraries used must be coordinated between the dentist, dental technician and drilling service provider. If the libraries are not included in the CAD software, they can be downloaded from www.thommenmedical.com.

In the case of non-supported CAD systems, please contact your local sales representative or country representative.

Scanning on the patient or model
In challenging situations, such as edentulous jaws, where an intraoral scan can lead to inaccurate data, the use of a desktop scanner on the master model is recommended.

Steps	Scanning on the patient	Scanning on the master model
Inspection		
	⚠ **Warning/precautionary measure:** Visually inspect the product for wear on the connection geometry and on the scan area.	
Positioning	– Clean the connection geometry of the abutment and remove any overhanging soft tissue. – **Torque:** hand-tight – Fit can be optionally checked by means of an x-ray.	– Clean the connection geometry of the analog. – **Torque:** hand-tight – Fit can be optionally checked by removing the gingival mask.
Scanning	The scanning processes are carried out in accordance with the manufacturer's instructions for the system used. For the selection of the correct scan abutment, see Section 4.2	
Cleaning	All coarse contamination must be removed from the scan abutment immediately after use.	

6.6 Conventional model fabrication for final tooth replacement

Stone model fabrication after impression taking	
Analog attachment: – Use the yellow screw (PF 3.5) by hand with no noticeable torque (approx. 5 Ncm). – **Recommended stone:** Class 4 (extra hard dental stone). **Note:** Hold the analog by the retentive section to prevent the impression coping from rotating.	

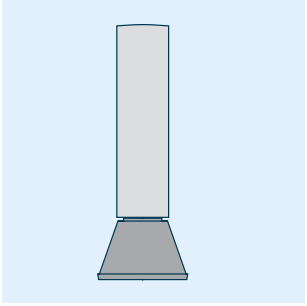
6.7 Conventional fabrication of final tooth replacement

Fabrication of prosthetic reconstructions using casting technique

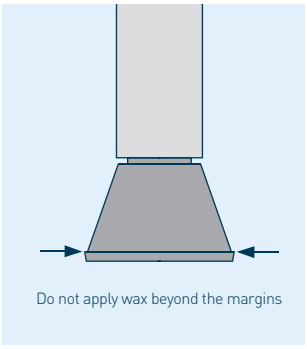
With VARIOmulti gold cap:
- Material: High-melting precious metal alloy (HSL, non-oxidizing) and made of plastic (burns out without residue).
- Reworking: Use special instruments (see Section 5.3 or the procedure in this section)

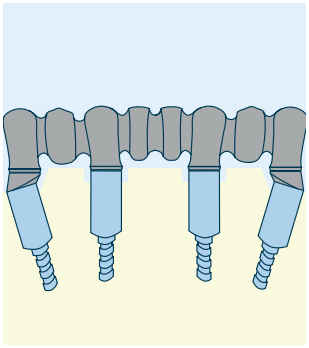
Material specification – VARIOmulti gold cap

Melting range	1400-1460°C
CTE 25-600°C	12.8 µm/mk
Precious metal content	0.3 g
Gold	60%
Platinum	24%
Palladium	15%
Iridium	1%

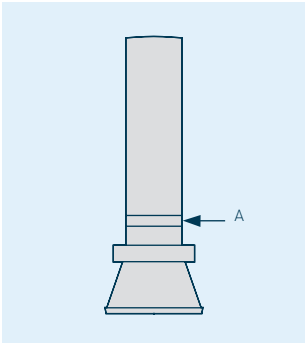


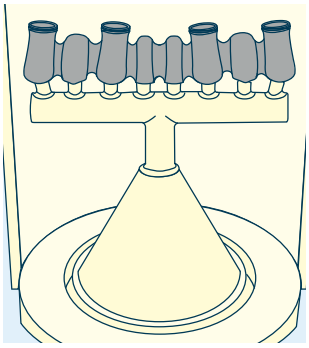
- The wall thickness must be ≥ **0.3 mm**
- Do not apply wax to delicate marginal areas.
- Degrease the surface before investing.
- Follow the alloy manufacturer's instructions.





With VARIOmulti plastic cap:
- Cap can only be reduced up to the marked limit (A) (A = minimum construction height).
- Tighten the screws firmly by hand.
- Apply a wax layer ≥ **0.3 mm**.
- Do not apply wax to delicate marginal areas.
- Match alloy and investment material (preferably high gold content).

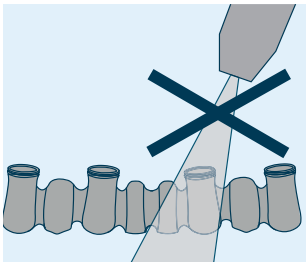




Reworking of the metal framework:

- Ultrasound, water jet, pickling acid or glass fiber brush are suitable for the careful removal of the investment mold.

⚠ **Warning/precautionary measure:** Sandblasting of prosthetic components in the neck area, in the screw channel or in the area of the mechanical connections is not permitted.

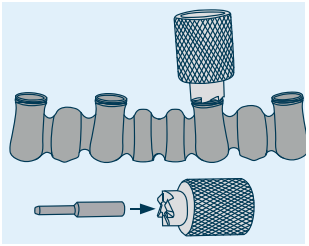


Tools for reworking:

Reworking of the sealing surface:

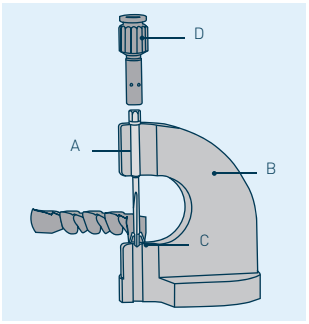
- Smooth with the VARIOmulti reamer (3.03.420, 3.03.424), preferably under a microscope.

Reamer for base (3.03.420)
VARIO guide pin (3.03.424)

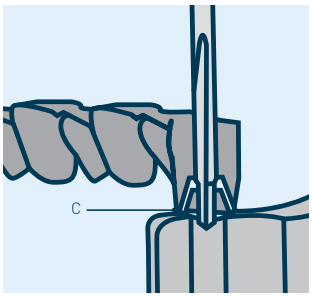


Reworking the screw seat:

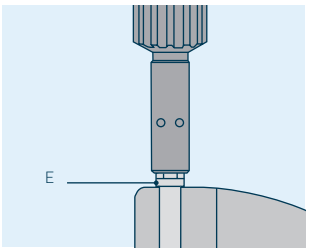
– Use the **VARIOmulti reamer for screw channel** (A) and the **gauge** (B).
– Place the bridge abutment on the gauge (C).
– Operate the reamer using the **MONO insertion device** (D).



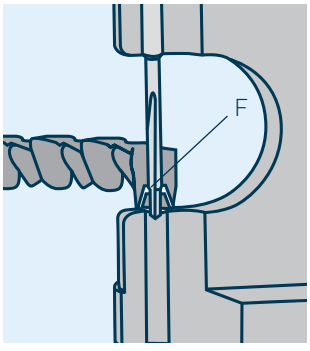
– Turn clockwise
– During processing, the sealing surface of the implant interface must lie flush against the gauge, otherwise the screw seat will be fabricated too deep.



– Turn the reamer as far as it will go (E) into the screw channel at each bridge abutment.



– Smooth the surface of the screw seat (F) with the reamer.
– The reamer is not suitable for removing coarse casting beads or overpouring in the screw channel or the screw seat.
– In the event of casting errors or damage, if the screw seat or the connection geometry is affected, the work must be redone.
– Prepare and veneer the framework using conventional methods.
– When polishing the outer crown margin, screw on VARIOmulti analog to protect the connection geometry and prevent damage to the margins.

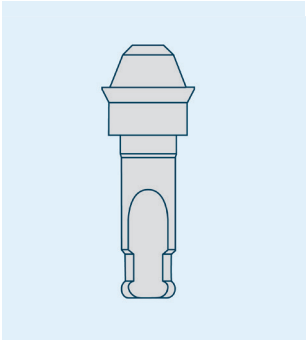


6.8 Digital model fabrication for final tooth replacement

VARIOmulti analog for CAD/CAM is used to fabricate the superstructure using the 3D printing process.

Model fabrication using 3D printing

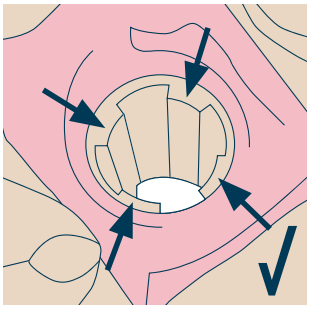
- **Due care and attention:** The analogs should be handled with care as they can be damaged by steel tweezers. Always check for wear or damage before use and replace if necessary.
- **Compatibility:** Suitable for 3D-printed models and stone models.

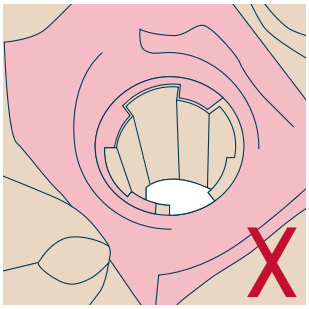


Procedure

Design of analog socket:

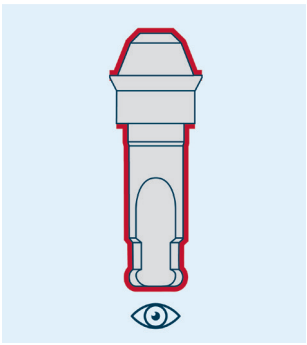
- The contact surface of the abutment analog must be exposed and must not be covered by the gingival mask.
- Take should also be taken to ensure that no cavity artifacts from the scan data are cutting into the socket.
- The diameter of the analog slot may vary depending on the printing system. If possible, adjustable via CAD program.





Inspect analog:

- Abutment analogs must be undamaged.

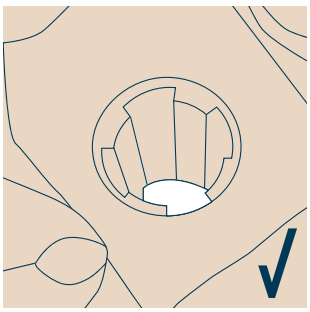


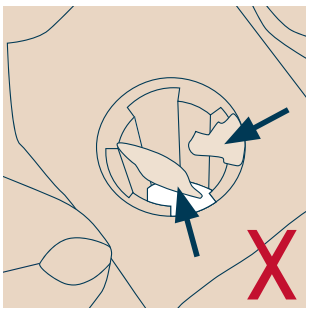
Construct:

- Design processes according to the specifications of the system used.

Check the printed analog socket:

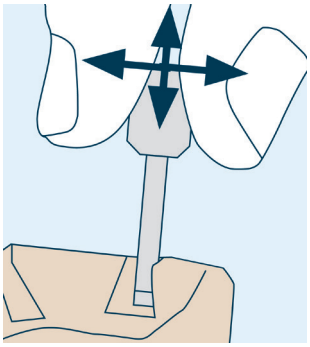
- Check the model and abutment analog for construction errors and residues.





Assembly:

– Use the insertion device to mount the analog in the 3D-printed model.

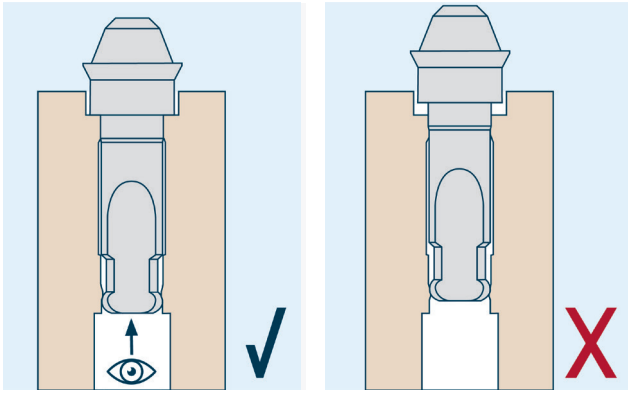


Check position:

– Check the end position by means visual inspection.

Note: Repeated insertion and removal can wear out the locking function.

The printed analog cavities may vary depending on the 3D printing system used. If corrections are necessary, adjustments can be undertaken in the design settings. The corresponding instructions are contained in the respective libraries.



6.9 Digital fabrication of final tooth replacement (CAD/CAM)

The VARIOmulti abutment lines enable the fabrication of occlusally screw-retained frameworks on implants in the mandible or maxilla.

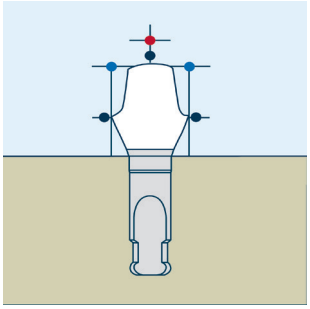
Choice of titanium base

Select the correct titanium base, see Section 4.5 on final restoration

Fabrication:

– The CAD process and CAM fabrication depend on the CAD/CAM system used. The specifications of the material supplier must be observed when designing the superstructure.

– Tighten the titanium base with the occlusal screw on the model firmly **by hand**.



⚠ **Warning/precautionary measure:**
The titanium base must not be exposed to high heat stress and must be removed before the burn-out process.

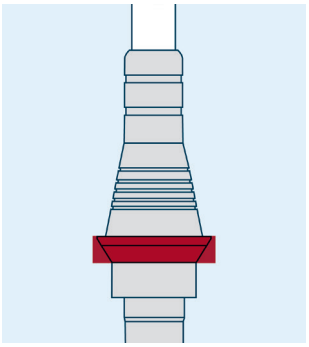
Bonding procedure between titanium base and superstructure

Attachment:

- Attach using the occlusal screw.
- The titanium base is centered on the analog by the conical screw seat.
- Before cementing, the precise fit of the superstructure must be checked on the model.

Blocking out:

- Screw the VARIOmulti titanium base to the abutment analog using a fabrication screw.
- The collar region (marked in red) must be covered with a suitable material before the blasting process.
- The analog together with the bonding base can be fixed into the handle for dental technicians for the blasting process.



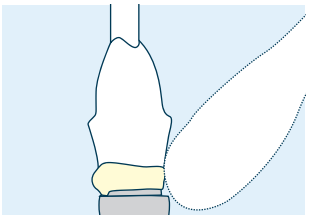
Further processing of titanium base and superstructure

Blasting process and cleaning of the bonded surface

- Sandblast with 50 µm aluminum oxide and max. 2 bar air pressure.
- Clean after sandblasting to remove dust or grease residues.

Bonding process:

- Tighten the titanium base with the occlusal screw on the model firmly **by hand**.
- To cement the superstructure onto the titanium base (e.g. PANAVIA V5), use the appropriate laboratory cylindrical pin.
- Spread the cement evenly over the bonding bases.
- Push the superstructure over the cylindrical pin and the bonding bases, and press it down as far as the collar region.
- Remove excess remaining cement at the margin with a suitable instrument before it cures.
- Allow the cement to harden according to the manufacturer's instructions.
- Remove the cylindrical pins and detach the occlusal screws.
- Carefully remove remaining cement residues at the margin under a microscope using a rubber sander/polisher.



⚠ **Warning/precautionary measure:** Cemented products must not be steam sterilized.

6.10 Inserting the final restoration

Remove the temporary restoration from the abutment and clean the abutment. Always use new occlusal screws for the final insertion of the prosthetic reconstruction. Remove the final restoration from the master cast and insert it into the patient's mouth in a clean condition. It is recommended to use a **tightening torque of 15 Ncm** to tighten the occlusal screws.

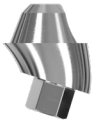
7 Further information

7.1 Product version

Sterile products differ from non-sterile products by an **"S"** in the article number (e.g. 4.03.300**S**). If you have a non-sterile VARIO-multi abutment available, the technical description V009 at www.ifu-tm.com/THM61118 applies.

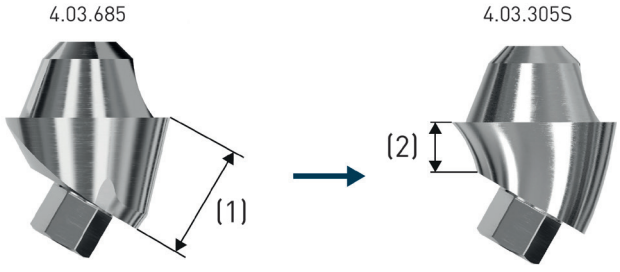
7.2 Backward compatibility

If an older version is to be replaced with a new version, this is possible without any problems, as the height and position of the interface are identical.

	17° 	17° 		30° 	30° 
	Non-sterile version	Sterile version "S"		Non-sterile version	Sterile version "S"
PF 3.5	4.03.680	4.03.300S		4.03.685	4.03.305S
PF 4.0	4.03.681	4.03.301S		4.03.686	4.03.306S
PF 4.5	4.03.682	4.03.302S		4.03.687	4.03.307S
PF 5.0	4.03.683	4.03.303S		403.688	4.03.308S
PF 6.0	4.03.684	4.03.304S		403.687	4.03.309S

Please note that in the sterile version "S", the abutment collar height is no longer specified distally[1] but mesially[2] in the current product version.

Non-sterile version **Sterile version "S"**



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