Processing

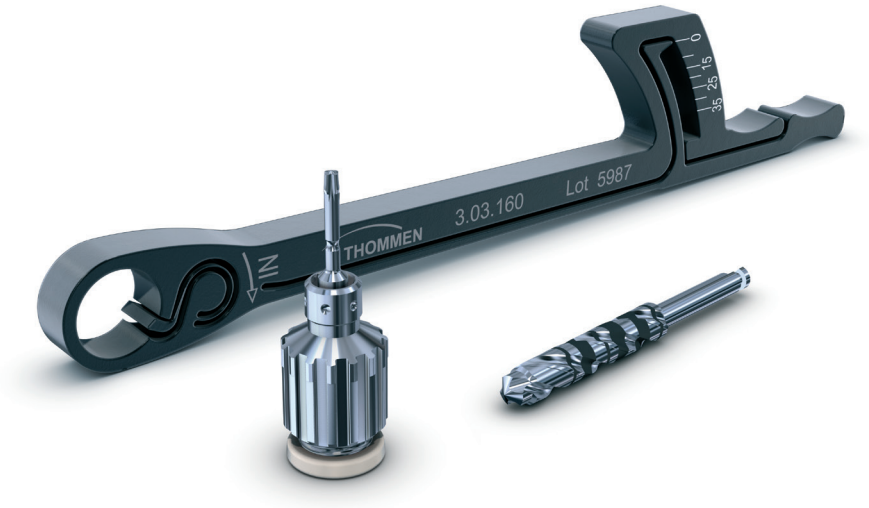
Thommen Medical surgical instruments and reusable prosthetic components. Manufacturer's information and instructions.

Instructions for use THM61131

Version 005_AA, Issue date 02/21

THOMMEN Medical

Content



1. Overview

INTENDED USE

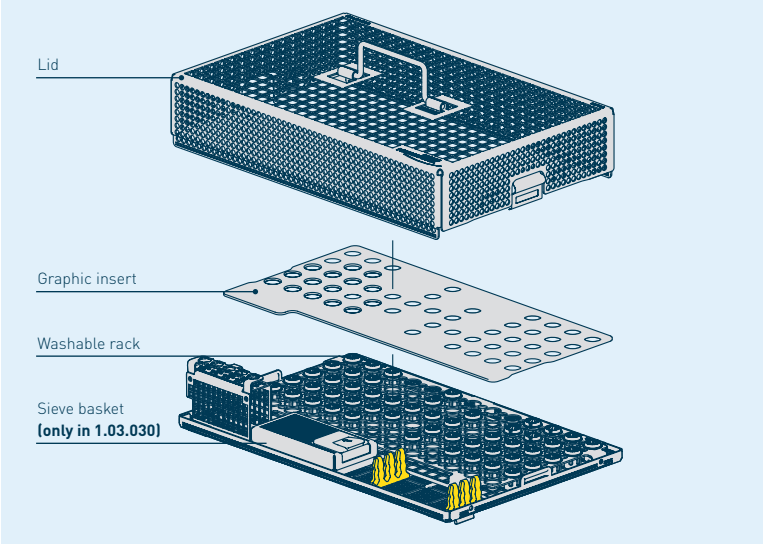
Thommen Medical surgical processing systems and instruments are used in combination with the Thommen Medical dental implant system in the upper and/or lower jaw.

SURGICAL CASSETTES FOR MECHANICAL CLEANING

The product range includes two different cassettes for mechanical cleaning:

a. Surgical cassette (art. no. 1.03.030), with appropriate flowchart template (art. no. 8.04.031)
b. Surgical cassette for guided surgery (art. no. 1.04.020), with appropriate flowchart template (art. no. 8.04.040)

Both surgical cassettes consist of a washable rack with cover and removable flowchart template:



All other parts (instrument holders and the sieve basket) are securely attached.

Art. no.	Components	Material
1.03.030 1.04.020	Surgical cassette for mechanical Cleaning, incl. flowchart template	Stainless steel, PEEK, aluminum, silicone
8.03.090 Q2 8.03.091	Instrument holders cassette	Stainless steel/PEEK
1.03.016 1.03.022	Surgical cassette, incl. screw organizer Prosthetic cassette, incl. screw organizer	Plastic

See pages 18-21 for loading the cassettes.

You can find other additional accessories for safe preparation that are compatible with the surgical cassette in the current product catalog.

Make sure that only persons with the corresponding training, knowledge and experience use these products and accessories.

2. Manufacturer's information on processing in accordance with EN ISO 17664

SURGICAL CASSETTE PLASTIC FOR MANUAL CLEANING

The surgical cassette plastic art. no. 1.03.016 is used for the sterilization and use of the surgical instruments. Mechanical cleaning of instruments or prosthetic components is not possible with this cassette, these must be cleaned manually in the ultrasonic cassette. See 5.B Manual cleaning/disinfection in the ultrasonic bath. The mechanical cleaning of the cassette without instruments is possible. The cassette consists of a base and cover and a removable flowchart template.

The same applies to the prosthetic cassette art. no. 1.03.022.

ESSENTIALS

Reusable instruments/prosthetic components must be cleaned, disinfected and sterilized before each use. This applies, in particular, also to the first use after delivery, as many instruments/prosthetic components are delivered in a non-sterile condition. See also additional information in the Packaging, sterilization and storage section.

The user is responsible for ensuring that the equipment and materials used for preparation, as well as the staff employed in the processing facility, achieve the required results. Only validated procedures may be used for cleaning/disinfection and sterilization. The user is responsible for validation. The devices/sterile containers used must be serviced and inspected regularly, and the validated parameters must be complied with for every cycle.

The user must observe the legal requirements for processing of the country within which they operate. This applies in particular to the specifications for inactivation of prions (not relevant for USA).

SCOPE OF THIS MANUFACTURER'S INFORMATION

⚠ **Important:** These manufacturer's instructions apply to all Thommen instruments (for multiple use) and prosthetic components of the Thommen Medical implant system. Prosthetic components are differentiated into prosthetic components for single use and prosthetic components that may be used multiple times.

Prosthetic components for single use or multiple use (e.g. abutments) must be repackaged for sterilization and sterilized directly after removal from the Thommen Medical original packaging (see chapter 7).

The preparation instructions apply only to products from Thommen Medical and not to products that are only distributed by Thommen Medical and that are not produced by Thommen Medical.

VALIDATED PROCEDURE

Thommen Medical has demonstrated that the procedures described in this manual are effective for preparation.

Cleaning and disinfection of steel cassettes
An efficiency check of the cleaning and disinfection of Thommen instruments and prosthetic components (multiple use) was carried out using the following materials/parameters by an independent, accredited and approved testing laboratory:

- Nylon cleaning brush (multi-tufted toothbrush with multiple planar bristle field)
- Interdental brushes in ISO sizes 0, 3, 4 and 6 (TePe Munhygienprodukter AB, Sweden)
- Syringe (Luer Solo 10 ml, B. Braun Medical, Melsungen, Germany)
- Cleaning and disinfectant agent:
  - For pre-cleaning and manual cleaning and disinfection of prosthetic components (multiple use):
    Cidezyme (for pre-cleaning and cleaning) and Cidex OPA (for disinfection) from ASP
    (Johnson & Johnson, New Brunswick, New Jersey, United States)
  - For pre-cleaning of instruments and their manual cleaning: Gigasept Instru AF (aldehyde-free combination
    cleaning and disinfectant agent from Schülke & Mayr, Norderstedt, Germany)
  - For pre-cleaning and mechanical cleaning of instruments and prosthetic components (multiple use) Neodisher MediZym (cleaning agent from Dr. Weigert, Hamburg, Germany)
- Ultrasonic cleaning cassette (art. no. 8.03.059) (Thommen Medical, Grenchen, Switzerland)
- Cleaning/disinfection device (RDG): Desinfektor G 7836 CD1 (Miele, Gütersloh, Germany)
- Surgical cassette for mechanical cleaning (art. No. 1.03.030, Thommen Medical, Grenchen, Switzerland)
- Cassette for guided surgery (art. no. 1.04.020, Thommen Medical, Grenchen, Switzerland)
- Surgical cassette plastic (art. no. 1.03.016, Thommen Medical, Grenchen, Switzerland)
- Prosthetic cassette (art. no. 1.03.022, Thommen Medical, Grenchen, Switzerland)
- Instrument bath (ultrasonic bath): SONOREX SUPER RK 514 H (BANDELIN electronic, Berlin, Germany)
- Autoclave: Autoclave HST 6x6x61 (Zirbus technology GmbH, Bad Grund, Germany)

Cleaning and disinfection of plastic cassettes
Manual
Surgical cassette plastic (art. no. 1.03.016)
Prosthetic cassette plastic (art. no. 1.03.022)

- Use fresh and combined cleaning and disinfectant solution for the cleaning/disinfection of the individual cassettes.
- For pre-treatment, disassemble the cassettes as far as possible and then place completely in a bath of combined cleaning and disinfectant solution (3% (v/v) Gigaset Instru AF (REF 107411, Schülke+Mayr GmbH) for 15 minutes and then clean intensively with a Nylon cleaning brush. Then rinse the cassettes well under running, de-ionized water for 1 minute.
- Finally, place the cassettes completely in an ultrasonic bath filled with cleaning and disinfectant solution (3% (v/v) Gigaset Instru AF (REF 107411, Schülke+Mayr GmbH) for 5 minutes. Then rinse the cassettes well under running, de-ionized water for 1 minute.

Mechanical
Surgical cassette plastic (art. no. 1.03.016)
Prosthetic cassette plastic (art. no. 1.03.022)

- For the pre-cleaning of individual cassettes, use fresh and combined cleaning and disinfectant solution (3% (v/v) Gigaset Instru AF (REF 107411, Schülke+Mayr GmbH).
- For pre-treatment, disassemble the cassettes as far as possible and then place completely in a bath of combined cleaning and disinfectant solution (3% (v/v) Gigaset Instru AF (REF 107411, Schülke+Mayr GmbH) for 15 minutes and then clean intensively with a Nylon cleaning brush. Then rinse the cassettes well under running, de-ionized water for 1 minute.
- Finally, place the cassettes in a cleaning and disinfection device (disinfection device G 7836 CD). Start the automated cleaning by using thermoseptic RKN-zyme and the thermal disinfection for 1 minute at 90°C.
- After the cleaning/disinfection, remove the cassettes from the disinfection under clean conditions.

Other cleaning and disinfectant agents, which are intended for the disinfectant cleaning of thermostable medical devices made of metal and plastic and fulfill the following criteria, can also be used. Rinsing agents or acidic neutralization agents must not be used, however.

When selecting the cleaning and/or disinfectant agent used make sure that:

- in principle, this is suitable for the cleaning of instruments made of metal and plastic
- if no thermal disinfection is used – in addition, a suitable disinfectant agent with appropriate intended use (invasive medical devices made of metal and plastic) of proven efficacy (e.g. VAH DGHM or FDA/EPA authorization/clearance/registration or CE mark) is used and that this is compatible with the cleaning agent used and the chemicals used are compatible with the instruments

Take care when selecting the cleaning and/or disinfectant agents, in particular that the following components are not included:

- organic, mineral and oxidizing acids
- stronger alkaline solutions > pH10
- organic solvents (e.g. alcohols, ethers, ketones, benzines)
- oxidation agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromide)
- aromatic/halogenated hydrocarbons

⚠ **Important:** Thommen Medical recommends use of neutral enzymatic detergents with a maximum pH of pH 8.5.
The cleaning agent or the combined cleaning/disinfectant agent must be suitable for ultrasonic cleaning.
Depending on the product used, the concentrations, temperatures and exposure times of the cleaning or disinfectant agent provided by the manufacturer as well as the guidelines on rinsing must be strictly adhered to. Only use freshly prepared solutions.
When selecting cleaning aids, comparable aids from other manufacturers may be selected in accordance with the aids listed in this manual (see above). But never clean the instruments/prosthetic components and cassettes/baskets with metal brushes or steel wool.

Furthermore, the following criteria apply to cleaning and disinfection:

⚠ **Important:** Use a mechanical procedure (CDD, cleaning and disinfection device) for cleaning and disinfection, if possible. A manual procedure – even if using an ultrasonic bath – should be used only if a mechanical procedure is not available due to the reduced efficacy and reproducibility of this method.

Perform «Preparation before cleaning» in both cases, if the instruments/prosthetic components (multiple use) have been contaminated prior to this. Contamination is indicated if e.g. prosthetic components have been placed in the mouth and it cannot be excluded that other instruments/prosthetic components in the surgical cassette, although they were not used in the same surgical procedure, could have been contaminated when taking out instruments/prosthetic components.

Packaging and sterilization
An efficiency check of the sterilization of Thommen instruments and prosthetic components (single use) was performed with the parameters as described from Section 5 onward and also by an independent, accredited and approved testing laboratory.

For sterilization of prosthetic components that are not approved for multiple use (e.g. abutments) and that have been removed directly from the original packaging, please refer to the information from Section 7 onward.

3. Preparation at point of use

ESSENTIALS

Immediately after use on the patient (within a maximum of 2 hours), coarse contaminations must be removed from the instruments.

The disinfectant agent used for the preparation at the site of use, as appropriate, only serves to protect people and is not a replacement for the following cleaning and disinfection steps.

A separation in accordance with materials is not necessary for the cleaning and disinfection, if the recommendations on the selection of instruments and products for processing (see chapter 2, «Validated procedure») have been followed.

The flowchart templates for the surgical cassettes (see p.4) must also be prepared at the site of use for the cleaning.

Select methods, cleaning and disinfection agents and specific procedures according to the table below:

	Scope	Detergents/aids	Specific procedure as described below:
MECHANICAL	Prior to mechanical cleaning and disinfection of instruments and prosthetic components 	Only for cleaning (C): Select the cleaning agent and other aids according to the criteria in the «Validated procedure» » chapter	«Separate cleaning, if necessary, disinfection – Step by step»
MANUAL	Prior to manual cleaning and disinfection of instruments (no prosthetic components) 	Combined cleaning and disinfection (C&D): Select the combined cleaning/disinfectant agent and other aids according to the criteria in the «Validated procedure»	«Combined procedure – Step by step» chapter
MANUAL	Prior to manual cleaning and disinfection of prosthetic components 	Cleaning (C): Select the cleaning agent and other aids according to the criteria in the «Validated procedure» » chapter	«Separate cleaning, if necessary, disinfection – Step by step»

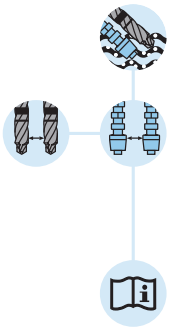
Freshly prepare the cleaning and/or disinfectant solution according to the manufacturer's information and comply with the solution's maximum standing times.

COMBINED PROCEDURE – STEP BY STEP

Cleaning/disinfection

1. Place the instruments in the combined cleaning/disinfectant agent solution.
2. Give the combined cleaning/disinfectant agent time to work in compliance with the selected indication/specified exposure time (follow the manufacturer's information) and then remove from the cleaning/disinfection bath.
3. Remove all visible contaminations manually using a clean, soft Nylon brush.
4. Finally, rinse for 1 minute under running water.

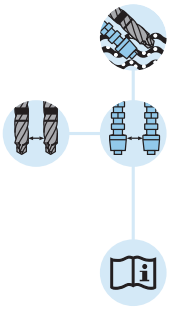
SEPARATE CLEANING, IF NECESSARY DISINFECTION – STEP BY STEP



Cleaning

1. Place the instruments/prosthetic components in the cleaning agent solution so that they are covered sufficiently and that the air can escape completely from instruments with hollow bodies. Make sure that the instruments/prosthetic components are not touching one another.
2. Give the cleaning agent time to work in compliance with the selected indication/specified exposure time (follow the manufacturer's information) and then remove from the disinfection bath.
3. Remove all visible contaminations manually using a clean, soft Nylon brush.
4. Without using a brush, rinse them at least 3 times for at least 1 minute each time under running water.

Disinfection (optional)



5. Place the instruments/prosthetic components in the disinfectant solution so that they are covered sufficiently and that the air can escape completely from instruments with hollow bodies. Make sure that the instruments/prosthetic components are not touching one another.
6. Give the disinfectant time to work in compliance with the selected indication/specified exposure time (follow the manufacturer's information) and then remove the instruments/prosthetic components from the disinfection bath.
7. Rinse them 5 times for at least 1 minute each time under running water.

4. Preparation before cleaning

ESSENTIALS

The «Preparation before cleaning» is an essential requirement for cleaning, independently of whether a mechanical or manual procedure is selected.

Select methods, cleaning and disinfection agents and specific procedures according to the table below:

	Scope	Detergents/aids	Specific procedure as described below:
MECHANICAL	Prior to mechanical cleaning and disinfection of instruments and prosthetic components 	Only for cleaning (C): Select the cleaning agent and other aids according to the criteria in the «Validated procedure» chapter.	«Separate cleaning, if necessary, disinfection – Step by step»
MANUAL	Prior to manual cleaning and disinfection of instruments (no prosthetic components) 	Combined cleaning and disinfection (C&D): Select the combined cleaning/disinfectant agent and other aids according to the criteria in the «Validated procedure» chapter.	«Combined procedure – Step by step» chapter
MANUAL	Prior to manual cleaning and disinfection of prosthetic components 	Cleaning (C): Select the cleaning agent and disinfectant agent and other aids according to the criteria in the «Validated procedure» chapter.	«Separate cleaning, if necessary, disinfection – Step by step»

Prepare the cleaning and disinfection solution fresh according to the manufacturer's instructions and comply with the maximum standing times.

The flowchart templates for the surgical cassettes (see page 4) must also be prepared for cleaning.

COMBINED PROCEDURE – STEP BY STEP

1. If necessary, disassemble the instruments (e.g. separate drill extension from the drill).

Cleaning/disinfection

2. Place the dismantled instruments in the combined cleaning/disinfectant agent solution so that they are covered sufficiently and that the air can escape completely from instruments with hollow bodies. Make sure that the instruments are not touching each other.

3. Give the combined cleaning/disinfectant agent time to work in compliance with the selected indication/specified exposure time (follow the manufacturer's information) and then remove the instruments from the cleaning/disinfection bath.

4. Remove all visible, adhering contaminations under running water and keep turning of the instruments while using a Nylon brush.

⚠ **Important:** Hard to reach areas, such as: blind drill holes or deep notches must be given special attention during cleaning.

It is explained separately from page 13 onwards how and with what mechanical aids it is possible to clean these areas especially easily and thoroughly.

For all other instruments, cleaning using a nylon brush under running water is sufficient.

5. Without using a brush, rinse them again for at least 1 minute each time under running water.

6. Visual inspection of cleanliness. If residual contaminations are detected, repeat pre-cleaning until no contamination is visible any longer.

SEPARATE CLEANING, IF NECESSARY DISINFECTION – STEP BY STEP

1. If necessary, disassemble the instruments (e.g. separate drill extension from the drill).

Cleaning

2. Place the disassembled instruments/prosthetic components in the cleaning agent solution so that they are covered sufficiently and that the air can escape completely from instruments with hollow bodies. Make sure that the instruments/prosthetic components are not touching one another.

3. Give the cleaning agent time to work in compliance with the selected indication/specified exposure time (follow the manufacturer's information) and then remove the instruments/prosthetic components from the cleaning bath.

4. Remove all visible, adhering contaminations under running water and keep turning the instrument/ prosthetic components while using a Nylon brush.

⚠ **Important:** Hard to reach areas, such as: blind drill holes or deep notches must be given special attention during cleaning.

It is explained separately from page 13 onwards how and with what mechanical aids it is possible to clean these areas especially easily and thoroughly.

For all other instruments/prosthetic components, cleaning using a nylon brush under running water is sufficient before disinfection is performed.

5. Without using a brush, rinse them 5 times for at least 1 minute each time under running water.

6. Visual inspection of cleanliness. If residual contaminations are detected, repeat pre-cleaning until no contamination is visible any longer.

Disinfection (optional)

7. Place the instruments/prosthetic components in the disinfectant solution so that they are covered sufficiently and that the air can escape completely from instruments with hollow bodies. Make sure that the instruments/prosthetic components are not touching one another.

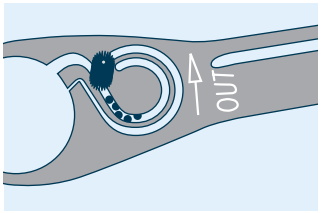
8. Give the disinfectant time to work in compliance with the selected indication/specified exposure time (follow the manufacturer's information) and then remove the instruments/prosthetic components from the disinfection bath.

9. Rinse them 5 times for at least 1 minute each time under running water.

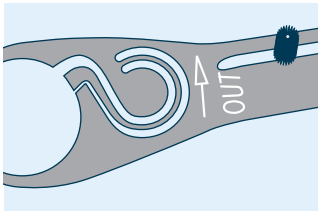
INSTRUMENT-SPECIFIC PROCEDURE

MONO torque ratchet (art. no. 3.03.160)
All surfaces: Brush the instrument a number of times while turning the instrument for at least 2 minutes.

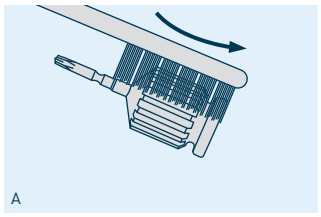
Spring in ratchet head: Clean using an interdental brush of ISO size 0.



Long gap in the area between the flexible and fixed arm of the ratchet: Position the interdental brush in the gap as shown and brush out the respective gap at least twice while moving it up and down.

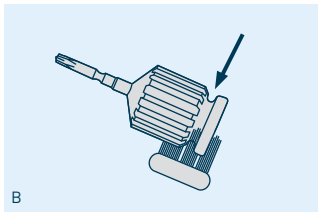


MONO screwdriver (art. nos. 3.03.165, 3.03.166, 3.03.167) and
MONO insertion device, short and long (art. nos. 3.03.162, 3.03.163),
MONO insertion device for retentive anchor (art. no. 3.03.169)
Grooves:
Guide the head of the screwdriver (or insertion device) along the longitudinal axis of the instrument with the Nylon brush and brush out all the grooves while turning the instrument (see Fig. A).

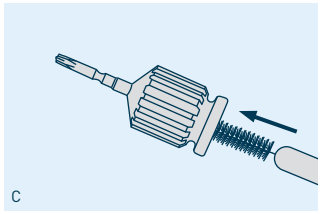

A

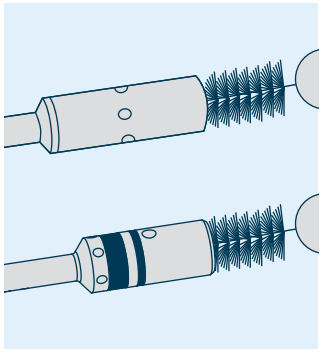
Finger rest:
Position the toothbrush perpendicular to the longitudinal axis of the instrument, and carry out a wiping movement while turning the instrument for at least 30 seconds. (see Fig. B).

Check if the notch of the finger rest is now free of contamination. If necessary, the interdental brush ISO size 4 can also be used, for which the instrument must also be turned.


B

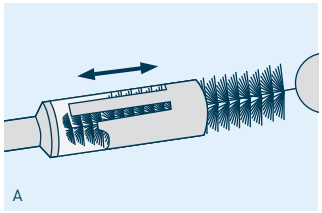
Brush out blind holes such as the central hollow body of the corresponding MONO instrument using an interdental brush of ISO size 6 (at least 30 seconds) (see Fig. C).


C



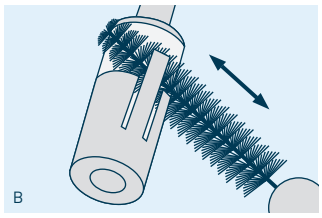
Adapter for hand piece (art. nos. 3.03.238, 3.03.240, 3.03.249 and 3.04.090)
Outer surfaces: using a Nylon brush, brush the instrument along its longitudinal axis while turning the instrument (at least 30 seconds).

Central hollow body: brush out using an interdental brush of ISO size 6 (at least 30 seconds).

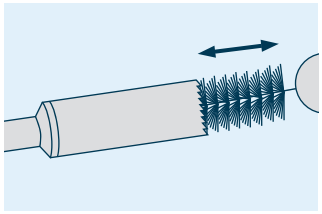


Drill extensions (art. nos. 3.03.230 and 3.03.231)
Outer surfaces: using a Nylon brush, brush the instrument along its longitudinal axis while turning the instrument (at least 30 seconds).

Central hollow body: brush out using an interdental brush of ISO size 4 (at least 30 seconds) (see Fig. A).



Side slit: brush through using an interdental brush of ISO size 4 (at least 30 seconds) (see Fig. B).



Mucosa punch, various diameters

(art. nos. 3.03.315, 3.03.316, 3.03.320, 3.03.317, 3.03.318)
Outer surfaces: using a Nylon brush, brush the instrument along its longitudinal axis while turning the instrument (at least 30 seconds).

Central hollow body: brush out using a Nylon brush (at least 30 seconds).

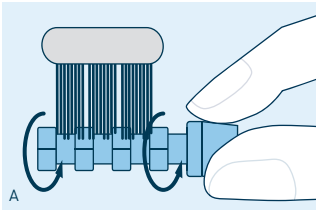
The inner areas of the instruments are otherwise accessible with interdental brushes. By guiding the interdental brush along the longitudinal axis of the instrument (at least 30 sec), as in the interdental gap, the inner area can be cleaned thoroughly.

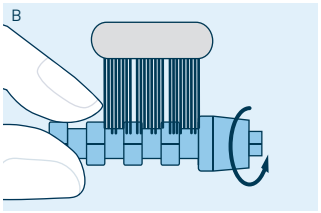
Mucosa punch PF 3.5 (art. no. 3.03.315) Interdental brushes of ISO size 4
Mucosa punch PF 4.0 (art. no. 3.03.316) Interdental brushes of ISO size 4
Mucosa punch PF 4.5 (art. no. 3.03.320) Interdental brushes of ISO size 6
Mucosa punch PF 5.0 (art. no. 3.03.317) Interdental brushes of ISO size 6
Mucosa punch PF 6.0 (art. no. 3.03.318) Interdental brushes of ISO size 6

SPECIFIC PROCEDURE FOR PROSTHETIC COMPONENTS (MULTIPLE USE)

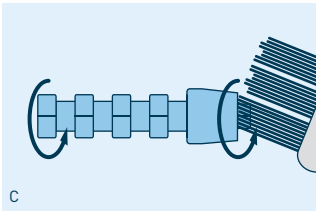
Impression coping for open-tray technique, cylindrical and conical (art. nos. 3.04.020–024, 3.04.028 and 3.04.037–040)

Outer surfaces: brush using a Nylon brush while turning continually (at least 30 seconds) according to the Figure. In doing so, hold it once by one side and then once by the other side (see Fig. A and B).

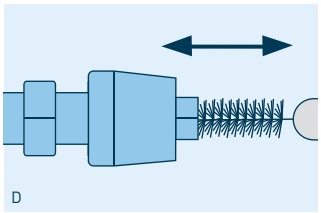




Clean end faces (e.g. connection geometry to the implant) in the same way. Turn the impression coping while brushing (at least 30 seconds) (see Fig. C).

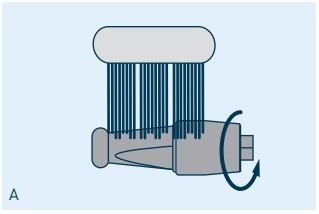


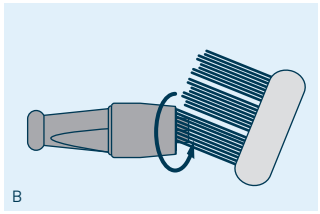
Central hollow body: brush through from both sides using an interdental brush of ISO size 4 (at least 30 seconds on each side). In between, rinse the hole and the brush with attached syringe once (see Fig. D).



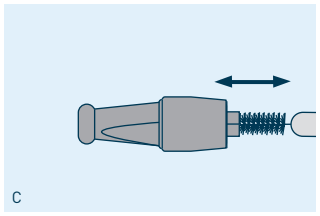
Impression coping for closed-tray technique (art. nos. 3.04.030–034, 3.04.046–050)

Outer surfaces: using a Nylon brush, brush in a transverse direction to the longitudinal axis while turning the impression coping completely at least once (at least 30 seconds) (see Fig. A).

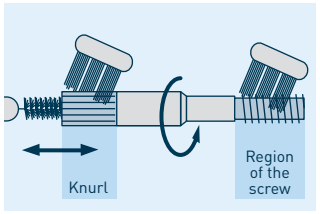



B

Clean end faces (e.g. connection geometry to the implant) in the same way. Turn the impression coping while brushing (at least 30 seconds) (see Fig. B)


C

Central hollow body: brush through from both sides using an interdental brush of ISO size 4 (at least 30 seconds on each side). In between, rinse the hole and the brush once (with attached syringe) (see Fig. C).



Screws for impression copings

(art. nos. 3.03.572–574, 3.03.580 and 3.03.575–577, 3.03.581)
Outer surfaces (region of the screw): brush using a Nylon brush along the longitudinal axis while turning the screw (at least 30 seconds).

Outer surfaces (knurl): brush in a transverse direction to the longitudinal axis using a Nylon brush while turning the knurl (at least 30 seconds).

Central hollow body: brush out using an interdental brush of ISO size 0 while turning (at least 30 seconds).

Scan abutment for implant level (art. nos. 2.03.770–774, 3.03.774–779)
Outer surfaces: using a Nylon brush, brush along the longitudinal axis while turning the scan abutment (at least 30 seconds).

End surfaces: clean in the same way while turning the scan abutment (at least 30 seconds).

Central hollow body: brush through from both sides using an interdental brush of ISO size 4 (at least 30 seconds on each side). In between, rinse the hole (with attached syringe) and the brush once.

Scan abutment for VARIOmulti abutments (art. no. 3.03.780, 3.03.781))
Outer surfaces: using a Nylon brush, brush along the longitudinal axis while turning the scan abutment (at least 30 seconds).

End surfaces: clean in the same way while turning the scan abutment (at least 30 seconds).

Central hollow body: brush out using an interdental brush of ISO size 0 while turning (at least 30 seconds).

Brush out thread and hole using an interdental brush of ISO size 4 while turning (at least 30 seconds).

Positioning handle (art. nos. 3.03.521, 3.03.522)
Outer surfaces (region of the screw): brush using a Nylon brush along the longitudinal axis while turning the positioning handle (at least 30 seconds).

Outer surfaces (knurl): brush in a transverse direction to the longitudinal axis using a Nylon brush while turning the knurl (at least 30 seconds).

5.A Mechanical cleaning/disinfection

ESSENTIALS

The mechanical cleaning takes place immediately after the «Preparation before cleaning».
When selecting a cleaning and disinfection device (CDD), ensure that:

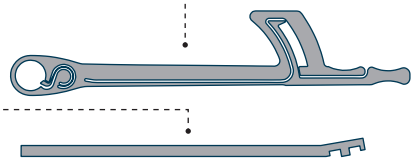
- the CDD has been thoroughly tested for efficacy (e.g. DGHM or FDA authorization/clearance/registration or has a CE mark in accordance with EN ISO 15883)
- if possible, a tested program for thermal disinfection is used (A_0 value> 3000 or – for older devices – at least 5 min at 90 °C/194 °F). With chemical disinfection, there is the hazard of residues from disinfectant agents remaining on instruments
- the program used is suitable for instruments and prosthetic components and has sufficient rinse cycles
- only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used for rinsing
- the air used for drying is filtered (oil-free, low-germ and low-particle) and
- the CDD is serviced and inspected regularly

Select the cleaning agent and other aids according to the criteria described in the «Validated procedure» chapter (in addition, consider suitability for mechanical cleaning and comply with the manufacturer's guidelines on concentration, exposure time and rinsing when selecting the cleaning program).

The surgical cassettes for mechanical cleaning art. nos. 1.03.030 and 1.04.020 play a pivotal role in the processing of Thommen instruments and prosthetic components (multiple use) according to validated processes and help to comply with hygiene regulations.

The surgical cassettes must be cleaned thoroughly before first use.

⚠ **Important:** The surgical cassettes may only be used for the mechanical cleaning of instruments/prosthetic components for multiple use.



MONO
torque ratchet

3.03.160

MONO
guide key

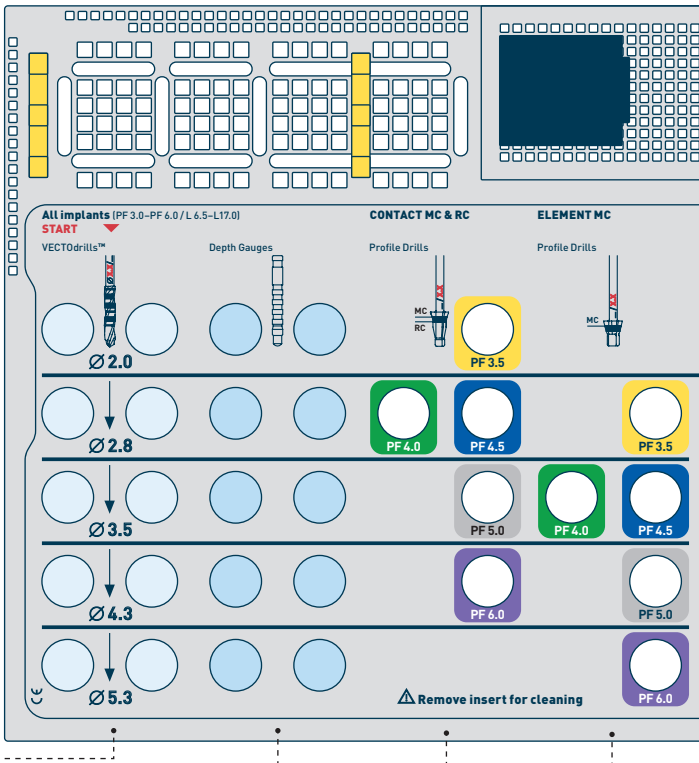
3.03.203

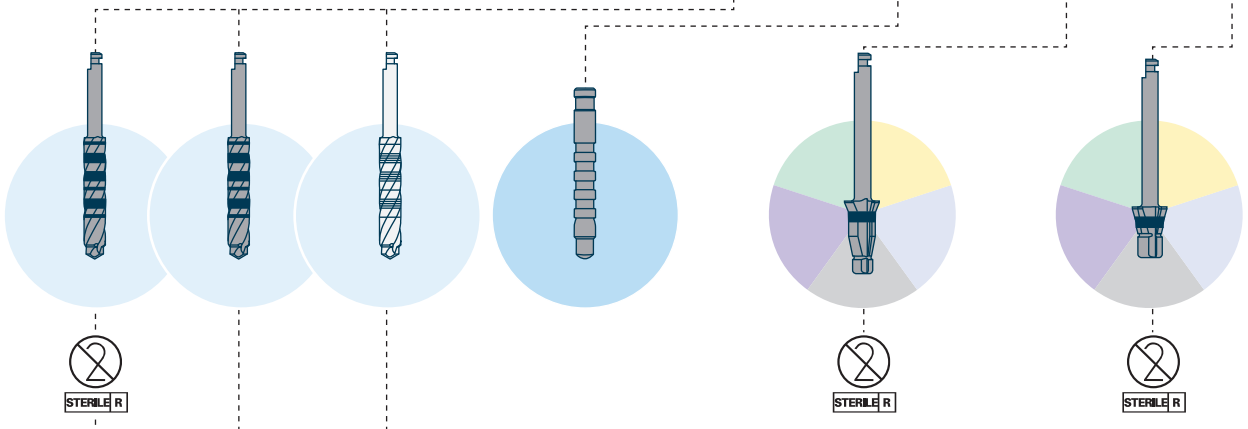
LOADING THE SURGICAL CASSETTE (ART. NO. 1.03.030) – GENERATION 02

Specific slots are provided for instruments and prosthetic components (multiple use) for loading the surgical cassette (art. no. 1.03.030).

⚠ **Important:** Sterile instruments for single use (⊗ STERILE R) may only be placed into the specific slots in the cassette after sterilization.

The previous version of the surgical cassette (art. no. 1.03.030) – generation 01 is not explained here, however its use is described, if required, in the instructions for use THM61131 – version 001: «www.ifu-tm.com THM61131».





⊗ single use

STERILE R

VECTOdrill™ Drills

∅	Length	Stainless steel	Stainless steel	Ceramic
∅ **2.0**	29.0	3.03.624 Q4	3.03.710	3.03.660
	34.0	3.03.610 Q4	3.03.720	3.03.661
	40.0	3.03.611 Q4	3.03.730	
∅ **2.8**	29.0	3.03.625 Q4	3.03.712	3.03.662
	34.0	3.03.612 Q4	3.03.722	3.03.663
	40.0	3.03.613 Q4	3.03.732	
∅ **3.5**	29.0	3.03.626 Q4	3.03.714	3.03.664
	34.0	3.03.614 Q4	3.03.724	3.03.665
	40.0	3.03.615 Q4	3.03.734	
∅ **4.3**	29.0	3.03.627 Q4	3.03.716	3.03.666
	34.0	3.03.616 Q4	3.03.726	3.03.667
	40.0	3.03.617 Q4	3.03.736	
∅ **5.3**	29.0	3.03.628 Q4	3.03.718	3.03.668
	34.0	3.03.618 Q4	3.03.728	3.03.669

Depth gauge

∅ **2.0**	3.03.630
∅ **2.8**	3.03.632
∅ **3.5**	3.03.634
∅ **4.3**	3.03.636
∅ **5.3**	3.03.638

When assigning drills, ∅ **X.X** **/_**, pay attention to the first diameter stated on the shaft.

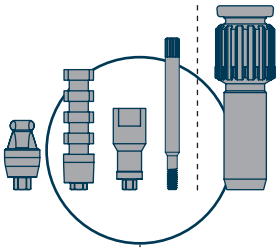
profile drill CONTACT MC & RC

	3.03.640/641 Q4
3.03.648/649 Q4	3.03.642/643 Q4
	3.03.644/645 Q4
	3.03.646/647 Q4

profile drill ELEMENT MC

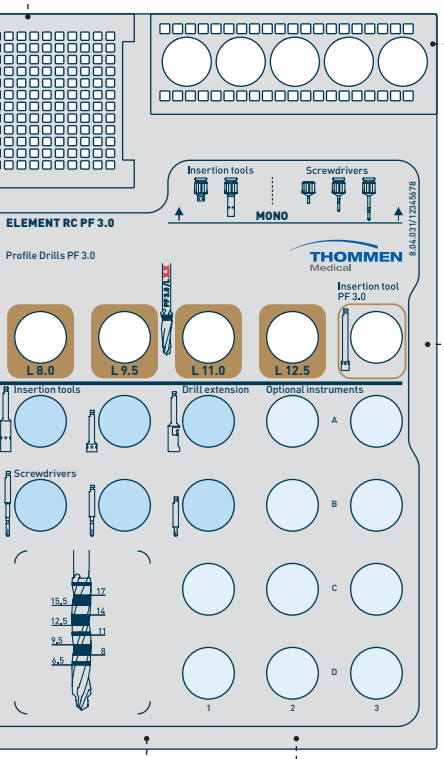
	3.03.651 Q4
3.03.657 Q4	3.03.653 Q4
	3.03.655 Q4
	3.03.659 Q4

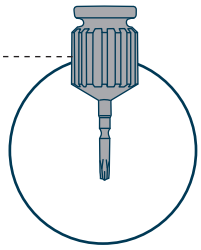
When assigning profile drills, **_ /X.X**, pay attention to the second diameter stated on the shaft. This corresponds to the platform.



Prosthetic components (multiple use) & MONO insertion device for retentive anchor

These may be cleaned in the sieve basket (max. three prosthetic components and the MONO insertion device for retentive anchor at the same time). Sterilization is performed separately.



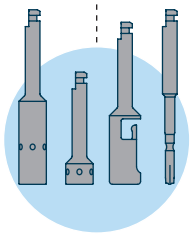


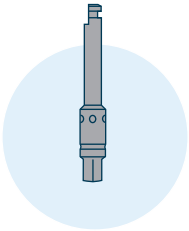
MONO insertion device

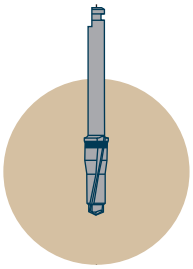
3.03.162	3.03.163

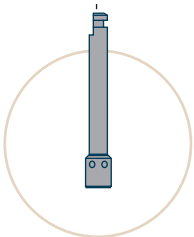
MONO screwdriver

3.03.165	3.03.166	3.03.167









Instruments for mechanical operation

	Adapter	Drill extension
3.03.249	3.03.240	3.03.230/231

	Screwdrivers	
3.03.502/503	3.03.501/502	3.03.500/501

Optional

In addition to the clearly designated slots for instruments, there are also slots that can be loaded as desired (optional instruments).

ELEMENT RC PF 3.0

Profile drill, length-specific			
L 8.0	L 9.5	L 11	L 12.5
3.03.740	3.03.741	3.03.742	3.03.743

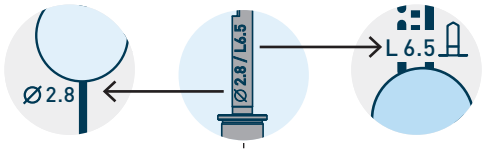
Adapter
3.03.238

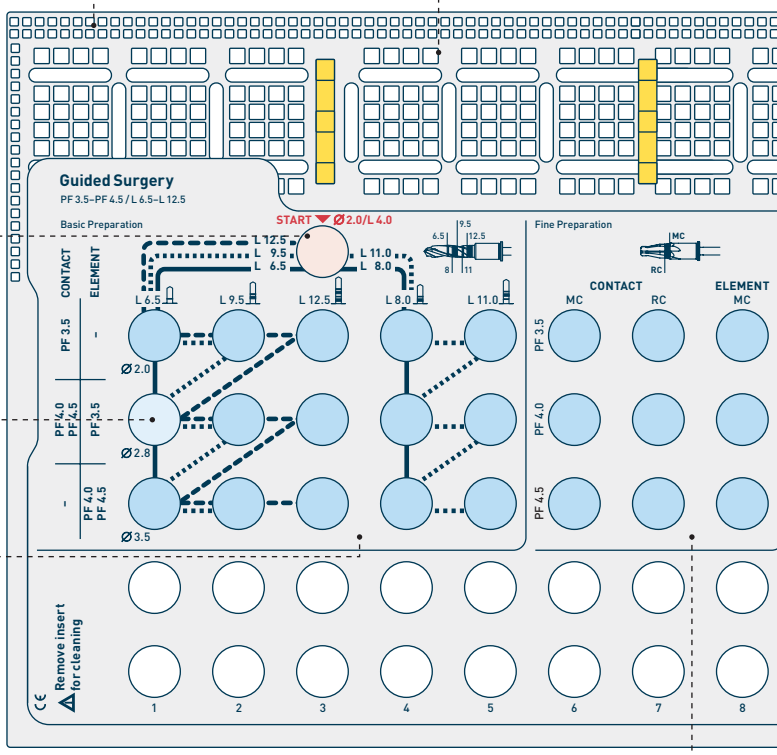
ELEMENT & CONTACT PF 3.5–PF 4.5 / L 6.5–L 12.5, ALL COLLAR HEIGHTS

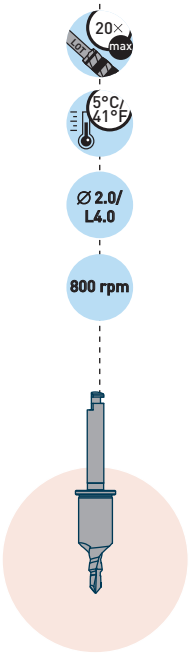
Cassette for guided surgery 1.04.020

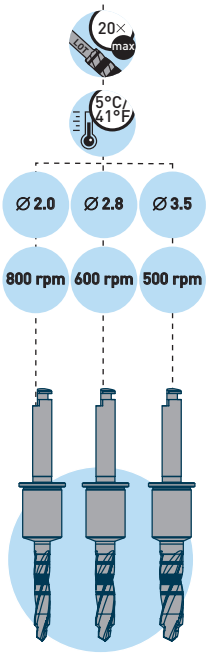
Warning:
Special slots are provided for loading the cassette with instruments. Pay attention to the dental shaft and graphic template.

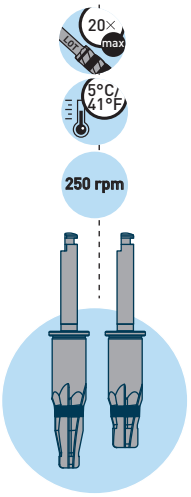
Example:











Basic preparation Initial drill, guided

Stainless steel

	L 4.0
Length mm	28.5
Ø **2.0**	3.04.110

Basic preparation VECTOdrill™ pilot drill and drill, guided

Stainless steel

	L 6.5	L 9.5	L 12.5	L 8.0	L 11.0
Length mm	31.5	34.5	37.5	33.0	36.0
Ø **2.0**	3.04.111	3.04.113	3.04.115	3.04.112	3.04.114
Ø **2.8**	3.04.121	3.04.123	3.04.125	3.04.122	3.04.124
Ø **3.5**	3.04.131	3.04.133	3.04.135	3.04.132	3.04.134

Fine preparation profile drill, guided

Stainless steel

	CONTACT MC	CONTACT RC	ELEMENT MC
Length mm	34.0	32.5	30.5
Ø **3.5**	3.04.171	3.04.161	3.04.151
Ø **4.0**	3.04.172	3.04.162	3.04.152
Ø **4.5**	3.04.173	3.04.163	3.04.153

MONO torque ratchet*

Titanium alloy

	3.03.160

MONO guide key*

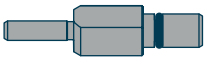
Stainless steel

	3.03.203

Guide sleeve

Stainless steel

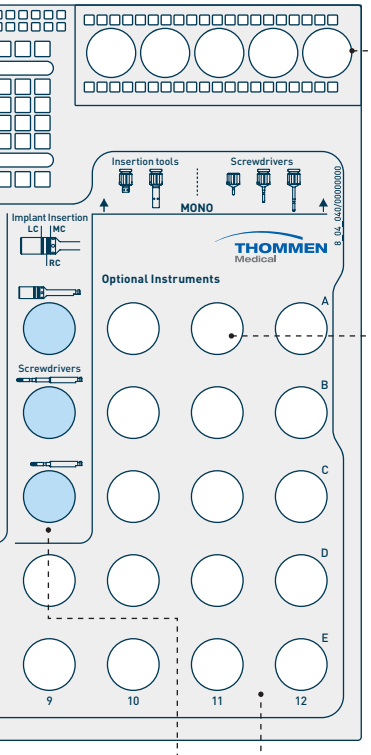
Length mm	5.0
∅ **4.8**	3.04.080 Q4

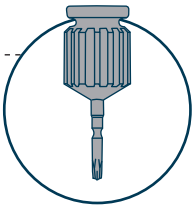


Seating instrument for guide sleeve

Stainless steel

∅ **4.8**	3.04.100





Optional instruments*

In addition to the clearly designated slots, additional slots are available for other instruments.

* Standard instruments (see www.ifu-tm.com/THM61141 and www.ifu-tm.com/THM31111)

MONO insertion device*

Stainless steel/PEEK

3.03.162	3.03.163	

MONO screwdriver*

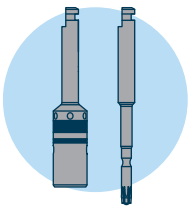
Stainless steel/PEEK

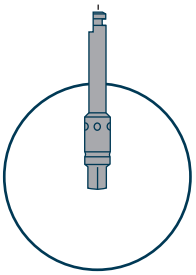
3.03.165	3.03.166	3.03.167		

Max. 20 use cycles (operation, cleaning, sterilization) for cutting instruments. Further use cycles no longer guarantee the function of the product.

Cooling during drilling, approx. 5° C/ 41 °F.

15 rpm





Implant insertion adapter, guided

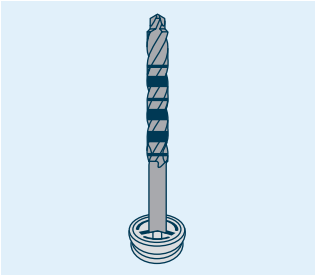
Stainless steel

	Adapter, guided	Screwdriver short	Screwdriver extra short
Length mm	25.5	22.0	17.0
	3.04.090	3.03.501	3.03.500

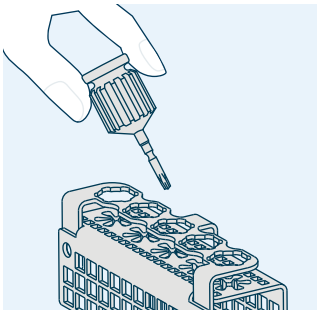
Adapter for handpiece, one-piece

Stainless steel

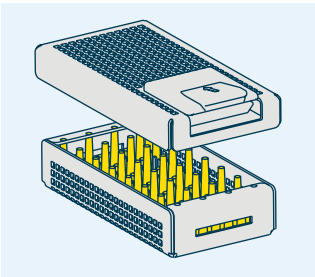
	∅ 3.5	∅ 4.0	∅ 4.5-6.0
Length mm			
24.0	3.03.248	3.03.251	3.03.241



Instruments with a dental latch are placed with their shaft pointing downward in the instrument holder so that the functional area of the instrument is pointing upward out of the holder.

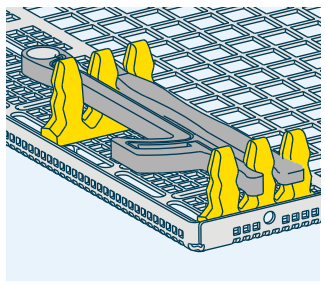


Die MONO instruments (art. nos. 3.03.162, 3.03.163, 3.03.165, 3.03.166, 3.03.167) are placed in the special holder with the functional area of the instrument pointing downward.



The MONO insertion device for retentive anchor (art. no. 3.03.169) is stored in the sieve basket for mechanical cleaning (component of the cassette art. no. 1.03.030). Prosthetic components (multiple use) are cleaned in the sieve basket.

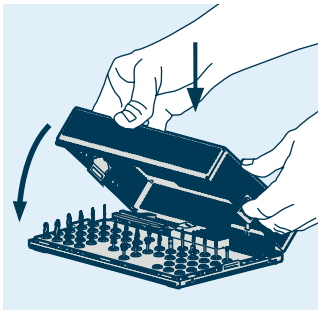
⚠ **Important:** Only three prosthetic components and the MONO insertion device for retentive anchor, if required, may be cleaned at the same time. Cleaning of additional instruments or other prosthetic components, such as abutments, is not permitted when cleaning in the sieve basket.

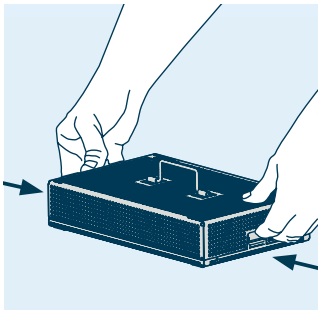


The MONO torque ratchet (art. no. 3.03.160) is stored in the silicon holders in the top of the cassette. It should be placed parallel to the cassette floor so that there is as little contact as possible with the silicon holders.

Instruments may not be stored outside of the holders or outside of the sieve basket (e.g. on the floor of the surgical cassette).

Note: For optimal closure of the cassette with the cover, the long side of the cover should first be inserted at the top and then clicked into place by tilting. The cover can be opened by pressing both sides.





⚠ **Important:** The flowchart template must not be stored in the cassette during mechanical cleaning. The flowchart template is placed separately in the cleaning and disinfection device (CDD) standing up.

STEP BY STEP

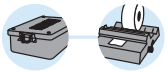
1. Sort the instruments into the specified holders in the surgical cassette for mechanical cleaning (art. nos. 1.03.030 or 1.04.020). With the surgical cassette (art. no. 1.03.030), prosthetic components can be placed into the sieve basket of the cassette, if needed. Close the cassette with the cover. The surgical cassette plastic art. no. 1.03.016 may only be cleaned mechanically without the instruments.

Place the surgical cassette (with the flowchart template removed) into the cleaning and disinfection device. In doing so, make sure that the instruments are not touching each other.

2. Start the program.

3. When the program has finished, remove the surgical cassette and flowchart template from the CDD and dry them.

4. Visual inspection of cleanliness. If residual contaminations can be detected, repeat the cleaning until no contamination is visible any more.



5. Pack the surgical cassette and components as soon as possible after removal (see chapter 7, «Packaging – Step by step»).

5.B Manual cleaning/disinfection in the ultrasonic bath

ESSENTIALS

Cleaning in the ultrasonic bath is a fixed component of the manual cleaning and disinfection of Thommen instruments. Cleaning in the ultrasonic bath takes place immediately after the «Preparation before cleaning». Select methods, cleaning and disinfection agents and specific procedures according to the table below:

Scope	Detergents/aids	Specific procedure as described below:
MANUAL Manual cleaning and disinfection of instruments (no prosthetic components) 	Combined cleaning and disinfection (C&D): Select the combined cleaning/disinfection agent and other aids according to the criteria in the «Validated procedure» section.	«Combined procedure – Step by step» chapter
MANUAL Manual cleaning and disinfection of prosthetic components 	Cleaning (C): Select the cleaning agent and disinfectant agent according to the criteria in the «Validated procedure» section.	«Separate cleaning and disinfection – step by step»

Prepare the cleaning and disinfection solution fresh according to the manufacturer's instructions and comply with the maximum standing times.

COMBINED PROCEDURE - STEP BY STEP

Cleaning/disinfection

1. Place the pre-cleaned instruments in the sieve container (e.g. ultrasonic cleaning cassette art. no. 8.03.059 from Thommen Medical) in the ultrasonic device filled with cleaning/disinfectant agent. Give the cleaning/disinfectant agent time to work in accordance with the selected indication/specified exposure time (follow the manufacturer's information) in the ultrasonic bath (at least 5 min).

The exposure time stated by the manufacturer only starts when the last instrument has been placed in the ultrasonic bath and must not be exceeded. The maximum temperatures indicated by the manufacturer of the cleaning/disinfectant agent must not be exceeded.

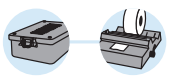
The instruments must not touch each other. To improve the cleaning/disinfection effect, remove the lid of the ultrasonic cleaning cassette during the cleaning process in the ultrasonic bath.

2. Once the exposure time has come to an end, remove the instruments from the cassette and rinse them at least 5 times thoroughly for at least 1 minute each time under running water.

Drying

3. Dry the instruments by blowing filtered compressed air in and out.

4. Visual inspection of cleanliness. If residual contaminations are detected, repeat cleaning/disinfection until no contamination is visible any longer.



5. Pack the instruments as soon as possible after removal (see chapter 7 «Packaging – Step by step»).

SEPARATE CLEANING, IF NECESSARY DISINFECTION – STEP BY STEP

Cleaning

1. Place the pre-cleaned prosthetic components in the sieve container (e.g. ultrasonic cleaning cassette art. no. 8.03.059 from Thommen Medical) in the ultrasonic device filled with cleaning agent. Give the cleaning agent time to work in accordance with the selected indication/specified exposure time (follow the manufacturer's information) in the ultrasonic bath (at least 5 min).

The exposure time stated by the manufacturer only starts when the last prosthetic component has been placed in the ultrasonic bath and must not be exceeded. The exposure time must not be exceeded. The maximum temperatures indicated by the manufacturer of the cleaning agent must not be exceeded.

The prosthetic components must not touch each other. To improve the cleaning effect, remove the lid of the ultrasonic cleaning cassette during the cleaning process in the ultrasonic bath.

2. Once the exposure time in the switched-on ultrasonic bath has come to an end, remove the prosthetic components from the sieve container and rinse the prosthetic components 5 times thoroughly for at least 1 minute each time under running water.

Disinfection

3. Place the prosthetic components in the sieve container (e.g. ultrasonic cleaning cassette art. no. 8.03.059 from Thommen Medical) in the disinfectant solution so that they are covered sufficiently and that the air can escape completely from instruments with hollow bodies.

The prosthetic components must not touch each other. To improve the disinfection effect, remove the lid of the ultrasonic cleaning cassette during the cleaning process in the ultrasonic bath.

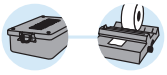
4. Give the disinfectant agent time to work in accordance with the selected indication/specified exposure time **without switching on the ultrasonic** (follow the manufacturer's information).

5. Once the exposure time has come to an end, remove the prosthetic components from the sieve container and rinse the prosthetic components at least 5 times thoroughly for at least 1 minute each time under running water.

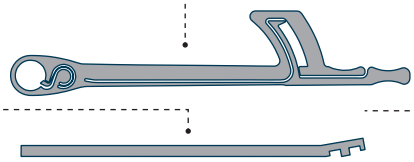
Drying

6. Dry the prosthetic components by blowing filtered compressed air in and out.

7. Visual inspection of cleanliness. If residual contaminations are detected, repeat cleaning and disinfection until no contamination is visible any longer.



8. Pack the prosthetic components as soon as possible after removal (see chapter 7 «Packaging – Step by step»).

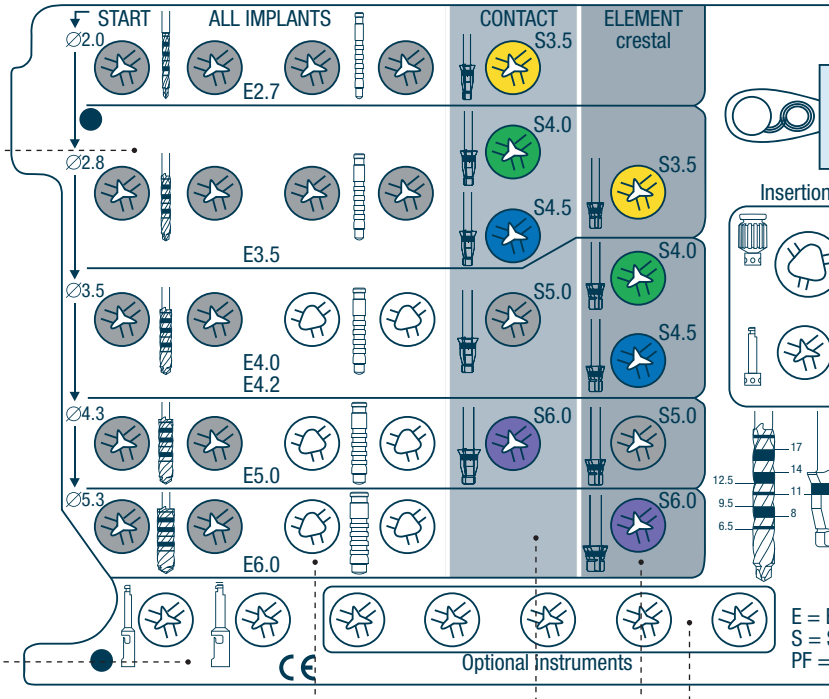


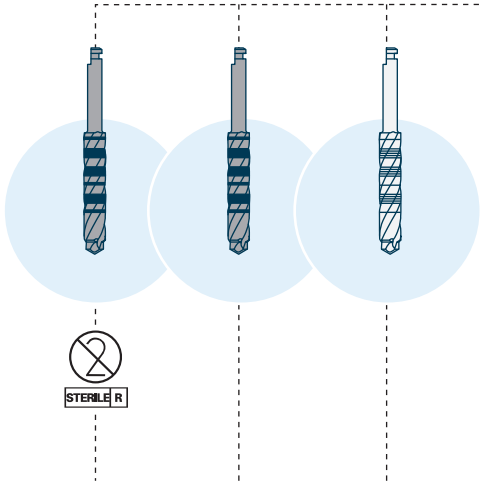
MONO
torque ratchet

3.03.160

MONO
guide key

3.03.203



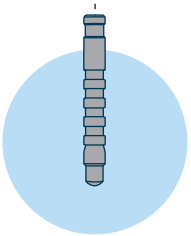


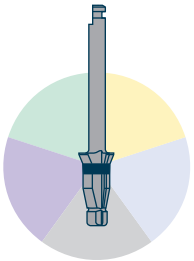
single use

STERILE R

VECTOdrill™ Drills

∅	Length	Stainless steel	Stainless steel	Ceramic
∅ **2.0**	29.0	3.03.624 Q4	3.03.710	3.03.660
	34.0	3.03.610 Q4	3.03.720	3.03.661
	40.0	3.03.611 Q4	3.03.730	
∅ **2.8**	29.0	3.03.625 Q4	3.03.712	3.03.662
	34.0	3.03.612 Q4	3.03.722	3.03.663
	40.0	3.03.613 Q4	3.03.732	
∅ **3.5**	29.0	3.03.626 Q4	3.03.714	3.03.664
	34.0	3.03.614 Q4	3.03.724	3.03.665
	40.0	3.03.615 Q4	3.03.734	
∅ **4.3**	29.0	3.03.627 Q4	3.03.716	3.03.666
	34.0	3.03.616 Q4	3.03.726	3.03.667
	40.0	3.03.617 Q4	3.03.736	
∅ **5.3**	29.0	3.03.628 Q4	3.03.718	3.03.668
	34.0	3.03.618 Q4	3.03.728	3.03.669





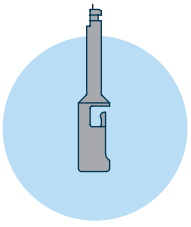
STERILE R

Depth gauge

∅ **2.0**	3.03.630
∅ **2.8**	3.03.632
∅ **3.5**	3.03.634
∅ **4.3**	3.03.636
∅ **5.3**	3.03.638

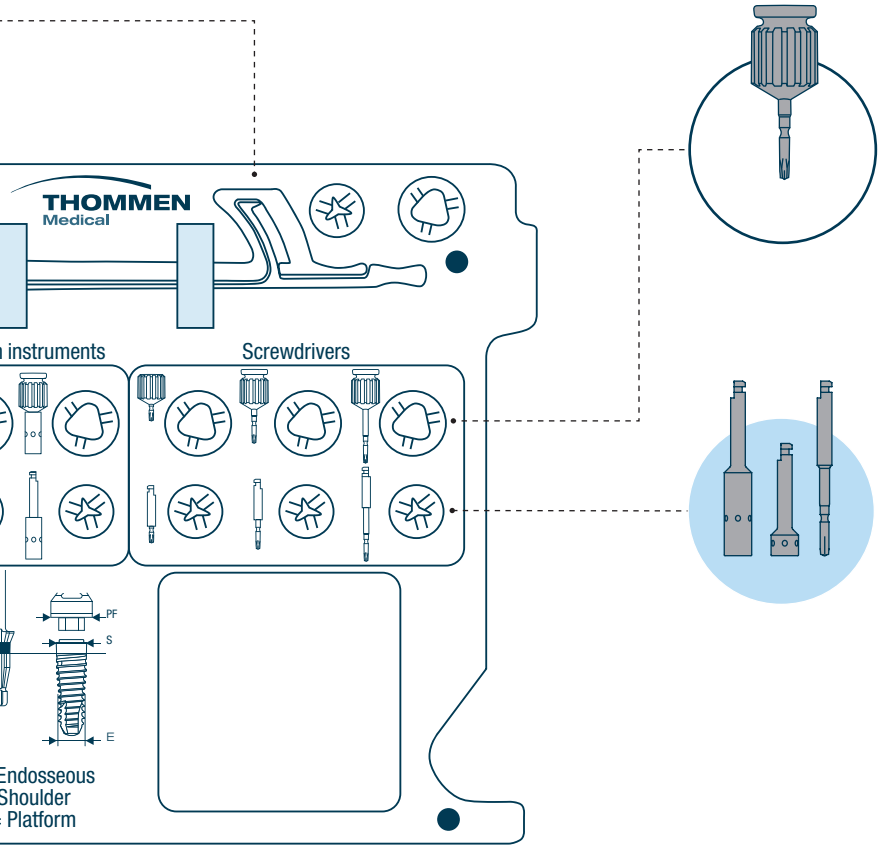
profile drill
CONTACT MC & RC

	3.03.640/641 Q4
3.03.648/649 Q4	3.03.642/643 Q4
	3.03.644/645 Q4
	3.03.646/647 Q4



Drill extension

3.03.230/231



MONO insertion device

3.03.162	3.03.163

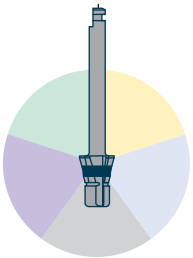
MONO screwdriver

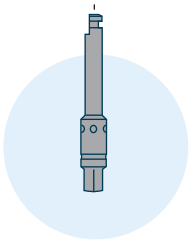
3.03.165	3.03.166	3.03.167

Instruments for mechanical operation

	Adapter
3.03.249	3.03.240

		Screwdrivers
3.03.500/501	3.03.501/502	3.03.502/503





STERILE R

profile drill ELEMENT MC

	3.03.651 Q4
3.03.657 Q4	3.03.653 Q4
	3.03.655 Q4
	3.03.659 Q4

Optional

In addition to the clearly designated slots for instruments, there are also slots that can be loaded as desired (optional instruments).

Loading the surgical cassette plastic (art. no. 1.03.016)

Specific slots for instruments are provided for loading the surgical cassette (art. no. 1.043.016).

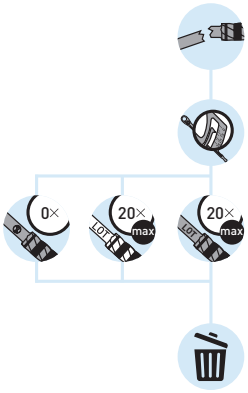
⚠ **Important:** Sterile instruments for single use (STERILE R) may only be placed into the specific slots in the cassette after sterilization.

6. Checking and servicing

ESSENTIALS

The check and servicing are a fixed component of each processing. Servicing is not necessary for any of the instruments of the Thommen implant system. No instrument oils may be used.
Use only surgical cassettes and containers that are free of defects. Replace damaged parts immediately with original parts. If it should become necessary to replace the instrument holders because of improper use or material fatigue, the instrument holders can be replaced individually. Please contact your local sales representative or the local state representative for the replacement of the instrument holders.

STEP BY STEP



1. Visual inspection for corrosion, damaged surfaces, splintering and distorted shapes, as well as restricted function.

   The MONO torque ratchet must be checked, if the flexible bending arm in the unloaded condition shows «0» on the scale.

2. Separate out damaged instruments and instruments which are limited to a certain number of uses: VECTOdrill ceramic twist drill: 20 uses, VECTOdril twist drill, stainless steel, for multiple use: 20 uses.

   Any use beyond this or the use of damaged and/or contaminated instruments is the responsibility of the user. All liability is excluded due to non-compliance.

7. Packaging, sterilization and storage

ESSENTIALS

The following requirements apply to selecting disposable sterilization packaging (disposable packaging) according to the respective material/process:

- EN ISO/ANSI AAMI ISO 11607-1/-2
- suitable for steam sterilization (temperature resistance to at least 142 °C (288 °F) and sufficient vapor permeability)
- adequate protection of the instruments and sterilization packaging from mechanical damage

When selecting sterile containers (referred to below as «Containers») the following requirements apply:

- EN ISO/ANSI AAMI ISO 11607-1/-2 and EN 868-8
- Regularly service and inspect containers

Only use the sterilization procedure mentioned below for sterilization. Other sterilization procedures are not permitted.

The following points must be complied with for the steam sterilization:

- fractionated vacuum process with at least 3 vacuum steps (with adequate product drying)
- steam sterilizer compliant with EN 13060/EN 285 or ANSI AAMI ST79

- according to DIN EN ISO 17665 validated performance assessment (validated process)
- maximum sterilization temperature 138 °C (280 °F); (plus tolerance in compliance with DIN EN ISO 17665-1)

Sterilization time (exposure time at the sterilization temperature) at least 4 minutes (or 18 minutes, for inactivation of prions; not relevant for USA) at 132 °C (270 °F)/134 °C (273 °F)

The use of the less effective gravitational procedure is only permitted in the event of non-availability of the fractionated process, in general requires a much longer exposure time and must be validated on the sole responsibility of the user.

The actual necessary drying time depends directly on the parameters, which lie with the sole responsibility of the user (e.g. loading configuration and density, condition of sterilizer) and must therefore be determined by the user. Nonetheless, drying times of 20 minutes should not be exceeded.

When sterilizing several surgical cassettes/sterile containers, the maximum loading capacity of the sterilizer must not be exceeded. Follow the instructions of the device manufacturer.

All instruments and sterilization trays must be exposed to a maximum temperature of 142 °C (288 °F).

Please contact the manufacturer of the sterilizer with regard to any questions on dimensions.

⚠ **Important:** No prosthetic components of any kind may be sterilized in the surgical cassette, rather they must be sterilized separately in disposable sterilization packaging (disposable packaging).

During sterilization of the instruments in the surgical cassette, the flowchart template must be placed in the cassette to ensure full functionality of the cassette later.

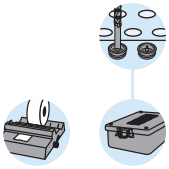
PACKAGING – STEP BY STEP

1. Inspection of dryness (e.g. blotting paper test) or dry in a clean place, if required

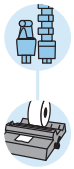
2. Packing

a. Surgical cassette: place the flowchart template in the surgical cassette

⚠ **Important:** When inserting the flowchart template art. nos. 8.04.031 and 8.04.040 make sure that they do not come into contact with the instruments. Using both hands, carefully hold the flowchart template oriented horizontally above the instruments and place it on the base of the surgical cassette without it coming into contact with the instruments.



Then pack the surgical cassette in disposable sterilization packaging (disposable packaging) or sterile container suitable for sterilization for the surgical cassettes art. nos. 1.03.030 and 1.04.020.



b. Prosthetic components: pack in disposable sterilization packaging (disposable packaging).

STERILIZATION – STEP BY STEP

1. Place the cassettes in the container and the prosthetic components packed in disposable sterilization packaging in the steam sterilizer. Do not stack the containers in the steam sterilizer.

2. Start the program.

3. After the sterilization cycle has ended, let the cassettes/containers cool down with sufficient air circulation.

STORAGE

The packaged sterile items must be protected from dust, humidity, light and recontamination during transport and storage. The instruments must be removed immediately before use.

IMMEDIATELY BEFORE USE

⚠ **Important:** Sterile instruments for single use (e.g. profile drills) may be placed into the designated instrument holders of the surgical cassette only after sterilization. Sterile instruments/prosthetic components must be loaded under sterile conditions (sterile assistant) and care must be taken to ensure that the sterile instruments in the cassette are not contaminated by this procedure.

8. 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
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 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.

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