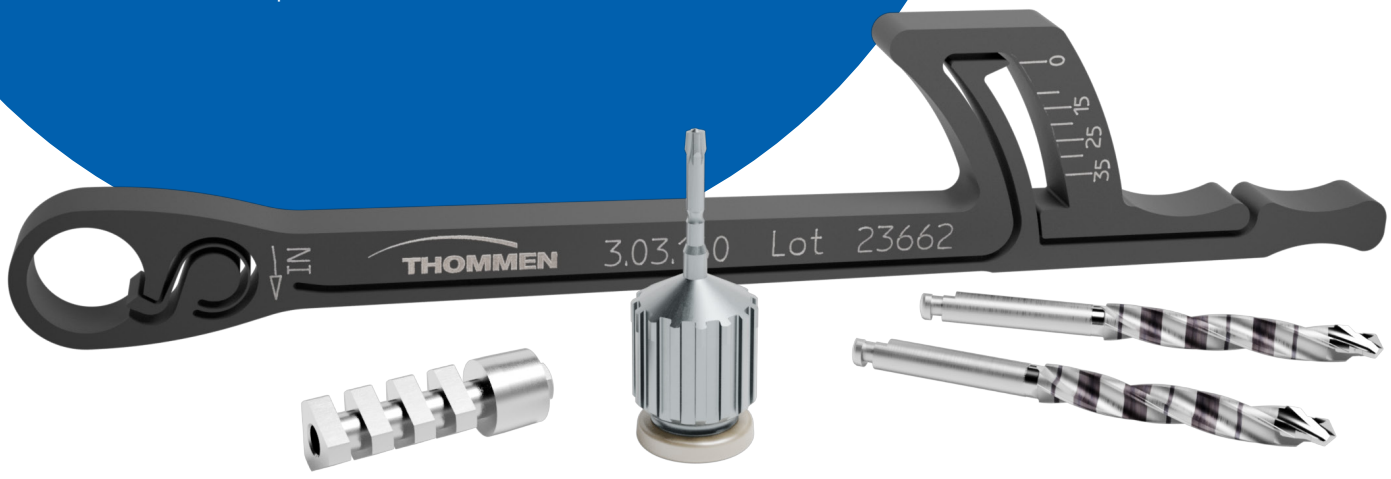
Reprocessing.

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

Technical description THM61131



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THOMMEN Medical

Content

5.B Manual cleaning/disinfection in the ultrasonic bath

6. Checking and servicing

7. Packaging, sterilization and storage

8. Symbols

9. Product list

1. Overview

General information

This technical description contains information on reprocessing the reusable surgical instruments and prosthetic components of the Thommen Medical AG implant system.

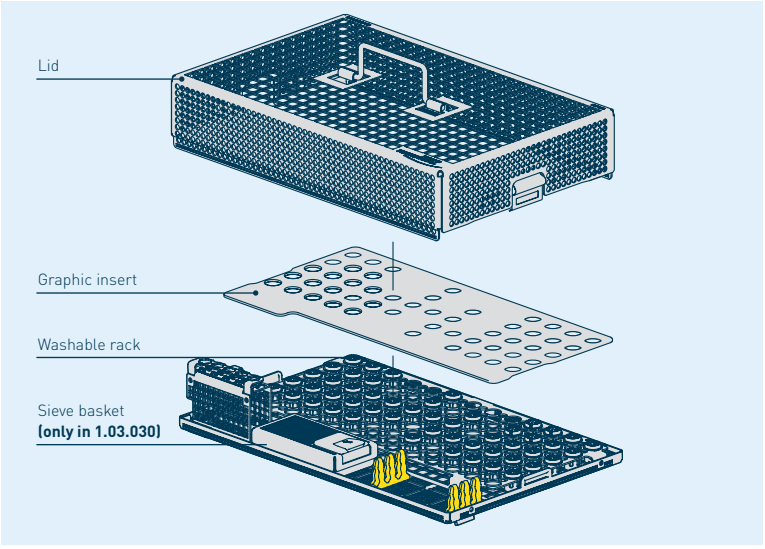
Intended use

Thommen Medical processing and storage equipment are to be used in conjunction with the Thommen Medical dental implant system in the maxillary and mandibular jawbone for implant-supported dentures. You can find more information on the implant system in the instructions for use for INICELL® implants THM61112 or implants with the standard surface THM61113.

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 graphic insert (art. no. 8.04.031)
b. Surgical cassette for guided surgery (art. no. 1.04.020), with appropriate graphic insert (art. no. 8.04.040)

Both surgical cassettes consist of a washable rack with lid and removable graphic insert:



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

Surgical cassette, incl. screw organizer for manual cleaning

The surgical cassette incl. screw organizer 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 cleaning 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 lid and a removable graphic insert.

The same applies to the prosthetic cassette, incl. screw organizer art. no. 1.03.022.

The surgical cassette, incl. screw organizer and prosthetic cassette, incl. screw organizer are thus collectively referred to as "Plastic cassettes".

Art. no.	Components	Material
1.03.030	Surgical cassette for mechanical cleaning, incl. graphic insert	Stainless steel/PEEK, aluminum, silicone
1.04.020	Cassette for guided surgery, for mechanical cleaning, incl. graphic insert	Stainless steel/PEEK, aluminum, silicone
1.03.016	Surgical cassette, incl. screw organizer	Plastic
1.03.022	Prosthetic cassette, incl. screw organizer	Plastic

See pages 18-25 and 34-35 for how to load the cassettes.

You can find additional accessories for safe reprocessing 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 this product and these accessories.

2. Manufacturer's information for reprocessing in accordance with EN ISO 17664

Essentials

Single-use instruments
Non-sterile instruments for single use must be cleaned, disinfected and sterilized before use.

Multiple-use instruments
Reusable instruments (except the handle for dental technicians art. no. 3.03.250) must be cleaned, disinfected and sterilized before each use. This also applies, in particular, to the first use after delivery of all cassettes and to reusable instruments that have been delivered in a non-sterile condition. An effective cleaning and disinfection are absolutely necessary prerequisites for an efficient sterilization for re-use.

Single-use prosthetic components
Prosthetic components for single use must be repackaged for sterilization and sterilized directly after removal from the Thommen Medical AG original packaging (see Section 7).

Multiple-use prosthetic components
Prosthetic components for multiple use must be repackaged for sterilization and sterilized directly after removal from the Thommen Medical AG original packaging (see Section 7). Reusable prosthetic components must be cleaned, disinfected and sterilized before each use.

The user is responsible for ensuring that the equipment and materials used for reprocessing, as well as the staff employed in the reprocessing facility, achieve the required results. Only validated methods 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 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 instruments (for multiple use and/or which are delivered in a non-sterile condition) and prosthetic components of the Thommen Medical AG implant system. Prosthetic components are differentiated into prosthetic components for single use and components that may be used multiple times.

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

Validated procedure

Thommen Medical AG has demonstrated that the methods described in these instructions are effective for reprocessing.

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

Pre-cleaning aids:
- Nylon cleaning brush (multi-tufted toothbrush with multiple planar bristle field)
- Interdental brushes in ISO sizes 0, 3, 4 and 6 (TePe D-A-CH GmbH, Hamburg, Germany)
- Syringe (Luer Solo 10 ml, B. Braun Medical, Melsungen, Germany)

Cleaning and disinfectant agents:
- Pre-cleaning and mechanical cleaning of instruments, cassettes and prosthetic components (multiple use):
  Neodisher MediZym (cleaning agent, Chemische Fabrik Dr. Weigert GmbH & Co. KG, Hamburg, Germany)
- Pre-cleaning and manual cleaning of instruments and cassettes:
  Gigasept Instru AF (aldehyde-free combination cleaning and disinfectant agent, Schülke & Mayr, Norderstedt, Germany)
- Pre-cleaning and manual cleaning and disinfection of prosthetic components (multiple use):
  Pre-cleaning and manual cleaning with Cidezyme, disinfection with Cidex OPA (Advanced Sterilization Products (ASP), Irvine, United States)

Aids and devices for mechanical cleaning and disinfection:
- Surgical cassette for mechanical cleaning (art. no. 1.03.030, Thommen Medical AG, Grenchen, Switzerland)
- Surgical cassette for guided surgery (art. no. 1.04.020, Thommen Medical AG, Grenchen, Switzerland)
- Cleaning/disinfection device (CDD): Desinfektor G 7836 CD1 (Miele, Gütersloh, Germany)

Aids and devices for manual cleaning and disinfection:
- Ultrasonic cleaning cassette (art. no. 8.03.059, Thommen Medical AG, Grenchen, Switzerland)
- Instrument bath (ultrasonic bath): SONOREX SUPER RK 514 H (BANDELIN electronic, Berlin, Germany)

Aids and devices for sterilization:
- Surgical cassette incl. screw organizer (art. no. 1.03.016, Thommen Medical AG, Grenchen, Switzerland)
- Prosthetic cassette incl. screw organizer (art. no. 1.03.022, Thommen Medical AG, Grenchen, Switzerland)
- Surgical cassette for mechanical cleaning (art. no. 1.03.030, Thommen Medical AG, Grenchen, Switzerland)
- Surgical cassette for guided surgery (art. no. 1.04.020, Thommen Medical AG, Grenchen, Switzerland)
- Autoclave: HST 6x6x6 (Zirbus technology GmbH, Bad Grund, Germany)

Water quality:
All rinsing processes under running water must be carried out with de-ionized water (DI water).
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, they are suitable for the cleaning of instruments made of metal and plastic
- if no thermal disinfection is used, in addition, a suitable disinfectant agent is used, which:
  – is intended for use for invasive medical devices made of metal and/or plastic, and
  – has proven efficacy, e.g. a VAH DGHM or FDA/EPA registration or a CE mark and
  – the chemicals used are compatible with the instruments

When selecting the cleaning and/or disinfectant agents, particularly pay attention 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 AG recommends use of neutral enzymatic detergents with a maximum pH of 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 these instructions (see above). However, 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 method (CDD, cleaning and disinfection device) for cleaning and disinfection, if possible. A manual method – even if using an ultrasonic bath – should be used only if a mechanical method 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 Medical AG 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. Pre-treatment at the point of use

Essentials

Immediately after use on the patient (within a maximum of 2 hours), coarse contamination must be removed from the instruments, prosthetic components and cassettes. Never allow the surgical residues (blood, secretions and tissue residues) to dry out onto an instrument, prosthetic components or cassettes.

The disinfectant agent used for the pre-treatment at the point of use, as appropriate, only serves to protect people and is not a substitute for the following cleaning and disinfection steps.

Separation of the prosthetic components (multiple use) from the instruments and cassettes is only necessary for a subsequent manual cleaning, because of the different cleaning and disinfectant agents.
(see Section 2, "Validated procedure")

The graphic inserts for the surgical cassettes (see p. 4) must also be prepared for cleaning at the point of use.

Warning
Damaged and/or blunt instruments must be removed, disinfected, cleaned and disposed of separately.

Selection of methods, cleaning and disinfection agents and specific approach

	Scope	Detergents/aids	Specific approach as described below:
Mechanical	Prior to mechanical cleaning and disinfection of instruments, prosthetic components and plastic cassettes 	Only for cleaning (C): Select the cleaning agent and other aids according to the criteria in the "Validated procedure" section	"Separate cleaning, if necessary, disinfection – Step by step"
Manual	Prior to manual cleaning and disinfection of instruments and plastic cassettes (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" **section**	"Combined method – Step by step"
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" section	"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 hold times.

Combined method – Step by step

Cleaning/disinfection

1. Place the instruments/plastic cassettes in the combined cleaning/disinfectant agent solution.

2. Give the combined cleaning/disinfectant agent time to take effect 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 contamination manually using a clean, soft Nylon brush.

4. Finally, rinse for 1 minute under running water.

Transport

5. The cassette, instruments and prosthetic components for multiple use must be placed in a closed container for transport.

Separate cleaning, if necessary, disinfection – Step by step

Cleaning

1. Place the instruments/prosthetic components/plastic cassettes in the cleaning agent solution so that they are covered sufficiently and that the air can escape completely from instruments with cavities. Make sure that the instruments/prosthetic components are not touching one another.

2. Give the cleaning agent time to take effect 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 contamination 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 cavities. Make sure that the instruments/prosthetic components are not touching one another.

6. Give the disinfectant time to take effect 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.

Transport

8. The cassette, instruments and prosthetic components for multiple use must be placed in a closed contained for transport.

4. Preparation before cleaning

Essentials

The "Preparation before cleaning" is an essential requirement for cleaning, independently of whether a mechanical or manual method is selected.

Selection of methods, cleaning and disinfection agents and specific approach

	Scope	Detergents/aids	Specific approach as described below:
Mechanical	Prior to mechanical cleaning and disinfection of instruments, prosthetic components and plastic cassettes 	Only for cleaning (C): Select the cleaning agent and other aids according to the criteria in the "Validated procedure" section	"Separate cleaning, if necessary, disinfection – Step by step"
Manual	Prior to manual cleaning and disinfection of instruments and plastic cassettes (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" section	"Combined method – Step by step"
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" section	"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 hold times for the solution(s).

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

Combined method – Step by step

1. The plastic cassettes as well as the instruments must be disassembled as far as possible (see p. 4), as necessary (e.g. separate the drill extension from the drill).

Cleaning/disinfection

2. Place the dismantled instruments/plastic cassettes in the combined cleaning/disinfectant agent solution so that they are covered sufficiently and that the air can escape completely from instruments with cavities. 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 contamination 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 which 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 contamination is detected, repeat pre-cleaning until no contamination is visible any longer.

Separate cleaning, if necessary, disinfection – Step by step

1. The plastic cassettes must be disassembled as far as possible (see p. 4), and the instruments must also be disassembled, as necessary (e.g. separate the drill extension from the drill).

Cleaning

2. Place the dismantled instruments/prosthetic components/plastic cassettes/graphic insert in the cleaning agent solution so that they are covered sufficiently and that the air can escape completely from instruments with cavities. 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 contamination 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 which 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 at least 5 times for at least 1 minute each time under running water.

6. Visual inspection of cleanliness. If residual contamination is 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 cavities. Make sure that the instruments/prosthetic components are not touching one another.

8. Give the disinfectant time to take effect 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.

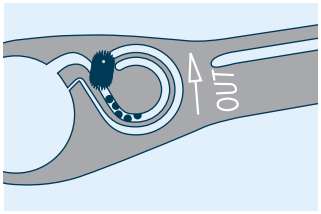
9. Rinse them 5 times for at least 1 minute each time under running water.

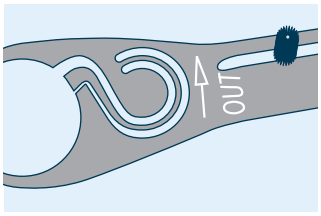
Instrument-specific procedure

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

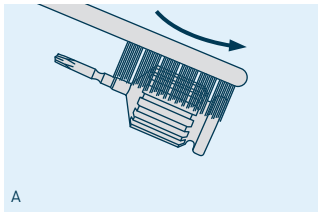
Spring in ratchet head: Clean using an interdental brush of ISO size 0.

Long gap as 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.



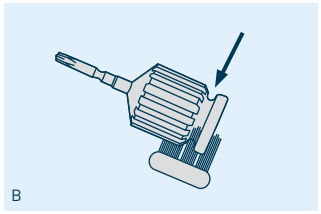


MONO screwdriver (art. nos. 3.03.165, 3.03.166, 3.03.167) and
MONO insertion device, short and long (art. nos. 3.03.162, 3.03.163),
MONO insertion device for retentive anchor (art. no. 3.03.169)
Grooves:
Guide the head of the screwdriver (or insertion device) along the longitudinal axis of the instrument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

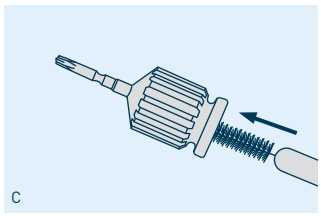

A

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

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


B

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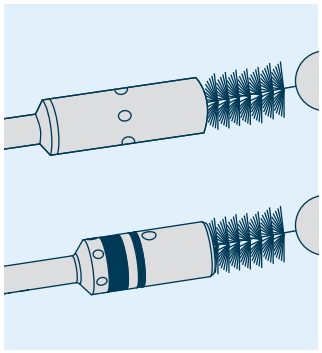
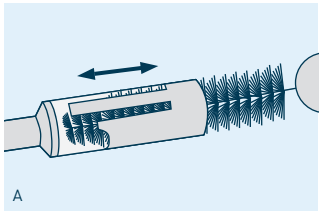


Adapter for handpiece (art. nos. 3.03.238, 3.03.240, 3.03.249 and 3.04.090)

Outer surfaces: using a Nylon brush, brush the instrument along its longitudinal axis while turning the instrument (at least 30 seconds).

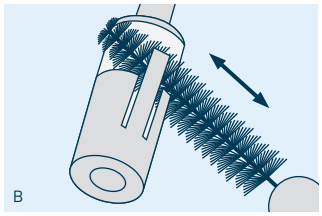
Central blind hole: brush out using an interdental brush of ISO size 6 (at least 30 seconds).



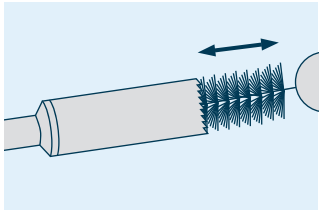
Drill extensions (art. nos. 3.03.230 and 3.03.231)

Outer surfaces: using a Nylon brush, brush the instrument along its longitudinal axis while turning the instrument (at least 30 seconds).

Central blind hole: brush out using an interdental brush of ISO size 4 while turning (at least 30 seconds) (see Fig. A).



Side slits: 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).

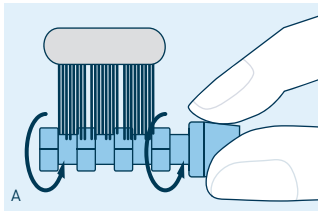
Central blind hole: brush out using a Nylon brush (at least 30 seconds).

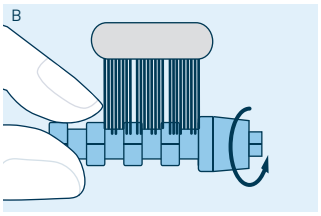
The inner areas of the instrument are accessible with interdental brushes. By guiding the interdental brush along the longitudinal axis of the instrument (at least 30 seconds), the inner area can be cleaned thoroughly.

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

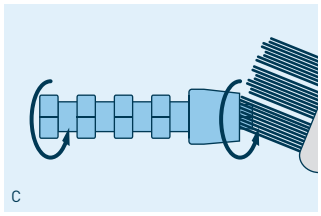
Specific procedure for prosthetic components (multiple use)

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).

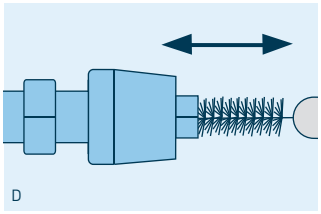




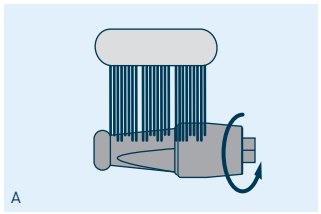
Clean the end surfaces (e.g. connection geometry for the implant) in the same way.
Turn the impression coping while brushing (at least 30 seconds) (see Fig. C).

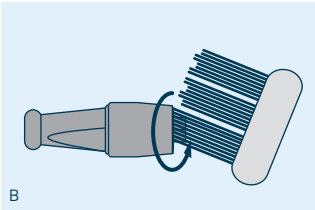


Central through-hole: brush through from both sides using an interdental brush of ISO size 4 (at least 30 seconds on each side) (see Fig. D). In between, rinse the hole and brush with the attached syringe once.



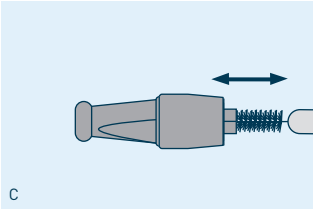
Impression coping for closed-tray technique (art. nos. 3.04.030-034, 3.04.046-050)
Outer surfaces: brush in a transverse direction to the longitudinal axis using a Nylon brush (see Fig. A) while turning the impression coping completely at least once (at least 30 seconds).





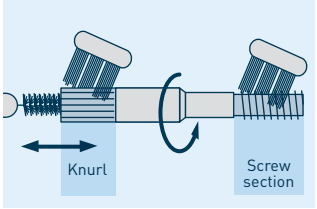
B

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



C

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



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): using a Nylon brush, 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 blind hole: 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 blind hole: 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 blind hole: 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 handles (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 cleared premarket notification 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 risk of residues from disinfectant agents remaining on instruments/prosthetic components.
- the program used is suitable for instruments and prosthetic components and has sufficient rinse cycles.
- Only sterile or low-bacteria (max. 10 bacteria/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-bacteria 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" section (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).

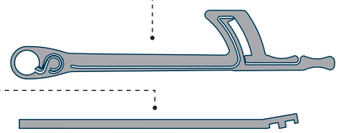
The surgical cassettes for mechanical cleaning art. nos. 1.03.030 and 1.04.020 play a pivotal role in the reprocessing of Thommen Medical AG instruments and prosthetic components (multiple use) according to validated processes and help to comply with hygiene regulations.

Carry out checking and servicing as soon as possible after cleaning/disinfection has finished (see Section 6) in order to package the devices as quickly as possible (see Section 7, "Packaging – Step by step").

⚠ **Important:** The surgical cassettes art. nos. 1.03.030 and 1.04.020 may only be used for the mechanical cleaning of instruments and prosthetic components for multiple use.

MONO torque ratchet

3.03.160



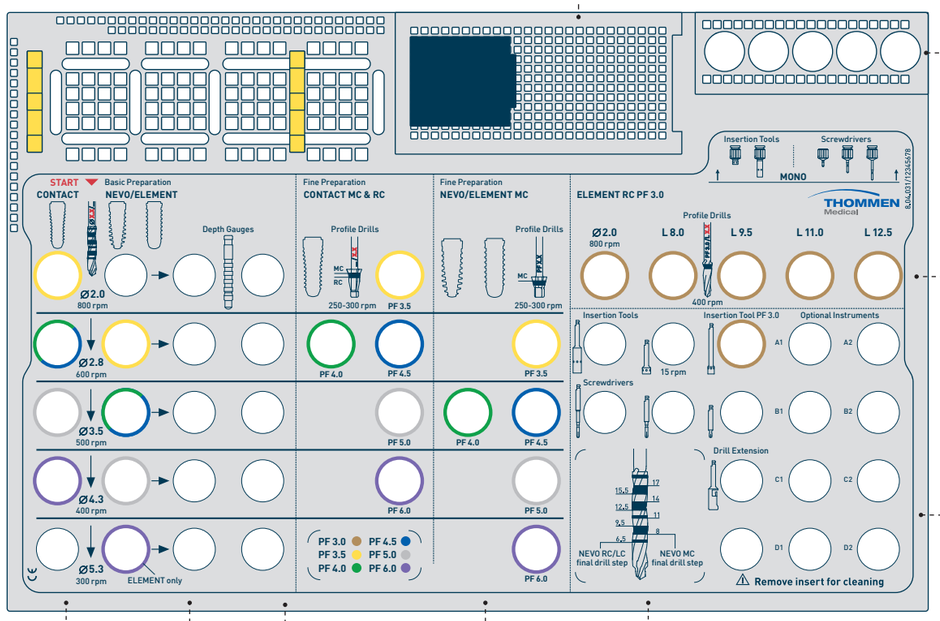
MONO guide key

3.03.203

Loading the surgical cassette (art. no. 1.03.030) – Generation 03 (incl. NEVO)

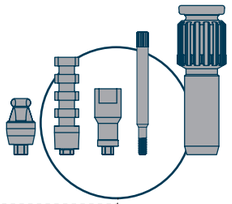
Specific slots are provided for instruments and prosthetic components (multiple use) for loading the surgical cassette (art. no. 1.03.030).

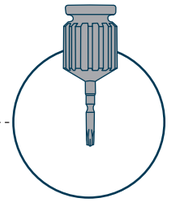
⚠ **Important:** Sterile instruments for single use (⊗ STERILE R) may only be placed into the specific slots in the cassette after sterilization.



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

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



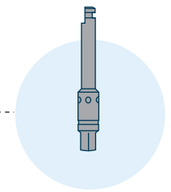


MONO insertion devices

3.03.162	3.03.163

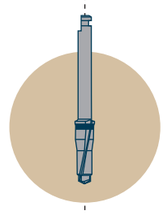
MONO screwdrivers

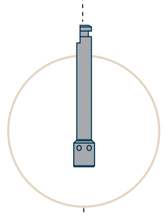
3.03.165	3.03.166	3.03.167



Optional

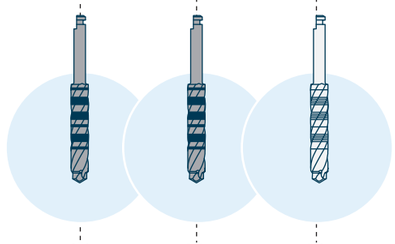
In addition to the clearly designated slots for instruments there are also slots that can be loaded as desired (optional instruments).





ELEMENT RC PF 3.0

Profile drill, length-specific				Adapter
L 8.0	L 9.5	L 11.0	L 12.5	
3.03.740	3.03.741	3.03.742	3.03.743	3.03.238



Single use

VECTOdrill™ twist drill

∅	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

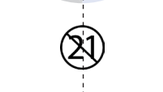
Depth gauge

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

Profile drill CONTACT

	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



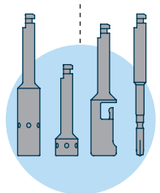
Profile drill NEVO/ELEMENT

	3.03.751
3.03.752	3.03.753
	3.03.754

Profile drill ELEMENT

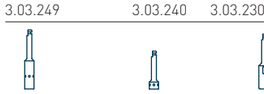
	3.03.651 Q4
3.03.657 Q4	3.03.653 Q4
	3.03.655 Q4
	3.03.659 Q4

When designating profile drills, _ /**X.X**, pay attention to the second number indicated on the shaft. It corresponds to the platform.



Instruments for mechanical operation

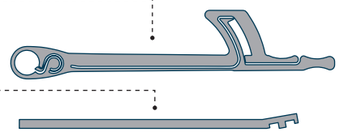
	Adapter	Drill extension
3.03.249	3.03.240	3.03.230/231



		Screwdrivers
3.03.502/503	3.03.501/502	3.03.500/501

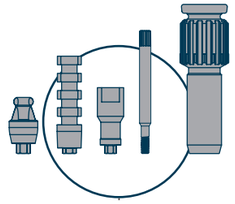
MONO torque ratchet

3.03.160



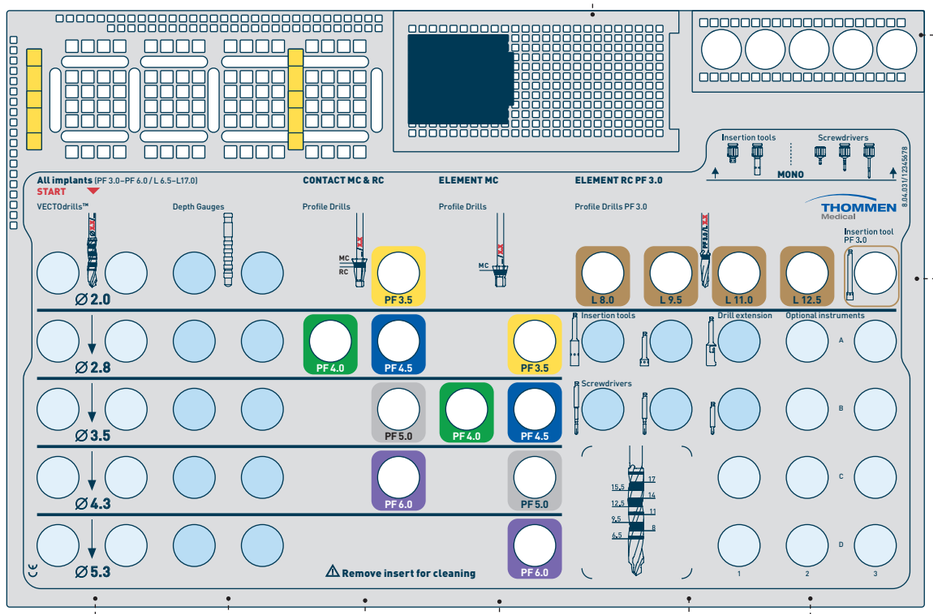
MONO guide key

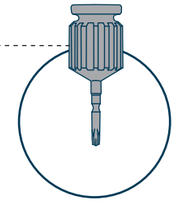
3.03.203



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

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





MONO insertion devices

3.03.162	3.03.163

MONO screwdrivers

3.03.165	3.03.166	3.03.167

Loading the surgical cassette (art. no. 1.03.030) – Generation 02 (without NEVO)

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.

Ⓢ Single use

VECTOdrill™ twist drill

∅	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 designating 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

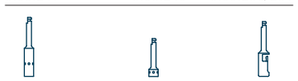
Profile drill ELEMENT MC

	3.03.651 Q4
3.03.657 Q4	3.03.653 Q4
	3.03.655 Q4
	3.03.659 Q4

When designating profile drills, _ /**X.X**, pay attention to the second number indicated on the shaft. It corresponds to the platform.

Instruments for mechanical operation

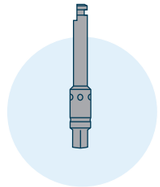
	Adapter	Drill extension
	3.03.249	3.03.240	3.03.230/231



	Screwdrivers	
3.03.502/503	3.03.501/502	3.03.500/501

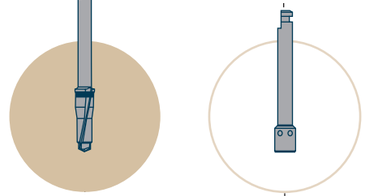
Optional

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



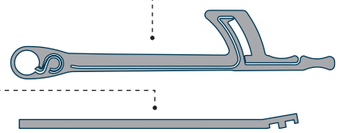
ELEMENT RC PF 3.0

Profile drill, length-specific				Adapter
L 8.0	**L 9.5**	**L 11.0**	**L 12.5**	
3.03.740	3.03.741	3.03.742	3.03.743	3.03.238



MONO torque ratchet

3.03.160



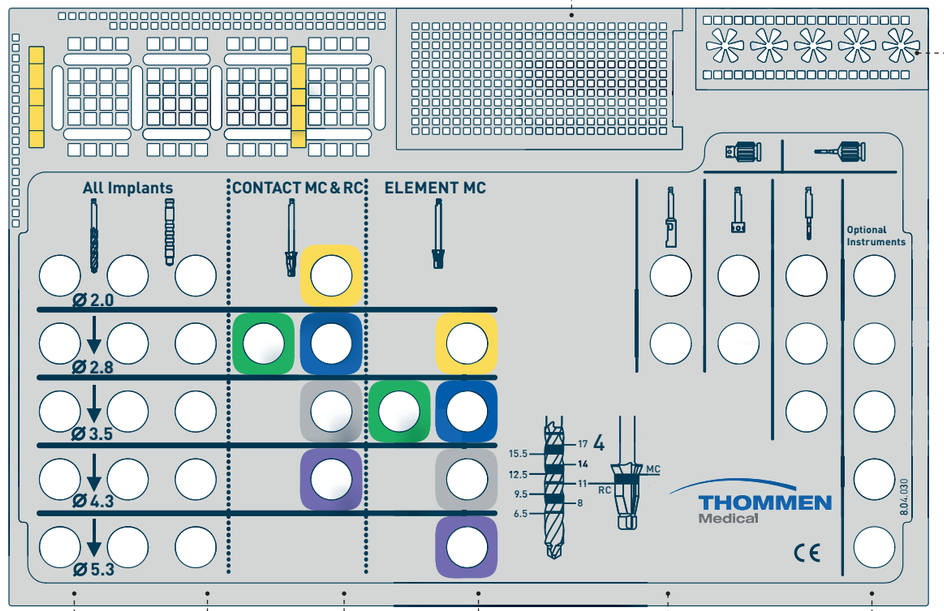
MONO guide key

3.03.203

Loading the surgical cassette (art. no. 1.03.030) – Generation 01

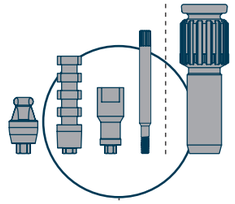
Specific slots are provided for instruments and prosthetic components (multiple use) for loading the surgical cassette (art. no. 1.03.030).

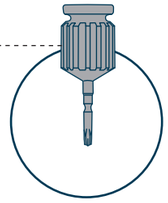
⚠ **Important:** Sterile instruments for single use (Ⓧ STERILE R) may only be placed into the specific slots in the cassette after sterilization.



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

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



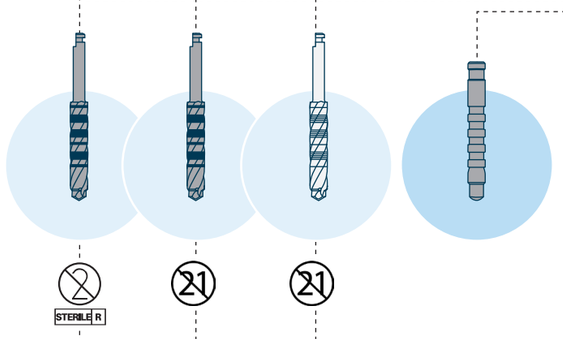


MONO insertion devices

3.03.162 3.03.163

MONO screwdrivers

3.03.165 3.03.166 3.03.167



Ⓧ Single use

VECTOdrill™ twist drill

∅	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 designating 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 designating profile drills, **_ /X.X**, pay attention to the second number indicated on the shaft. It corresponds to the platform.

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).

NEVO, ELEMENT & CONTACT PF 3.5–PF 4.5 / L 6.5–L 12.5, all collar heights

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

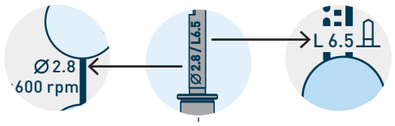
Seating instrument for guide sleeve
Stainless steel

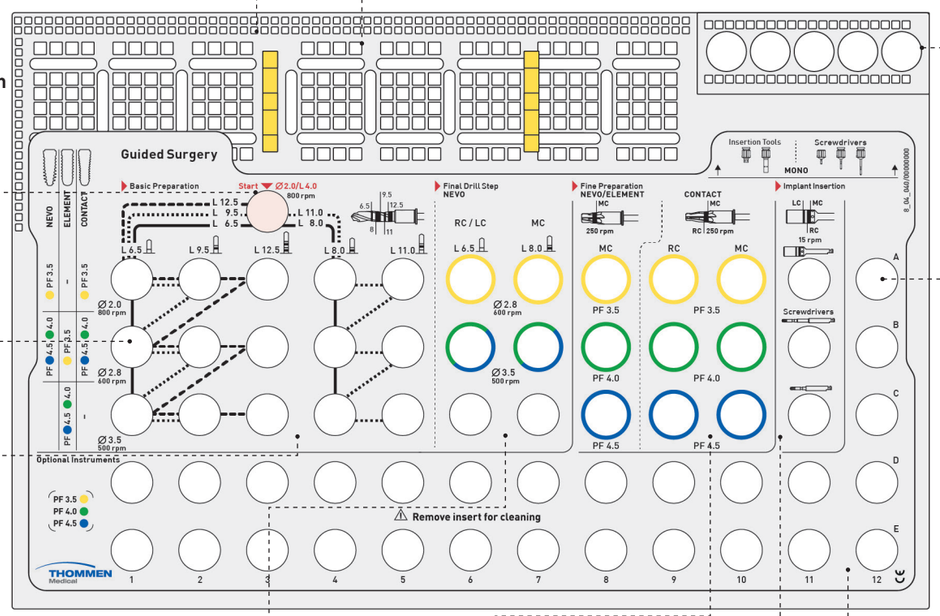
∅ **4.8**	3.04.100

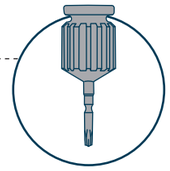
Cassette for guided surgery 1.04.020 (including NEVO)

⚠ **Attention:**
Special slots are provided for loading the cassette with instruments. When loading, pay attention to the identification code on the dental shaft and graphic insert.

Example:







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

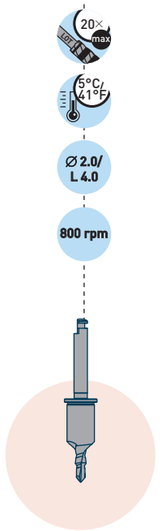
3.03.162	3.03.163

MONO screwdrivers*
Stainless steel/PEEK

3.03.165	3.03.166	3.03.167

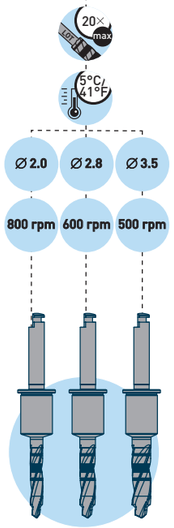
⚠ **Max. 20 use cycles (surgery, cleaning, sterilization) for cutting instruments. Further use cycles no longer guarantee the function of the product.**

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



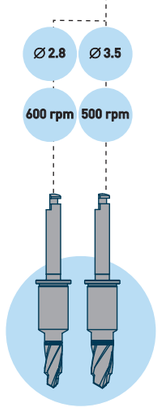
Basic preparation
Initial drill, guided

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



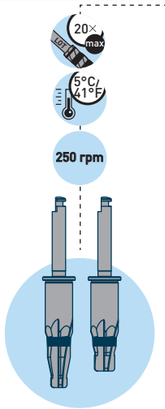
Basic preparation
VECTOdrill™ pilot drill and twist drill, guided
Stainless steel

	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
∅ **2.0**	3.04.111	3.04.113	3.04.115	3.04.112	3.04.114
∅ **2.8**	3.04.121	3.04.123	3.04.125	3.04.122	3.04.124
∅ **3.5**	3.04.131	3.04.133	3.04.135	3.04.132	3.04.134



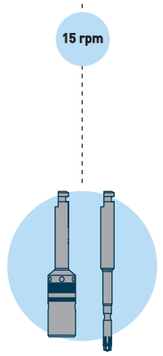
Basic preparation (soft and medium bone)
NEVO final drill step
VECTOdrill™ twist drill, guided
Stainless steel

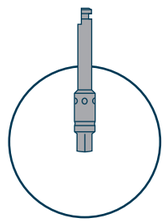
	L 6.5	L 8.0
Length mm	31.5	33.0
∅ **2.8**	3.04.121	3.04.122
∅ **3.5**	3.04.131	3.04.132



Fine preparation
Profile drill, guided
Stainless steel

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





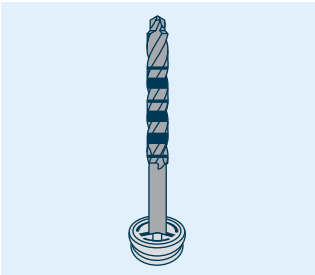
Implant insertion
Adapter, guided
Stainless steel

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

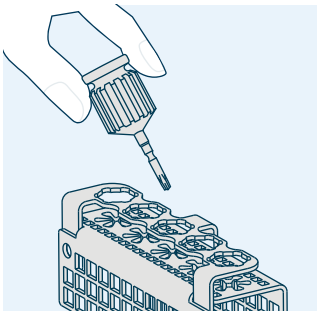
Adapter for handpiece, one-piece
Stainless steel

	PF 3.5	PF 4.0	PF 4.5
Length mm			
24.0	3.03.248	3.03.251	3.03.241

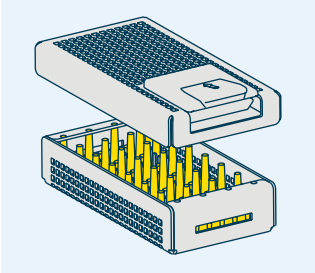
If you have an older version or generation of the cassette for guided surgery, please see the information on loading in the older instructions for use: www.ifu-tm.com/THM61144.



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

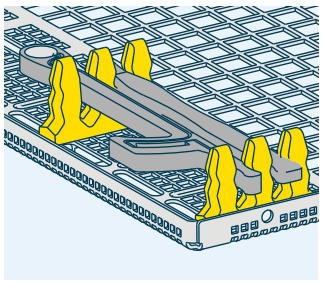


The MONO instruments (art. nos. 3.03.162, 3.03.163, 3.03.165, 3.03.166, 3.03.167) are placed in the special holder with the functional area of the instrument pointing downward.



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.

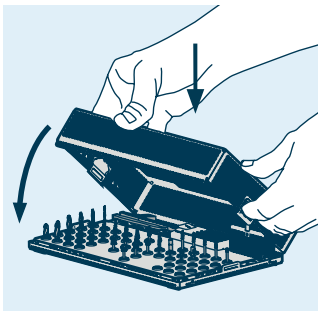
⚠ **Important:** Only three prosthetic components and the MONO insertion device for retentive anchor, if required, may be cleaned at the same time. Cleaning of additional instruments or other prosthetic components, such as abutments, is not permitted when cleaning in the sieve basket.

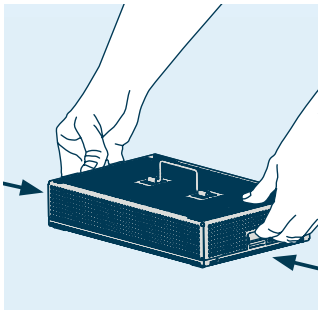


The MONO torque ratchet (art. no. 3.03.160) is stored in the silicone holders in the top of the cassette. It should be placed parallel to the cassette base so that there is as little contact as possible with the silicone holders.

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

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





⚠ **Important:** The graphic insert must not be stored in the cassette during mechanical cleaning. The graphic insert 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 lid. The surgical cassette incl. screw organizer art. no. 1.03.016 may only be cleaned mechanically without the instruments.

Place the surgical cassette (with the graphic insert 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 all items from the CDD and dry them.

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

5.B Manual cleaning/disinfection in the ultrasonic bath

Essentials

Cleaning in the ultrasonic bath is an integral part of manual cleaning and disinfection of Thommen Medical AG devices. The cleaning in the ultrasonic bath takes place immediately after the "Preparation before cleaning". Carry out checking and servicing as soon as possible after the cleaning/disinfection has finished (see Section 6) in order to package the devices as quickly as possible (see Section 7, "Packaging – Step by step").

Selection of methods, cleaning and disinfection agents and specific approach

	Scope	Detergents/aids	Specific approach as described below:
Manual	Manual cleaning and disinfection of instruments/plastic surgical cassettes (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" section.	"Combined method – Step by step"
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, if necessary, disinfection – Step by step"

Prepare the cleaning and disinfection solution fresh according to the manufacturer's instructions and comply with the maximum hold times for the solution(s).

Combined method – 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 AG)/plastic cassettes in the ultrasonic device filled with cleaning/disinfectant agent. Give the cleaning/disinfectant agent time to take effect 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 this period of time must be observed. 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/plastic cassettes from the ultrasonic bath 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 contamination is detected, repeat cleaning/disinfection until no contamination is visible any longer.

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 AG) in the ultrasonic device filled with cleaning agent. Give the cleaning agent time to take effect 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 it has been switched on. The length of the exposure time must be observed. 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 AG) 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.

Give the disinfectant agent time to take effect in accordance with the selected indication/specified exposure time (follow the manufacturer's information) **without switching on the ultrasound** (at least 5 minutes).

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

Drying

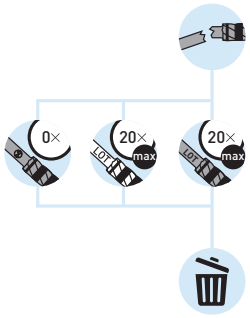
6. Dry the prosthetic components by blowing filtered compressed air in and out.

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

6. Checking and servicing

Essentials

Checking and servicing are an integral part of each reprocessing. Servicing is not necessary for any of the instruments of the Thommen Medical AG 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.

2. Separate out damaged instruments and instruments which are limited to a certain number of uses: VECTOdrill™ ceramic drill: VECTOdrill™ twist drill, stainless steel, for multiple use: NEVO/ELEMENT profile drill, multiple use, initial drill, guided, VECTOdrill™ guided and profile drill, guided: 20 uses.

   Any use beyond this or the use of damaged and/or contaminated instruments is not permitted. Thread tap, bone contouring instrument, bone contouring instrument+ and bone contouring instrument PF 3.0 are also limited to 20 cycles.

7. Packaging, sterilization and storage

Essentials

The following requirements apply to selecting disposable sterilization packaging (single-use 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) of at least 4 minutes (or 18 minutes, prion inactivation, 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 method, in general this requires a much longer exposure time and must be validated solely under the responsibility of the user.

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

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).

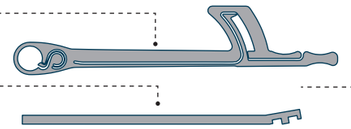
Please contact the manufacturer of the sterilizer with regard to any questions on dimensions.

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

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

Loading the surgical cassette, incl. screw organizer (art. no. 1.03.016) – with NEVO

Specific slots for instruments are provided for loading the surgical cassette (art. no. 1.03.016).

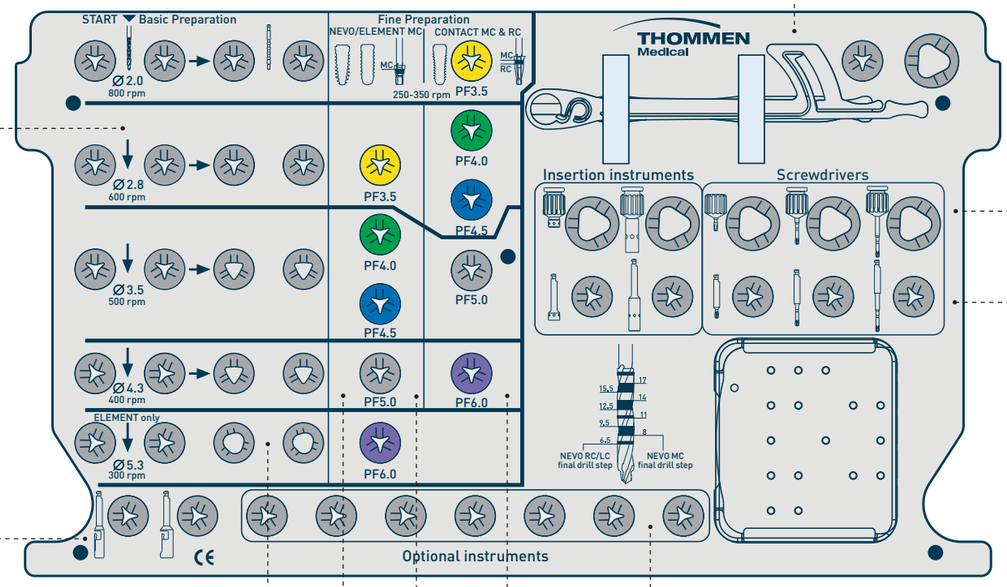


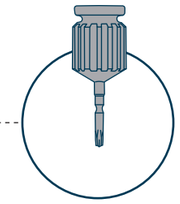
MONO torque ratchet

3.03.160

MONO guide key

3.03.203



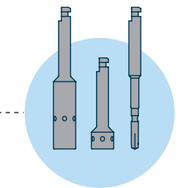


MONO insertion devices

3.03.162	3.03.163

MONO screwdrivers

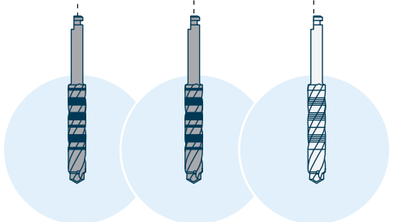
3.03.165	3.03.166	3.03.167



Instruments for mechanical operation

	Adapter
3.03.249	3.03.240

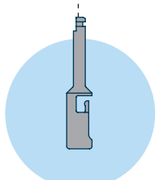
	Screwdrivers	
3.03.500/501	3.03.501/502	3.03.502/503



Single use

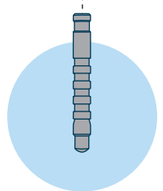
VECTOdrill™ twist drill

Ø	Length	Stainless steel	Stainless steel	Ceramic
Ø **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	
Ø **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	
Ø **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	
Ø **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	
Ø **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



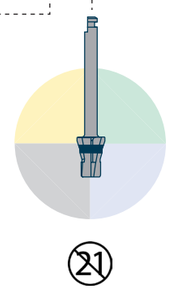
Drill extension

3.03.230/231



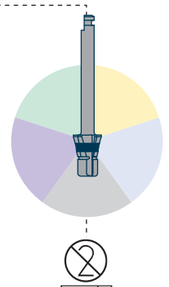
Depth gauge

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



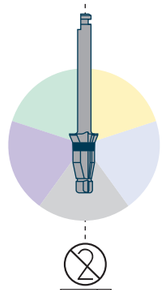
Profile drill NEVO/ELEMENT

	3.03.751
3.03.752	3.03.753
	3.03.754



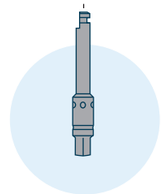
Profile drill ELEMENT

	3.03.651 Q4
3.03.657 Q4	3.03.653 Q4
	3.03.655 Q4
	3.03.659 Q4



Profile drill CONTACT

	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



Optional

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

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

If you have an older version or generation of the cassette, please see the information on loading in the older instructions for use: www.ifu-tm.com/THM61131.

Packaging – Step by step

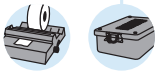
1. Inspection of dryness (e.g. blotting paper test), additional drying in a clean place, if required.

2. Packing

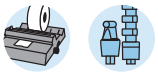
a. Surgical cassette (art. nos. 1.03.030 and 1.04.020): place the graphic insert in the surgical cassette.

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

Surgical cassette, incl. screw organizer (art. no. 1.03.016): place the instruments in the slots provided.



Then pack the surgical cassette in disposable sterilization packaging (single-use 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 (single-use 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 and transport

Sterilized medical devices should be used immediately after sterilization. If it is necessary to store these devices, it is important to precisely follow the instructions for the sterile containers and accessory systems used.

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:** Additional sterile instruments for single use (e.g. profile drills) may only be placed into the designated instrument holders of the surgical cassette 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 process.

11. Symbols

Thommen Implant System

Manufacturer: Thommen Medical AG
Neckarsulmstrasse 28
2540 Grenchen, Switzerland
www.thommenmedical.com

Symbols

LOT	Lot number
	Use by date
	Date of manufacture
STERILE R	Sterilized using irradiation
	Single sterile barrier system
	Single sterile barrier system with protective packaging inside
21	Not more than 20 reprocessing cycles
EC REP	European representative
	Temperature limitation
	Do not re-use
NON STERILE	Non-sterile
	Caution
REF	Article number
CE 0297	Conformity symbol in accordance with Directive No: MDD 93/42/EEC or Regulation (EU) No: 2017/745 MDR (see corresponding conformity declaration)
	Consult instructions for use
	Do not resterilize
	Do not use if package is damaged and consult instructions for use
	Atmospheric pressure limitation
	Manufacturer
	Importer
	Distributor
	Keep away from sunlight
Rx only	May only be sold to and prescribed by physicians (USA)
MD	Medical device
UDI	Unique device identifier

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

Sterile indicator – red means it has passed through a source of radiation

9. Product list

Article number	Description	UDI-DI
1.03.016	Surgical cassette, incl. screw organizer, 291.0 x 170.0 x 65.5 mm	07640156476590
1.03.022	Prosthetic cassette, incl. screw organizer, 190.0 x 140.0 x 58.0 mm	07640156476583
1.03.030	Surgical cassette, for mechanical cleaning 276.0 x 176.0 x 59.5 mm	07640156478181
1.03.056	Silicone holder set, for surgical and prosthetic cassettes	07640156476576
1.03.057	Silicone holder set, for profile drill, colored, for surgical cassette	07640156472486
1.04.020	Cassette for guided surg., PF3.5-PF4.5/L6.5-L12.5 for mechanical cleaning, 276.0 x 176.0 x 59.5 mm	07640182640637
8.03.018	Screw organizer for surgical cassette, 50.0 x 56.0 x 20.5 mm	07640156472943
8.03.019	Screw organizer for prosthetic cassette, 56.0 x 47.0 x 28.0 mm	07640156472936
8.03.059	Ultrasonic cleaning cassette	07640156472912
8.03.090Q2	Instrument holders, cassette, size S	07640156478235
8.03.091	Instrument holder, cassette, size M	07640156478266

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