Milling abutment for CAD/CAM Type I & II.

For customized abutments. Prosthetic procedure

Instructions for use THM61137

Version 003_AA, Issue date 08/20

THOMMEN Medical

1. At a glance

Components	Material	Reusable
Milling abutment for CAD/CAM Type I	Pure Titanium Grade 4 ASTM F67/ISO 5832-2	No
Milling holder for CAD/CAM Type I	Stainless steel	Yes
Milling abutment for CAD/CAM Type II	Pure Titanium Grade 4 ASTM F67/ISO 5832-2	No
Abutment screw	Titanium alloy	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 6).

2. Application and handling

APPLICATION

The milling abutments for CAD/CAM type I & II are used to produce individualized titanium abutments. The milling abutments for CAD/CAM type I & II can also be used for conical and telescopic crowns as well as for parallelized abutments for cemented bridge constructions.

The milling abutments for CAD/CAM type I can only be individually customized by milling centers with the corresponding equipment which have been approved by Thommen Medical. The milling abutments for CAD/CAM type II can be individualized by milling centers as well as by laboratories with the corresponding equipment. The finished abutments must be sterilized before intraoral use. The milling abutments for CAD/CAM are intended for single use

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 values for the definitive attachment of milling abutments:
- 15 Ncm for PF 3.5
- 25 Ncm for PF 4.0–6.0

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

IMPRESSION-TAKING

The prosthetic restoration with the milling abutment for CAD/CAM Type I & II requires taking an impression at the implant level. Thommen Medical scan abutments are used for digital impression taking and can be used intraorally or for scanning from the master model.

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

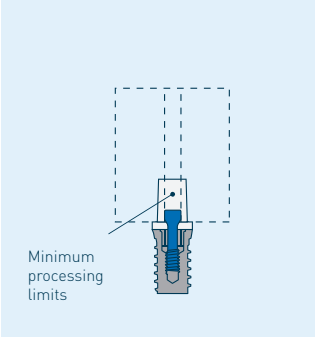
Information on taking conventional impressions can be found online at www.ifu-tm.com/THM61127.

FABRICATING THE LABORATORY MODEL

Implant analogs are available for CAD/CAM Type I & II in all platform sizes.

MODIFYING THE ABUTMENT

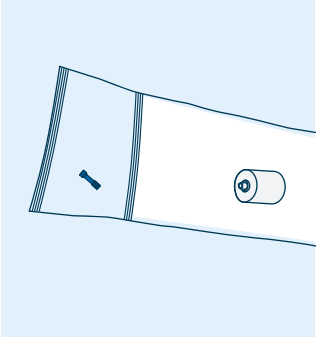
Thommen Medical can provide libraries for dental CAD programs. For this, please visit: www.thommenmedical.com



Minimum machining boundaries have been defined by Thommen Medical to ensure sufficient wall thickness in the individualized area. Check whether the models and minimum machining boundaries are in the library of the CAD software being used. Contact the Technical Service Department of Thommen Medical if a model with the minimum machining boundaries is not available.

Parameter:	
Maximum angulation	20°
Minimum wall thickness	0.4 mm
Maximum gingival height	7.0 mm

SCOPE OF DELIVERY/ASSEMBLY



The milling abutment for CAD/CAM Type I & II is supplied together with an abutment screw. The shrink-wrapped abutment screw is intended for the definitive restoration of the patient and must be forwarded to customers together with the individualized milling abutment (traceability). The shrink-wrapped abutment screw provided in the package may not be used to fix the milling abutment on the milling holder and may not be used in the milling process. Individually packaged abutment screws for the milling abutment for CAD/CAM Type I are available for the milling process. Milling holders for CAD/CAM Type I are intended for multiple use. The product must be replaced as soon as it shows signs of wear and tear and/or damage.

When assembling the milling abutment for CAD/CAM Type I on the milling holder for CAD/CAM Type I, pay attention to the torque value. The abutment screw must be tightened to the following torque value using the 4-lobe screwdriver:

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

The milling abutment for CAD/CAM Type II is processed in a suitable milling system using an original Medentika® PreFace® Abutment Holder. The PreFace® Abutment Holder must be ordered directly from the machine manufacturer. The instructions for use for the Medentika® PreFace® Abutment Holder can be obtained from your milling machine manufacturer.

You can find information on the compatible milling machines at:
www.thommenmedical.com

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
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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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