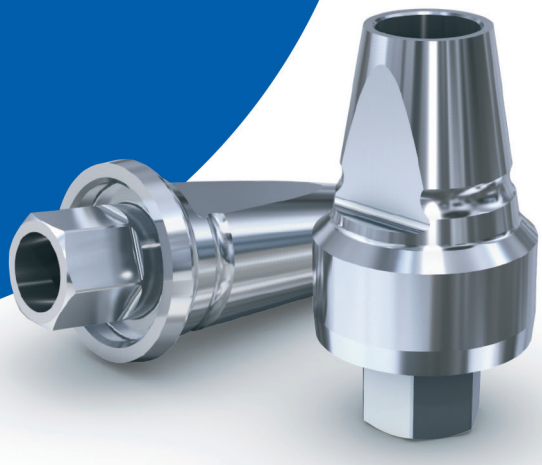
SPI®EASY

Cemented restorations.

Instructions for use THM61115



Version 005_AA, Issue date 08/20

THOMMEN Medical

1. At a glance

These instructions for use apply to all EASY abutments including the EASY e.p. and associated EASY auxiliary parts 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 the product catalog.

Components	Material	Reusable
EASY Abutment, EASY Abutment e.p.	Pure Titanium Grade 4	No
Abutment screw	Titanium alloy	No
EASY impression coping	POM	No
EASY temporary cap	PMMA-based	No
EASY analog	Stainless steel	No
EASY burn-out cap, for crowns and bridges	POM	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

In general, do not exceed a maximum angulation of 20°.
You can find general restrictions of use on page 7.

STORAGE

The EASY impression coping and protective and temporary caps must be protected from exposure to strong light or high heat during storage.

2. Application and handling

CLINICAL USE

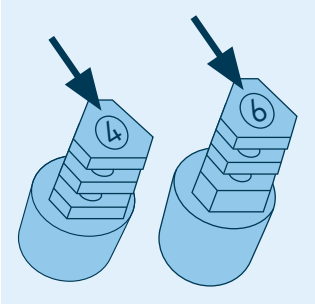
The Thommen Medical EASY Abutments are particularly suitable for cemented crown and bridge restorations.

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 the for the definitive insertion. The following torque values must be adhered to for the definitive attachment of EASY abutments:
Torque value for the definitive attachment of EASY 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 abutments can be found at www.ifu-tm.com/THM61122.

IMPRESSION TAKING AT ABUTMENT LEVEL



Taking the impression on the abutment level requires:
1. An unmodified abutment
2. The definitive fixture of the abutment (see Clinical use)
3. The corresponding impression coping

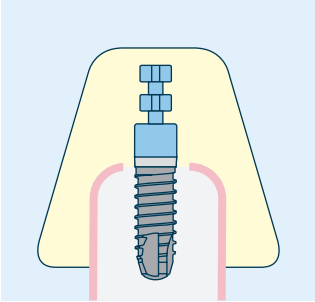
The impression must be carried out using a closed-tray technique and an elastomer impression material (no hydrocolloids).

The cone height of the abutment (4.0 or 6.0 mm) is specified on top of the impression coping.

The antirotation surface of the impression coping must match its EASY abutment counterpart and be correspondingly aligned.

Press the impression coping onto the abutment until the snap mechanism engages. When the impression has been taken, the abutment is inserted temporarily (see Page 4). EASY impression copings are intended for single use.

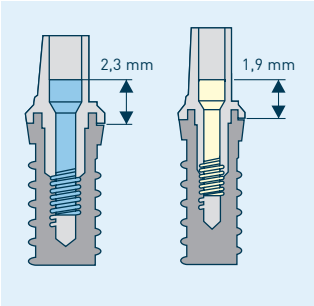
IMPRESSION TAKING AT IMPLANT LEVEL



If the EASY Abutment is modified, the impression must be taken at the implant level. Different impression copings for taking an impression at the implant level are provided for open or closed tray techniques, as are the corresponding impression screws for securing the impression copings on the implant (see Product Catalogue). In such cases, gingiva formers or temporary abutments are suitable as temporary restorations.

You can find general information on impression taking at www.ifu-tm.com/THM61127.

MODIFYING THE ABUTMENT



EASY abutments can be shortened to the minimal height of 2.3 mm (PF 4.0–6.0) or 1.9 mm (PF 3.5) according to need.

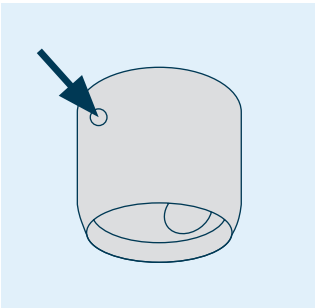
Moreover, with the EASY abutments with the collar height long, extra-long or EASY abutments e.p, the crown margin can also be adapted individually to match the gingival profile.

The minimal wall thickness after grinding must not be less than 0.5 mm and a minimal collar height of 0.5 mm must be maintained.

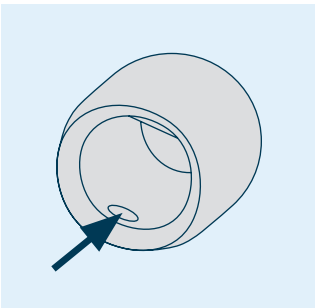
FABRICATING THE LABORATORY MODEL

Various abutment or implant analogs are available for fabricating the laboratory model. These can be used in the usual way. Only abutment analogs can be used when taking the impression at the abutment level. Apart from the implant analog for CAD/CAM, all model analogs are intended for single use.

FABRICATING THE TEMPORARY RESTORATION CHAIRSIDE



A dot-shaped marking on the outside of the temporary cap makes it easier to locate the antirotation surface inside the cap. The marking is on the opposite inner side of the antirotation surface.



When fabricating a bridge, the snap mechanism can be removed to eliminate the safety lock. If the abutment is modified, the EASY temporary coping must be modified accordingly. Seal the screw channel of the EASY abutment with a suitable removable material before cementing the EASY temporary coping. Clean the cone of the EASY abutment thoroughly. Fix the EASY temporary coping (protective coping) on the EASY abutment using temporary cement. The temporary coping must be out of occlusion.

If an EASY temporary cap is to be veneered to be like a tooth, then all current fabrication methods can be used; for chemical bonding to the EASY temporary cap a two-component PMMA-based veneer resin must be used: Follow the manufacturer's instructions.

Alternatively, the fabrication can be carried out on the laboratory model by the dental technician.

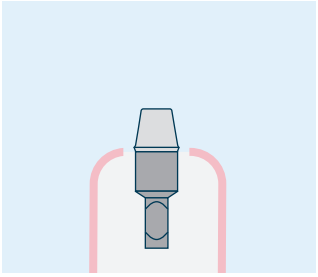
FABRICATING THE DEFINITIVE PROSTHETIC RESTORATION

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.

Place the appropriate EASY burn-out cap onto the EASY analog and allow the snap mechanism to engage in the inner cone. For modified abutments the framework modelling is carried out after application of a "cement spacer" and wax insulation directly on the abutment, without a plastic burn-out cap.

WAX-UP AND FRAMEWORK FABRICATION

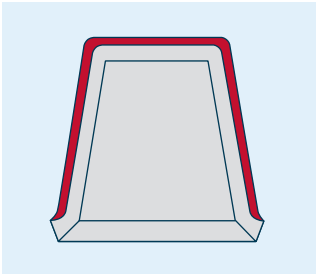
The outside of the plastic burn-out cap must be covered with a wax layer of at least 0.2 mm (see red line).



The wax layer added during the fabrication provides the necessary expansion zone for the plastic during burn-out. Insufficient coverage of the EASY plastic cap with wax can cause the investment mold to fracture due to the expansion of the plastic material, which may result in casting failure.

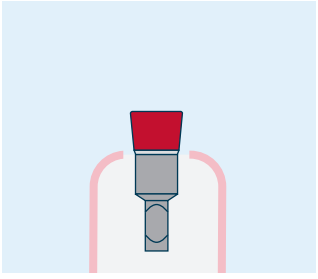
The delicate marginal area must not be covered with wax.

A sufficiently thick layer of wax must be applied if a framework is fabricated without a plastic burn-out cap.



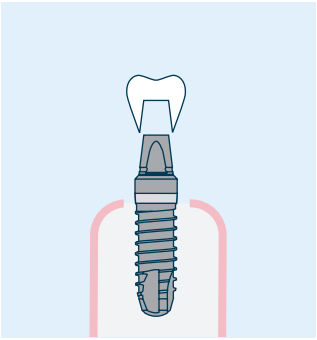
Fabrication of the framework can then be finished and the casting channels attached. Remove the fabricated framework carefully from the EASY abutment. Make sure that the investment material is matched with the alloy to be used (preferably with a high gold content).

To help ensure a successful casting, a stepped heating of the oven to the required temperature is recommended when using plastic burn-out caps.



VENEERING THE FRAMEWORK

Before the cast cap is positioned on the abutment analog or original abutment, remove the snap mechanism (now in the casting object). Do not sandblast the cast inner contour. Veneering takes place according to dental guidelines.



DEFINITIVE ATTACHMENT OF THE PERMANENT RESTORATION WITHOUT ABUTMENT MODIFICATION

Remove the temporary coping on the EASY abutment, completely remove any remaining cement and clean the cone of the EASY abutment thoroughly. Seal the screw channel of the EASY abutment with a removable material (Teflon, gutta-percha, etc.) and fix the supraconstruction on the EASY abutment using a commercially available cement.

DEFINITIVE ATTACHMENT OF THE PERMANENT RESTORATION WITH ABUTMENT MODIFICATION

The procedure with a modified EASY abutment requires taking an impression on the implant level. The temporary restoration is removed completely from the implant before insertion of the modified EASY abutment. Fix the EASY abutment on the implant using the abutment screw (see Clinical use, Page 3). Then, seal the screw channel with a suitable sealing material as described above.

The supraconstruction is then fixed on the EASY abutment using a commercially available cement.

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).

EASY impression coping and protective and temporary caps are intended for single use and must not be sterilized. Disinfect the products with 30% alcohol solution, if required. The alcohol must be allowed to evaporate completely prior to any further processing.

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
	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.

HEADQUARTERS

Thommen Medical AG
Neckarsulmstrasse 28
2540 Grenchen | Switzerland
Tel. +41 61 965 90 20
Fax +41 61 965 90 21
info@thommenmedical.com

SUBSIDIARIES/NATIONAL DISTRIBUTORS

AUSTRIA
Thommen Medical Austria GmbH
Mühlgasse 3
2322 Zwölfaxing | Austria
Tel. +43 660 2011953
info@thommenmedical.at

BENELUX
Thommen Medical Benelux B.V.
Dierenriem 1
3738 TP Maartensdijk | Netherlands
Tel. +31 30 68 68 468
Info.benelux@thommenmedical.nl

CHINA
Shanghai Yujing Trading Co., Ltd.
Room G | Floor 15th | Plaza JiaFa | No.1
Lane 129 | DaTian Road | JingAn District
Shanghai | China
Tel. +86 21 62723077
Fax +86 21 62175264

CZECH REPUBLIC
C. Witt Dental spol. s r.o.
Cihlárská 643/19
602 00 Brno
Tel. +420 739 043 449
helena.novak@cwittdental.cz

FINLAND
Vector Laboratories Oy
Engelinaukio 8 B
00150 Helsinki | Finland
Tel. +358 400 940 700
labs@vektor.fi

FRANCE
Thommen Medical France
10 avenue Gabriel Pierné
77680 Roissy-en-Brie | France
Tel. +33 1 83 64 06 35
Fax +33 3 89 33 52 53
infos@thommenmedical.fr

GERMANY
Thommen Medical Deutschland GmbH
Am Rathaus 2
79576 Weil am Rhein | Germany
Tel. +49 7621 422 58 30
Fax +49 7621 422 58 41
info@thommenmedical.de

HONG KONG
Shengyuan (Hong Kong) Int. Trade Co. Ltd.
Level 13, 68 Yee Wo Street
Causeway Bay | Hong Kong
Tel. +852 530 876 41

ITALY
Dental Trey S.r.l.
Via Partisani, 3
47016 Fiumana | Predappio (FC) | Italy
Tel. +39 0543 929111
Fax +39 0543 940659
implantologia@dentaltrey.it
www.dentaltrey.it

JAPAN
J. Morita Corporation
3-33-18, Tarumi-cho
Suita | Osaka 564-8650 | Japan
Tel. +81 6 6384 6921
Fax +81 6 6384 6746
www.morita.com

LITHUANIA/LATVIA
ČERNIKIS MEDICAL PROJECTS, UAB
Šiaurės prospektas 5B, Kaunas
Lithuania LT-49191
Tel. +370 37 201072
Mobile +370 65 771550
info@cmp.lt
www.cmp.lt

MIDDLE EAST
Star Science International GmbH
Jupiterstrasse 57
3015 Bern | Switzerland
Tel. +41 31 941 07 31
Fax +41 31 941 07 33
star.science@bluewin.ch

NORWAY
Novus Dental AS
Johannes Bruns gate 5
0452 Oslo | Norway
Tel. +47 951 07 007
post@novusdental.no
www.novusdental.no

POLAND
C.WITT DENTAL Sp. z o. o.
Ul. Granitowa 10
87-100 Toruń | NIP 951-15-08-371 | Poland
Tel. +48 56 623 61 23
biuro@cwittdental.pl
www.cwittdental.pl

REPUBLIC OF CROATIA
Futura Dental d.o.o.
Kralja Zvonimira 108
10 000 Zagreb | Republic of Croatia
Tel. +385 91 6814 860
info@futura-dental.hr
www.futura-dental.hr

RUSSIAN FEDERATION
CIS – JSC Geosoft
Build. 14, Ap. 16, 3-ya Mytishchinskaya ul.
Moscow, 129626 | Russian Federation
Tel. +7 495 663 22 11
thommenmedical@geosoft.ru

SINGAPORE
FONDACO Pte Ltd
7 Kaki Bukit Road 1, #03-06
Eunos Techno Link
Singapore 415937 | Singapore
Tel. +65 6392 2806
Fax +65 6392 1296
fondaco@fondacosg.com

SOUTH KOREA
KMbio
02 Ho, 129, Dongseo-daero
Seobuk-gu, Cheonan-si
Chungcheonnam-do
Republic of Korea
Tel. +82 070 3141 2875
kmbio149@naver.com

SPAIN/PORTUGAL
Thommen Medical Ibérica
C/Los quintos n 1
03350 Cox (Alicante) | Spain
Tel. +34 96 536 10 20
Mobile +34 606 99 78 34
info@thommeniberica.com

SWITZERLAND
Thommen Medical AG
Neckarsulmstrasse 28
2540 Grenchen | Switzerland
Tel. +41 32 644 30 20
Fax +41 32 644 30 25
info@thommenmedical.ch

TAIWAN
En-Jye International Co., Ltd.
No. 18 | Lane 177 | Sec 3 | Chengde Rd.
Taipei, 103 Taiwan
Tel. +886 2 2585 1669
Fax +886 2 2585 0892
enjye168@gmail.com

TURKEY
Bioport Biyolojik Maddeler A.Ş.
Büyükdere cd. Subay evleri 9. Blok D1 Esentepe
Şişli 34394 Istanbul | Turkey
Tel. +90 212 2727577
Fax +90 212 2727628
info@bioport.com.tr
www.bioport.com.tr

USA/CANADA
Thommen Medical USA L.L.C.
1375 Euclid Avenue | Suite 450
Cleveland OH 44115 | USA
Tel. +1 866 319 9800 (toll free)
Fax +1 216 583 9801
info.us@thommenmedical.com
orders.us@thommenmedical.com

CE
0297

THOMMEN
Medical