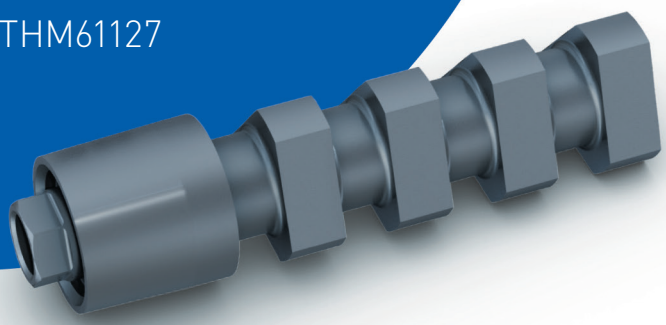
# Impression-taking

## At the implant level. Prosthetic procedure

Instructions for use THM61127



Version 002_AA, Issue date 08/20

THOMMEN Medical

# 1. At a glance

These instructions for use apply to all impression components required at the implant level including associated screws for impression copings and model analogs. Information on the identifying elements (geometries, dimensions) of the individual components are listed in the product catalog (www.ifu-tm.com/THM31111). Impression taking at the abutment level is specified in the corresponding instructions for use for the abutments.

| Components | Material | Reusable |
|---|---|---|
| Impression copings retentive 10.0 mm | Aluminum, anodized | No |
| Impression copings retentive 16.0 mm | Pure Titanium Grade 4 | Yes |
| Repositionable impression copings 8.0/12.0 mm | Aluminum, anodized | No |
| Repositionable impression copings 8.0/12.0 mm | Pure Titanium Grade 4 | Yes |

## 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.

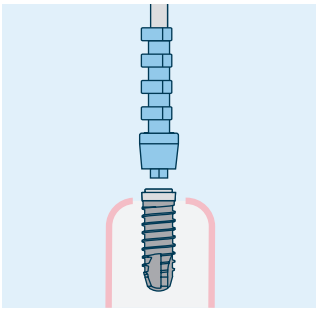
## RESTRICTIONS OF USE

See the general restrictions of use (page 7).

# 2. Application and handling

## VARIANT WITH IMPRESSION COPING RETENTIVE (SCREW-RETAINED) FOR THE OPEN-TRAY TECHNIQUE

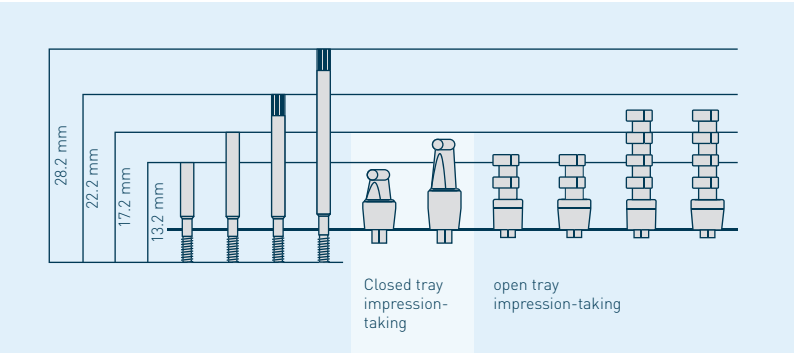
Remove the healing cap, gingiva former or temporary restoration after successful osseointegration of the implant and completion of soft tissue conditioning. The implant and prosthetic components must be clean and not show any signs of damage before the components are inserted and attached. Additionally, make sure that the implant shoulder is free of all overhanging soft tissue.



Selecting the impression coping and screw length:
Impression coping retentive is available in lengths of 10 mm and 16 mm Where occlusal space is limited, the impression coping can be shortened. However, at least one retention ring must be retained. If the impression coping was shortened, suitable impression screw lengths are determined using the height of the impression tray or the occlusal space.

⚠ **Warning:** After shortening the impression coping, break off the resulting rough or sharp edges at the separation site using a suitable sander/polisher.

The conical impression copings have an emergence profile similar to that of the EASY abutment. The cylindrical impression copings are especially suitable for tight interdental spaces. Insert the impression coping retentive into the internal hexagon of the implant.



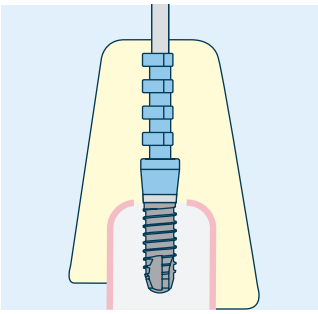

The following instruments are suitable especially in tight spaces or in the molar region to position the impression coping more easily in the internal hexagon of the implant:

- Art. No. 3.03.522, positioning handle
- Art. No. 332.10.20, forceps

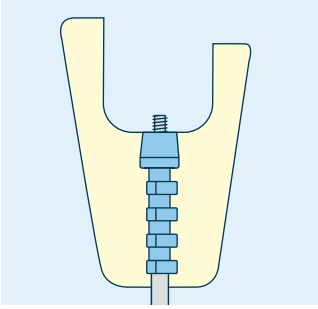
Impression copings made of titanium (16.0 mm) are radiopaque, but impression copings made of aluminum (10.0 mm) are not radiopaque. The selection of the height of the product is based on the occlusal space and the gingival height.

## USING THE IMPRESSION COPING RETENTIVE

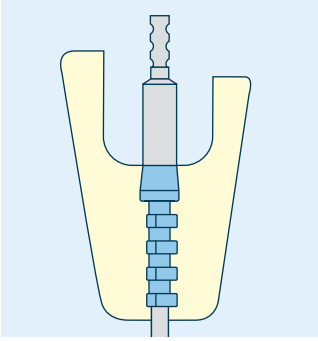
Tighten the impression coping retentive by hand (approx. 5 Ncm) using the appropriate screw for impression coping (see table on page 3 or the product catalog). The impression coping retentive made of aluminum is intended for single use.



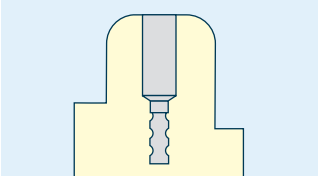
Use the custom impression tray with the required perforation for the screw. The impression must be taken using an elastomer impression material (polyvinylsiloxane or polyether rubber). Hydrocolloids and alginates are not suitable for this use.



After the impression material has set, completely unscrew the screw from the implant and remove the impression. The impression coping must remain in the impression material. Give the impression and screw for the impression-coping to the dental technician for fabrication of the laboratory model.



**Fabricating the laboratory model**
Place the analog onto the impression coping taking the correct platform diameter (color coding) into account. Hold the analog by the retentive part to avoid distorting the impression coping in the impression. Type 4 dental stone (improved dental stone) is recommended for master cast fabrication using the crown and bridge technique.



⚠ **Warning:** Use of gingival masks in the anterior area simplifies the design of an optimal emergence profile on the crown collar. Impression copings made of titanium are intended for multiple use.

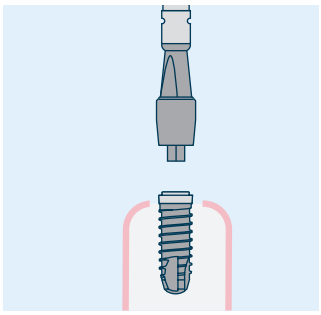
However, they must be replaced if:

- there is damage in or on the connection geometry or signs of wear and tear
- the color of the impression coping is no longer clearly identifiable due to multiple use

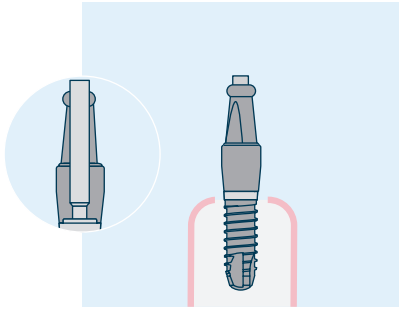
## VARIANT WITH REPOSITIONABLE IMPRESSION COPING RETENTIVE (SCREW-RETAINED) FOR THE CLOSED-TRAY TECHNIQUE

**Selection of the impression coping and screw length**
The selection of the height of the product is based on the occlusal space and the gingival height. Repositionable impression copings cannot be shortened. Repositionable impression copings made of aluminum are intended for single use.

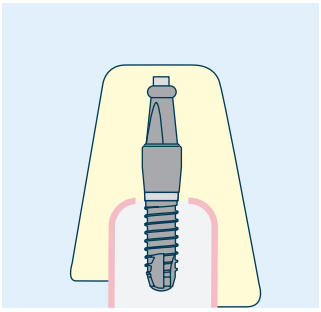
**Use of repositionable impression coping**
Remove the healing cap, gingiva former or temporary restoration after successful osseointegration of the implant and completed soft tissue conditioning. The inner configuration of the implant must be cleaned thoroughly and dried before the impression coping is placed in position.



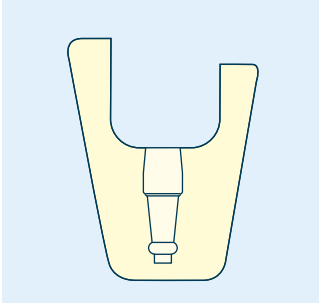
Tighten the repositionable impression coping by hand (approx. 5 Ncm) using the appropriate screw for the impression coping (see table page 3 or product catalog)  The protruding head of the screw prevents impression material flowing into the screw channel of the impression coping.

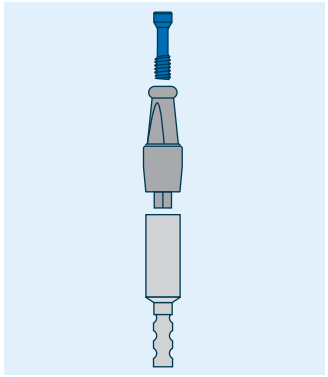


When using impression coping, it is recommended to use a custom impression tray. The impression must be taken using an elastomer impression material (polyvinylsiloxane or polyether rubber). Hydrocolloids and alginates are not suitable for this use.

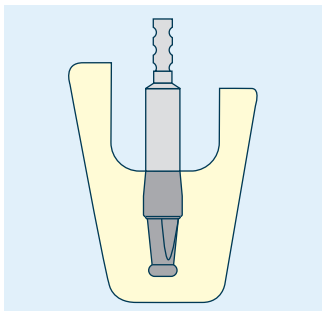


**Fabricating the laboratory model**
After carefully removing the impression, loosen and remove the screw for the impression coping together with the impression coping from the implant. The repositionable impression coping must be given to the dental technician for fabrication of the laboratory model.

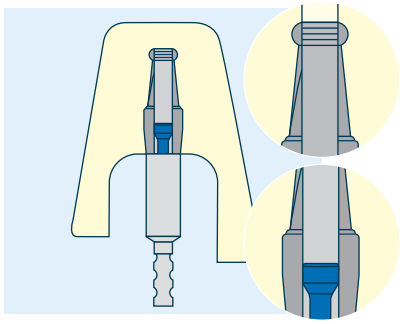




Replace the screw for the impression coping with the appropriate abutment screw (Art. No. 4.03.500 for PF 3.5 and Art. No. 4.03.501 for PF 4.0–6.0).



Then, reposition this unit in the impression and fabricate the model. Type 4 dental stone (improved dental stone) is recommended for master cast fabrication using the crown and bridge technique.



By using the shorter abutment screw, the interfering effect of a screw head protruding from the impression coping is avoided. This creates a cavity that allows for accurate repositioning of the impression coping in the impression.

## 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

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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 |
| | 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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