SPI® VARIO
FOR OCCLUSAL – SCREW RETAINED RESTORATIONS.
PROSTHETIC PROCEDURE
1. At a glance

These instructions apply to all VARIO gold abutments, including associated VARIO 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.

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
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</thead>
<tbody>
<tr>
<td>VARIO gold abutment for crown</td>
<td>HSL/POM (burn-out plastic)</td>
</tr>
<tr>
<td>VARIO old abutment for bridge</td>
<td>HSL/POM (burn-out plastic)</td>
</tr>
<tr>
<td>Abutments screw</td>
<td>Titanium alloy</td>
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</table>

INDICATION

Thommen Medical VARIO gold abutments are 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 11).

STORAGE

VARIO gold abutments and burn-out plastic cylinder for must be protected from exposure to strong light and heat sources and stored at room temperature.
2. Application and handling

CLINICAL USE

VARIO gold abutments are used to fabricate occlusal screw-retained solutions. Restorative options include single crowns, custom abutments and multiunit bridge restorations. They consist of a nonoxidizing cast-on alloy base and a plastic cylinder that forms the screw channel. The plastic cylinder will be incorporated into the pattern and leave no residues after burn-out.

VARIO gold abutments for crowns (with hexagon connection) are for use with single tooth reconstructions and custom abutments. They are not suitable for bridges because axial divergences cannot be compensated. VARIO gold abutments for bridges (with cone connection) are for use with bridges and splinted constructions. Axial divergences of up to 30° can be bridged.

Before insertion and attachment of the prosthetic components, the implant shoulder and inner configuration must be free of contaminants and overhanging soft tissue.

For permanent insertion, it is essential to use new abutment and occlusal screws. Torque value for the attachment of the VARIO gold 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.

TAKING AN IMPRESSION

A prosthetic restoration with VARIO gold abutments requires an impression to be taken at implant level. For more information about impression techniques, please refer to www.ifu-tm.com/THM61127.

MODIFICATION OF THE ABUTMENT

Modification of the gold portion is not permitted, with the exception of the pre-assembled plastic cylinder. The minimal construction height of 2.5 mm is measured from the implant shoulder and applies to PF Ø 3.5–6.0 mm. After casting/grinding, there must always be a minimal wall thickness of 0.5 mm.

MASTER CAST FABRICATION

Implant analogs are available in all platform sizes for VARIO abutments. Standard procedures apply and do not require specific instruction.
CONSTRUCTION OF THE FINAL PROSTHETIC RESTORATION

Place the VARIO gold abutments on the implant analogs and secure them using the matching abutment screws.

The length of the plastic cylinder should be sufficiently shortened, such that maximum intercuspidation is possible. Avoid any occlusal contact between the plastic cylinder and the opposing tooth.

The minimum construction height of VARIO gold abutments for bridges and for crowns is 2.5 mm.

Material specification
VARIO gold abutments
Nonoxidizing precious metal cast-on alloy
Melting interval 1400–1460 °C
WAK 25–600 °C 12,8 μm/mk
Gold 60 %
Platinum 24 %
Palladium 15 %
Iridium 1 %
Wax modeling is then carried out directly on the abutment. If ceramic veneer is to be applied to the framework, a minimum thickness of 0.3 mm of casting alloy must remain over the VARIO gold abutment after framework finishing. It is advisable to allow additional wax thickness for casting and finishing. Please refer to the information provided by the alloy manufacturer for additional technical information. Since the VARIO gold abutment does not form an adhesive oxide layer, the ceramic veneer must not come in contact with the VARIO gold coping. Porcelain that directly contacts the VARIO gold coping will result in bonding problems.

In order to prevent casting errors and casting flash, the 0.5 mm collar of the VARIO gold coping must not be covered in wax.

The 0.5 mm collar and all machined surfaces of the gold abutment must be scrupulously clean before investing.

After finishing the wax modeling, the sprues are attached. In doing so, ensure that the casting alloy has an unhindered direction of flow.

Therefore, the abutment screw channel should be positioned as close to vertical as possible in the casting cylinder. Do not use any wax surfactant.

A phosphate bonded investment material is recommended. Please refer to the instructions of the manufacturer of the investment material.
After casting, allow the casting ring to cool slowly to room temperature. Carefully devest the framework using suitable means, e.g. ultrasound, a water jet, pickling solution or a glass fiber brush.

Connection geometry and screw channel must not be sandblasted under any circumstances. Modification of the precision connection will no longer guarantee the long-term success of both the prosthetic solution and the implants.

If minor casting flash is detected on the machined mating surface of the base, this surface can be smoothed-off using the corresponding VARIO reamers for base, preferably under a microscope.

<table>
<thead>
<tr>
<th>PF Ø 3.5</th>
<th>PF Ø 4.0</th>
<th>PF Ø 4.5–6.0</th>
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<tbody>
<tr>
<td>VARIO reamer for Basis Art. Nr.</td>
<td>3.03.420</td>
<td>3.03.421</td>
</tr>
<tr>
<td>VARIO guide pin for VARIO reamer Art. Nr.</td>
<td>3.03.424</td>
<td>3.03.425</td>
</tr>
</tbody>
</table>

If any casting errors or other forms of damage are detected, in particular related to the screw seat or connection geometry, the work must be redone.

Special care must be taken when polishing the VARIO collar. In order to reduce the risk of damaging the collar, an analog should be secured to protect the connection geometry.

The minimal wall thickness of the cast-on fuse-on alloy must be no less than 0.3 mm after the finishing of the cast superstructure. Exposed sites of the VARIO gold abutment may lead to fissures in the ceramic veneer.

**Note:** The screw seat must not be reworked under any circumstances with the handpiece.

The seat of the abutment screw would thus be shifted deeper into the internal configuration and the mechanical stability of the abutment would no longer be guaranteed. As a result, the abutment screw would collide with the bottom of the implant screw channel (end of thread), no longer allowing the restoration to be fixed.
The screw seat is manually reworked only after smoothing of the base perimeter. For correct reworking of the screw seat, use the VARIO reamer for the screw channel (A) and the associated guide (B) [Art. 3.03.460]. Two reamers are available for the screw channel:
- For Platform Ø 3.5 mm (Art. no. 3.03.435)
- For Platform Ø 4.0–6.0 mm (Art. no. 3.03.436)

Position the bridge abutment to be reworked on the contact area of the guide (C). Operate the reamer manually using the MONO insertion device (D).

Introduce the VARIO screw-channel reamer into the screw channel and rotate it clockwise. During the finishing process, the perimeter of the abutment’s base must completely cover the contact area of the guide (C).

Rotate the VARIO reamer into the screw channel until it stops (E). Perform the finishing process in the same way for 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 overflows in the screw channel or screw seat.

If any casting errors or other forms of damage are detected, the work must be redone.

Prepare and veneer the framework using conventional methods.

Special care must be taken when polishing the VARIO collar. In order to reduce the risk of damaging the collar, an analog should be secured to protect the connection geometry.
The correct position of the screw seat can be determined by measuring with a caliper rule.

First, the appropriate abutment screw must be inserted into the abutment until it stops.

Then the distance between the base and the end of the screw is measured. Adhering to the measurements listed below is critical. Going above or below the provided tolerance range is not permitted. If the tolerance range is not met, the work is to be redone.
CLEANING, DISINFECTION, 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 DIN EN 13060/DIN EN 285 and/or ANSI AAMI ST 79 (for USA: FDA clearance)
- Maximum sterilization temperature of 138 °C (280 °F; plus tolerance in compliance with DIN EN ISO 17665)

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

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

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.

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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Platform Color code

<table>
<thead>
<tr>
<th>Platform</th>
<th>Color code</th>
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</thead>
<tbody>
<tr>
<td>PF Ø 2.5 mm</td>
<td>Yellow</td>
</tr>
<tr>
<td>PF Ø 4.0 mm</td>
<td>Green</td>
</tr>
<tr>
<td>PF Ø 4.5 mm</td>
<td>Blue</td>
</tr>
<tr>
<td>PF Ø 5.0 mm</td>
<td>Grey</td>
</tr>
<tr>
<td>PF Ø 6.0 mm</td>
<td>Brown</td>
</tr>
<tr>
<td>PF Ø-independent</td>
<td>Neutral</td>
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</tbody>
</table>

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