Titanium Base for CAD/CAM.

For screw-retained and cemented restorations Prosthetic procedure

Instructions for use THM61123

Version 005_AA, Issue date 08/20

THOMMEN Medical

1. At a glance

These instructions for use apply to the titanium base for CAD/CAM including associated 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
Titanium Base with hexagon/bridge for CAD/CAM	Pure Titanium Grade 4	No
Abutment screw	Titanium alloy	No
Burn-out cap	POM	No
Laboratory screw	Stainless steel	Yes
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

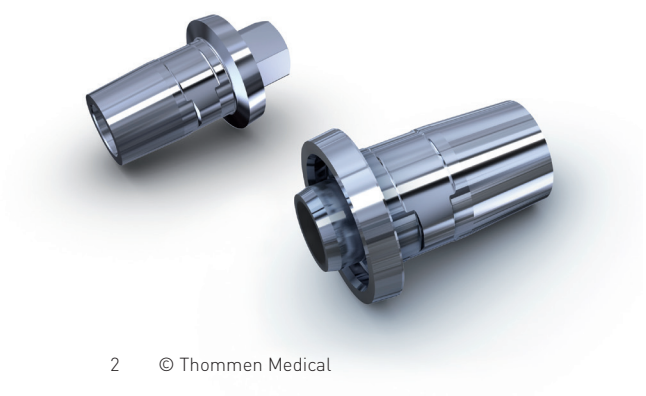
Thommen Medical prosthetic components are used in combination with the Thommen Medical Dental Implant System in the upper and lower jaw for implant-borne tooth replacement.

RESTRICTIONS OF USE

See the general restrictions of use (page 11).

STORAGE

Burn-out caps must be protected from exposure to strong light or high heat.



2. Application and handling

CLINICAL USE

Titanium bases, also known as bonding bases or abutment interfaces, are mainly used for manufacturing single abutments. Together with e.g. an individual, CAD/CAM zirconia superstructure, it is possible to manufacture an optimal emergence profile. Furthermore, with the zirconia superstructure it is very easy to achieve the necessary coloring in the collar area of the crown/bridge abutment. For example, this makes highly aesthetic cemented restorations possible in the anterior area. Thommen Medical titanium bases are available with hexagon for a single tooth restoration or as non-rotation-lock variants for screw-retained bridge restorations.

Above all, we recommend checking the abutments for suitability (insertion direction, crown length) in advance, especially for larger screw-retained bridge constructions with medium-sized to largest implant divergences.

If the requirements stated above are not fulfilled, we recommend switching to another abutment (e.g. VARIOmulti).

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 final insertion. Torque value for the definitive attachment of the titanium base:
- 15 Ncm for PF 3.5
- 25 Ncm for PF 4.0–6.0

An overview of all tightening torques for the definitive attachment of Thommen abutments can be found at www.ifu-tm.com/THM61122.

IMPRESSION-TAKING

The prosthetic restoration with the titanium base for CAD/CAM requires taking an impression at the implant level. Thommen Medical scan abutments are used for digital impression taking and can be used either intraorally or for scanning from the master model.

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.

MODIFYING THE ABUTMENT

Modification of the titanium base for CAD/CAM is not permitted.

FABRICATING THE LABORATORY MODEL

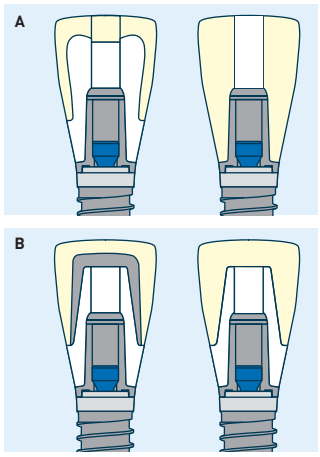
Implant analogs are available for the titanium base for CAD/CAM. We recommend the fabrication of a gingival mask.

FABRICATING THE DEFINITIVE PROSTHETIC RESTORATION

The definitive reconstruction should be carried out in accordance with the current level of dental technology taking the manufacturer's instructions for the materials used into consideration.
Thommen scan abutments are used for digital impression taking and can be used intraorally or for scanning from the master model. Titanium bases for CAD/CAM are intended for single use.

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

ABUTMENT AND FRAMEWORK FABRICATION



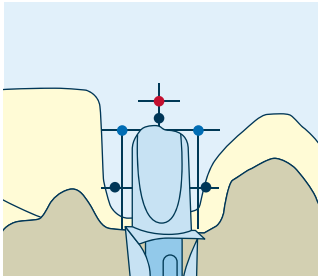
The following restoration options are available:

- Screw-retained restorations (A):
  Abutments or crown and bridge frameworks are designed in accordance with the requirements for direct veneering. The corresponding frameworks are first constructed on the titanium base and completed later. Bonding of the titanium base to an abutment or crown or bridge framework is carried out only after the framework veneering has been finished.
- Cemented restorations on individual abutments (B):
  Individual abutments for all-ceramic crowns that have been cemented on or bridges require a special design (e.g. a step). The bonding of a titanium base to an individually fabricated zirconium dioxide abutment is carried out before the crown or bridge is fabricated.

General notes:

- Do not go below the minimum wall thickness of an individually fabricated abutment or crown or bridge framework. Follow the recommendations of the material supplier.

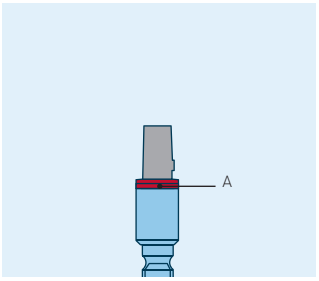
1. Fabrication of an individual abutment
   The design for the CAD procedure for meso- or superstructures using CAD depends on the CAD/CAM system used. The corresponding procedures and details should be taken from the user documentation, or from the software belonging to the individual system supplier.



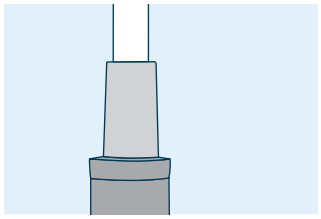
   Thommen Medical provides up-to-date CAD libraries for the most commonly used systems. You can find an overview at:
   www.thommenmedical.com

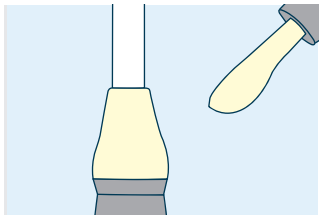
2. Preparation of the titanium base for the blasting process
   Screw the titanium base onto an analog using an abutment screw. The margin and the screw channel of the titanium base (A) must be covered with a suitable material before the blasting process. The analog with the screw-retained titanium base can be fixed in the handle for dental technicians for the blasting process.

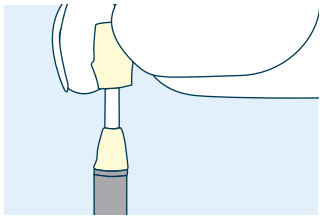
3. Blasting
   The bonded surfaces of the titanium base and zirconium oxide construction are briefly blasted using 50 µm aluminum oxide and max. 2 bar pressure.

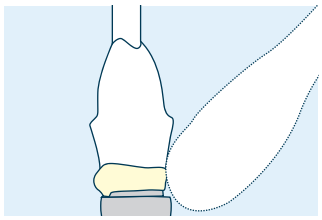


4. Cleaning
   After the blasting process, clean the titanium base and the zirconium oxide construction using a steam cleaner or alcohol. All residual dust and grease must be removed from the surface.









5. Preparation and applying the cement
   For cementing (e.g. PANAVIA™F 2.0 from Kuraray or ReliyX Unicem™ from 3M) the titanium base to the construction, we recommend the laboratory cylindrical pin 70.0 mm, available for the PF 3.5 and 4.0–6.0.

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

   When shortened to the desired length and inserted into the screw channel, the cylindrical pin prevents the screw channel being sealed or bonded during the bonding process.

6. Bonding the construction to the titanium base
   Push the construction over the cylindrical pin and titanium base until resistance can be felt. By turning the construction, the definitive position of the rotation lock is reached.

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

7. Remove remaining cement
   Remove excess remaining cement at the margin with a suitable instrument before it cures.

8. Curing of the cement and reworking
   Possible measures for curing the cement should be taken from the instructions for use of the cement manufacturer.

   Remove the cylindrical pin after curing. Carefully remove remaining cement residues at the margin under a microscope using a rubber sander/polisher.

PROCEDURE FOR SCREW-RETAINED BRIDGE RESTORATIONS

For a screw-retained bridge restoration, only use the titanium base bridge.

The alignment of the screw channel must be occlusal in posterior restorations and palatinal/lingual in anterior restorations.

There is a choice of 2 cementing methods for screw-retained bridge constructions:

- Cementing on the model
- Cementing off the model

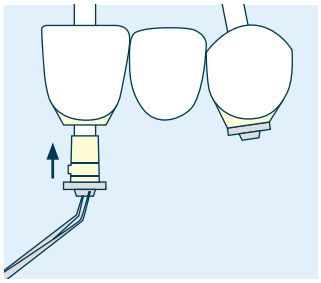
Cementing on the model is only possible if an insertion direction between the titanium bases is achievable. Use of these bonding methods strongly depends on the implant divergences. Only minimal retouching should be required on the actual bridge framework, in order to achieve a good fit and/or insertion on the titanium base.

In the majority of cases, bonding directly onto the model is not possible. Otherwise, the bonding process generally takes place off the model, as described below.

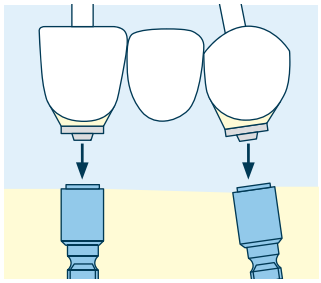
BOND THE TITANIUM BASE WITH THE ALREADY MILLED BRIDGE

1. To prepare the titanium bases, see Steps 2–5 on page 5–6.

2. Mix and apply the cement (e.g. PANAVIA™F 2.0 from Kuraray) to the titanium base in accordance with the manufacturer's instructions. The cement must absolutely be in a soft condition during the following processes.



3. Place each titanium base individually with the inserted cylindrical pin into the corresponding bridge abutment off the model.



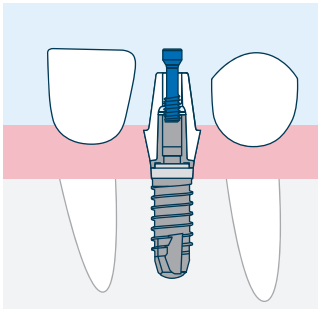
4. Then position the bridge reconstruction in the analogs on the model. Check that the bridge is fully and correctly seated. Remove the cylindrical pins, insert the abutment screws (or laboratory screws) and tighten firmly. Let the cement cure, remove any remaining cement residues and then finish the bridge restoration. The laboratory screws are intended for multiple use. The product must be replaced as soon as it shows signs of wear and tear and/or damage.

DEFINITIVE ATTACHMENT OF THE FINISHED RESTORATION INTRAORAL

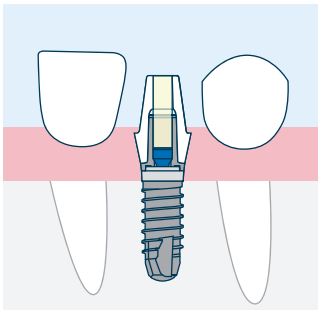
Cemented

1. Remove the gingiva former or temporary crown/bridge from the implant. Clean and dry the inner configuration of the implant thoroughly.

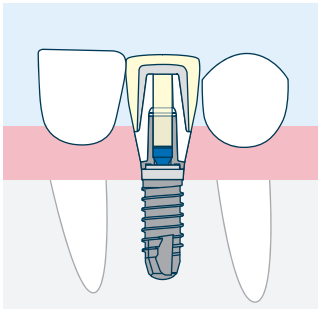
   Position the individually fabricated abutment(s) in a clean condition on the implant(s), check that they are correctly seated and fix definitively (see Clinical use, page 3).



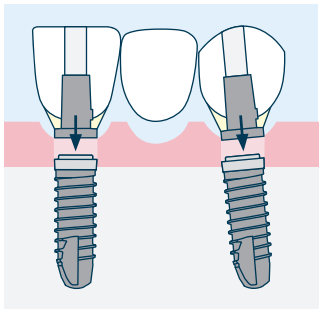
2. Seal the screw channel with a removable material (e.g. gutta-percha).

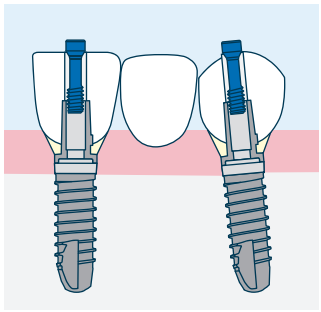


3. Cement an all-ceramic crown or bridge on the individual abutment(s). Carefully remove excess cement residues.



⚠ **Warning:**
Sterilization of the titanium base in the cemented state is not permitted.





Screw-retained

1. Remove the gingiva former or temporary crown/bridge from the implant. Clean and dry the inner configuration of the implant thoroughly. Position the crown/bridge on the implant(s), check that they are seated correctly and fix definitively (observe the torque value specifications on page 3).

2. Fill the screw channel with a removal material (e.g. gutta-percha). Then seal with a suitable composite material.

⚠ **Warning:**
Sterilization of the titanium base in the cemented state is not permitted.

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

THOMMEN Medical

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
STERILIZE	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.

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. 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.

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