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/THM3111]. There, you will also find directions on the identifying characteristics (geometries, dimensions) of the individual components.

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**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 is 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: www.ifu-tm.com/THM61127.

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. 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.

2. 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.

3. 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.

4. 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 (270 °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 (wwwifu-tmcom/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

Sterilized using irradiation

Sterilized using steam or dry heat

Temperature limitation

Do not re-use

Non-sterile

Caution

Temperature limitation

Consult instructions for use

Do not re-sterilize

Do not use if package is damaged

Atmospheric pressure limitation

Keep away from sunlight

Rx Only

Guarantee

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. For technical advice, the responsible country representative or distributor of Thommen Medical AG informs about availability 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 moments do not occur. 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 exclusion and functional loading of the prosthetic supraconstruction very carefully.

WARNINGS/PRECAUTIONS All Thommen Medical products that come into effect inside the oral cavity must be protected against aspiration. Thommen Medical products have not been evaluated for safety and compatibility in the MR environment. Thommen Medical products have not been tested for heating, migration, or image artifact in the MR environment. The safety of Thommen Medical products in the MR environment is unknown. Scanning a patient who has this product may result in patient injury.

RESPONSIBILITY/LIABILITY As part of an overall scheme, Thommen Medical products may be used only with the 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 professionally in accordance with the instructions for use. Thommen Medical products should only be used in accordance with the instructions for use provided by Thommen Medical. 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 color marks, corrosion). Detailed information about the possible consequences, which may result from negligence to follow this information, can be obtained from the responsible country representative or distributor of Thommen Medical AG. Caution: Federal law (USA) restricts this device to sale by or on the order of a dentist or physician.

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

TRANSPORT AND STORAGE Please note the specifications on all labels and package leaflets regarding transportation, storage and instructions for use. Products whose packaging is damaged must not be used. 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 anymore.

INSTRUCTIONS FOR USE The following information is not intended as comprehensive for the Thommen Implant System. New customers are advised to undergo training by a specialist experienced in the use of this system.

GUARANTEE OF STERILITY Products of the Thommen Implant System supplied in sterile packaging must not be re-sterilized. If the sterile packaging is damaged during transport or storage, the product may under no circumstances be used. Products that have been opened and have not been immediately used for the intended operation must not be used thereafter. After resterilization, the safety, function and efficacy of the product 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 (such as scratches, cracks, nicks, notches), as well as bent parts means that they must not be used anymore. The number of reproccessing 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.

DISPOSAL In 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. Products that have been used on a patient are at risk of infection. After application, they must be disposed of safely and properly in compliance with all applicable legal and regulatory requirements.

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