SPI®VARIOmulti

Multi-unit occlusal screw-retained bridge restorations. Prosthetic procedure

Instructions for use THM61118

Version 009_AA, Issue date 2022-09

THOMMEN Medical

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1. At a glance

These instructions for use describe VARIOmulti abutments and all other products which are intended for use in combination with VARIOmulti abutments. You can find information on the identifying elements (geometries, dimensions) of the individual products in the product catalog (www.ifu-tm.com/THM31111).

Article number	Description	Material	single use	Sterile	UDI-DI
1.04.850	VARIOmulti titanium base for CAD/CAM, H 4.5 mm including occlusal screw	Titanium/TAN	Yes	No	7640182641627
1.04.851	VARIOmulti titanium base for CAD/CAM set, shortenable H 9.0 mm, including occlusal screw	Titanium/TAN	Yes	No	7640182641634
2.03.450Q5	Laboratory cylindrical pin, PF 3.5, L 70.0 mm	PTFE	Yes	No	7640156476163
2.03.600	VARIOmulti gold cap, incl. burn-out plastic cylinder, ∅ 4.8mm, H 4.2/13.5mm	Gold/POM	Yes	No	7640156476149
2.03.601Q2	VARIOmulti plastic cap, burn-out, ∅ 4.8 mm, H 13.5 mm	POM	Yes	No	7640156476132
3.03.083	VARIOmulti analog for CAD/CAM, L 13.2 mm	Titanium	No	No	7640182641672
3.03.157	Insertion device for VARIOmulti analog for CAD/CAM	Stainless steel	No	No	7640182641689
3.03.420	VARIO/VARIOmulti reamer for base, for VARIO PF 3.5 - 4.0 and VARIOmulti ∅ 4.8 mm, L 16.0 mm	Tungsten carbide	No	No	7640156475012
3.03.424	VARIO guide pin for VARIOmulti reamer and VARIO PF 3.5, L 15.0 mm	Stainless steel	No	No	7640156474978
3.03.430	Gauge for reamers for screw channel	Stainless steel	No	No	7640156472288
3.03.437	Reamer for screw channel for VARIOmulti, L 40.0 mm	Stainless steel	No	No	7640156472257
3.03.521	Positioning handle for angled VARIO and VARIOmulti abutments, L 25.0 mm	Stainless steel	No	No	7640156474923
3.03.598Q4	Fabrication screw for VARIOmulti temporary cap	Stainless steel	Yes	No	7640156477771
3.03.670	Bone contouring instrument+ for PF 3.5, L 29.0 mm	Stainless steel	No	No	7640156478105
3.03.672	Bone contouring instrument+ for PF 4.0, L 29.0 mm	Stainless steel	No	No	7640156478112
3.03.674	Bone contouring instrument+ for PF 4.5, L 29.0 mm	Stainless steel	No	No	7640156478129
3.03.676	Bone contouring instrument+ for PF 5.0, L 29.0 mm	Stainless steel	No	No	7640156478136
3.03.780	VARIOmulti scan abutment, H 8.0 mm	Titanium	No	No	7640182641641
3.03.781	VARIOmulti scan abutment, short, H 5.0 mm	Titanium	No	No	7640182641665
3.03.800	VARIOmulti analog ∅ 4.8 mm, H 21.2 mm	Stainless steel	Yes	No	7640156474169
3.03.801	VARIOmulti impression coping, ⊟ 5.3 mm, H 18.0 mm	Aluminum	Yes	No	7640156474152
3.03.802	VARIOmulti temporary cap, incl. fabrication screw, ∅ 5.0 mm, H 18.0 mm	Titanium/aluminum	Yes	No	7640156474145
3.03.803	VARIOmulti temporary cap, incl. fabrication screw, ∅ 5.0 mm, H 18.0 mm	Titanium/stainless steel	Yes	No	7640156478099
3.03.804	VARIOmulti temporary cap, ∅ 5.2, H 15.0 mm, incl. fabrication screw	Titanium/stainless steel	Yes	No	7640182642426
3.04.805	VARIOmulti impression coping, ⊟ 5.3 mm, H 18.0 mm	Titanium	No	No	7640182642419

Article number	Description	Material	single use	Sterile	UDI-DI
4.03.500	Abutment screw (4-lobe) for PF 3.5, L 5.8 mm	TAN	Yes	No	7640156473704
4.03.501	Abutment screw (4-lobe) for PF 4.0 - 6.0, L 7.2 mm	TAN	Yes	No	7640156471830
4.03.507	Occlusal screw (4-lobe), L 3.5 mm	TAN	Yes	No	7640156473674
4.03.600	VARIOmulti abutment, with handle, PF 3.5/4.8 mm, H 3.0/0.8 mm	Titanium	Yes	No	7640156473360
4.03.601	VARIOmulti abutment, with handle, PF 4.0/4.8 mm, H 3.0/0.8 mm	Titanium	Yes	No	7640156473353
4.03.602	VARIOmulti abutment, with handle, PF 4.5/4.8 mm, H 3.0/0.8 mm	Titanium	Yes	No	7640156473346
4.03.603	VARIOmulti abutment, with handle, PF 5.0/4.8 mm, H 3.0/0.8 mm	Titanium	Yes	No	7640156473339
4.03.604	VARIOmulti abutment, with handle, PF 6.0/4.8 mm, H 3.7/1.5 mm	Titanium	Yes	No	7640156472165
4.03.605	VARIOmulti abutment, with handle, PF 3.5/4.8 mm, H 4.2/2.0 mm	Titanium	Yes	No	7640156473322
4.03.606	VARIOmulti abutment, with handle, PF 4.0/4.8 mm, H 4.2/2.0 mm	Titanium	Yes	No	7640156473315
4.03.607	VARIOmulti abutment, with handle, PF 4.5/4.8 mm, H 4.2/2.0 mm	Titanium	Yes	No	7640156473308
4.03.608	VARIOmulti abutment, with handle, PF 5.0/4.8 mm, H 4.2/2.0 mm	Titanium	Yes	No	7640156473292
4.03.610	VARIOmulti abutment, with handle, PF 3.5/4.8 mm, H 5.2/3.0 mm	Titanium	Yes	No	7640156473285
4.03.611	VARIOmulti abutment, with handle, PF 4.0/4.8 mm, H 5.2/3.0 mm	Titanium	Yes	No	7640156473278
4.03.612	VARIOmulti abutment, with handle, PF 4.5/4.8 mm, H 5.2/3.0 mm	Titanium	Yes	No	7640156473261
4.03.613	VARIOmulti abutment, with handle, PF 5.0/4.8 mm, H 5.2/3.0 mm	Titanium	Yes	No	7640156473254
4.03.680	VARIOmulti abutment 17°, PF 3.5/4.8 mm, H 4.3/2.7 mm	Titanium	Yes	No	7640156473247
4.03.681	VARIOmulti abutment 17°, PF 4.0/4.8 mm, H 4.3/2.7 mm	Titanium	Yes	No	7640156473230
4.03.682	VARIOmulti abutment 17°, PF 4.5/4.8 mm, H 4.3/2.7 mm	Titanium	Yes	No	7640156473223
4.03.683	VARIOmulti abutment 17°, PF 5.0/4.8 mm, H 4.3/2.7 mm	Titanium	Yes	No	7640156472158
4.03.684	VARIOmulti abutment 17°, PF 6.0/4.8 mm, H 4.3/2.7 mm	Titanium	Yes	No	7640156472141
4.03.685	VARIOmulti abutment 30°, PF 3.5/4.8 mm, H 4.4/3.3 mm	Titanium	Yes	No	7640156472523
4.03.686	VARIOmulti abutment 30°, PF 4.0/4.8 mm, H 4.4/3.3 mm	Titanium	Yes	No	7640156472516
4.03.687	VARIOmulti abutment 30°, PF 4.5/4.8 mm, H 4.4/3.3 mm	Titanium	Yes	No	7640156472509
4.03.688	VARIOmulti abutment 30°, PF 5.0/4.8 mm, H 4.4/3.3 mm	Titanium	Yes	No	7640156472134
4.03.689	VARIOmulti abutment 30°, PF 6.0/4.8 mm, H 4.4/3.3 mm	Titanium	Yes	No	7640156472127
4.03.800	VARIOmulti protective cap, incl. occlusal screw, ∅ 5.3 mm, H 4.2 mm	Titanium/TAN	Yes	No	7640156472974
4.03.801	VARIOmulti protective cap ∅ 5.3 mm, H 4.5 mm	Titanium	Yes	No	7640182642433

Indication

Thommen Medical prosthetic components are used in conjunction with the Thommen Medical Dental Implant System in partially edentulous/edentulous upper and lower jaws for the restoration of masticatory function.

Intended purpose

Thommen Medical prosthetic components are used in conjunction with the Thommen Medical Dental Implant System in the upper and lower jaws for implant-borne tooth replacements.

Restrictions of use

General restrictions of use, see Page 25.

- VARIOmulti abutments must not be used for bridge restorations on less than three implants or single tooth restorations.

- Angled VARIOmulti abutments on reduced diameter implants (PF 3.5) may only be used in the molar region if they are splinted to larger diameter implants.

- Abutments, titanium bases, gold caps, temporary and protective caps are intended for single use.

Storage

VARIOmulti burn-out plastic caps and VARIOmulti gold cap incl. burn-out plastic cylinder must be stored so that they are protected from exposure to strong light or high heat.

Link to summary report on safety and clinical performance

The summary of safety and clinical performance for the products listed in these instructions for use is available in the Download Center at: www.thommenmedical.com.

Implant card for implantable devices

Fill in the implant card available at: www.ifu-tm.com/THM61155 as instructed at: www.ifu-tm.com/THM61154 and give the completed implant card to the patient. If anything is unclear, please contact the responsible member of the field sales force.

2. Application and handling

2.1 Clinical use

The Thommen Medical VARIOmulti abutment is suited for multi-unit, screw-retained bridge restorations on at least three implants.

Depending on the number and position of implants, implant divergences of up to 40° are bridgeable with VARIOmulti abutments.

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.

Always use new abutment and occlusal screws for the definitive insertion. The torque values for definitive attachment are:

VARIOmulti abutment straight/angled (abutment screw)
- 15 Ncm for PF 3.5
- 25 Ncm for PF 4.0–6.0

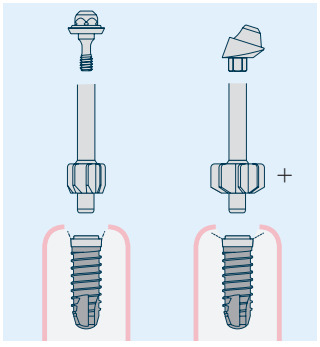
Occlusal screw
- 15 Ncm

VARIOmulti protective cap
- 10 Ncm

An overview of all torque values for the definitive attachment of Thommen Medical abutments can be found at www.ifu-tm.com/THM61122.

2.1.1. VARIOmulti abutments

Preparing
The implant interface must be cleaned thoroughly before the abutment is inserted.



If the bone prevents the insertion of the VARIOmulti abutment, the contour of the bone can be prepared using the bone contouring instrument in order to create room for the precise fit of the abutment.

The regular bone contouring instrument should be used for preparing VARIOmulti abutments straight and the bone contouring instrument+ should be used for the VARIOmulti abutments angled.

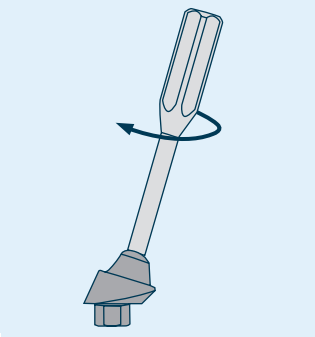
The bone contouring instrument can either be used manually with the short MONO insertion device or under power. If a contra-angle hand-piece is used, cooling and a maximum speed of 200 rpm is recommended.

Further information on using the bone contouring instrument can be found at: www.ifu-tm.com/THM61141.

VARIOmulti straight
Position the abutments on the implants using the plastic handle and tighten manually. Remove the plastic handle from the abutment and tighten the VARIOmulti abutments definitively with the MONO torque ratchet and MONO insertion devices.

Fix the VARIOmulti abutment directly onto the implant with a tightening torque of:
- 15 Ncm for PF 3.5
- 25 Ncm for PF 4.0–6.0

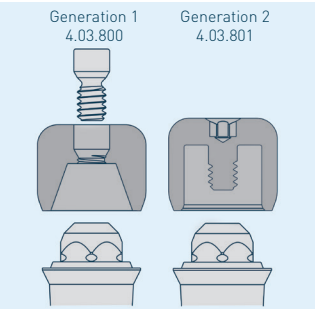
VARIOmulti angled
A handle (Art. No. 3.03.521) is available as a positioning aid for angled VARIOmulti abutments. The handle is screwed onto the abutment without exerting any force. When inserting angled VARIOmulti abutments, the abutment can only be optimally aligned if the implant/internal hexagon was correctly aligned during implantation. The abutment screw is then inserted and tightened using a 4-lobe screwdriver. Remove the positioning handle and screw in the abutment screw using the definitive tightening torque.



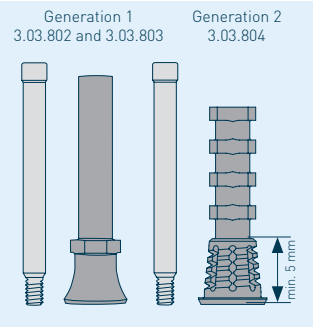
Fix the angled VARIOmulti abutment with the abutment screw on the implant with a tightening torque of:
- 15 Ncm for PF 3.5
- 25 Ncm for PF 4.0–6.0

⚠ **Warning**
Modification of both straight and angled VARIOmulti abutments is not permitted.

2.1.2. VARIOmulti protective cap
Tighten the protective cap with a tightening torque of max. 10 Ncm. The protective cap must not be subjected to any stress loading. The generation 2 protective cap is a one-piece design, while the generation 1 cap is attached using a separate occlusal screw.



2.1.3. VARIOmulti temporary cap



VARIOmulti temporary caps are intended to be used with liquid polymers to fabricate temporary dental prostheses. They can be shortened to 5.0 mm, if required. Sandblasting (50 µm aluminum oxide/air pressure max. 2 bar) is recommended in order to improve adhesion.

The screw channel and the connection geometry must be protected during processing. Ideally, this should be done using the fabrication screw (designed only for occlusal thread, included in the delivery). The following applies:

- Do not use for definitive insertion
- Isolate with Vaseline before modeling
- Tighten gently by hand only (max. 5 Ncm)

Always use new occlusal screws for the definitive insertion of the temporary supraconstruction. A tightening torque of 15 Ncm is recommended for tightening occlusal screws. After inserting the restoration, cover the occlusal screw openings with a removable material (e.g. Teflon or gutta-percha) and seal with composite.

⚠ **Warning**
The temporary cap must not be steam sterilized when it is embedded in polymer.

⚠ **Warning**
The temporary cap must not be sandblasted in the region of the connection geometry and screw channel.

Precautionary measure
The VARIOmulti analog can be used to protect the connection geometry when processing the temporary cap.

⚠ **Warning**
Shrinkage of the curing polymer can cause the abutment interface of the temporary cap to shift its position.

Precautionary measure
In order to minimize such displacements, it is recommended to apply the polymer over the entire area and as close as possible to the abutment interface.

⚠ **Warning**
Follow the instructions for use for the liquid polymer. If applicable, ensure that no polymer enters the wound area.

Precautionary measure
Using a rubber dam can reduce contamination of the wound area.

2.2. Digital workflow

2.2.1. Digital impression taking at abutment level

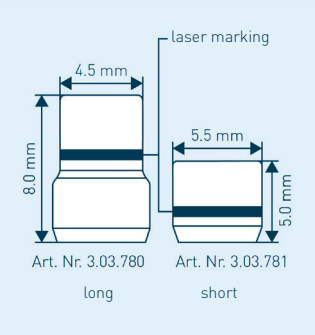
The prosthetic restoration with the VARIOmulti system requires taking an impression at the abutment level. Thommen Medical VARIOmulti scan abutments are used to transfer the position and location of abutments for digital impression taking. Digital impression taking is carried out on the master model or intraorally.

Challenging anatomical situations, such as edentulous jaws, for example, can mean inaccurate data collection with intraoral digital impression taking and consequently lead to imprecise implant and/or abutment positions. In such situations, data collection on the master model via a desktop scanner is recommended.

A short and a long scan abutment are available for digital impression taking at abutment level. In principle, the circular laser marking should be above the gingiva (supragingival) or in the visible region. The scan abutments should be used as follows:

- Laboratory scan: Long scan abutment
- Intraoral scan with neighboring teeth: Long scan abutment
- Intraoral scan without neighboring teeth: Short scan abutment, as long as the circular laser marking projects above the gingiva.

So that it can be distinguished later in the scan data which scan abutment was used for the process, the long scan abutment has a diameter of 4.5 mm on the coronal side and the short one has a diameter of 5.5 mm.



Scan abutments can be reused and it is not necessary to use a coating spray.
See also the general instructions (page 25).

Note: The scan abutments must be sterilized before intraoral use.
General information on processing can be found at
www.ifu-tm.com/THM61131.

⚠ **Warning**
Modification of the VARIOmulti scan abutment is not permitted.

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 contractor). 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.

Note: They may be processed a maximum of 20 times.

For information on the processing of prosthetic components see THM61131, «www.ifu-tm.com/THM61131».

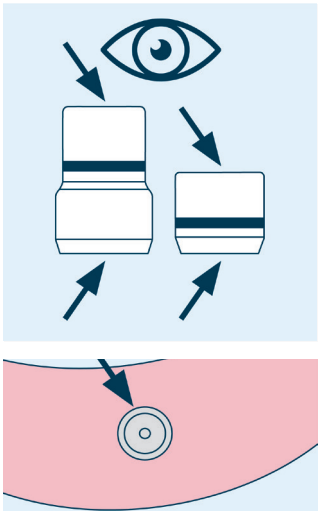
Scanning on the patient
The following procedure with scan abutments is suitable for the most commonly used CAD/CAM systems.

a) Checking
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.

b) Positioning the scan abutment
Clean the connection geometry of the abutment thoroughly. Make sure that the abutment shoulder is free of all overhanging soft tissue. The scan abutment is attached to the abutment by applying 5 Ncm. The correct seating of the scan abutment can be checked using an x-ray.

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

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

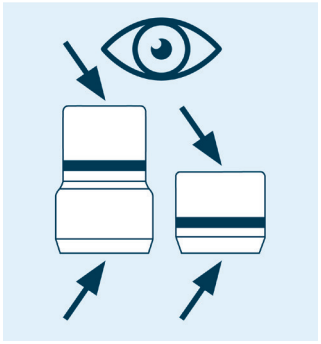


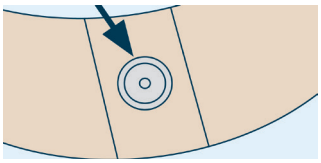
Scanning on the master model
The following procedure with scan abutments is suitable for the most commonly used CAD/CAM systems.

a) Checking
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.

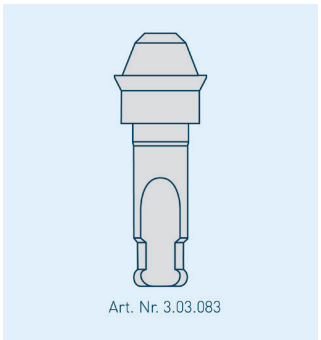
b) Positioning the scan abutment
Clean the connection geometry of the analog thoroughly. Attach the scan abutment to the analog by applying 5 Ncm. The correct seating of the scan abutment can be checked more easily by removing the gingival mask.

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





2.2.2. Master cast fabrication using 3D printing system
The VARIOmulti analog for CAD/CAM is the precise copy of the abutment-connection geometry and is used in the 3D-printed master cast for the fabrication of the superstructure.

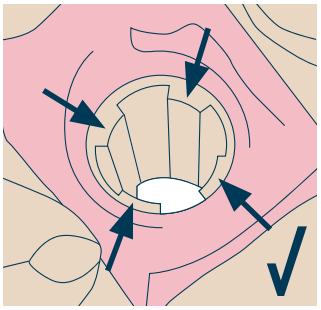


Due care and attention
The analogs must be handled with due care and attention. Surfaces can be damaged if touched with steel forceps. Analogs must be checked visually before use. Analogs must be replaced if there are signs of wear or surface damage.

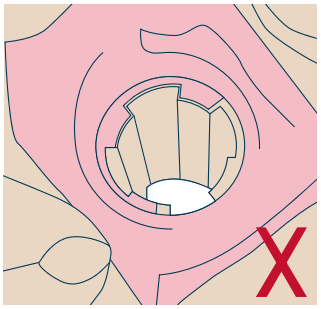
The VARIOmulti analog for CAM/CAM is suitable for use in 3D-printed master casts and plaster master casts.
The following procedure for the VARIOmulti analog for CAD/CAM is suitable for the most commonly used CAD/CAM systems.

a) Design of analog socket

When designing the master cast make sure that the segmented contact surface of the abutment analog is completely exposed and not covered/overlaid, for example, by the removable gingival mask. It should also be ensured that no cavity artifacts from the scan data are cutting into the socket. The diameter of the constructed and printed analog sockets may vary depending on the corresponding 3D printing system. If the dental CAD program used supports correction of the diameter, this can be adjusted in the material library or directly in the CAD workflow.

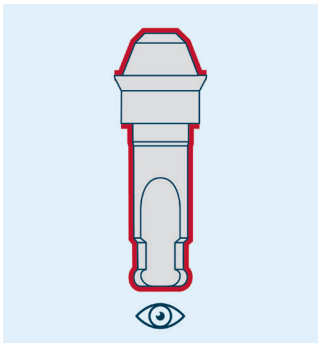


Segmented contact surface



b) Checking the abutment

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

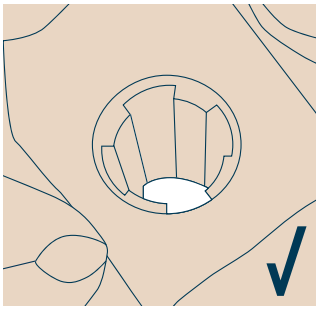


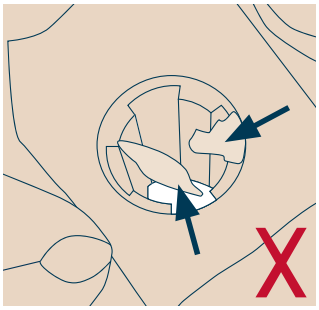
c) Constructing

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

d) Checking the printed analog socket

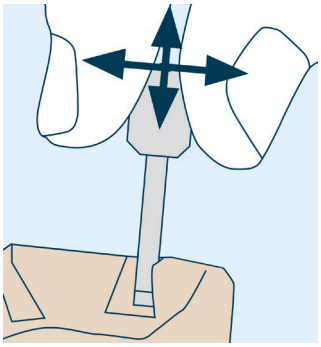
The master cast and abutment analog must be checked in advance. The analog cavity in the master cast must be free of any visible fabrication defects or debris.





e) Assembly

When inserting the analog into the 3D-printed master cast, the insertion device for the VARIOmulti analog for CAD/CAM is used.

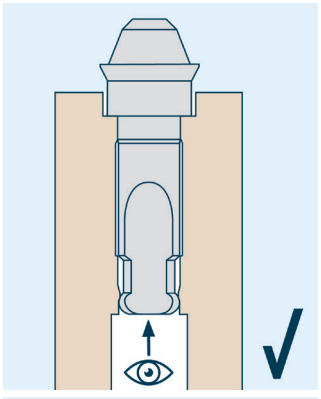


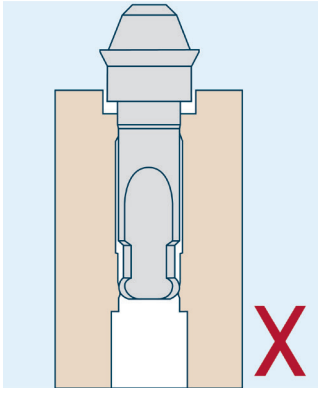
f) Checking position

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

The printed analog cavities may vary depending on the 3D printing system used. If corrections are necessary, adjustments can be undertaken in the design settings.

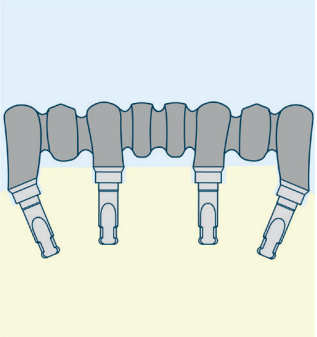
The corresponding instructions are contained in the respective libraries.





2.2.3. Fabricating the prosthetic reconstruction using CAD/CAM

With the VARIOmulti system, a multi-unit occlusal screw-retained framework can be fabricated on implants in partially edentulous/edentulous upper and lower mandibles using a CAD/CAM procedure.



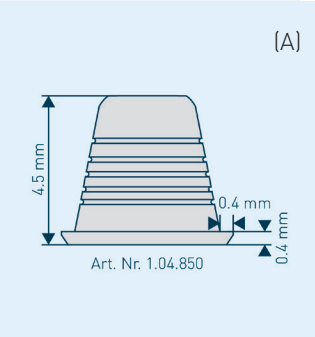
Titanium bases, also known as bonding bases or abutment interfaces, are mainly used for manufacturing single finished superstructures. The hybrid abutment restoration includes the function of an abutment and a bridge in a single construction. The hybrid abutment restoration is screw-retained directly using the VARIOmulti primary abutment and the present screw opening is sealed after fixation with the light-cured composite.

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 minimum wall strength of an individually fabricated superstructure must not be lower than the specifications of the material supplier.

Fabrication process using VARIOmulti titanium bases

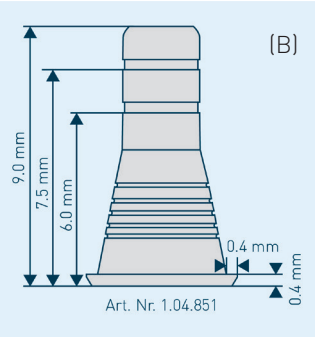
a) Selecting the bonding base
2 variants of bonding bases are available:

(A) VARIOmulti titanium base for CAD/CAM



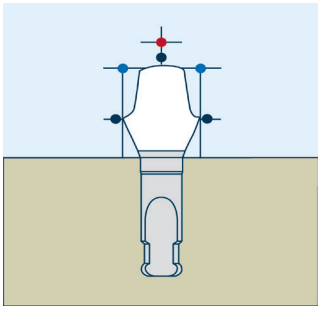
⚠ **Warning**
Modification of the VARIOmulti titanium base for CAD/CAM with the height of 4.5 mm is not permitted.

(B) VARIOmulti titanium base for CAD/CAM, shortenable
The maximum modification of this bonding base permitted is to the lowest retention ring (height 6.0 mm). The length of the bonding base should be selected in correspondence with the spatial conditions. It is recommended to use the longest possible version of the bonding base.



⚠ **Warning**
Modification of wall thickness and the collar area of the VARIOmulti titanium base is not permitted.

b) The CAD process for the design of the superstructure and fabrication using CAM technology depend on the CAD/CAM system used. The corresponding procedures and details should be taken from the user documentation, or from the software belonging to the respective system supplier.



c) Veneering
In order to apply the veneer material to the framework, this can be placed on the VARIOmulti titanium bases. Titanium bases are attached to the master cast by applying 5 Ncm for this purpose.

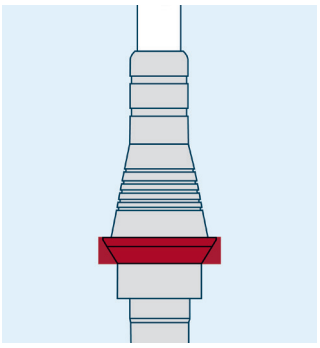
⚠ **Warning**
The VARIOmulti titanium base must not be exposed to high heat stress and must be removed before sintering or layering the framework.

2.2.4. Bonding procedure between VARIOmulti titanium base and Superstructure

a) Attachment
By using the occlusal screw for the attachment, the titanium base is centered on the analog, due to the conical screw seat.

Before cementing, the precise fit of the superstructure must be checked on the master cast.

b) Blocking out
Screw the VARIOmulti titanium base to the abutment analog using a fabrication screw. The collar region (area marked in red) must be covered with a suitable material before the blasting process. The analog together with the bonding base can be fixed into the handle for dental technicians for the blasting process.



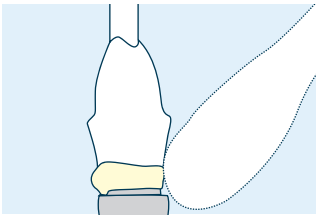
c) Blasting process
The bonded surface of the titanium base and the superstructure are sandblasted using 50 µm aluminum oxide and max. 2 bar air pressure.

d) Cleaning
After the sandblasting, the titanium bases and the superstructure must be cleaned. All residual dust and grease must be removed from the surface.

Note: If no common insertion direction is attained between the bonded base and the framework, the cementing must be carried out step-by-step on the master cast.

e) Bonding process

Attach the titanium base to the master cast using the occlusal screw by applying 5 Ncm. When cementing (e.g. PANAVIA V5) the superstructure to the titanium base, use the laboratory cylindrical pin for PF 4.0-6.0. The cylindrical pin is made of PTFE and does not bond to the cement. When shortened to the desired length and inserted firmly into the screw channel, the cylindrical pin prevents the screw channel from being sealed or bonded during the bonding process.



Spread the cement evenly over the bonding bases. Then push the superstructure over the cylindrical pin and the bonding bases, and press it down as far as the collar region. Remove excess remaining cement at the margin with a suitable instrument before it cures.

Allow the cement to cure in accordance with the instructions from the cement manufacturer. Remove the cylindrical pins and detach the occlusal screws. Carefully remove remaining cement residues at the margin under a microscope using a rubber sander/polisher.

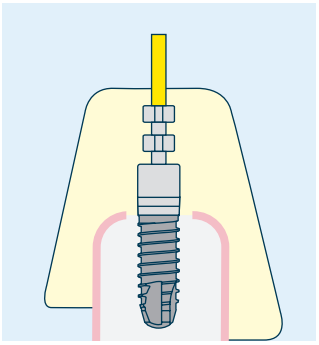
⚠ **Warning**

Sterilization of the VARIOmulti titanium base in the cemented state is not permitted.

2.3. Conventional workflow

2.3.1. Impression taking at abutment level

The prosthetic restoration with the VARIOmulti system requires taking an impression at the abutment level.

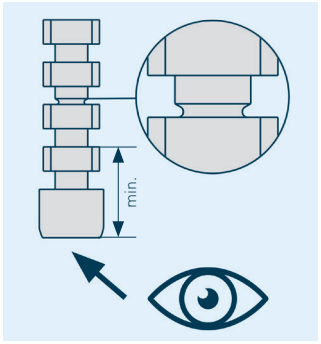


a) Open-tray technique

The impression must be taken using an open-tray technique.

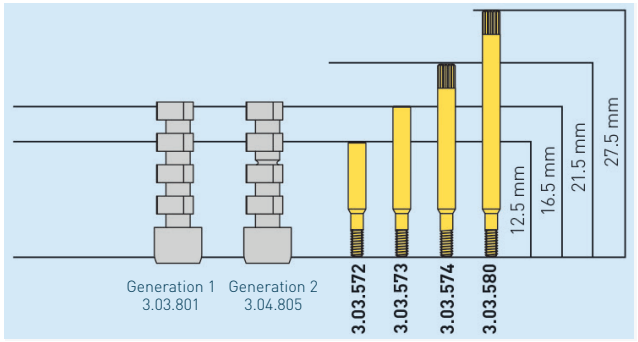
b) Checking

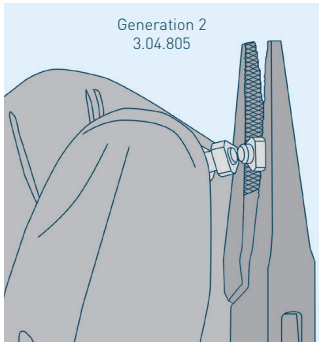
The impression coping must be checked visually for signs of wear on the connection geometry before use.



c) Selecting screw height and length

VARIOmulti impression copings may be shortened. In order to ensure an adequate retention, the final retention ring must be retained. The predetermined breaking point on the VARIOmulti impression coping 3.04.805 makes shortening easy as it can be broken off with forceps. If the impression coping has been shortened, suitable impression screw lengths are determined using the height of the impression tray or the occlusal spaces.





⚠ **Warning**

After shortening the VARIOmulti impression coping, remove any rough or sharp edges at the separation site using a suitable rotary cutter or polisher.

d) Positioning the impression coping

Clean the connection geometry of the abutment thoroughly. Make sure that the abutment shoulder is free of all overhanging soft tissue. Attach the impression coping to the abutment by applying 5 Ncm. The correct seating of the impression coping can be checked using an x-ray.

e) Impression taking

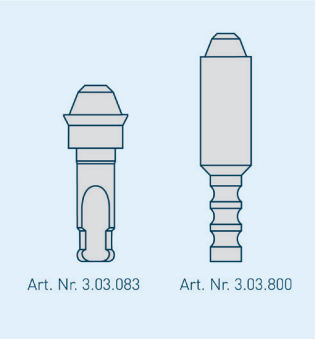
The impression must be taken using an elastomer impression material (polyvinylsiloxane or polyether rubber). Hydrocolloids and alginates are not suitable for this use.

After the impression material has set, completely unscrew the screw from the abutment and remove the impression. The impression coping must remain in the impression material. Send the impression with the screws to the dental technology laboratory for the fabrication of the master cast.

2.3.2. Fabricating the laboratory model

The two analogs below are available for fabricating the laboratory master cast after taking the impression at abutment level:

- VARIOmulti analog
- VARIOmulti analog for CAD/CAM



Both VARIOmulti analogs are suitable for the fabrication of plaster master casts. The analogs are attached to the VARIOmulti impression copings using the yellow screws for PF 3.5 manually and without applying a strong torque value (approx. 5 Ncm).

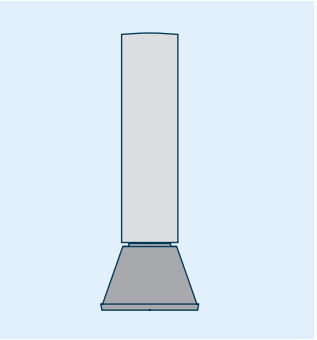
Hold the analog by the retentive part to avoid distorting the impression coping in the impression when tightening the screw. Type 4 dental stone (improved dental stone) is recommended for master cast fabrication using the crown and bridge technique.

2.4. Fabricating the prosthetic reconstruction using casting technique

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.

2.4.1. Fabrication process using VARIOmulti gold cap

VARIOmulti gold caps for occlusal screw-retained bridges consist of a base element made of non-oxidizing high melting point precious metal alloy (NOA) and a cylindrical abutment made of non-residue burn-out plastic.

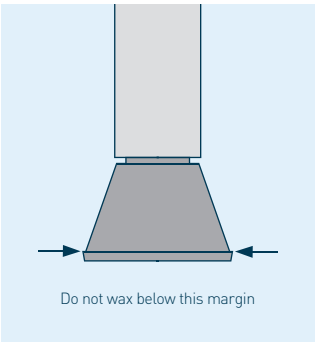


Special instruments from Thommen Medical are available for reworking the perimeter of the base and the screw seat after casting (pages 21–22).

Material specification
VARIOmulti gold cap

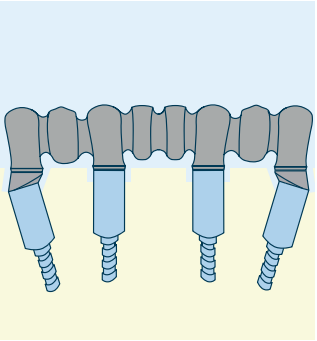
Melting range	1400–1460 °C
WAK 25–600 °C	12.8 µm/mk
Precious metal content	0.3 gr
Gold	60 %
Platinum	24 %
Palladium	15 %
Iridium	1 %

When waxing up the framework, make sure that the prefabricated VARIOmulti gold caps are covered with wax on the spots where the ceramic will be bonded.



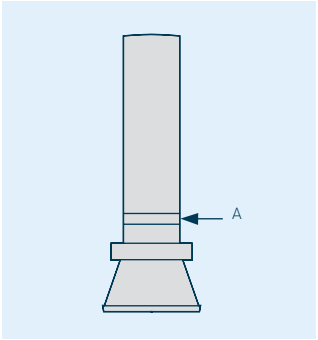
The layer of cast-on alloy must later have a minimal wall thickness 0.3 mm. As VARIOmulti gold caps are made of a non-oxidizing alloy and do not form an adhesive oxide layer, you cannot bond directly onto this alloy. Likewise, an alloy that is cast on too thinly or perforated can also lead to bonding problems with the ceramic veneer; follow the instructions of the alloy manufacturer.

To prevent the casting alloy from flowing into the inner surface of VARIOmulti gold caps, do not cover the delicate marginal area with wax. Remove grease residues from the visible surfaces of VARIOmulti caps before the investment process.



2.4.2. Fabrication process using VARIOmulti plastic cap

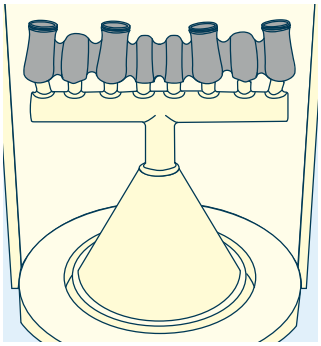
The outer ring strengthens the screw seat and serves as a retention for the fabrication wax. The cylindrical abutment for the screw channel can be reduced by no more than to the lower margin (A) of the circular groove. This limit marks the minimal construction height.



Tighten the occlusal screw used for fabrication gently by hand only until you feel resistance. Do not exert force.

If a tightening torque is used that is too high, this would deform and damage the plastic, especially in the region of the screw seat.

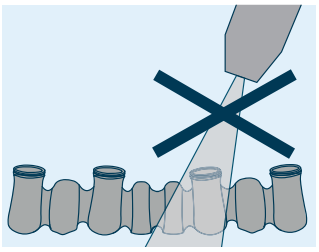
The outside of the plastic burn-out cap must be covered with a wax layer of at least 0.3 mm. The delicate marginal area must not be covered with wax.



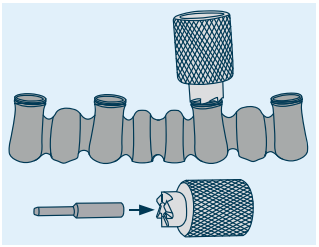
Fabricate the framework, match the investment mold with the alloy used (preferably with a high gold content).

Preparing the metal framework

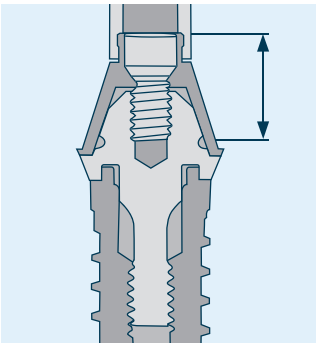
The connection geometry and screw channel must not be sandblasted under any circumstances. Ultrasound, water jet, pickling acid or glass fiber brush are suitable for the careful removal of the investment mold.



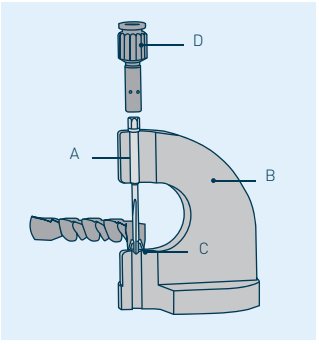
Smooth disturbing particles of the casting alloy on the base edge with the VARIOmulti reamer for base (Art. No. 3.03.420) and the exchangeable guide pin for VARIOmulti finisher (Art. No. 3.03.424) preferably under the microscope.



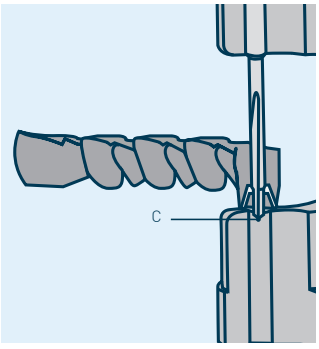
Do not rework the screw seat with the handpiece under any circumstances. The seat of the occlusal screw would move deeper into the inner configuration and the mechanical strength of the cap would no longer be guaranteed.



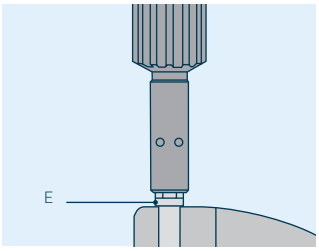
The screw seat is reworked manually and is only done after smoothing the perimeter of the base. For correct reworking of the screw seat, use the VARIOmulti reamer for the screw channel (A) and the associated guide (B). Position the bridge abutment to be reworked on the contact area of the guide (C). Operate the reamer manually using the MONO insertion device (D).



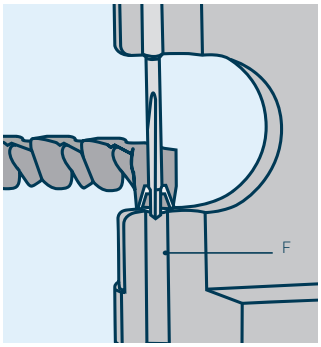
Introduce the VARIOmulti screw channel reamer into the screw channel and rotate it clockwise. During the finishing process, the perimeter of the abutment's base must completely cover the contact area of the guide (C).



Rotate the VARIOmulti reamer into the screw channel as far as it will go (E). Perform the finishing process in the same way for each bridge abutment.



Smooth the surface of the screw seat (F) with the reamer. The reamer is not suitable for removing coarse casting beads or overflows in the screw channel or screw seat.
In the event of casting errors or damage, in particular if the screw seat or the connection geometry is affected, the work must be redone.



Prepare and veneer the framework using conventional methods.

When polishing the outer crown margin, screw on the VARIOmulti analog to protect the connection geometry in order to prevent the danger of damaging the margins.

2.5. Definitive attachment of the finished reconstruction

Remove the temporary restoration from the abutment and clean the abutment. Always use new occlusal screws for the definitive insertion of the prosthetic reconstruction. Remove the definitive restoration from the master cast and insert it into the patient's mouth in a clean condition. It is recommended to use a tightening torque of 15 Ncm to tighten the occlusal screws.

2.6. 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). Steam sterilize straight VARIOmulti abutments and plastic handles.

3. Warnings

VARIOmulti abutment

⚠ **Warning**

Modification of both straight and angled VARIOmulti abutments is not permitted.

VARIOmulti temporary cap

⚠ **Warning**

The temporary cap must not be steam sterilized when it is embedded in polymer.

⚠ **Warning**

The temporary cap must not be sandblasted in the region of the connection geometry and screw channel.

Precautionary measure

The VARIOmulti analog can be used to protect the connection geometry when processing the temporary cap.

⚠ **Warning**

Shrinkage of the curing polymer can cause the abutment interface of the temporary cap to shift its position.

Precautionary measure

In order to minimize such displacements, it is recommended to apply the polymer over the entire area and as close as possible to the abutment interface.

⚠ **Warning**

Follow the instructions for use for the liquid polymer. If applicable, ensure that no polymer enters the wound area.

Precautionary measure

Using a rubber dam can reduce contamination of the wound area.

VARIOmulti scan abutment

⚠ **Warning**

Modification of the VARIOmulti scan abutment is not permitted.

VARIOmulti titanium base

⚠ **Warning**

Modification of the VARIOmulti titanium base for CAD/CAM with the height of 4.5 mm is not permitted.

⚠ **Warning**

Modification of wall thickness and the collar area of the VARIOmulti titanium base is not permitted.

⚠ **Warning**

The VARIOmulti titanium base must not be exposed to high heat stress and must be removed before sintering or layering the framework.

⚠ **Warning**

Sterilization of the VARIOmulti titanium base in the cemented state is not permitted.

VARIOmulti impression coping

⚠ **Warning**

After shortening the VARIOmulti impression coping, remove any rough or sharp edges at the separation site using a suitable rotary cutter or polisher.

4. 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
	Simple sterile barrier system
	Simple sterile barrier system with protective packaging on the inside
21	No more than 20 processing cycles
EC REP	EU authorized representative
	Temperature limitation
	Do not re-use
NON STERILE	Non-sterile
	Caution
REF	Article number
CE 0297	Conformity mark according to Directive MDD 93/42/EEC or Regulation (EU) 2017/745 MDR (see corresponding declaration of conformity)
	Consult instructions for use
STERILIZE	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 also 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 for Thommen Medical AG can provide information about availability of Thommen Medical products for the country in question.

GENERAL RESTRICTIONS OF USE Reconstructions 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 a 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. Possible additional side effect: Implant loss.

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 user's local competent authority.

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.

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

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