SPI®VARIO Abutment 17°

Screw-retained restorations. Prosthetic procedure

Instructions for use THM61136

Version 003_AA, Issue date 08/20

THOMMEN Medical

1. At a glance

These instructions apply to all VARIO abutment 17° including associated VARIO abutment 17° auxiliary parts as listed in the product catalog (www.ifu-tm.com/THM31111). You can also find information on the identifying elements (geometry, dimensions) of the individual components in this.

Components	Material	Reusable
VARIO abutment 17° Type A and Type B	Pure Titanium Grade 4	No
VARIO screw seat	NOA/POM (burn-out plastic)	No
Abutment screw	Titanium alloy	No
Occlusal screw	Titanium alloy	No

INDICATION

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

INTENDED USE

Thommen Medical prosthetic components 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

Angled abutments on small diameter implants (PF 3.5) are not recommended for use in the molar region, unless they are splinted to larger diameter implants.

See also the general restrictions of use (page 7).

STORAGE

The VARIO screw seat incl. burn-out plastic cylinder must be protected from exposure to strong light or high heat during storage.

2. Application and handling

CLINICAL USE

VARIO abutments 17° are used in situations with occlusal screw-retained single-tooth restorations and small-unit bridges where there is a pronounced deviation of the implant axis from the planned prosthetics. The pure titanium abutments are available in two different cone alignments/orientations (Type A (0°) or B (30°)) with respect to the hexagon to ensure optimal abutment alignment on the implant. The prefabricated screw seat for the occlusal screw is made of a cast-on gold alloy and ensures a precise connection between the finished crown/bridge and the abutment. The VARIO abutments 17° are intended for single use.

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

New abutment screws must always be used for the final insertion. Torque values for the definitive attachment of VARIO abutments 17°:
- 15 Ncm for PF 3.5
- 25 Ncm for PF 4.0–6.0

Occlusal screw:
- 15 Ncm

An overview of all tightening torques for the definitive attachment of Thommen abutments can be found at www.ifu-tm.com/THM61122.

IMPRESSION-TAKING

The prosthetic restoration with VARIO abutments requires an impression to be taken at the implant level; for this please see www.ifu-tm.com/THM61127.

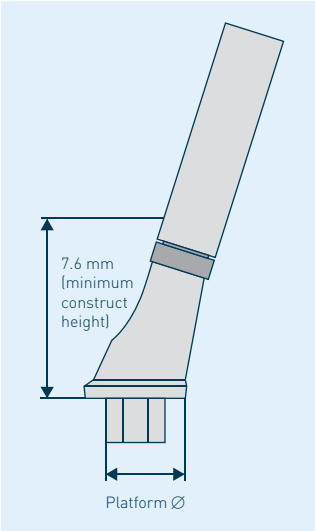
MODIFYING THE ABUTMENT

Modification of the VARIO abutment 17° is not permitted (see Fabricating the definitive prosthetic restoration).

FABRICATING THE LABORATORY MODEL

Implant analogs are available in all platform sizes for VARIO abutments. These are used for traditional master cast fabrication.

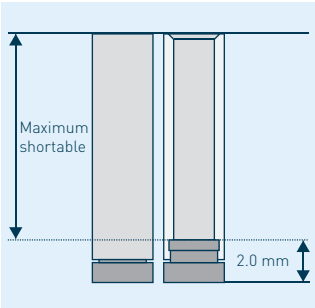
FABRICATING THE DEFINITIVE PROSTHETIC RESTORATION



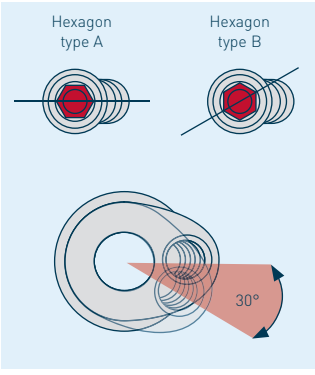
VARIO abutments 17° are suitable for single tooth crowns or smaller bridge restorations consisting of two implants with minimal divergence and one or two pontic elements. The maximum divergence of two implants is

- PF 3.5, 6.0°
- PF 4.0, 7.0°
- PF 4.5, 8.5°
- PF 5.0, 11.0°

The VARIOmulti abutment system is recommended for large bridge constructions and for larger implant divergences within a bridge. The minimum height incl. screw seat measured from the implant shoulder is 7.6 mm.

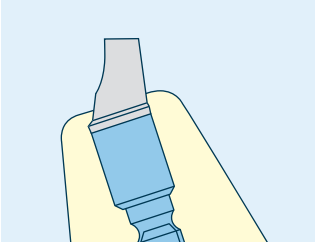


The prefabricated, cast-on VARIO screw seat must be used for fabrication of the crown or bridge framework. The burn-out plastic cylinder can be shortened to the upper edge of the screw seat.



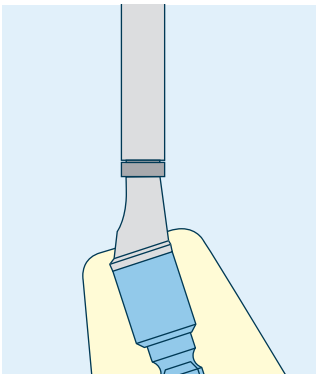
An optimal alignment of the abutment facilitates access to the occlusal screw, which fixes the suprastructure to the abutment. In principle, the abutment should thus have a mesial alignment in the posterior region.

If both abutment types (Typ A (0°) oder B (30°) are fixed on the analog one after the other on the same hexagon position by way of comparison, the difference in the abutment alignment of 30° becomes clear. Depending on the existing spatial conditions, implant divergences and alignment of the implant internal hexagon, either the abutment with hexagon Type A or B will be suitable, as the case may be.



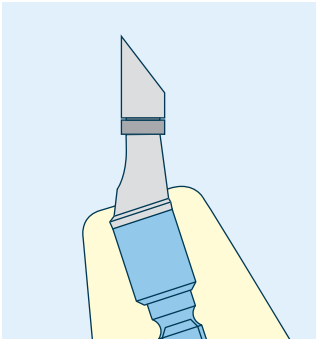
For the framework modeling of the superstructure, the selected abutment is aligned and placed on the analog, and then fixed with the corresponding abutment screw.

The cast-on VARIO screw seat is then tightened onto the VARIO abutment 17° using the occlusal screw.



When constructing the superstructure, always take care to ensure that the occlusal screw is easily accessible with the screwdriver. If the screw seat cannot be placed in position because of an obstructing neighboring tooth, the whole abutment is unscrewed and realigned on the analog. If access to the occlusal screw is suboptimal because of the new position or the neighboring tooth is still causing an obstruction, the abutment with the other hexagon type can be used. Access to the occlusal screw with the screwdriver must never be impeded by obstructing neighboring teeth or even be completely blocked.

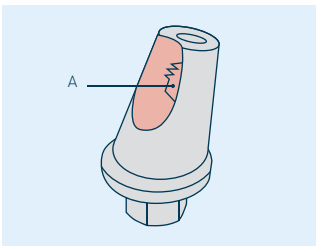
The plastic cylinder on the VARIO screw seat is then shortened to enable maximum intercuspidation. Occlusal contact of the plastic cylinder with the antagonistic structures must always be avoided.



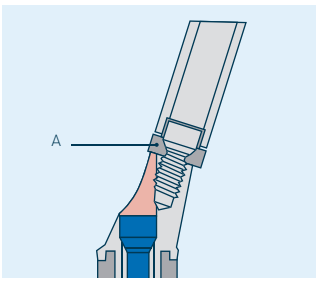
The minimum construction height of 7.6 mm must be observed.

VARIO abutments 17° must not be modified under any circumstances, otherwise the accuracy of fit of the screw seat can no longer be guaranteed.

Before starting framework modeling, the abutment screw channel is blocked out with a removable material (A) that can be easily and completely removed again when the modeling is finished. For single crowns, block-out of the screw channel is designed to be flat so that an antirotation surface is created on the inner side of the crown. A corresponding crown or bridge framework (in a bridge situation) is then modeled directly onto the abutment with the screw seat.

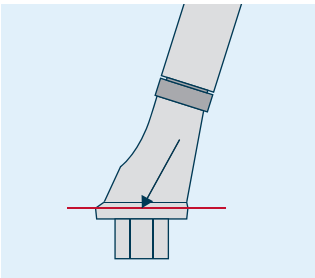


Since the cast-on VARIO screw seat (A) consists of a non-oxidizing gold alloy and does not form an adhesive oxide, it cannot bond directly onto this alloy. Likewise, an alloy that is cast on too thinly or perforated can result in bonding problems with the ceramic. The layer of cast-on alloy must later have a minimal wall thickness 0.3 mm. Always follow the general instructions of the alloy manufacturer for the alloy used.

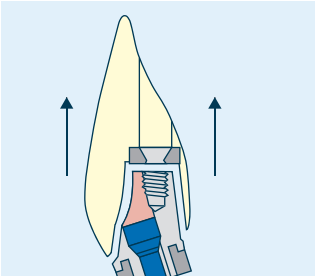


Material specification
VARIO screw seat

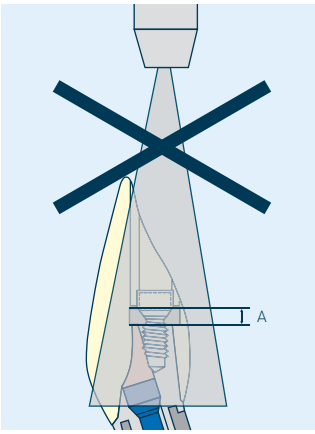
Non-oxidizing precious metal alloy	
Melting range	1400–1460 °C
WAK 25–600 °C	12.8 µm/mk
Gold	60 %
Platinum	24%
Palladium	15 %
Iridium	1 %



The modeled crown or bridge framework must fit precisely with the abutment margin (see red line).



After unscrewing and removing the occlusal screw, remove the prefabricated framework from the abutment carefully. The investment and casting processes are carried out in the normal way. Coordinate the investment mold with the alloy used (preferably with a high gold content). The procedure for the investment process is also described in the VARIOmulti instructions for use (www.ifu-tm.com/THM61118).



After casting, remove the framework from the investment mold and clean it carefully using standard methods, such as ultrasound, water jet, pickling solution or glass fiber brush. The cast-on VARIO screw seat (A) must not be sandblasted or reworked under any circumstances as this may affect the precision fit of the components used. In the event of casting errors or damage, in particular if the screw seat is affected, the work must be redone. Caution should be exercised when polishing the outer crown margin. Process and finish the construction in the additional working steps according to standard procedures. We recommend the fabrication of a transfer key for the insertion of abutments.

CLEANING, DISINFECTION AND STERILIZATION

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).

3. General notes

THOMMEN IMPLANT SYSTEM

THOMMEN Medical

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

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

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

NEW HANDLING
New design – the application has not been changed.

NEW DESIGN

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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