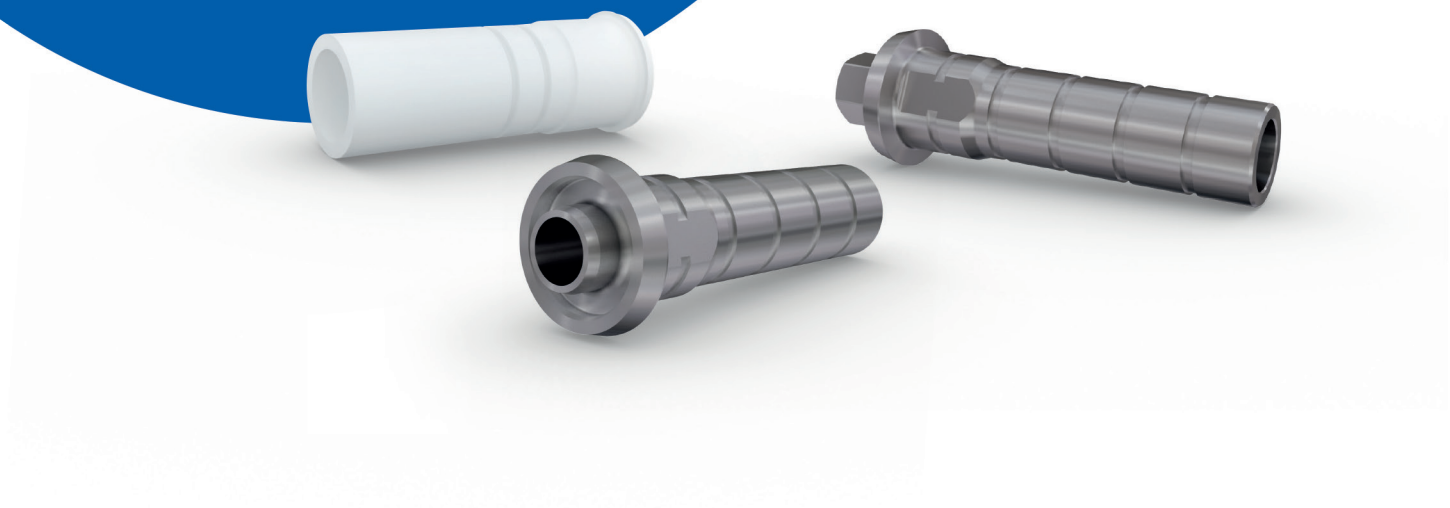
SPI®VARIOflex

For occlusal screw-retained & cemented restorations. Prosthetic procedure

Instructions for use THM61119



Version 009_AA, Issue date 01/21

THOMMEN Medical

1. At a glance

These instructions for use apply to all VARIOflex abutments including associated VARIOflex auxiliary products 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 this.

Components	Material	Reusable
VARIOflex crowns/bridges	Pure Titanium Grade 4	No
Abutment screw	Titanium alloy	No
Fabrication screw	Stainless steel	No
Burn-out cap	POM	No
Laboratory cylindrical pin	PTFE	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

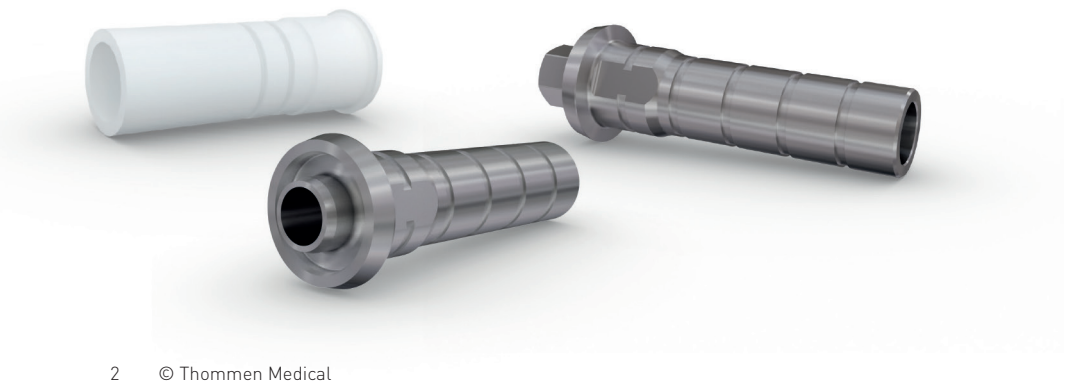
Thommen Medical prosthetic components are used in combination with the Thommen Medical Dental Implant System in the upper and lower jaw for implant-borne tooth replacement.

RESTRICTIONS OF USE

See also the general restrictions of use (page 10).

STORAGE

VARIOflex burn-out plastic caps must be protected from exposure to strong light or high heat.



2. Application and handling

CLINICAL USE

The VARIOflex abutment PF 3.5–6.0 is a modifiable bonding base and is used for manufacturing crown and bridge restorations.

The abutment is suitable for bonding non-precious metal alloys, pressed ceramic or CAD/CAM fabricated ceramic restorations. The VARIOflex abutment PF 3.5–6.0 is supplied for the final restoration with a burn-out plastic cap and abutment screw (VARIOflex abutment set). Suitable composite adhesives are recommended for bonding.

VARIOflex for crowns (with hexagon) must only be used for single teeth and must not be used for splinted reconstructions, as implant divergences cannot be bridged by hexagonal connection geometries. VARIOflex abutments are intended for single use.

The VARIOflex abutment PF 3.5–6.0 for bridges (VARIOflex abutment set for bridges) must be used exclusively for screw-retained bridge restorations. Depending on the number and position of implants, implant divergences of up to approximately 30° are bridgeable with VARIOflex for bridges.

IMPRESSION-TAKING

The prosthetic restoration with the VARIOflex abutment requires taking an impression at the implant level. Impression copings for open and closed impression trays are available as impression copings for conventional impression-taking. Thommen Medical scan abutments can be used to take digital impressions. These can be used either intraorally or for scanning from the master cast.

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 VARIOflex abutments. These can be used for conventional or digital processes.

Information on producing digital models can be found online at:
www.ifu-tm.com/THM61143

CAD LIBRARIES

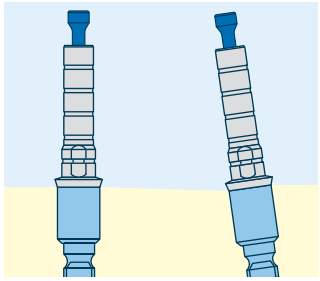
Thommen Medical can provide libraries for dental CAD-software. The libraries used must be aligned between the users (e.g.: dentist, dental technician, milling center). Conventionally, it is the final link in the value creation chain which administers the final configuration of the library and distributes this to other 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.

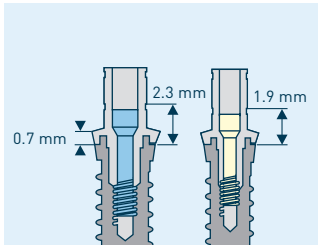
CONVENTIONAL FABRICATION OF DEFINITIVE RESTORATIONS

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. The VARIOflex abutment with hexagon should be selected for the manufacture of single crowns and the same procedure should be carried out as for the preparation of bridge restorations.

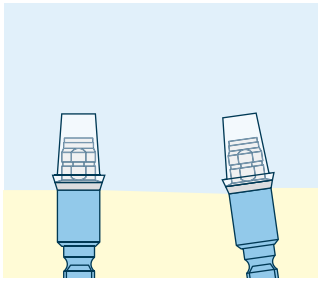
1. Screw the VARIOflex for bridges onto the model analogs using abutment screws.



2. VARIOflex abutments can be shortened by no more than to the upper edge of the lowest retention ring. Do not go below the minimum height of 2.3 mm for PF 4.0–6.0 and 1.9 mm for PF 3.5, measured from the implant-shoulder. A minimum height of 4.0 mm (2nd retention groove from the implant shoulder) must be maintained. Reducing the wall thickness and grinding the collar area is not permitted.

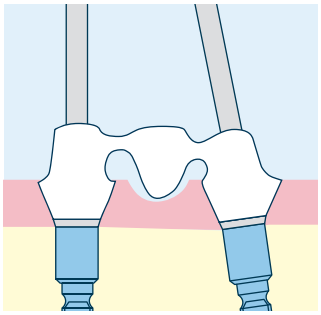


Place the VARIOflex burn-out caps that match the platform size on the abutments. The circular grooves on the plastic cap serve to identify the platform. The PF 3.5 has one groove. Each next higher platform has an additional groove. The plastic caps have a rotation lock. Move the cap onto its final position by exerting slight pressure. Pay attention to the alignment of the abutment when fitting it. If the height of the abutment prevents maximum intercuspidation, the cylindrical part or screw channel must be shortened. Occlusal contact of the antagonistic structures with the abutment must be avoided.



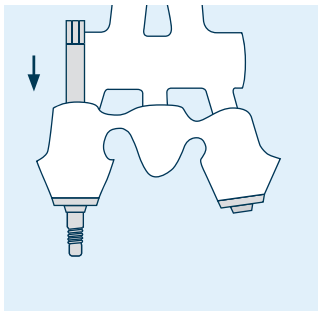
VARIOflex burn-out caps are not suitable for use with plastic temporary restorations.

3. The bridge framework must be fabricated by means of the plastic caps. The use of fabrication screws (available for PF 3.5 Art. No. 3.03.590 Q4 and PF 4.0–6.0 Art. No. 3.03.591 Q4) prevents residual wax from getting into the screw channel. The layer of wax on the outside of the caps must be at least 0.3 mm. During the burn-out process, the applied wax provides an expansion zone for the plastic. Insufficient coverage of the cap with wax can cause the investment mold to fracture in the oven during warming due to expansion of the plastic material.

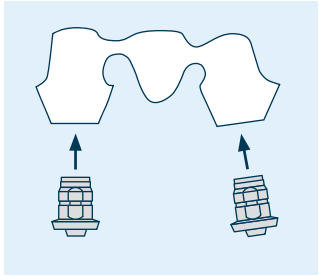


   After attaching the sprues and runner bar, unscrew and remove all screws.

4. Remove the wax construction including. the VARIOflex simultaneously from the analogs or cast. Completely remove the VARIOflex abutment remaining in the wax framework. The modeling screw can be used to remove the VARIOflex abutments from the framework construction. The fabricated framework can then be embedded and cast as usual.



5. Adapt the cast framework construction after divesting and subsequent cleaning off the model on the VARIOflex. Be careful of the rotation lock for single tooth restorations.

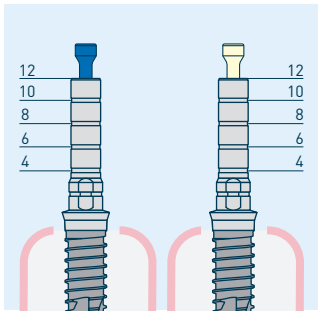


Important note: Ceramic veneering
VARIOflex must not be exposed to high temperatures. VARIOflex abutments must be removed from the framework before each veneer firing.

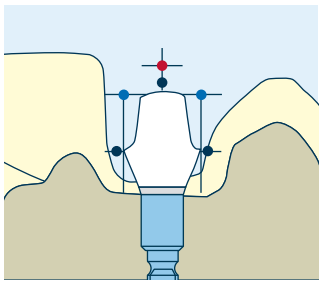
DIGITAL FABRICATION OF THE DEFINITIVE RESTORATION

See Steps 1 and 2 under «Fabricating the final restoration conventionally».

3. The virtual cylinder height of the abutment is selected in the CAD library according to Step 1.



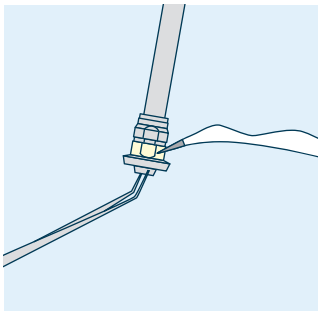
4. Computer-assisted fabrication of superstructures depends on the CAD/CAM system used. The corresponding procedures must be taken from the user documentation of the system supplier.



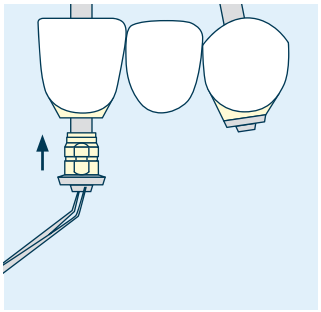
BONDING VARIOFLEX WITH FINISHED CROWNS OR BRIDGE RESTORATIONS

1. Sand blast the bonding surface of the VARIOflex abutment using 50 µm aluminum oxide and max. 2 bar pressure, and clean thoroughly (free of grease). Cover the marginal area with suitable material before the blasting process.

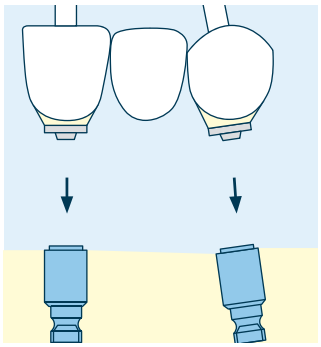
   Shorten the appropriate laboratory cylindrical pin to the desired length and insert as a placeholder into the screw channel of the VARIOflex abutment. Mix and apply the appropriate composite adhesive in compliance with the manufacturer's instructions. The bonding agent must be in a soft condition during the next two steps.



2. Place the VARIOflex abutment with the laboratory cylinder pin in the crown off the model.

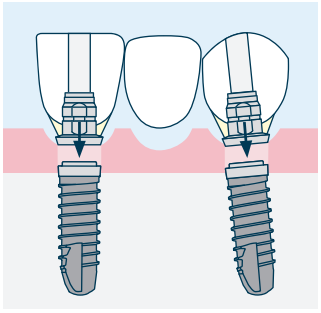


3. Then position the construction on the model. Check that the bridge is fully and correctly seated. Remove the laboratory cylindrical pins, insert the abutment screws (or laboratory screws) and tighten firmly. Let the cement cure, remove any remaining cement residues and then finish the bridge restoration. Bonded constructions are no longer sterilizable.

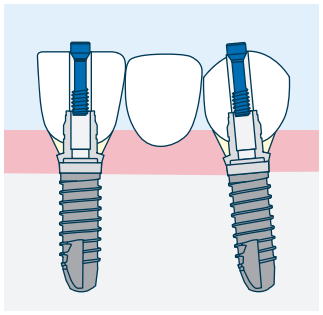


⚠ **Warning:**
Sterilization of abutments in the bonded state is not permitted

ATTACHMENT OF THE FINISHED DEFINITIVE RESTORATION



1. The implant and prosthetic components must not show any signs of damage or contamination before the components are inserted and attached. Additionally, make sure that the implant shoulder is free of all overhanging soft tissue. Position crowns/bridges on the implant(s) and check that these are correctly seated.



2. Definitively attach crowns/bridges using abutment screw(s) (see Clinical use, page 3 for the tightening torque). Fill the screw channel with a removable material (e.g. gutta-percha). Then seal with a suitable composite material.

New abutment screws must always be used for the final insertion. The screw channel is sealed with a suitable material.

Torque value for the definitive attachment of the VARIOflex abutment:
- 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 online at: www.ifu-tm.com/THM61122.

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

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.

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.

VALIDITY© Thommen Medical AG. All previous versions lose their validity with the publication of this instruction for use.

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