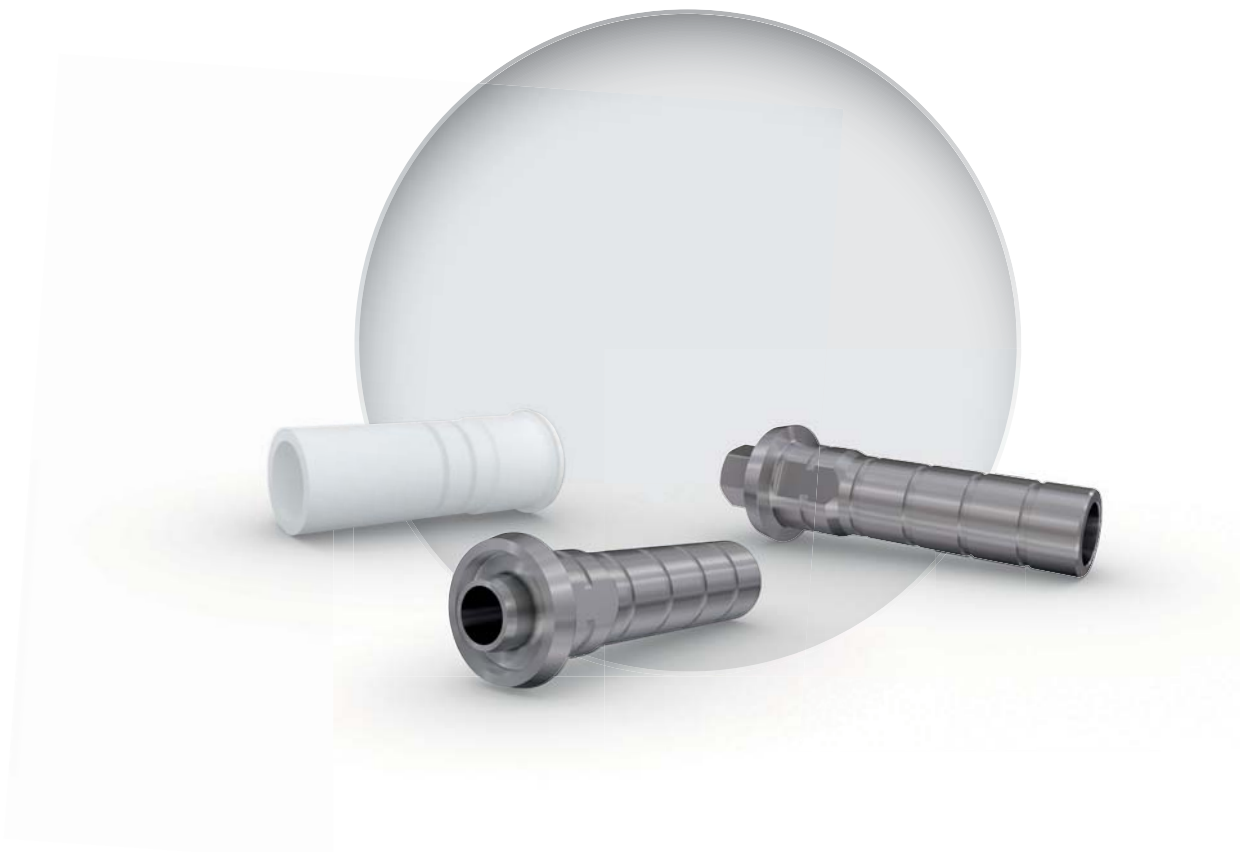


VARIOflex

FOR OCCLUSAL – SCREW RETAINED & CEMENTED RESTORATIONS.

PROSTHETIC PROCEDURE



1. At a glance

These instructions apply to all VARIOflex Abutments, including associated VARIOflex auxiliary parts, as listed in the product catalogue (www.ifu-tm.com/THM31111). There, you will also find directions on the identifying characteristics (geometries, dimensions) of the individual components.

Component	Material
VARIOflex crown/bridge	Pure titanium grade 4
Abutment screw	Titanium alloy
Fabrication screw	Stainless steel
Burn-out plastic cap	POM
Laboratory cylindrical pin	PTFE

INDICATION

The Thommen Medical VARIOflex Abutments PF 3.5–6.0 are intended to be used in conjunction with Thommen System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges and overdentures.

RESTRICTIONS FOR USE

See general restrictions of use (Page 10).

STORAGE

VARIOflex burn-out caps must be protected from exposure to strong light and heat sources and stored at room temperature.



2. Application and handling

CLINICAL USE

The VARIOflex abutment PF 3.5–6.0 is a modifiable bonding base and is used for fabrication of crown and bridge restorations.

The abutment is suitable for bonding metal, pressed ceramic or CAD/CAM fabricated ceramic restorations. The VARIOflex abutment PF 3.5–6.0 is supplied for the final restoration with a burn-out plastic cap and abutment screw (VARIOflex abutment set). Suitable composite adhesives are recommended for bonding.

VARIOflex for crowns (with hexagon) must only be used for single teeth and must not be used for splinted constructions, as implant divergences cannot be bridged by hexagonal connection geometries.

VARIOflex abutment PF 3.5–6.0 for bridges (VARIOflex 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 VARIOflex for bridges.

TAKING AN IMPRESSION

A prosthetic restoration with VARIOflex abutments requires taking an impression at implant level. The impression coping for open and closed-tray techniques is available as for conventional impression-taking. The Thommen scan abutment can be used to take digital impressions. Both of these products can be used either intraorally or for scanning from the master model.

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

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

MASTER CAST FABRICATION

Implant analogs are available for VARIOflex 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

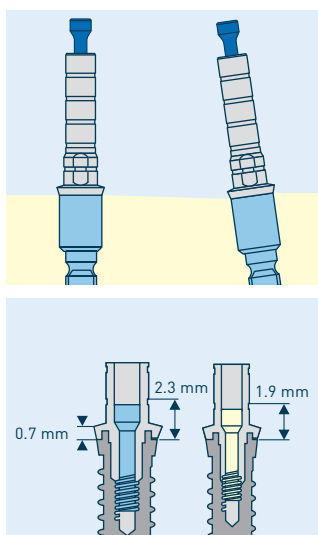
CAD-LIBRARIES

Thommen Medical provides libraries for dental CAD software. These libraries must be aligned between the systems of 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. To obtain the Thommen Medical library for your system, 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 THE FINAL PROSTHETIC RESTORATION

The final reconstruction must be carried out in accordance with the most up-to-date dental technology in compliance with the manufacturer's instructions for the materials used. The VARIOflex abutment set for crown (with hexagon) should be selected for the production of single crowns. The same preparation procedure should be carried out for crown restorations as with bridge restorations.



1. Screw the VARIOflex for bridge onto the model analogs using abutment screws.
2. VARIOflex abutments can be shortened to the upper edge of the lowest retention ring, at the maximum. A minimum construction height must be maintained of 2.3 mm for PF Ø 4.0–6.0 mm and 1.9 mm for PF Ø 3.5 mm measured from the implant shoulder. A minimum construction height of 4.0 mm (second retention ring above the implant shoulder) must be maintained for pressed ceramic and zirconium oxide restorations. Reducing the wall thickness and grinding the collar area is not permitted.

Place the VARIOflex burn-out plastic caps which match the platform size onto the abutments. The circular grooves on the burn-out cap are used to identify the platform. The PF Ø 3.5 mm has a single groove. Each next-larger platform has an additional groove. The plastic caps have an antirotation design feature, therefore pay particular attention to the alignment of the abutment during insertion. Move the cap onto its final position by exerting slight pressure. If the height of the abutment prevents maximal intercuspitation, reduce the cylindrical part, resp. the screw channel. The opposing tooth must be kept from being in occlusal contact with the abutment.

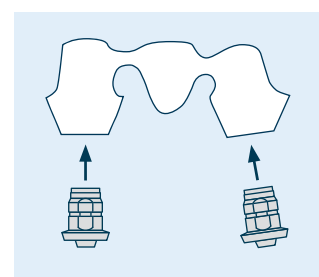
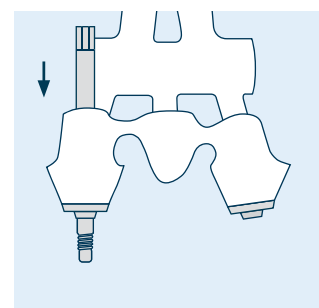
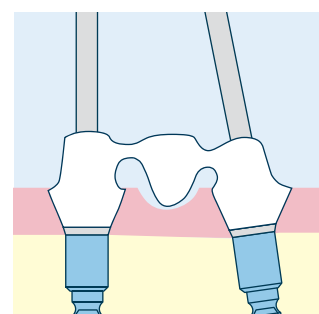
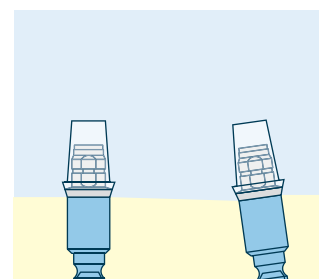
The plastic caps are not suitable for producing temporary plastic restorations!

3. Wax-up the bridge framework on the plastic caps. Using the fabrication screw (available for PF Ø 3.5 mm art. no. 3.03.590 Q4 and PF Ø 4.0–6.0 mm art. no. 3.03.591 Q4) ensures that no wax residue gets into the screw channel. The outside of the plastic cap must be covered by a minimum wax layer of 0.3 mm. During the wax burn-out, it provides space for the plastic material to swell. If the plastic cap is insufficiently covered by wax, the swelling of the plastic material may cause the investment material to fracture and the casting may fail.

After attaching the sprues and runner bar, unscrew and completely remove all the abutment screws.

4. Remove simultaneously the wax-up, incl. the VARIOflex abutment, from the analog. Completely remove the VARIOflex abutments that remain in the framework wax-up. The fabrication screw can be used to remove the VARIOflex abutments from the framework construction. The fabricated framework can then be embedded and cast as usual.

5. Adapt the cast framework construction on the VARIOflex after divesting and subsequent cleaning of the model. Be careful of the antirotation design for single tooth restorations.

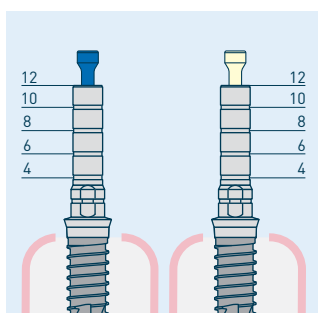


Important note: Ceramic veneering

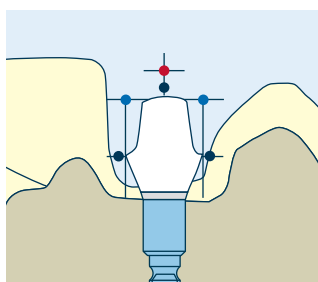
VARIOflex must not be exposed to high temperatures. VARIOflex abutments must be removed from the framework before each veneer firing.

DIGITAL FABRICATION OF THE FINAL RESTORATION

See Steps 1 and 2 under «Conventional fabrication of the final prosthetic restoration».



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



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

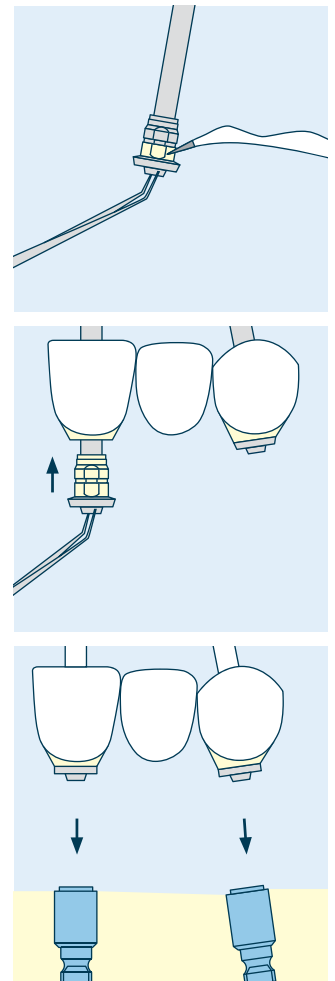
BONDING THE VARIOFLEX TO THE FINISHED CROWN OR BRIDGE CONSTRUCTION

1. Blast the surface of the VARIOflex abutment with 50 µm of aluminium oxide and at a max. pressure of 2 bar. The connection platform to the implant must be protected during blasting.

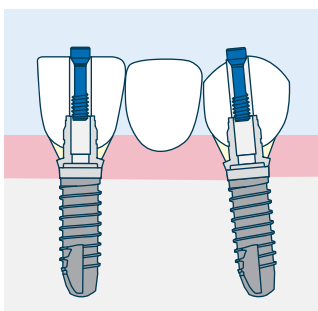
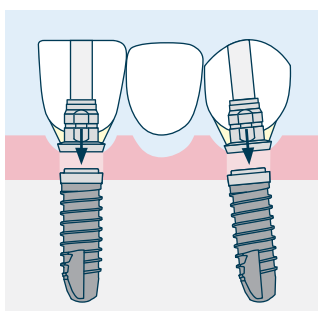
Shorten the appropriate cylindrical pin for laboratory to the desired length and insert as a placeholder into the screw channel of the VARIOflex abutment. Mix and apply the appropriate composite adhesive in compliance with the manufacturer's instructions. The bonding agent must be in a soft condition during the next 2 steps.

2. When working off of the model, place the VARIOflex abutment with inserted cylindrical pin for laboratory into the crown.

3. Finally, align the construction on the model. Verify correct and complete seating of the bridge. Proceed to remove cylindrical pins for laboratory, insert the abutment screws (or laboratory screws) and tighten. Allow the adhesive to cure on the model, carefully remove any residual adhesive and complete the bridge. Bonded constructions cannot be sterilized.



INSERTION OF THE FINISHED PERMANENT RESTORATION



1. Remove the gingiva former or temporary crown/bridge from the implant. Clean and dry the inner configuration of the implant thoroughly before attaching the permanent crown or bridge. Position the clean crown/bridge on the implant(s) and check for correct seating. It is important to ensure that no soft tissue is pinched.
2. Attach the crown/bridge permanently using abutment screw(s). (For torque values, see Clinical Application, Page 3). After inserting the restoration, refill the screw channel with a removable material (e.g. gutta-percha). Seal the screw channel with a suitable composite material.

For permanent insertion, it is essential to use new abutment and occlusal screws. Seal the screw channel with a suitable composite material.

Torque value for the attachment of the VARIOflex Abutments:

- 15 Ncm for PF Ø 3.5 mm
- 25 Ncm for PF Ø 4.0–6.0 mm

You can find an overview of all torque values for the attachment of Thommen Abutments online at: www.ifu-tm.com/THM61122.

STERILIZATION

Thommen abutments and components are not supplied in a sterile state. Unless directed otherwise, a steam sterilization of the abutment is recommended:

- Fractionated vacuum procedure with at least 3 vacuum steps, (with adequate product drying)
- A steam sterilizer compliant with EN 13060/ EN 285 and/or ANSI AAMI ST79
- in correspondence with EN ISO 17665 in a validated (valid IQ/OQ (Commissioning)) and product-specific performance qualification.
- Maximum sterilization temperature of 138 °C (280 °F; plus tolerance in compliance with EN ISO 17665)

Sterilization time, exposure time at sterilization temperature, of at least 4 minutes at 132 °C (270 °F) or (not relevant for USA) 18 minutes at 134 °C (273 °F), prion inactivation.

For further instructions on the sterilization of prosthetic components, please refer to the respective valid Thommen Medical processing manuals (www.ifu-tm.com/THM61131).

3. General notes

Thommen Implant System



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



Conformity symbol as specified by EU
Directive MDD 93/42/EEC



URL:

Consult instructions for use



Non-sterile



Catalogue number/Article number



Manufacturer



Batch code



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



Do not re-use



Keep away from sunlight

A number of different abutments in various shapes and sizes are available for the prosthetic restoration of Thommen implants.

Availability

Not all of the products mentioned in these instructions for use are available in all countries. Please consult with your country's sales representative.

Coloured warning sticker

Application has changed - follow the instructions in the corresponding documentation.

NEW HANDLING

New design – the application has not been changed.

NEW DESIGN

Responsibility/Liability

As a part of an overall scheme, Thommen implants may be used only with the original components and instruments in accordance with the manufacturer's instructions. The use of the product 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 (fitting and/or cutting properties) as well as their safe use (risk of infection, disease transmission, fading of the laser or color marks, corrosion). Detailed information about the possible consequences, which may result from negligence to follow this information, is available from your dealer. Caution: Federal law (USA) restricts this device to sale by or on the order of a dentist or physician.

Product information

The information given here on the intended purpose/restrictions of use describes the application of Thommen abutments. This information is available in electronic form online at: www.ifu-tm.com. For technical advice, please contact your Thommen Medical country representative.

Compatibility

The compatibility of Thommen abutments for Thommen ELEMENT and CONTACT implants has been comprehensively established. The compatible size of the connection point between the abutment and implant is regulated by the platform size. So that the abutment and implant can fit together, they must both be available in the same platform size. The platform diameter is listed separately on the packaging and is identified by a colour code, this also applies to numerous auxiliary parts.

	Platform	Color code
ELEMENT & CONTACT	PF Ø 3.5 mm	Yellow
	PF Ø 4.0 mm	Green
	PF Ø 4.5 mm	Blue
Abutments	PF Ø 5.0 mm	Grey
	PF Ø 6.0 mm	Violet
	PF Ø-independent	Neutral

Guarantee

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

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 Ø 3.5), the prosthetic restoration should be constructed in such a way that large bending torque does not occur.

The abutments and/or auxiliary parts 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.

Warnings/Precautions

All components of the Thommen Implant System must be protected against aspiration.

The Thommen abutments have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Thommen abutments in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Validity

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