Preparation instructions.

Prosthetic components, instruments and accessories.

These instructions apply to all Dentaurum prosthetic components, instruments, rotary instruments and accessory components that are approved for use on patients.

These instructions comply with the requirements of DIN EN ISO 17664:2018 and RKI (Robert Koch Institute) guidelines.

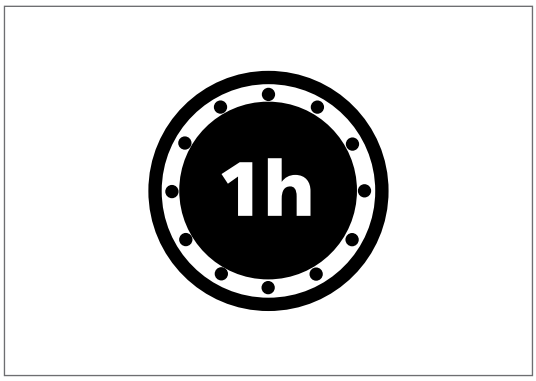
DENTAURUM

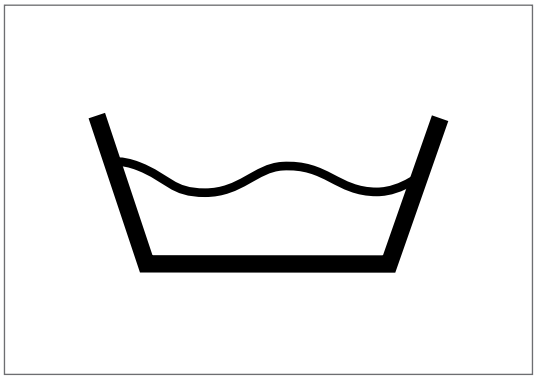
General requirements

Instruments and accessory components must be cleaned, disinfected and, if necessary, sterilized before each use. This also applies for initial use following delivery. Instruments and accessory components are normally delivered non-sterile (clean and disinfect following removal of the protective transport packaging; sterilize after packing). Thorough cleaning and disinfection are essential for an effective sterilization. This includes rotary instruments (drills), hereafter referred to as instruments.

During use ensure that contaminated instruments are either collected separately or replaced to their correct position in the Surgical Tray for tioLogic® TWINFIT or Surgical Tray ADVANCED for tioLogic®. Clean / disinfect the contaminated instruments. Then replace them in the instrument tray and sterilize the fully loaded surgical tray if necessary. Single-use items may not be reprocessed as it is not possible to guarantee functionality and safe preparation.

Manual preclean





Surface contamination must be removed from instruments and accessory components immediately after use, at the latest within one hour.

Dismantle the instruments and accessory components as far as possible, (e.g. torque ratchet, silicone holder in the Surgical Tray for tioLogic® TWINFIT or the Surgical Tray ADVANCED for tioLogic®, manual insertion keys). Preparation for manual preclean, disassembly and reassembly of the torque ratchet, see chapter Torque ratchet.

Rinse instruments and accessories under running water and immerse in a disinfectant solution.

Use only a soft brush (nylon brush) or a clean soft cloth intended for this purpose only to remove contamination manually.

Do not use metal brushes or steel wool.

If applicable: rinse all hollow sections of the instruments five times using a disposable syringe (minimum volume 5.0 ml).

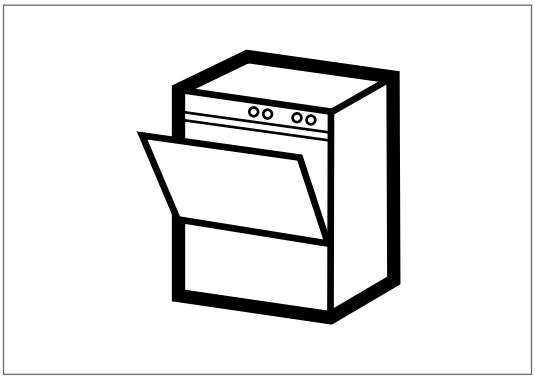
Disinfectants should be aldehyde-free (otherwise fixation of blood residue), have a certified effectiveness (e.g. DGHM [German Society for Hygiene and Microbiology] or FDA approval and CE marking), be suitable for disinfecting instruments and compatible with the instruments (see chapter Material resistance).

Do not immerse osteotomes in a NaCl solution (danger of pitting corrosion or stress corrosion cracking).

Note that the disinfectant used for preconditioning is only for personal protection and cannot be regarded as a substitute for subsequent disinfection after cleaning.

Machine-based cleaning and disinfection

When using a washer disinfector, please make sure that:



- the efficacy of the washer disinfector has been certified (e.g. DGHM or FDA approved or CE marking according to DIN EN ISO 15883) and is validated specifically for the appliance and product,
- a certified program for thermal disinfection (minimum 5 mins at 90 °C / 194 °F or an A_0 > 3000) is used if possible (with chemical disinfection there is the risk of disinfectant residue on the instruments),
- the program used is suitable for the instruments and has an adequate number of rinse cycles,
- the water used for rinsing is sterile or has a low bacteria count (max. 10 bacteria / ml) and is low in endotoxins (max. 0.25 endotoxin units / ml) (e.g. purified water / highly purified water),
- the air used for drying is filtered,
- the disinfector is regularly serviced and checked,
- the Instructions for use for the washer disinfector are observed.

Important: To guarantee adequate cleaning conform with Robert Koch Institute regulations, the osteotomes must be cleaned separately and not in the osteotome tray. The osteotome tray serves only to hold the osteotome during sterilization and then to store the osteotome. For sterilization, the loaded osteotome tray is packed in disposable packaging dedicated to the sterilization process in accordance with ISO 11607.

When choosing a cleaning agent system, make sure that:

- it is suitable for cleaning metal and plastic instruments,
- an additional disinfectant with certified efficacy (e.g. DGHM or FDA approved and CE marking) is used – provided that thermal sterilization is not used – and that it is compatible with the cleaning agent used, and
- the chemicals used are compatible with the instruments (see chapter Material resistance).

Adhere to the concentrations given by the manufacturer of the cleaning agent and disinfectant.

Cleaning / disinfection procedure

❶ Dismantle the instruments and accessory components as far as possible (e.g. torque ratchet, silicone holder in the Surgical Tray for tioLogic® TWINFIT, in the Surgical Tray ADVANCED for tioLogic®, manual insertion keys).

❷ Preparation of the torque ratchet for manual cleaning/disinfection, disassembly and reassembly of the torque ratchet, see chapter Torque ratchet.

❸ Place the dismantled instruments in a lockable container in the washer disinfector. Instruments and accessory components should not come into contact. Place the insert of the Surgical Tray for tioLogic® TWINFIT and the Surgical Tray ADVANCED for tioLogic® in the upper rack of the washer disinfector.

❹ Start the program.

❺ Remove the instruments and accessory components or the trays from the washer disinfector at the end of the program.

❻ Check, possibly reassemble and pack the instruments, accessory components (torque ratchet and silicone holder for ratchet) and trays in a clean area as soon as possible after removal (see chapters Monitoring and maintenance, Packaging), if necessary after additional drying.

Note:
If the washer disinfector does not have an automatic drying program, leave the door of the unit slightly open to dry the instruments.

Proof of basic suitability for effective automatic cleaning and disinfecting was provided by an independent, accredited test laboratory using a G 7836 GD disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany) and the cleaning agent neodisher® Medizym (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account during the tests.

Manual cleaning and disinfection.

Observe the following points when choosing a cleaning agent and disinfectant:

- metal and / or plastic instruments and accessory components must be suitable for cleaning and disinfecting,
- the cleaning agent must be suitable for ultrasonic cleaning (no foaming),
- use only disinfectants with certified effectiveness (e.g. DGHM or FDA approval and CE marking). Disinfectants should be compatible with the cleaning agent used.

Do not use combined cleaning / disinfecting agents.

The concentrations and reaction times given by the cleaning agent and disinfectant manufacturer should be strictly adhered to. Use only freshly mixed solutions, only water that is sterile or has a low bacteria count (max. 10 bacteria / ml) and is low in endotoxins (max. 0.25 endotoxin units / ml) (e.g. purified water / highly purified water), and only filtered air for drying.

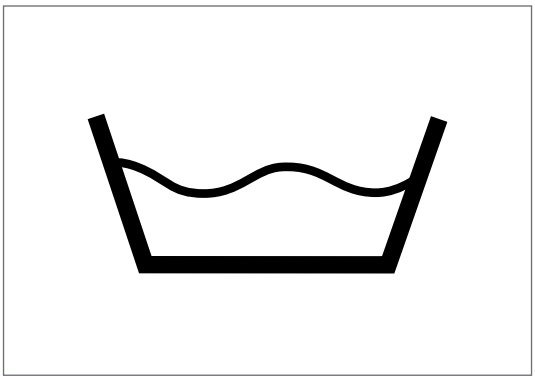
Important: To guarantee adequate cleaning conform with Robert Koch Institute regulations, the osteotomes must be cleaned separately and not in the osteotome tray. The osteotome tray serves only to hold the osteotome during sterilization and then to store the osteotome. For sterilization, the loaded osteotome tray is packed in disposable packaging dedicated to the sterilization process in accordance with ISO 11607.

Cleaning procedure

1. Dismantle the instruments and accessory components as far as possible (e.g. torque ratchet, silicone holder in the Surgical Tray for tioLogic® TWINFIT, in the Surgical Tray ADVANCED for tioLogic®, manual insertion keys).
2. Preparation of the torque ratchet for manual cleaning/disinfection and disassembly and reassembly of the torque ratchet, see chapter Torque ratchet.
3. Immerse the dismantled instruments and the accessory components fully in the cleaning solution for the recommended reaction time (if required use an ultrasonic cleaner, or brush carefully with a soft brush).
   Instruments and accessory components should not come into contact. Rinse all hollow sections of the instruments using a disposable syringe (minimum volume 5.0 ml) before and after the reaction time. Special holders, e.g. bur blocks, should be used if necessary.
4. Remove the instruments and accessory components from the disinfectant solution and rinse thoroughly at least three times with water.
5. If applicable: rinse all hollow sections of the instruments five times using a disposable syringe (minimum volume 5.0 ml).
6. **Check that the pliers and instruments have been properly cleaned**
   (see chapters Monitoring and maintenance, Packaging).

Disinfection procedure

1. Place the disassembled instruments and accessory components in the disinfectant solution according to the prescribed reaction time. Ensure that the instruments and accessory components are covered and are not in contact. Rinse all cavities in the instruments using a disposable syringe (minimum volume 5.0 ml) before and after the reaction time.
2. Remove the instruments and accessory components from the disinfectant solution and rinse thoroughly at least three times with water.
3. If applicable: rinse all hollow sections of the instruments five times using a disposable syringe (minimum volume 5.0 ml).
4. Do not reassemble and pack the instruments and accessory components until they are dry. Reassemble and pack dry instruments and accessory components as soon as possible (see chapters Monitoring and maintenance, Packaging).



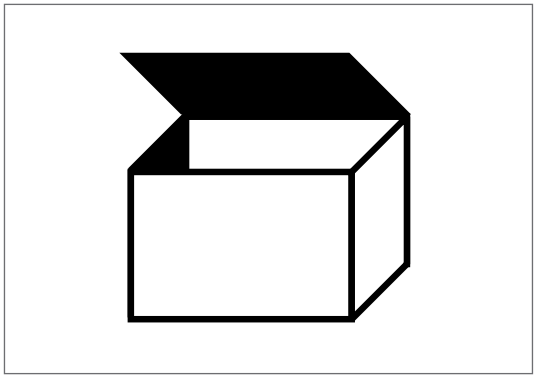
Proof of basic suitability for effective manual cleaning and disinfecting was provided by an independent, accredited test laboratory using Bodedex® forte cleaning agent and Korsolex® plus disinfectant (Bode Chemie, Hamburg, Germany). The procedure described above was taken into account during the tests.

Monitoring and maintenance

Check all instruments and accessory components after cleaning or cleaning / disinfecting for corrosion, damaged surfaces, chipped areas or contamination and remove damaged instruments and accessory components. Instruments and accessory components that are still contaminated must be cleaned and disinfected again.

Instrument oils should not be used if possible. If oil is to be used, ensure that only instrument oils (white oil) are used, which – depending on the maximum sterilization temperature used – are approved for steam sterilization and are certified as biocompatible.

Packaging



Arrange the cleaned and disinfected instruments and accessory components as required in the sterilization tray. Wrap the instruments, accessory components or sterilization trays in disposable sterilization packaging (single or double wrap) and / or pack in sterilization containers. The following requirements must be met:

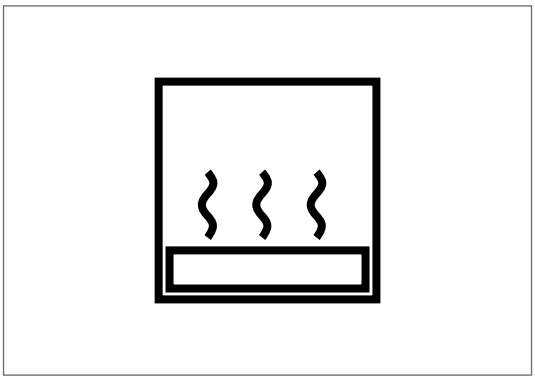
- DIN EN ISO/ANSI AAMI ISO 11607-1/2 (formerly: DIN EN 868/ ANSI AAMI ISO 11607)
- suitable for steam sterilization (temperature resistant to min. 134 °C / 273 °F and adequate steam permeability)
- adequate protection of the instruments and accessory components or sterilization packaging against mechanical damage
- regular servicing according to manufacturer's instructions (sterilization container)

Sterilization

Only the following sterilization procedures should be used for sterilization. Other sterilization procedures are not suitable. Flash sterilization or gravitational method should not be used. Other procedures that should not be used are: hot-air sterilization, X-ray sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization.

Steam sterilization

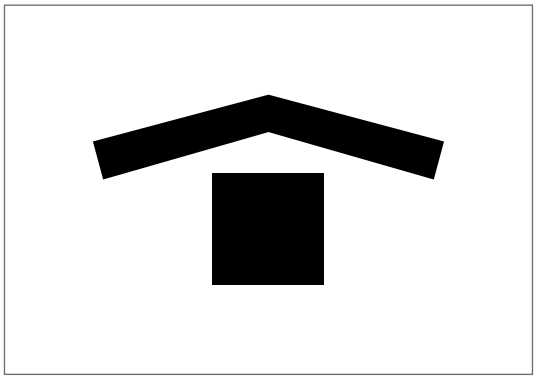
- fractional vacuum process (with adequate product drying)
- steam sterilizer in accordance with DIN EN 13060-2004 or DIN EN 285
- validated in accordance with DIN EN ISO / ANSI AAMI ISO 17665 (formerly: DIN EN 554 / ANSI AAMI ISO 11134) (valid commissioning and product-specific performance evaluation)
- maximum sterilization temperature 134 °C / 273 °F (plus tolerance in accordance with DIN EN ISO / ANSI AAMI ISO 17665 (formerly: DIN EN 554 / ANSI AAMI ISO 11134))
- sterilization time (exposure time at the sterilization temperature) minimum 5 mins at 134 °C / 273 °F
- max. pressure: 2.2 bar



Proof of basic suitability for effective steam sterilization was provided by an independent, accredited test laboratory using a EuroSelectomat steam sterilizer (MMM Münchener Medizin Mechanik GmbH, Planegg, Germany) and the fractional vacuum process as well as a Systec V-150 steam sterilizer (Systec GmbH Labor-Systemtechnik, Wettenberg, Germany) and the gravitation process. The procedure described above was taken into account during the tests.

Note: Preparation of the torque ratchet for sterilization, see chapter Torque ratchet.

Storage



Following sterilization, instruments and accessory components should be stored dry and dust-free in the sterilization packaging.

Documentation and approval

The preparation of medical products ends with a documented release for use.

Material resistance

When choosing the cleaning agent and disinfectant ensure that they do not contain the following components:

- organic, mineral or oxidizing acids (maximum permitted pH 9.5, a neutral / enzymatic cleaner is recommended)
- strong alkali
- organic solvents (e.g. alcohols, ethers, ketones, benzines)
- oxidation agents (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- aromatic/ halogenated hydrocarbons
- heavy metal salts

Do not immerse osteotomes in a NaCl solution (danger of pitting corrosion or stress corrosion cracking).

Do not clean instruments, accessory components and sterilization trays with metal brushes or steel wool. Do not expose instruments, accessory components and sterilization trays to temperatures above 134 °C / 273 °F !

Reusability

Rotary instruments – used with proper care and provided that they are not damaged or contaminated – can be reused in dense bone 15 to 20 times. The dental professional bears responsibility for any further reuse or use of damaged and/ or contaminated rotary instruments. Instruments and accessories must be replaced if they cannot be clearly identified or if the function is impaired due, for example, to poor readability of the markings or labels. No liability is accepted if these instructions are disregarded.

Remove and, if necessary, dispose of damaged or corroded instruments and trays.

Important: To guarantee adequate cleaning conform with Robert Koch Institute regulations, the osteotomes must be cleaned separately and not in the osteotome tray. The osteotome tray serves only to hold the osteotome during sterilization and then to store the osteotome. For sterilization, the loaded osteotome tray is packed in disposable packaging dedicated to the sterilization process in accordance with ISO 11607.

Disposal

Products to be disposed of should be decontaminated observing the relevant regulations for medical waste disposal.

References

Further tips on the correct conditioning of medical products in the practice and laboratory are provided by the German "Instrument Conditioning Research Group" (Arbeitskreis Instrumenten-Aufbereitung) in its yellow brochure.

www.a-k-i.org

www.rki.de

Further information on the materials for implantology products can be found in the Materials list (989-801-06).

Notes on the validations:

Deviations from the listed procedures must be carefully evaluated for their effectiveness and possible adverse consequences. It is the responsibility of the dental professional performing the reconditioning to ensure that the equipment, materials and staff of the reconditioning facility are adequate to achieve the desired results. This requires validations and routine monitoring of the reconditioning process.

Torque ratchet

After assembly and before each use, check the correct function of the torque ratchet.

A mechanical procedure (washer disinfector) should be used if possible for cleaning and disinfection. Because of its inferior efficacy and reproducibility, a manual procedure – even with an ultrasonic cleaner – should only be used if a mechanical procedure is not an option.

The preparation and preconditioning described below are required in both cases.

①

Ratchet wheel

Disassembly

Preparation for decontamination

Coarse impurities should be removed from the instruments immediately after use (within maximum 1 hours).
Before cleaning (regardless of the selected cleaning method), the torque ratchet must be dismantled into the individual parts. This can be done without tools. Completely unscrew the torque adjustment screw ⑤, and remove the spring ④ and the ratchet head ◁ with threaded rod.
Take care not to lose the plastic washer ▽ as this would have a negative impact on the instrument's precision. The plastic washer needs only to be removed if there is visible contamination. It can be pulled off if necessary and replaced after cleaning.

Remove ratchet wheel

Pull back the pin ⑥ in the direction of the arrow using your thumb and index finger and remove the ratchet wheel ①.

Preconditioning

Procedure / Preconditioning

Regardless of the cleaning method chosen, it is always necessary to preclean the torque ratchet. Hold the parts under cold mains water (drinking water quality, <40 °C / <104 °F) until all visible contamination has been removed. Use a soft brush to remove stubborn dirt. Rinse hollow sections with a water pistol (or similar) using cold mains water (drinking water quality, <40 °C / <104 °F) for more than 30 seconds.

Machine process – thermal disinfection

Proof of basic suitability of the instruments for effective automatic cleaning and disinfecting was provided by an independent, accredited test laboratory, recognized by the ZLG test laboratory (Central Authority of the Länder) (§15 (5) MDR) using a G 7835 CD washer disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany) and the cleaning agent neodisher® mediClean (Dr. Weigert GmbH & Co. KG, Hamburg, Germany). The procedure described was taken into account during the tests.

Washer disinfector and media

When selecting a washer disinfector, please ensure that

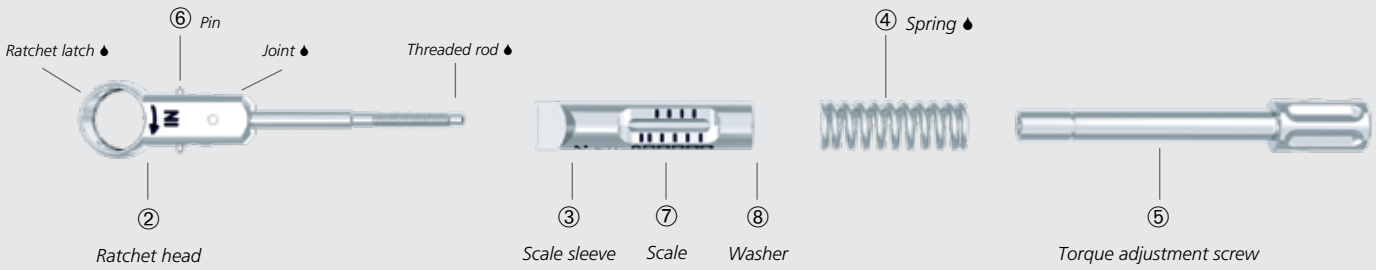
- its efficacy has been certified (e.g. DGHM or FDA approved/ clearance/registration or CE marking according to DIN EN ISO 15883),
- a certified program for thermal disinfection (A0 > 3000 or - for older appliances - minimum 5 mins at 90 °C / 194 °F) is used (with chemical disinfection there is the risk of disinfectant residue on the instruments),
- the program used is suitable for the instruments and has an adequate number of rinse cycles,
- only demineralized water is used for rinsing,
- the air used for drying is filtered (oil-free, low in particles and of low microbiological contamination), and,
- the appliance is regularly serviced and checked.

The material applications, concentrations, temperatures and reaction times given by the cleaning agent and disinfectant manufacturer along with instructions for rinsing should be strictly adhered to.

Machine-based cleaning / disinfection (→ RECOMMENDED)

The following parameters were used to prove the suitability (program: Des-Var-TD / washer disinfector Miele G7835 CD):

- The parts must be placed in the mobile injection unit (E450/1) on a tray
- Preclean 1 minute (cold mains water in drinking water quality <40 °C / <104 °F) → Drain water →Preclean 3 minutes (cold mains water in drinking water quality <40 °C / <104 °F)→Drain water
- Clean 10 minutes at 55±5 °C / 131±5 °F with 0.2% alkaline cleaning agent (0.2% Neodisher® MediClean) → Drain water
- Rinse 1 minute with demineralized water <40 °C / <104 °F →Drain water →Rinse 2 minutes with demineralized water <40 °C / < 104 °F → Drain water
- Automatic disinfection >5 minutes at 92±2 °C / 197.6±2 °F with demineralized water.
- Automatic drying program in washer disinfector at 90±2 °C / 194±2 °F, minimum 30 minutes (60±5 °C / 140±5 °F in rinsing area).



Procedure during (repeated) preparation:

• Place the instruments in the washer disinfector. Ensure that the instruments do not come into contact with one another.

• Start the program.

• Remove the instruments immediately when the program has finished; ensure the instruments are dry enough before packing.

• Check and pack the instruments, immediately after removal if possible.

Additional manual drying

Should it be necessary to dry the instruments manually, use a lint-free cloth and/or blast the lumens with sterile, oil-free compressed air.

Manual process

Proof of basic suitability of the instruments for effective manual cleaning and disinfecting was provided by an independent, accredited test laboratory, recognized by the ZLG (Central Authority of the Länder) (§15 (5) MDR) using the cleaning and disinfection agents named below. The procedure described was taken into account during the tests.

Manual cleaning

1. Place the products in an alkaline cleaner (e.g. 0.5 % neodisher® MediClean) in an ultrasonic bath for 10 minutes. A maximum temperature of 40 °C / 104 °F should not be exceeded. Follow the instructions of the manufacturer of the cleaning agent.

2. Clean the products with a soft brush. Rinse hollow sections and lumens intensively with a water pistol (or similar), if present (for more than 30 seconds).

3. Rinse the products under running mains water (drinking water quality) to remove the cleaning agent (>15 seconds).

Manual disinfection

1. Dip the products into a disinfectant that is listed by the Robert Koch Institute (RKI) or the Association for Applied Hygiene (VAH). Follow the instructions of the manufacturer of the disinfectant. It is important that the disinfectant reaches all areas of the product (move the parts around in the disinfectant solution; if necessary, use a syringe without needle to rinse obscure surfaces).

2. The following disinfectant provided proof of the efficiency of the process: 0.25% - 1.5 % Korsolex ® med AF (Bode Chemie, Hamburg) 15 minutes.

3. Rinse the products (full rinse on the inside, outside and in hollow areas)

Manual drying

1. Dry the products with a lint-free cloth for single use. To avoid moisture remaining in hollow areas, blast the areas with sterile, oil-free compressed air.

Monitoring

The best method to identify and remove defect instruments is by examining them and carrying out functional tests before and after each use. Specific functional areas (e.g. connection for adapter, torque initiator) and moving parts require special attention.

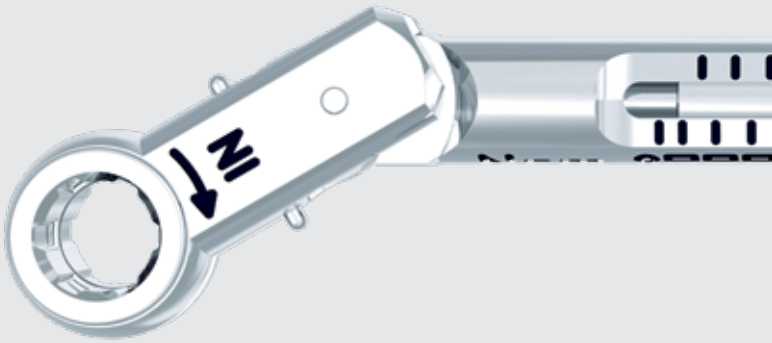
Allow the parts to cool down to room temperature. Parts with damaged surfaces, chippings, contamination, discoloration or corrosion must be removed. Discard any instruments that are deformed, worn in their functionality or otherwise damaged.

Instruments that are still contaminated should be cleaned and sterilized again.

Maintenance

If several torque ratchets are in use, do not interchange the individual parts. Each individual part belongs to one instrument.

Torque ratchet



Assembly

To assemble the torque ratchet correctly, connect the components in the following order: first pull back the pin ⑥ as described above and insert the ratchet wheel ①.

Caution: To avoid confusion, the ratchet wheel ① can only be inserted on one side.

Lubricating point (♦)

Lubricate the areas marked with the "drop" symbol lightly with maintenance oil for instruments.

Ensure that only instrument oils (paraffinic white oil without corrosion inhibitor or other additives) are used, which – depending on the maximum sterilization temperature used – are approved for steam sterilization and are certified as biocompatible. The oil should be used sparingly.

Reassemble the ratchet and perform a function test.

Slide the spring ④ back over the torque adjustment screw ⑤. Pass the ratchet head ② with the threaded rod through the scale sleeve ③ and screw to torque adjustment screw ⑤.

After assembly and before each use, check the correct function of the torque ratchet. If there is an audible regular ratchet noise and the mechanism of the torque limit functions, the instrument is ready for use.

After reassembly and before sterilization, the torque ratchet should be stress-relieved at max. 10 Ncm.

Sterilization

The products should be sterilized in suitable sterilization packaging. The manufacturer used two-fold sterilization packaging (standard for hospitals) for verification; it is therefore also possible to use suitable single-fold sterilization packaging.

Ratchet head, assembled.

Ratchet head, disassembled.

Flash sterilization or the sterilization of unpacked instruments is not permitted. Proof of basic suitability of the instruments for effective sterilization was provided by an independent, accredited test laboratory, recognized by the ZLG (Central Authority of the Länder) (§15 (5) MDR) using an Autoklav EHS3870 (Tuttnauer Europe B.V., Breda, NL), pre- and post-vacuum, and using sterilized packaging RB 51-3P and RB 52-3P (Steriking-foil). The procedure described above was taken into account during the tests. These specifications must be adhered to.

3 vacuum cycles | 132 °C / 270 °F | ≥ 1.5 minutes holding time | Dry under vacuum for at least 20 minutes[3]

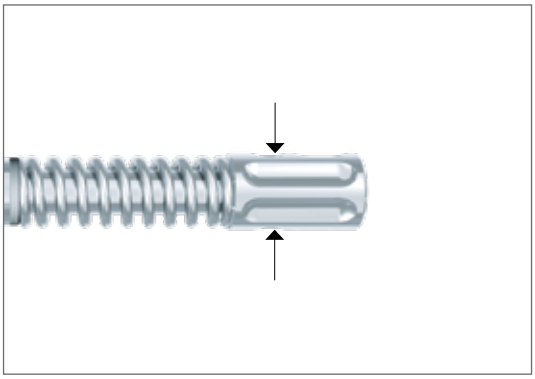
Sterilization process – Fractionated vacuum process

Only the following sterilization procedures should be used for sterilization.

Other sterilization procedures are not permitted; the dental professional must provide their own proof of efficiency if another procedure is taken.

- **Fractionated vacuum process[1;2] (with adequate product drying[3])**
- Steam sterilizer according to DIN EN 13060 / DIN EN 285 or ANSI AAMI ST 79 (for USA: FDA Clearance)
- Validated in accordance with DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance qualification (PQ))
- Maximum sterilization temperature 134 °C / 273 °F plus tolerance in accordance with DIN EN ISO 17665
- Sterilization time

Blocking function – „∞" mark.



Never loosen these screws as the ratchet will lose its torque function.

[1] Min. 3 vacuum stages
[2] Use of the less effective gravitation process is only permitted if a fractionated vacuum process is not available. The gravitation process requires much longer sterilization times which must be determined and validated for the specific instruments, equipment, procedure and parameters used at the responsibility of the dental professional in charge.
[3] The actual drying time required for the product depends directly on the parameters used, for which the dental professional alone is responsible (loading configuration and density, state of sterilization, ...) and which must therefore be determined by this person. Generally speaking, the drying time should not be less than 20 minutes.

Notes

Notes

Dentaurum

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