Customizable gingiva former.

For soft tissue management. Prosthetic procedure

Instructions for use THM61125

Version 002_AA, Issue date 08/20

THOMMEN Medical

1. At a glance

These instructions for use apply to the customizable gingiva former including associated auxiliary products (fabrication screw) as listed in the product catalog. (www.ifu-tm.com/THM31111) You can also find information in this on the identifying elements (geometries, dimensions) of the individual components.

Components	Material	Reusable
Gingiva former	Pure titanium grade 4/PMMA plastic	No
Fabrication screw	Stainless steel	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

Customizable gingiva formers must only be used for single-tooth restorations. As axial divergences cannot be bridged, the customizable gingiva former must not be splinted directly to other columns.

The customizable gingiva former may remain in the mouth for a maximum of 30 days.

STORAGE

The customizable gingiva former must be protected from exposure to strong light or high heat during storage.

2. Application and handling

CLINICAL USE

The customizable gingiva former enables a variety of possible uses, for example:
- as a gingiva former, shortened to gingival level
- as a provisional abutment for a cement-retained temporary crown
- as a directly veneered, temporary screw-retained single-tooth replacement

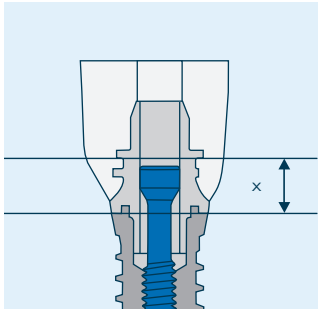
The implant and prosthetic components must be clean and not show any signs of damage before the components are inserted and attached. Additionally, make sure that the implant shoulder is free of all overhanging soft tissue.

New abutment screws must always be used for the final insertion. Torque value for the definitive attachment of the customizable gingiva former:
Torque value directly after implantation
- 10 Ncm

The tightening torque after successful osseointegration
- 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.

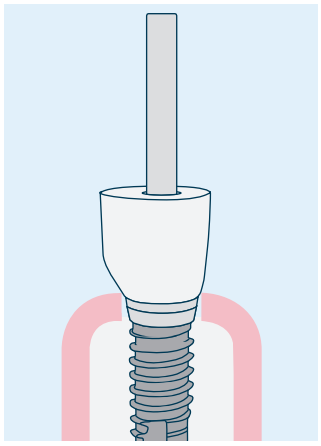
MODIFICATION OF THE GINGIVA FORMER



The customizable gingiva former can be shortened to a minimum height of 2.7 mm (PF 4.0–6.0) or 2.3 mm (PF 3.5).

Contour shaping by grinding
Customization and removal of excess material is carried out outside the mouth. A circular plastic element must be left in place in order to ensure that the preinstalled plastic remains stable on the abutment. The customizable gingiva former must be out of occlusion. For safe processing and to protect the implant-abutment connection, the customizable gingiva former should always be fixed on the appropriate implant analog.

Contour shaping by applying plastic
A PMMA-based plastic veneer must be used for processing (follow the manufacturer's instructions). Due to the chemical bond between PMMA plastics, application of mechanical retentions is not necessary. The screw channel must be protected during the veneering process. Ideally, this is carried out using the appropriate fabrication screw that can also be used to lengthen the screw channel of the restoration. The fabrication screw is available in 2 sizes: for PF 3.5 and PF 4.0–6.0. Fabrication screws can be tightened by hand using a maximum torque value of 5 Ncm.



Fabrication screws are not supplied with the gingiva former. The screws are only intended for use as a fabrication aid and are intended for single use. They must not be use for definitive insertion of the gingiva former on patients.

CLEANING, DISINFECTION AND STERILIZATION

The customizable gingiva former is intended for single use and may not be sterilized. The customizable gingiva former can be disinfected with 30% alcohol solution, if required. The alcohol must be allowed to evaporate completely before inserting the gingiva former in the mouth.

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
	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