Digital impression taking & master cast fabrication.

Prosthetic procedure

Instructions for use THM61143

Version 004_AA, Issue date 08/20

THOMMEN Medical

1. At a glance

These instructions apply to all impression components required for taking digital impressions at the implant level, including associated screws for impression copings and scan abutments. These instructions also apply to digital master cast fabrication.

Components	Material	Reusable
Scan abutment, steel, coated	Stainless steel	Yes
Scan abutment, PEEK	PEEK	Yes
Screw for impression coping	Stainless steel	Yes
Implant analog for CAD/CAM	Pure Titanium Grade 4	Yes
Insertion device	Stainless steel	Yes

APPLICATION

Thommen Medical scan abutments are used to transfer the position and location of Thommen implants for digital impression taking. Digital impression taking is carried out on the master model or intraorally.

Implant analogs show the exact likeness of the implant connection geometry in the corresponding diameter and are used in the master cast for fabrication of the superstructure.

The adapter helps when inserting the implant analog into printed master casts for CAD/CAM.

See also the general instructions (page 10).

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.

STORAGE

Scan abutments must be protected from exposure to strong light or high heat.

2. Application and handling

DIGITAL IMPRESSION TAKING

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

Scan abutments can be reused and it is not necessary to use a coating spray.

The coated steel scan abutment has an improved scan geometry and is radiopaque. This makes it possible to control the correct positioning on the implant via X-rays when used intraorally. The scan abutment made of PEEK is not radiopaque.

DIGITAL MASTER CAST FABRICATION

Implant analogs show the exact likeness of the implant connection geometry in the corresponding diameter and are used in the master cast for fabrication of the superstructure.
The insertion device helps when inserting the implant analog for CAD/CAM In printed master casts.

MODIFYING THE ABUTMENT

Modification of the scan abutment is not permitted.

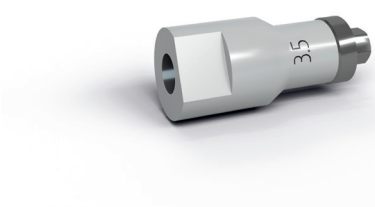
CONVENTIONAL IMPRESSION TAKING

General information on conventional impression taking can be found online at www.ifu-tm.com/THM61127.

LIBRARIES

Thommen Medical can provide libraries for dental CAD-software. The libraries used must be aligned between the users (e.g.: dentist, dental technician, milling center). Conventionally, it is the final link in the value creation chain which administers the final configuration of the library and distributes this to the upstream users. If the basic libraries have not been included when the CAD-software was installed, they can be downloaded from the Thommen Medical website. For this, please visit: www.thommenmedical.com

If no library is available for the CAD - system in use, please contact your local sales representative or country's sales representative.



DUE CARE AND ATTENTION

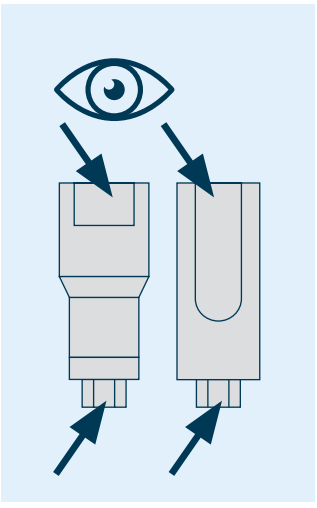
Thommen Medical scan abutments must be handled with due care and attention. Surfaces can be damaged if touched with steel forceps, or if dropped (e.g. into the instrument tray). Scan abutments must be checked visually before use. If there are signs of wear on the connection geometry and/or if there is damage to the surface in the scan area, the scan abutments must be replaced.

CHAIRSIDE SCAN

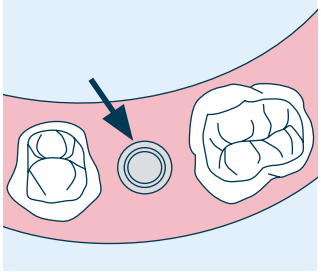
Thommen Medical scan abutments are supplied in a non-sterile state. They must be cleaned and sterilized in the dental practice before intraoral use.

General information on processing can be found at www.ifu-tm.com/THM61131.

The following procedure with scan abutments is suitable for the most commonly used CAD/CAM systems. Other procedures must be discussed directly with the CAD/CAM supplier.



1. Checking the scan abutment and implant
   The scan abutment must be checked visually for signs of wear on the connection geometry and for surface damage to the scan area before use.



2. The implant connection geometry of the implant must be cleaned thoroughly before the scan abutment is placed in position.

3. Positioning the scan abutment
   Note: The scan abutment should be positioned in such a way that the lateral rotation surface is clearly visible to the scanner. The scan abutment is fixed onto the implant manually, but without applying a high torque (approx. 5 Ncm) with the extra short screw for impression coping. The correct seating of the coated steel scan abutment can be checked using an x-ray.

4. Scanning
   The necessary scan processes are carried out in accordance with the instructions for the system used/from the manufacturer.

5. Cleaning
   All obvious contamination must be removed from the scan abutment immediately after use.

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.

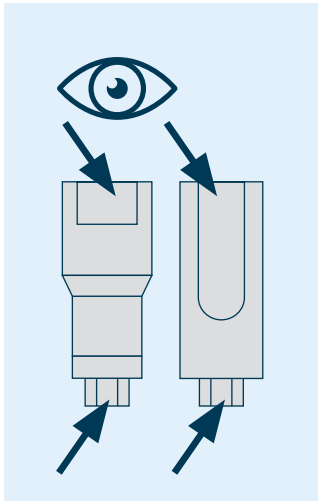
Multiple-use products:
All multiple-use products must be cleaned, disinfected and sterilized before first use. An effective cleaning and disinfection are absolutely necessary requirements for an efficient sterilization for re-use.
Steam sterilization is recommended:

- 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)

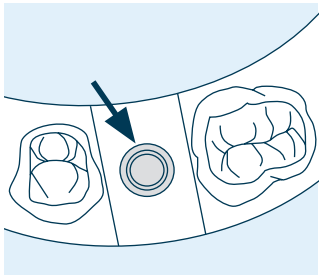
Sterilization time, i.e. exposure time at the sterilization temperature, is at least 4 minutes at 132°C (270°F) or 18 minutes at 134°C (273°F) for prion inactivation (not relevant for USA).
For further instructions on the sterilization of prosthetic components, please refer to the valid Thommen Medical processing instructions (www.ifu-tm.com/THM61131).

SCANNING IN THE LABORATORY

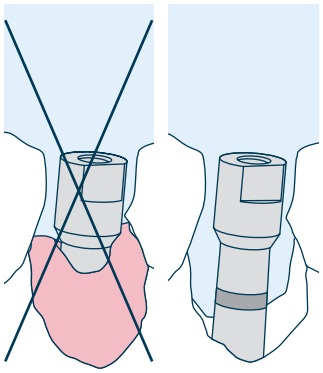
The following procedure with scan abutments is suitable for the most commonly used CAD/CAM systems. Other procedures must be discussed directly with the CAD/CAM supplier.



1. Check the scan abutment and analog
   The scan abutment must be checked visually for signs of wear on the connection geometry and for surface damage to the scan area before use.



2. The implant connection geometry of the implant analog must be cleaned thoroughly before the scan abutment is placed in position.



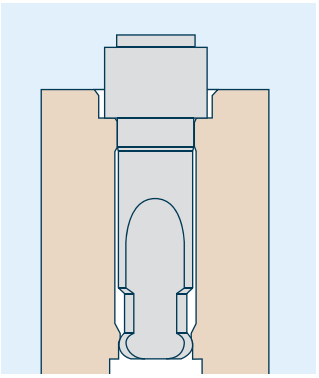
3. Positioning the scan abutment
   The correct seating of the scan abutment can be checked more easily by removing the gingival mask. The scan abutment should be positioned in such a way that the lateral rotation surface is clearly visible to the scanner. The scan abutment is fixed onto the analog by hand, but without applying a high torque (approx. 5 Ncm) with the extra short screw for impression coping.

4. Scanning
   The necessary scan processes are carried out in accordance with the instructions for the system used/from the manufacturer.

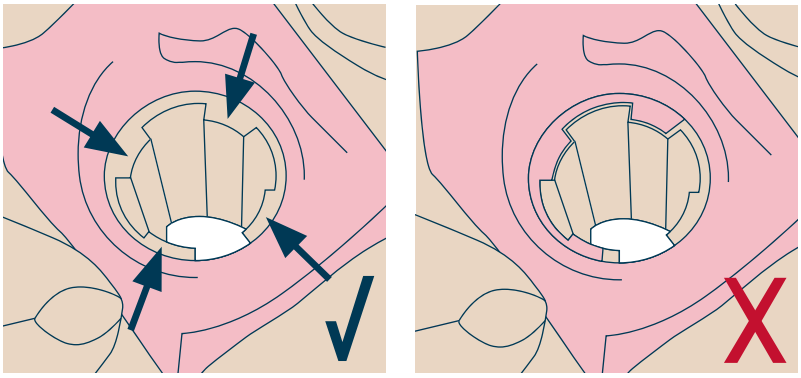
DIGITAL MASTER CAST FABRICATION

When designing the master cast, make sure that the segmented contact surface of the implant analog is present in full.

The diameter of the printed analog cavities may vary depending on the 3D printing system used. If the dental CAD program used supports correction of the diameter, this is saved in the material library or can be adjusted there.



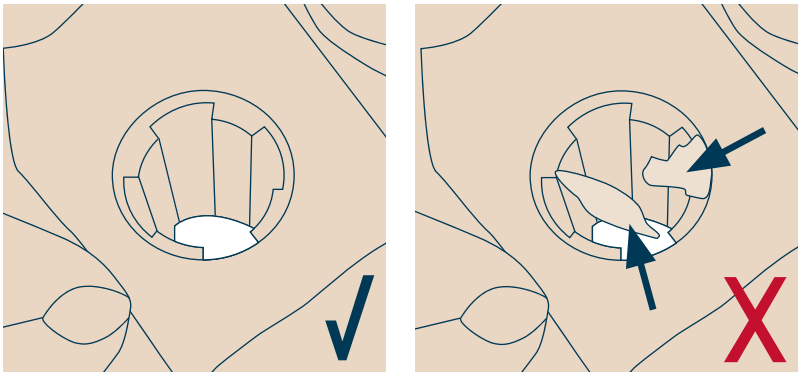
Saw-cut model

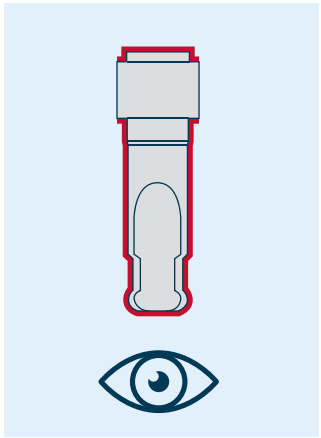


Segmented contact surface

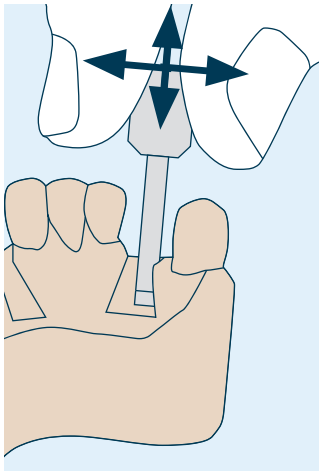
ASSEMBLY

Check the master cast and implant analog in advance. The analog cavity in the model must be free of any visible construction defects or residues.





Implant analogs must be undamaged. See the red outline in the image.



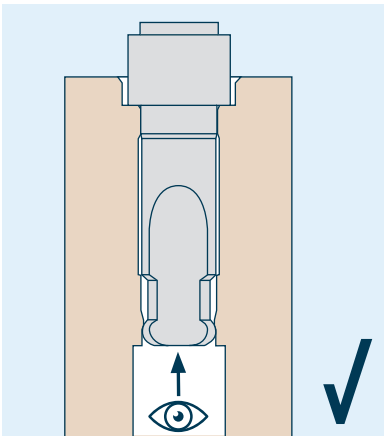
Note: When inserting the implant analog, pay attention to the following:

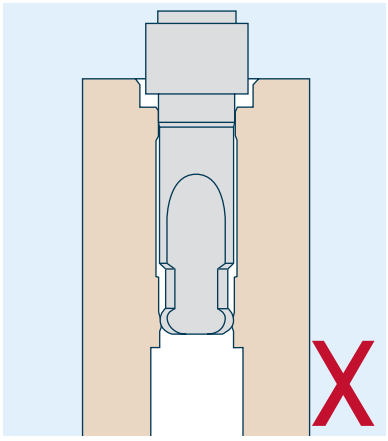
- The insertion device is screwed onto the analog hand tight
- The rotational position is then found by turning
- When the end position is reached, it clearly snaps into place

Checking that the seating of the analog is free of play can be performed more easily by moving the insertion device. The insertion devices are intended for multiple use. The product must be replaced as soon as it shows signs of wear and tear and/or damage.

Check the visible basal surface to make sure that the final position has been reached.

Repeated removal and insertion in the same master cast can cause wear to the locking function

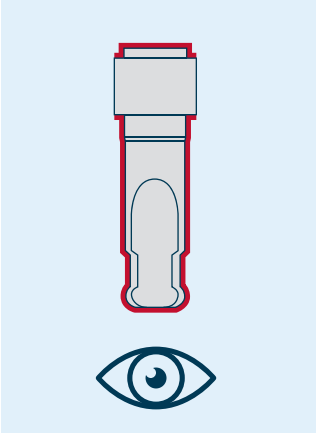




FURTHER USE

Implant analogs for CAD/CAM may also be used for conventional master cast fabrication.

Using the handle for dental technicians allows for easy handling during manual work. After use, check the implant analog for any damage. The product must be replaced as soon as it shows signs of wear and tear and/or damage.



3. General notes

THOMMEN IMPLANT SYSTEM

THOMMEN Medical

Manufacturer: Thommen Medical AG
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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
	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.

DISPOSALIn 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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