TITANIUM BASE FOR CAD/CAM.
FOR SCREW-RETAINED AND CEMENTED SOLUTIONS.

PROSTHETIC PROCEDURE
1. At a glance

These instructions apply to Titanium Base for CAD/CAM, including associated auxiliary parts, as listed in the product catalogue (wwwifu-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>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium base with hexagon</td>
<td>Pure titanium grade 4</td>
</tr>
<tr>
<td>Abutment screw</td>
<td>Titanium alloy</td>
</tr>
<tr>
<td>Burn-out plastic cap</td>
<td>POM</td>
</tr>
<tr>
<td>Laboratory screw</td>
<td>Stainless steel</td>
</tr>
<tr>
<td>Cylindrical pin for dental laboratory</td>
<td>PTFE</td>
</tr>
</tbody>
</table>

**INDICATION**

The Thommen Medical Titanium Base for CAD/CAM is 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.

**RESTRICTED USE**

See general restrictions of use (Page 11).

**STORAGE**

The scan abutments must be protected from exposure to strong light or high heat.
2. Application and handling

CLINICAL USE

The Titanium Base, also known as a bonding base or abutment interface, is mainly used for manufacturing a single abutment. In conjunction with a custom CAD/CAM zirconia superstructure, it is possible to manufacture an optimal emergence profile. Further, both components make it easy to achieve the desired colouring along the collar area of the crown/bridge and abutment. This makes it possible to achieve highly aesthetic cemented restorations in the anterior region. The Thommen Titanium Base is available with a hexagonal connection for a single tooth restoration or with non-rotation-lock variants for screw-retained bridge restorations.

For larger bridge constructions with medium to heavy implant divergences, we suggest confirming the suitability of the abutment dimensions prior to placement (e.g. crown length, insertion direction).

If the requirements above cannot be achieved, we suggest the selection of a different abutment type (e.g. VARIOmulti).

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 screws. The torque of the abutment screws on crowns/bridges with a titanium base is:
- 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 the Titanium Base for CAD/CAM requires taking an impression at the implant level. Thommen scan abutments are used for digital impression taking and can be used intraorally or for scanning from the master model.

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

Information on conventional impression taking can be found at:

MODIFICATION OF THE ABUTMENT

Modification of the Titanium Base for CAD/CAM is not permitted.
MODEL CASTING

Implant analogs are available exclusively for the Titanium Base for CAD/CAM. A gingival mask (gingival simulation material) is recommended.

CONSTRUCTING 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. Thommen scan abutments are used for digital impression taking and can be used intraorally or for scanning from the master model.

ABUTMENT AND FRAMEWORK DESIGN

The following restoration options are available:

- Screw-retained restorations [A]:
  Designs for crown or bridge abutment frameworks are made according to the requirements for direct veneers. The corresponding frameworks are first constructed on the titanium base and then completed later. The titanium base is not bonded to the abutment (crown or bridge, respectively) until after completion of the framework veneer.

- Cemented restorations on individual abutments [B]:
  Individual abutments for cement-retained porcelain crowns or bridges require attention to the design. Margin location, chamfer and path of placement are important factors to consider. The titanium base and the custom-manufactured zirconia superstructure are bonded together before the crown or bridge is manufactured.
In general:

1. It is necessary to comply with the minimum wall thickness of a custom-manufactured abutment framework. Please comply with the recommendations of the supplier of the respective material.

2. Fabrication of the customized abutment
   The CAD process for meso- or superstructures depends on the CAD/CAM system used. For information about corresponding procedures and details, please refer to the user documentation and software of the various providers of your chosen systems.

   Thommen provides you with the latest CAD libraries of the established systems. An overview can be found at: www.thommenmedical.com.

3. Preparation of the titanium base for the blasting process
   Screw the titanium base onto an analog using an abutment screw. The margin as well as the screw channel of the titanium base (A) should be covered with a suitable masking material before performing the blasting procedure. For ease of handling, the analog and screw-retained titanium base can be attached to the dental laboratory handle.

4. Blasting process
   Blast the bonding sites of the titanium base and zirconia superstructure briefly with 50 μm aluminium oxide at a max. pressure of 2 bars.

5. Cleaning
   After sandblasting, the titanium base and zirconia superstructure are cleaned using steam jet or alcohol. All dust and grease must be removed from the surface.
5. Cement preparation and application
   To bond the titanium base to the superstructure, we recommend the 70.0 mm cylindrical pin for laboratory, available for platform sizes Ø 3.5 mm and Ø 4.0–6.0 mm.

   The cylindrical pin is made of PTFE and does not form a bond with the cement.

   Once it has been shortened to the desired length and inserted into the screw channel, the cylindrical pin keeps the screw channel free from cement material.

6. Bonding the superstructure to the titanium base
   Push the superstructure over the cylindrical pin down onto the titanium base until resistance is felt. Turn the superstructure until it clears the positioning index and seats completely on the titanium base.

   Then press the construction as far as it will go onto the titanium base.

7. Removing residual cement agent
   Remove any excess of cement from the margin with an appropriate instrument before it sets.

8. Curing the cement and finishing
   Instructions for curing the cement should be carried out in accordance with the instructions provided by the cement manufacturer.

   Remove the cylindrical pin for laboratory after the cement has cured. Carefully remove any residual cement under the microscope with a rubber-polishing burr/wheel.


**APPROACHES FOR SCREW-RETAINED BRIDGE RESTORATIONS**

The Titanium Base for Bridge is used exclusively for multi-unit, screw-retained bridge restorations. Please note the following two prerequisites.

The alignment of the screw channel has to be occlusally located in posterior restorations and palatal/lingual in anterior restorations.

Two cementing methods are available for screw-retained bridge restorations:
- Cementing on the model
- Cementing off the model

Cementing on the model is feasible only if a path of placement between the bases is achievable. This bonding method strongly depends on implant divergences. In order to achieve a proper fit and/or insertion on the titanium base, minimal retouching should be attempted on the actual bridge framework.

In the majority of cases, bonding directly on to the model is not possible. Otherwise, the bonding process takes place off the model, as described below.
BOND THE TITANIUM BASE WITH THE MILLED BRIDGE

1. Preparing titanium bases, see steps 2–5 on page 5–6.

2. Mix the bonding agents [PANAVIA™F 2.0 made by Kuraray] in accordance with the manufacturer’s instructions and apply to the titanium base. The bonding agent must be in a soft state during the following processes.

3. Working off the model, place each titanium base with inserted cylindrical pin into the corresponding bridge abutment.

4. Place the bridge reconstruction in the analog on the model. Verify correct and complete seating of the bridge. Remove the cylindrical pin for laboratory, insert the abutment screws (or laboratory screws) and tighten firmly. Let the cement cure, remove any remaining cement residue and then finish the bridge restoration.
PERMANENT ATTACHMENT OF THE FINISHED RESTORATION

Cemented

1. Remove the gingiva former or temporary crown(s)/bridge from the implant. Clean and dry the inner configuration of the implant thoroughly before attaching the permanent crown or bridge.

   Position the clean custom-made abutment(s) onto the implant(s) and verify complete seating and fit (see clinical use on page 3).

2. Fill the screw orifice with a removable material (e.g. PTFE).

   See study:
   Osvaldo D. Moraguez, DMD,a and Urs C. Belser, DMD,
   Prof Dr Med Dentb, School of Dental Medicine, University of Geneva, Geneva, Switzerland

3. Cement the porcelain crown or bridge onto an individual abutment or abutments. Carefully remove all residual cement.

   Important: Do not sterilize the titanium base in the cemented state.
Screw-retained

1. Remove the gingiva former or temporary crown(s)/bridge from the implant. Clean and dry the inner configuration of the implant thoroughly before attaching the permanent crown or bridge. Position the crown/bridge on the implant(s) and check for correct seating and fit (see torque value on page 3).

2. After inserting the restoration, refill the screw channel with a removable material (e.g. PTFE). Seal the screw channel with a suitable composite material.

**Important:** Do not sterilize the titanium base after bonding.

**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 ST 79
- 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).
A number of different abutments in various shapes and sizes are available for the prosthetic restoration of Thommen implants.

### 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: wwwifu-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 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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