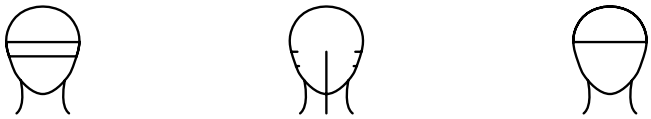
PMS
Precision Medical Specialities

INSTRUCTIONS FOR USE & STERILIZATION FOR INSTRUMENTS



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Processing (cleaning, disinfection and sterilization)

General information
Please read these instructions carefully before using the PMS reusable surgical instruments.

Prior to each use, all instruments must be cleaned, disinfected, sterilized and checked for proper functioning; this particularly applies to the first use after delivery, since PMS instruments are generally delivered non-sterile.

We manufacture our instruments as standard instruments for surgery on/in the eye, microsurgery and general surgery. However, the treating physician is responsible for the selection of instruments for specific applications or surgery. The physician is also responsible for providing adequate training and information to the operating room personnel and must have sufficient experience in handling the equipment.

Within the scope of your responsibility for the sterility of the instruments during use, please ensure that only device-specific and product-specific methods which have been sufficiently validated for cleaning/disinfection and sterilization are used, that the equipment used (disinfector, sterilizer) is regularly maintained and checked and that the validated parameters are compiled with in each cycle.

Please also observe the legal regulations applicable in your country as well as the hygiene regulations of the medical practice or hospital. This applies in particular to the different specifications regarding an effective prion inactivation.

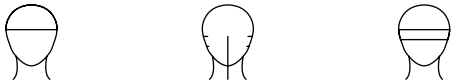
The working ends of instruments (cutting edges, tips, etc.) are highly sensitive to mechanical contact; for this reason, during manipulation and especially during cleaning and during storage, it is necessary to avoid that the instruments touch each other or come into contact with other hard materials.

Cleaning and disinfection
Effective cleaning and disinfection is an indispensable prerequisite for effective sterilization.

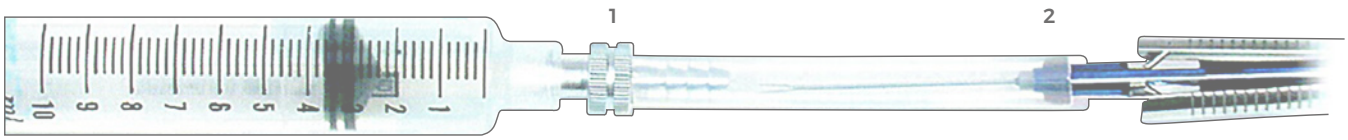
Basics
In principle, a mechanical method should be used to process the instruments used. Due to their design, however, not all instruments can be processed mechanically without manual pre-cleaning, since residual contamination remains in non-visible areas, i.e. joints, tube shafts and gaps. Pretreatment in recommended in both cases.

Pretreatment
Remove surface soiling with a disposable cloth / paper towel. Immediately after use (within a maximum of 2 hours), coarse contamination must be removed from the instruments. To do this, use running water or a cleaning solution; the cleaning agent should be compatible with the instruments.

If instruments are dismountable, disassemble them before processing. Make sure that scissors, clamps, needle holders, and other forcipate tools are open during cleaning / sterilization.



Manual pre-cleaning (always before manual and automatic cleaning)



1. Pre-cleaning products
Pre-cleaning with flushing unit

- After use, push the flushing unit onto the working end.
- Rinse the working end with demineralized water at least 2-3 times.
- Then rinse the working end with isopropyl alcohol to remove the residual water.
- Remove alcohol residues by injecting air with a syringe 1-2 times.

2. Rinse products under running cold tap water (<40 °C) until all visible contamination has been removed. Stubborn dirt should be removed with a soft brush. Cavities, lumens are to be rinsed intensively (> 60 sec) with cold tap water (<40 °C) using a water pressure gun (or similar).

A) Manual cleaning/disinfection
For the instruments of group 1 with simple design (Critical A) according to the RKI guideline, manual cleaning and disinfection as described below is sufficient.

- Immediately after use, clean the instruments with a soft cloth, sponge and suitable soft brushes by immersing them in a cleaning solution.
- The cleaning solution used must be suitable for cleaning steel, titanium and aluminum products.
- Observe the concentration of the cleaning solution and the exposure time according to the manufacturer's instructions; the cleaning agent should be a non-foaming solution.
- Take the instruments out of the cleaning solution using disposable gloves. Thoroughly rinse channels and cavities with water or wet steam.
- After rinsing with clear, running water, dry them thoroughly.

Mechanical cleaning / disinfection effectively complements mechanical processing. Nevertheless, machine cleaning and disinfection are recommended due to the significantly better effectiveness and reproducibility.

A-1) Manual cleaning process

- Immerse the products in an alkaline cleaner (0.5% neodisher® MediClean forte) in an ultrasonic bath with a sonication time of 10 min. and a frequency of 35 kHz. Follow the instructions of the cleaning agent manufacturer.
- Thoroughly clean products with a soft brush. Thoroughly rinse (> 30 sec) cavities and lumens, if any, using a water pressure gun (or similar).
- Rinse the products under running tap water to remove the cleaning agent (> 15 sec).

A-2) Manual disinfection

- Immerse the products in one of the disinfectants listed in the RKI or VAH list in an ultrasonic bath. Follow the instructions of the disinfectant manufacturer. It must be ensured that the disinfectant reaches all areas of the product. Cavities, lumens, gaps and slots should be thoroughly rinsed with the disinfectant using a syringe and a fine cannula (3 x 10 ml).
- The process is validated using the following disinfectant: 3% Korsolex Plus, 15 minutes.
- Rinsing of the products (complete rinsing inside, outside and cavities) in deionized water > 15 sec.

A-3) Manual drying
Manual drying with a lint-free disposable cloth. In order to avoid water residues in cavities, it is recommended to blow them out with sterile, oil-free compressed air.

B) Automatic cleaning / disinfection
When selecting the disinfector (RDG), it should be ensured

- that the disinfector has been tested for effectiveness (e.g. DGHM or FDA approval or CE marking according to DIN EN ISO 15883),
- that, if possible, a tested thermal disinfection program (at least 10 minutes at 93 °C or A0 value> 3000) is used,
- that the program used is suitable for the instruments and contains a sufficient number of rinsing cycles,
- that only sterile or germ-free (max 10 germs / 10 ml) and low-endotoxin (max 0.25 endotoxin units / ml) water is used for final rinsing,
- that the air used for drying is filtered, and
- that the disinfector is regularly maintained and checked.

When selecting the cleaning agent system used, it should be ensured

- that it is basically suitable for the cleaning of instruments made of steel, aluminum alloy, titanium and silastic materials,
- that - provided no thermal disinfection is used - a suitable disinfectant with proven effectiveness (for example DGHM or FDA approval or CE marking) is additionally used and that is compatible with the cleaning agent used,
- that the chemicals used are compatible with the instruments

The concentrations specified by the manufacturer of the cleaning agent and, if applicable, of the disinfectant must be strictly adhered to.

Procedure:
- Insert the instruments into the disinfector. Make sure that the instruments do not touch.
- Close the machine, select and start the program.
- Open the disinfection device, remove the instruments with disinfected hands or using disposable gloves.
- Dry channels and cavities with compressed air; if necessary, dry the instrument with a lint-free cloth
- Check and pack the instruments as soon as possible after removal; after additional drying in a clean place, if necessary.

B-1) Automatic cleaning process (Miele G 7835 CD) (after manual pre-cleaning)
- 1 min. pre-cleaning with cold tap water <40 °C
- Water drainage
- 3 min. pre-cleaning with cold tap water <40 °C
- Water drainage
- 5 min. cleaning at 55 °C ± 5 °C with 0.5% alkaline cleaning agent (0.5% neodisher® Mediclean forte)
- Water drainage
- 3 min neutralization (neodisher® Z, 0.1%) with warm tap water (> 40 °C)
- Water drainage
- 2 min. rinsing with deionized water (> 40 °C)
- Water drainage

The special instructions of the manufacturer of the cleaning machine are to be observed

B-2) Automatic disinfection (Miele G7835 CD)
Mechanical thermal disinfection in a cleaning and disinfection device, taking into account the national requirements for the A0-3000 value; > 5 minutes at 92 °C ± 2 °C.

B-3) Automatic drying
Automatic drying according to the automatic drying process of the cleaning and disinfection device 30 minutes at 60 °C ± 5 °C; if necessary, additional manual drying with lint-free cloth and lumen insufflation with sterile, oil-free compressed air.



Check
After cleaning or cleaning / disinfection, check the instruments for corrosion, damaged surfaces, chipping, soiling as well as proper functioning. After cleaning, no dirt particles, encrustations, deposits or films should be visible with normal or corrected vision at 10x magnification. Instruments which are still contaminated must be cleaned and disinfected again.

Visibly damaged instruments with cracks in the surface and on the fastener, or with dents or nicks on the cutting edges, must be sorted out. Return damaged instruments to the manufacturer for repair. Prior to shipment, the instruments must be cleaned, disinfected and / or sterilized.

Maintenance
No instrument oils should be used, if possible. Nevertheless, if you want to use them (for example joint, screw and sliding constructions), these instruments must be treated with a special physiologically harmless surgical oil (paraffin oil) on the hard-to-reach and hidden surfaces prior to sterilization; this oil, amongst other things, is approved for steam sterilization and has been tested for biocompatibility - provided that the max. sterilization temperature is observed.

Packaging
The instruments should be packed before sterilization in a suitable container or sterilization packaging in accordance with DIN EN ISO 11607, Part 2. In practice, the following packages are referred to as sterile barrier systems (SBS):

- Bags and sacks closed by sealing
- Closed, reusable containers
- Folded sterilization wrap

The sterilization packaging depends on the sterilization procedure, the transport and the storage. The packaging must be chosen so that the products fit into the packaging, do not touch each other and are sufficiently protected against manipulation and mechanical damage.

The traditionally used instrument tray or sieve is by no means suitable for microsurgical instruments and ophthalmic instruments. The ideal container must be made of metal-friendly materials and arranged in such a way that it can be equipped with silicone inserts (mats, plates, press-on bars) so that the delicate instruments do not touch and do not hit the sensitive working ends.

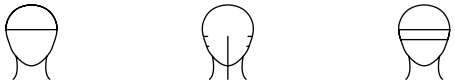
Sterilization
Steam sterilization is also effective for instruments designed in such a way that they are difficult to reach, does not use hazardous substances and is toxicologically safe. We recommend the following sterilization procedures for the sterilization of instruments.

Steam sterilization
- Fractionated vacuum process (at least 3 pre-vacuum cycles)
- Steam sterilizer according to DIN EN 13060 or DIN EN 285
- Validated according to EN 554, today EN ISO 17665-1:2006
- Sterilization time (exposure time at sterilization temperature) is 5 min at 134 °C (possibly at least 15 min at 121 ° C) and 3 bar overpressure.
- Drying for at least 20 minutes
- After sterilization, check the sterile packaging for integrity
- Regularly check sterilizers with bioindicator

Use a sterilization indicator for the packaging and note the sterilization and expiry date. An additional security seal protects them from being taken out improperly and guarantees sterility until the moment they are used.

Do not use hot air, radiation or plasma sterilizers to sterilize anodized aluminum and titanium instruments, as the coated surfaces may be destroyed or worn away and then look unsightly.

Note
It is the sole responsibility of the person in charge of processing that the processing actually carried out with the equipment, materials and personnel used in the processing facility achieves the results desired by the legislator. This usually requires validation and routine monitoring of the process.



Storage
After sterilization, the instruments in the sterile packaging must be stored - if possible - in a closed cabinet protected from dust, moisture and temperature fluctuations.

Reusability
With corresponding care and as long as the instruments are undamaged and not soiled, PMS instruments can be reused several times.

Disposal
If the instruments can no longer be repaired, they should be disposed of according to the usual procedure used in the respective hospital.

Warranty
The products are made from high quality materials and undergo quality control prior to delivery. If, however, material or manufacturing defects occur, please contact our service department (Phone: +49 (0) 7461 13131, e-mail info@pms-tuttlingen.de). We cannot guarantee that the instruments are suitable for the specific operation. This must be determined by the user himself.

Liability
PMS GmbH, as the distributor of these products, assumes no liability for accidental or consequential damages caused by improper use and handling, in particular by non-observance of the instructions for use or by improper care or maintenance.

Statement of warranty
PMS Precision Medical Specialities GmbH is solely responsible for ensuring that every single product has been manufactured, inspected and packed with the utmost care. Since PMS has neither influence nor control over indications and / or applications, PMS cannot be held responsible for any complication or failure of an application. PMS single products and sets are compatible with each other. Nevertheless, the user is asked to ensure the compatibility of the products with each other before use. This applies especially if the user uses PMS products in combination with products of other manufacturers. Employees of PMS are not authorized to modify the aforementioned conditions or to extend liability or to enter into additional product-related commitments.

References
„Instrumenten-Aufbereitung richtig gemacht“ AKI (Arbeitskreis Instrumentenaufbereitung)
„Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten“ RKI (Robert Koch Institut)

For more information and help please contact:

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Attention!
If the instruments are used for patients with Creutzfeldt-Jakob disease or HIV infection, we decline any responsibility for reusability.