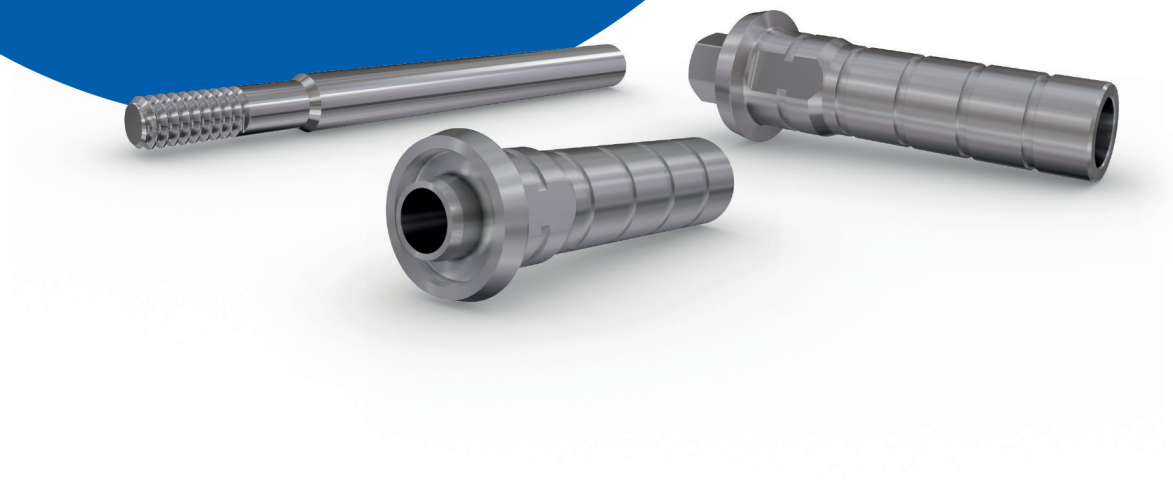
SPI®VARIOtemp

For temporary restorations. Prosthetic procedure

Instructions for use THM61121



Version 007_AA, Issue date 01/21

THOMMEN Medical

1. At a glance

These instructions for use apply to all VARIOtemp abutments including associated VARIOtemp auxiliary products 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
VARIOtemp crowns/bridges	Pure Titanium Grade 4	No
Abutment screw	Titanium alloy	No
Fabrication screw	Stainless steel	No
Laboratory cylindrical pin	PTFE	No

INDICATION

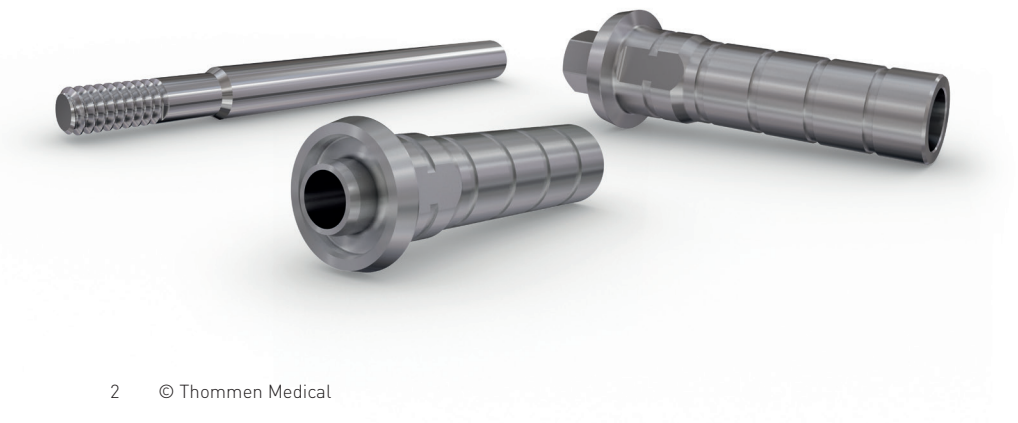
Thommen Medical prosthetic components are used in combination with the Thommen Medical Dental Implant System in partially edentulous/edentulous upper and lower jaws for restoration of masticatory function.

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

See the general restrictions of use (page 7).



2. Application and handling

CLINICAL USE

The VARIOtemp abutment PF 3.5–6.0 is a modifiable bonding base and is suitable for provisional restorations until the final restoration is inserted. The abutment is also suitable as a basis for individual soft-tissue conditioning. A provisional restoration can be carried out chairside by the dentist or in the laboratory. VARIOtemp abutment PF 3.5–6.0 is supplied with a fabrication screw (VARIOtemp abutment set).

VARIOtemp for crowns (with hexagon) must only be used for single teeth and must not be used for splinted constructions, as the axial divergences of implants cannot be bridged by hexagonal connection geometries.

The VARIOtemp abutment PF 3.5–6.0 for bridges (VARIOtemp abutment set for bridges) must be used exclusively for screw-retained bridge restorations. Depending on the number and position of implants, implant divergences of up to approximately 30° are bridgeable with VARIOtemp for bridges. VARIOtemp abutments are intended for single use.

It is recommended to sandblast the surface of the abutment to achieve better bonding of the plastic to the abutment.

IMPRESSION TAKING

The prosthetic restoration with the VARIOtemp abutment requires an impression to be taken at the implant level. Impression copings for open and closed impression trays are available as impression copings for conventional impression-taking. Thommen scan abutments can be used to take digital impressions. These can used either intraorally or for scanning from the master cast.

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

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

FABRICATING THE LABORATORY MODEL

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

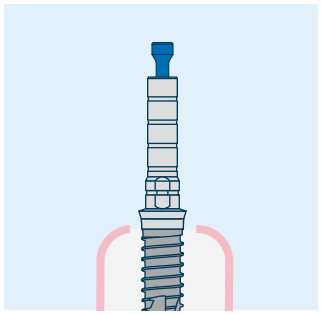
Information on producing digital models can be found online at:
www.ifu-tm.com/THM61143

CAD LIBRARIES

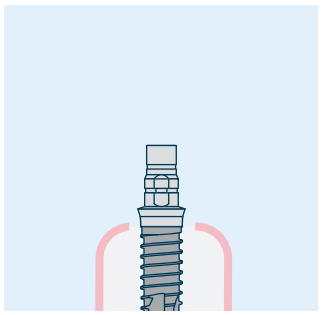
Thommen Medical can provide libraries for dental CAD-software. The libraries used must be aligned between the users (e.g.: dentist, dental technician, milling center). Conventionally, it is the final link in the value creation chain which administers the final configuration of the library and distributes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

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

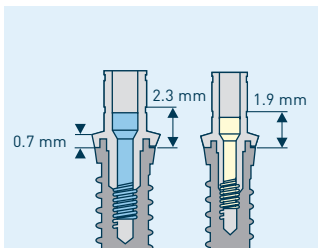
CONVENTIONAL FABRICATION OF TEMPORARY RESTORATIONS



1. Attach the VARIOtemp abutment on the implant. Make sure that the rotation surface is aligned in a mesio-distal direction.

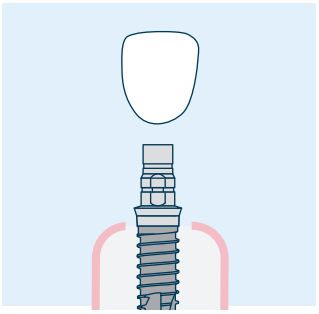


2. If the height of the abutment prevents maximum intercuspidation, the cylindrical part or screw channel must be shortened. Occlusal contact of the antagonistic structures with the abutment must be avoided.



VARIOtemp abutments can be shortened by no more than to the upper edge of the lowest retention ring. Do not go below the minimum height of 2.3 mm for PF 4.0–6.0 and 1.9 mm for PF 3.5, measured from the implant shoulder. Reducing the wall thickness and grinding the collar area is not permitted.

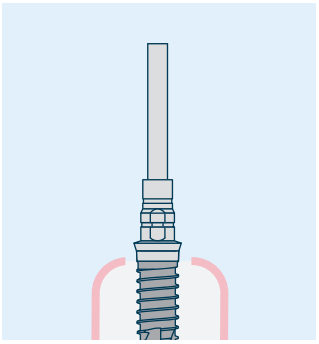
3. The temporary restoration can be fabricated using a prefabricated plastic denture tooth, silicone key, a crown form prefabricated in the laboratory or using prefabricated crown forms.

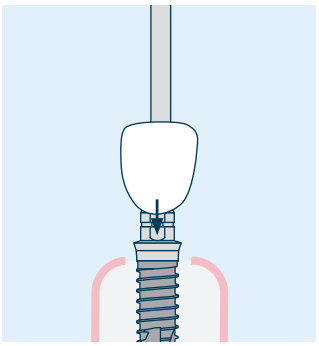


4. The abutment screw can be replaced with the fabrication screw supplied before the plastic material is processed. The use of the fabrication screw facilitates better handling and prevents the liquid plastic material from flowing into the screw channel while the plastic veneering material is being processed. The fabrication screw must be lightly coated with Vaseline before processing and must only be tightened by hand using a maximum tightening torque of 5 Ncm.

   The fabrication screw supplied is only intended for use as a fabrication aid and is intended for single use. It must not be used for definitive insertion of temporary restorations on patients.

   To reduce the forces acting on the abutment, the prefabricated temporary restoration must not have occlusal contact.

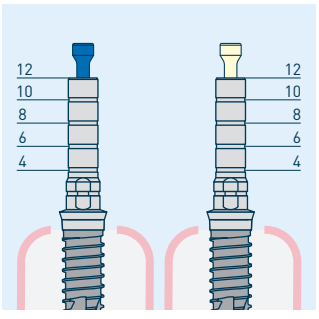


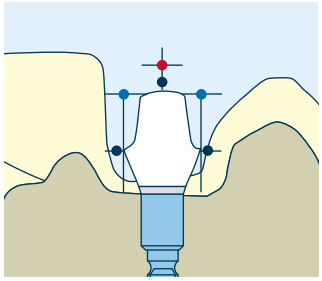


DIGITAL FABRICATION OF TEMPORARY RESTORATIONS

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

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





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

Step 5, see Step 4 under "Fabricating the temporary restoration conventionally".

DEFINITIVE ATTACHMENT OF THE FINISHED TEMPORARY RESTORATION

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 definitive insertion (Art. No. 4.03.500 for PF 3.5, Art. No. 4.03.501 for PF 4.0–6.0). The screw channel is sealed with a suitable material.

Torque value for the definitive attachment of the VARIOtemp abutment:
- 15 Ncm for PF 3.5
- 25 Ncm for PF 4.0–6.0

An overview of all torque values for the definitive attachment of Thommen abutments can be found online at:
www.ifu-tm.com/THM61122.

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

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
	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.

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

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