



Instructions for the reprocessing of pliers and instruments

These instructions apply to all Dentaurem pliers, instruments and rotary instruments that are approved for use on patients.

These instructions comply with the requirements of the latest version of DIN EN ISO 17664 and the Robert Koch Institute guidelines.

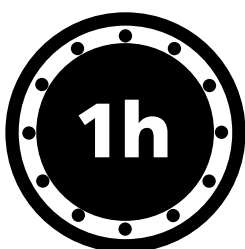
General requirements

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

During use, ensure that contaminated instruments are collected separately and are not placed back in the instrument tray to avoid greater contamination of the loaded instrument tray. Clean/disinfect the contaminated instruments. Then replace them in the instrument tray and sterilize the fully loaded instrument tray if necessary.

Should the dental professional and/or the patient become aware of serious problems arising from the use of the product, it is important that the manufacturer and the competent authority in the country in which the dental professional and/or the patient are resident is informed accordingly.

Manual reprocessing

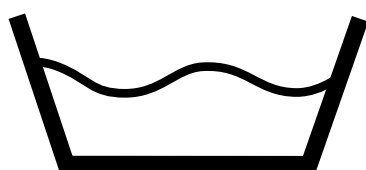


Surface contamination must be removed from pliers and instruments immediately after use, at the latest within one hour.

Rinse pliers and instruments under water and immerse in a disinfectant solution.

Use only a soft brush (nylon brush) or a clean soft cloth for manual removal of contamination.

Do not use metal brushes or steel wool.

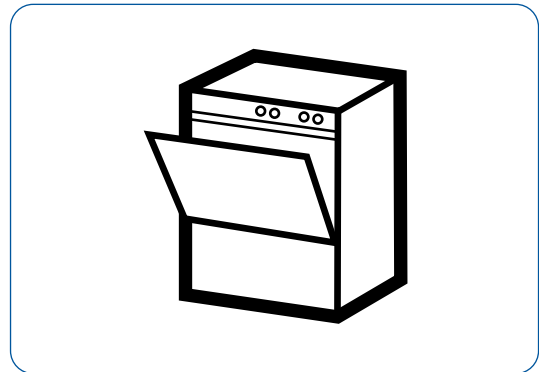


Disinfectants should be aldehyde-free (otherwise fixation of blood residue), have a certified efficacy (e.g. DGHM [German Society for Hygiene and Microbiology] or FDA approval or CE marking), be suitable for disinfecting instruments and compatible with the instruments.

Machine-based cleaning and disinfection

When using a disinfectant, make sure:

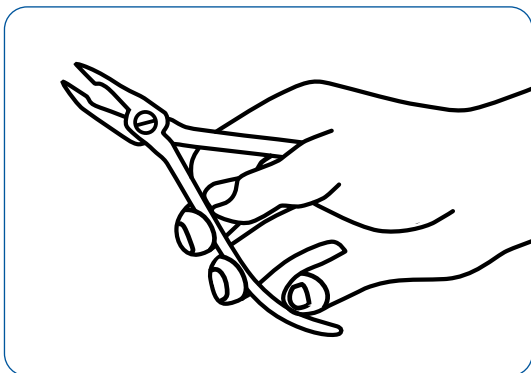
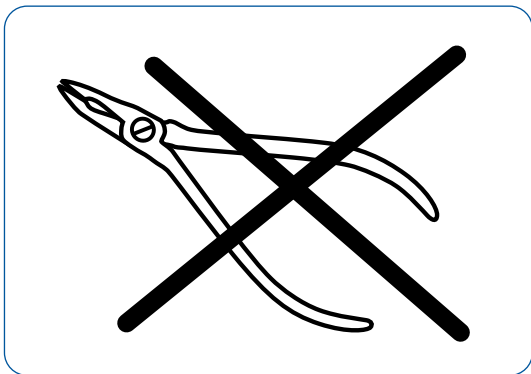
- the efficacy of the disinfectant has been certified (e.g. DGHM or FDA approved or CE marking according to DIN EN ISO 15883),
- a certified program for thermal disinfection (minimum 10 mins at 93°C/199°F or an $A_0 > 3000$) is used (with chemical disinfection there is the risk of disinfectant residue on the instruments),
- it uses 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) for rinsing, and
- the air used for drying is filtered.



When choosing a cleaning agent system, make sure:

- it is suitable for cleaning metal and plastic instruments,
- an additional disinfectant with certified efficacy (e.g. DGHM or FDA approved or 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.



Procedure

- 1 Dismantle the pliers and instruments as far as possible.
- 2 Place the disassembled, half-opened (hand-width) pliers and instruments in the disinfector. Pliers and instruments should not come into contact with one another.
- 3 Start the program.
- 4 Remove the pliers and instruments from the disinfector at the end of the program.
- 5 Check and pack the instruments, immediately after removal if possible.
- 6 **If the 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 machine-based 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, Germany). 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 pliers and instruments must be suitable for cleaning and disinfecting.
- the cleaning agent must be suitable for ultrasonic cleaning.
- use only disinfectants with certified efficacy (e.g. DGHM or FDA approval or CE marking). Disinfectants should be compatible with the cleaning agent used.

Combined cleaning agents/disinfectants should not be used if possible. Combined cleaning/disinfecting agents can only be used if there is minimal contamination (no visible contamination).

The concentrations and reaction times given by the cleaning agent and disinfectant manufacturer should be strictly adhered to. Use only freshly mixed solutions, only sterile or low-germ (max. 10 germs/ml) as well as low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) and only filtered air for drying.

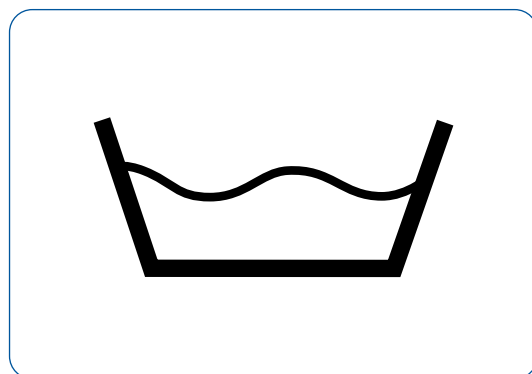
Cleaning procedure

- 1 Dismantle the pliers and instruments as far as possible.
- 2 Place the disassembled pliers and instruments half-opened (hand-width) into the cleaning solution for the prescribed reaction time; ensure that the pliers and instruments are adequately covered. Pliers and instruments should not come into contact with one another. Rinse all hollow sections in the instruments using a single-use syringe (minimum volume 5 ml) before and after the reaction time. Special holders, e.g. bur blocks, should be used if necessary.
- 3 Remove the pliers and instruments from the cleaning solution and rinse thoroughly with water.
- 4 **Check that the pliers and instruments have been properly cleaned.**

Disinfection procedure

- 1 Place the disassembled pliers and instruments in the disinfectant solution according to the prescribed reaction time. Ensure that the pliers and instruments are covered and are not in contact with one another. Rinse all hollow sections in the instruments using a single-use syringe (minimum volume 5 ml) before and after the reaction time.
- 2 Remove the pliers and instruments from the disinfectant solution and rinse thoroughly at least three times with water.
- 3 Do not pack the pliers and instruments until they are dry. Pack the dry pliers and instruments immediately.

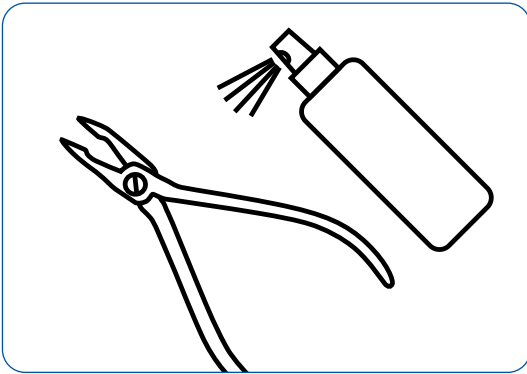
Proof of basic suitability for effective manual cleaning and disinfecting was provided by an independent, accredited test laboratory using Bodedex® forte cleaning agent and Korsolex® plus disinfectant (Bode Chemie, Hamburg, Germany). The procedure described above was taken into account during the tests.



Check

Check all pliers and instruments after cleaning or cleaning/disinfecting for corrosion, damaged surfaces, chipped areas or contamination and separate damaged pliers and instruments. Pliers and instruments that are still contaminated must be cleaned and disinfected again.

Pliers and instrument care



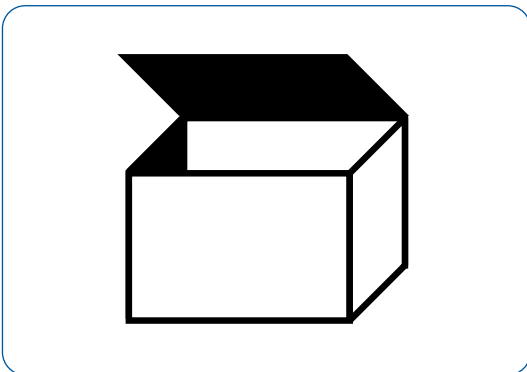
General:

Instrument oil should not be used if possible. If it has to be used, however, ensure that only instrument oils (white oil) that are approved for steam sterilization and have certified biocompatibility are used – taking into account the maximum sterilization temperature.

Pliers:

Following drying and before sterilization, plier jaws, locks, sliding surfaces for springs and other critical surfaces must be conditioned with medical white oil, which is steam permeable and temperature resistant. The oil protection on the extra-hard plier inserts reduces the risk of corrosion. We recommend cleaning/protective oil (white oil) for pliers and instruments (REF 055-201-00).

Packaging



Pack the pliers and instruments or sterilization tray in a single-use sterilization pack (single or double packaging) and/or sterilization container, which comply with the following requirements:

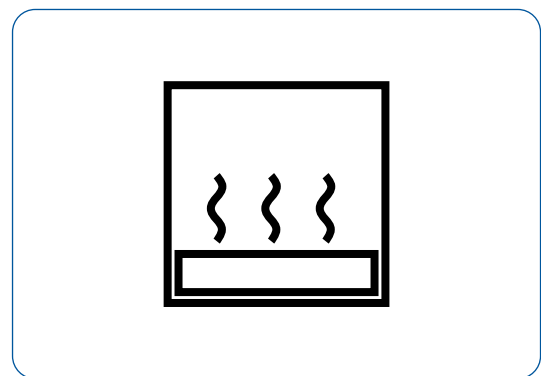
- DIN EN ISO/ANSI AAMI ISO 11607-1/2 (formerly: DIN EN 868/ANSI AAMI ISO 11607)
- suitable for steam sterilization (temperature resistant to min. 134 °C/273 °F and adequate steam permeability)
- adequate protection of pliers and instruments and sterilization packaging against mechanical damage
- regular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

Sterilization

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

Steam sterilization

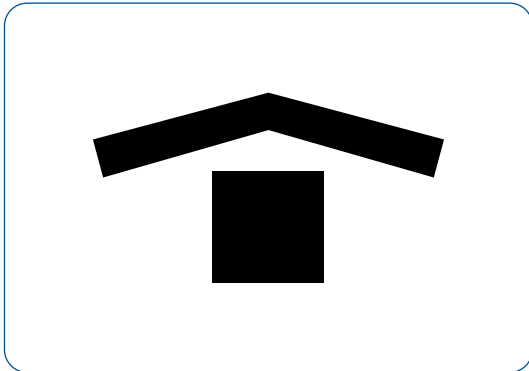
- fractional vacuum or gravitation process* (with adequate product drying)
- steam sterilizer according to DIN EN 13060-2004 and DIN EN 285
- validated (valid commissioning and product-specific performance evaluation) in accordance with DIN EN ISO/ ANSI AAMI ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134)
- 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



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 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.

* Use of the less effective gravitation process is only permitted if a fractional vacuum process is not available.

Storage



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

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, neutral/enzymatic cleaner recommended)
- strong alkali solutions
- organic solvents (e.g. alcohols, ethers, ketones, benzines)
- oxidation agents (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons
- salts of heavy metals

Never clean pliers and instruments, sterilization and tomas® trays with metal brushes or steel wool.
Do not expose pliers and instruments, sterilization and tomas® trays to temperatures above 134°C/273°F !

Reusability

All rotary instruments can be reused up to 5 times. The operator bears responsibility for any further reuse or use of damaged and/ or contaminated rotary instruments.

Special instructions regarding Dentaurem pliers and instruments

Pliers:

- only pretreat in half-opened (hand-width) position (open and close several times when conditioning)
- clean
- disinfect
- after each cleaning process, apply oil to plier jaws, locks, sliding surfaces for springs and other critical areas of the pliers using the cleaning/protective oil (white oil) for pliers and instruments (REF 055-201-00)
- pack and sterilize

















Note: The oil protection on the extra-hard plier inserts reduces the risk of corrosion.

Product group Instruments:

The ligator (and its individual parts) must always be cleaned and disinfected by machine.
















Overview of pliers/ instruments

The overview contains all pliers and instruments approved for use on patients. The processing instructions given should be adhered to, unless directed otherwise. Further information is included in the respective Instructions for use; refer to www.dentaurum.com, leaflets and Orthodontics catalog.

| Designation | REF |
|--|------------|
|  Nance loop bending pliers, EQ-Line | 000-001-00 |
|  Needle holder Medium Clean and disinfect in the open position, sterilize in the first lock. | 000-030-00 |
|  Needle holder Mini Clean and disinfect in the open position, sterilize in the first lock. | 000-031-00 |
|  Needle holder Medium with finger ring Clean and disinfect in the open position, sterilize in the first lock. | 000-035-00 |
|  Mosquito forceps without hook Clean and disinfect in the open position, sterilize in the first lock. | 000-730-00 |
|  Mosquito forceps with hook Clean and disinfect in the open position, sterilize in the first lock. | 000-731-00 |
|  Mosquito forceps, curved Clean and disinfect in the open position, sterilize in the first lock. | 000-732-00 |
|  Nance loop closing pliers, Premium-Line | 001-002-00 |
|  Lingual bending pliers, Premium-Line | 003-001-00 |
|  Band seater Do not use alkaline/acid cleaners. | 003-006-00 |
|  How pliers, curved, Premium-Line | 003-111-00 |
|  How pliers, straight, Premium-Line | 003-112-00 |
|  Johnson contouring pliers, Premium-Line | 003-114-00 |
|  Weingart universal pliers, Premium-Line | 003-120-00 |
|  Weingart universal pliers Mini, Premium-Line | 003-121-00 |
|  Jarabak Light Wire pliers, Premium-Line | 003-125-00 |
|  Light Wire pliers, Premium-Line | 003-130-00 |

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|  | Angle wire bending pliers Standard, Premium-Line | 003-139-00 |
|  | Facebow bending pliers Magnum, Premium-Line | 003-180-01 |
|  | Lingual arch bending pliers, Premium-Line | 003-185-00 |
|  | Anderer 3-Prong pliers Extra-Mini, Premium-Line | 003-205-00 |
|  | Bracket removing pliers, Premium-Line Remove the insert for cleaning and disinfecting. | 003-349-00 |
|  | Hollow chop pliers Extra-Mini, Premium-Line | 003-350-00 |
|  | Loop forming pliers Mini, Premium-Line | 003-351-00 |
|  | Hammerhead pliers, Premium-Line | 003-355-00 |
|  | Angle/Tweed ribbon arch pliers, Premium-Line | 003-442-00 |
|  | Distal end cutter Maxi, Premium-Line | 003-700-00 |
|  | Distal end cutter Mini, Premium-Line | 003-701-00 |
|  | Distal end cutter Mini with longer handle, Premium-Line | 003-702-00 |
|  | Distal end cutter, lingual | 003-703-00 |
|  | Flush Cutter Mini with silicone O-ring, Premium-Line Remove silicone O-Ring for cleaning, disinfecting and sterilizing. | 003-705-00 |
|  | Flush Cutter Maxi with silicone O-ring, Premium-Line Remove silicone O-Ring for cleaning, disinfecting and sterilizing. | 003-706-00 |
|  | Crimping pliers for Herbst TS/SUS, Premium-Line | 003-710-00 |
|  | Crimping pliers, Premium-Line | 003-711-00 |
|  | Ortho-Cast M-Series cap removal pliers, Premium-Line Remove the blade for cleaning and disinfection; sterilize when the blade has been put back into place. | 003-805-00 |
|  | De La Rosa contouring pliers, Premium-Line | 004-109-00 |
|  | Begg Light Wire pliers, Premium-Line | 004-130-00 |
|  | Angle wire bending pliers, Premium-Line | 004-139-00 |
|  | Side cutter Maxi, Premium-Line | 004-266-00 |
|  | discovery® pearl debonding instrument | 019-001-00 |
|  | Bracket removing pliers, straight, Premium-Line | 004-346-00 |
|  | Bracket removing pliers, angled, Premium-Line | 004-347-00 |
|  | Bracket removing pliers, Premium-Line Remove the insert for cleaning and disinfecting. | 004-349-00 |

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|---|--|-------------------|
|  | Special bracket debonding pliers, 45° angled, Premium-Line | 004-350-00 |
|  | Tweed loop forming pliers, Premium-Line | 012-350-00 |
|  | Tweed loop forming pliers with individually replaceable hard metal tip, Premium-Line Remove the insert for cleaning and disinfecting. | 012-351-00 |
|  | Ligature cutter Mini, Premium-Line | 014-151-00 |
|  | Ligature cutter 45°, Premium-Line | 014-152-00 |
|  | Ligature cutter, lingual | 014-153-00 |
|  | Ligature cutter | 014-154-00 |
|  | Double beak pliers, Premium-Line | 015-157-00 |
|  | Ligature forming pliers, Premium-Line | 015-158-00 |
|  | Separating pliers, Premium-Line | 015-160-00 |
|  | Side cutter Medium, Premium-Line | 016-153-00 |
|  | Separating strip holder Remove the separating strip before cleaning, disinfecting and sterilizing. | 018-000-00 |
|  | Distal end bender, double-ended | 019-000-00 |
|  | Ligature adapter, double-ended | 021-273-00 |
|  | Ligature tightener and adapter | 022-274-00 |
|  | LinguBall instrument | 023-275-00 |
|  | sl-instrument, gold | 023-276-00 |
|  | sl-instrument, silver | 023-277-00 |
|  | Positioning tool, lingual | 023-278-00 |
|  | Dental mirror with reference lines (assembled), lingual Fully disassemble for cleaning and disinfecting | 023-279-00 |
|  | Dental mirror with reference lines (without grip), lingual | 023-279-10 |
|  | Ligator Completely disassemble for cleaning and disinfecting; remove the wire from the guidance. The ligator and its individual parts must always be cleaned and disinfected by machine. | 023-292-00 |
|  | Ligator Completely disassemble for cleaning and disinfecting; remove the wire from the guidance. The ligator and its individual parts must always be cleaned and disinfected by machine. | 023-288-00 |
|  | Ligator Completely disassemble for cleaning and disinfecting; remove the wire from the guidance. The ligator and its individual parts must always be cleaned and disinfected by machine. | 023-284-00 |
|  | Band pusher | 024-300-01 |
|  | Mershon band pusher | 024-300-00 |








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|  | Crimping tweezers, with long placement and angulation aid Blow dry the joint gap after reprocessing (e.g. with compressed air gun). | 025-276-00 |
|  | Crimping tweezers, delicate design Blow dry the joint gap after reprocessing (e.g. with compressed air gun). | 025-277-00 |
|  | Crimping tweezers, for posterior teeth Blow dry the joint gap after reprocessing (e.g. with compressed air gun). | 025-279-00 |
|  | Crimping tweezers, delicate tweezer design Blow dry the joint gap after reprocessing (e.g. with compressed air gun). | 025-280-00 |
|  | Oliver-Jones band removing pliers, Premium Line Remove the insert for cleaning and disinfecting. | 026-347-00 |
|  | Molar band seater, with replaceable plastic head and hard metal triangular tip Do not use cleaning agents or disinfectants that contain solvents. Unscrew the head before cleaning and disinfecting. | 026-354-00 |
|  | Molar band seater, plastic Do not use disinfectants that contain solvents. | 026-355-00 |
|  | Scaler, double-ended | 027-349-00 |
|  | Bracket positioning gauge, with metal tips | 030-390-00 |
|  | Ruler | 044-730-01 |
|  | Angle/Tweed ribbon arch pliers, EQ-Line | 045-000-00 |
|  | Tweed loop forming pliers, EQ-Line | 045-001-00 |
|  | Angle wire bending pliers, EQ-Line | 045-002-00 |
|  | Weingart universal pliers, EQ-Line | 045-003-00 |
|  | Oliver-Jones band removing pliers, EQ-Line Remove the insert for cleaning and disinfecting. | 045-004-00 |
|  | Bracket removing pliers, EQ-Line Remove the insert for cleaning and disinfecting. | 045-005-00 |
|  | How pliers, straight, EQ-Line | 045-006-00 |
|  | Jarabak Light Wire pliers, EQ-Line | 045-009-00 |
|  | Nance loop bending pliers, EQ-Line | 045-010-00 |
|  | Distal end cutter, EQ-Line | 045-021-00 |
|  | Side cutter Medium, EQ-Line | 045-022-00 |
|  | Eby band seater Fully disassemble for cleaning and disinfecting: unscrew the tip; unscrew the sleeve from the handle; remove the hammer and spring Only sterilize the tip. | 051-023-00 |
|  | Lip retractor, large Reprocessing: max. 50 x; cleaning/disinfecting: only use cleaning and disinfecting agents suitable for polycarbonate and observe the manufacturer's instructions; sterilization: steam sterilization, 121 °C/249.8 °F, holding time 15 mins | 075-600-00 |
|  | Lip retractor, small Reprocessing: max. 50 x; cleaning/disinfecting: only use cleaning and disinfecting agents suitable for polycarbonate and observe the manufacturer's instructions; sterilization: steam sterilization, 121 °C/249.8 °F, holding time 15 mins | 075-601-00 |
|  | tomas®-screwdriver Fully disassemble for cleaning and disinfecting. Sterilize fully assembled. | 302-004-10 |
|  | tomas®-applicator | 302-004-20 |

| Designation | REF |
|---|------------|
|  tomas°-applicator, long version | 302-004-70 |
|  tomas°-wheel | 302-004-30 |
|  tomas°-torque ratchet Fully disassemble for cleaning and disinfecting. | 302-004-40 |
|  tomas°-driver | 302-004-50 |
|  tomas°-driver, long version | 302-004-60 |
|  Manually turned unit mod. acc. to Pauls Fully disassemble for cleaning and disinfecting. Sterilize fully assembled. | 302-004-81 |
|  tomas°-stop screw | 302-013-01 |
|  tomas°-tool tray | 302-156-00 |
|  tomas° PI-reusable punch | 303-210-10 |
|  tomas° PI-round drill | 303-220-00 |
|  tomas° PI-lance drill | 303-230-00 |
|  tomas° PI-pre drill 2.0 | 303-240-20 |
|  tomas° PI-final drill 3.4 | 303-204-34 |
|  tomas° PI-depth gauge | 303-240-54 |
|  tomas° PI-driver 2.5 | 303-310-00 |
|  tomas° PI-applicator | 303-320-00 |
|  tomas° PI-torque ratchet Fully disassemble for cleaning and disinfecting. Sterilize fully assembled. | 303-330-00 |
|  tomas° PI-wheel | 303-340-00 |
|  tomas° PI-lock key | 303-350-00 |
|  tomas° PI-driver 1.3 | 303-360-00 |
|  tomas° PI-guide sleeve | 303-500-10 |
|  tomas° PI-trepan | 303-500-20 |
|  tomas° PI-tool tray | 303-010-10 |
|  Hexagon socket key 0.9 | 607-129-00 |
|  Hexagon socket key 1.5 | 607-144-00 |

Designation**REF**

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|---|-----------------------------------|-------------------|
|  | Expansion screw key, large | 611-116-00 |
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Rotating instruments**REF**

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|---|---|----------------------------------|
|  | tomas®-drill SD 1.1, short pilot drill | 302-103-00 |
|  | Carbide burs, coarse | 123-603-00 123-603-30 |
|  | Carbide burs, fine | 123-604-00 123-604-30 |
|  | Adhesive residue remover, conical shaped | 123-700-00 |
|  | Adhesive residue remover, wheel | 123-701-00 |
|  | Adhesive residue remover, pear shaped, large | 123-702-00 |
|  | Adhesive residue remover, pear shaped, small | 123-703-00 |

References

Further tips on the correct reprocessing of pliers and instruments in the practice and laboratory are provided by the "Instrument Reprocessing Working Group" in its "Yellow Brochure".

www.a-k-i.org

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