GEBRAUCHSANWEISUNG OPHTHALMISCHE INSTRUMENTE / ENGLISCH

KLASSE IR / IM

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PMS Präzisions Medizinische Spezialitäten GmbH
Kreuzstraße 5
78532 Tuttlingen
Germany

Contents

1 Instructions for use

1.1 Symbols for instructions for use and packaging / label

Symbol	Explanation	Symbol	Explanation
	Follow the instructions for use		Manufacturer
CE	CE mark	LOT	Batch designation
	Attention!		Product is supplied non-sterile

1.2 Important note

Read these instructions for use carefully before each use and
Keep them easily accessible for the user or the corresponding specialised personnel.

Read the warnings marked with this symbol carefully.
Improper use of the products can cause serious injury to the user.
patients, the user or third parties.

1.3 Area of application

The instruments may only be used for their intended purpose in the medical specialities by appropriately trained and qualified personnel. The attending physician or user is responsible for the selection of the instruments for specific applications or surgical use, the appropriate training and information and sufficient experience in handling the instruments.

1.4 Precautions and warnings

⚠ **Attention!**

- The medical devices are supplied non-sterile and must be cleaned, disinfected and sterilised before first use!
- Before each use, the instruments must be **checked** for breaks, cracks, bends, damage and functionality. The end of work areas and all moving parts must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged products must be discarded.
- Defective products must not be used and must have undergone the entire reconditioning process before being returned!
- Remove all protective covers and protective films before first use or preparation!
- The safe combination of the products with each other or of the products with implants must be checked by the user before clinical use!

- Avoid throwing or dropping instruments improperly!
- To avoid any contact corrosion, instruments with a damaged surface must be discarded immediately!
- If the products are used on patients with Creutzfeldt-Jakob disease or HIV infection, we decline all responsibility for reuse!

1.5 ⚠ Intended use

The products contained herein are instruments intended for cutting, separating, scraping, measuring, manipulating, grasping, blocking, suctioning and rinsing during eye surgery. The products included here are standard instruments.

1.5.1 Indication

Surgical eye instruments that are used to cut, scrape, split, separate, manipulate, grasp, lock tissue during eye surgery, as well as instruments for measuring, sucking and rinsing involving the iris.
In the case of instruments with a measuring function, certain measurements can be taken or a value can be set.

1.5.2 Contraindication

No contraindications are known to date

1.5.3 Patient group

There is no restriction here
The type of treatment must be determined in each individual case by the surgeon in collaboration with the internist and the anaesthetist.

1.6 Reading accuracy for instruments with a measuring function

For the instrument groups listed here with a measuring function, the scales are indicated with the following reading accuracy:

- Diamond knife µm
- Eye compass mm
- Measuring/marking spatula mm
- Jameson measuring instrument mm
- Scale mm/inches
- Incision marker mm
- Incision gauge mm
- Marker mm
- Scleral marker mm

1.7 Sterility

Delivery condition

The medical devices are supplied in a non-sterile condition and must be prepared and sterilised by the user in accordance with the following instructions before the first and each subsequent use.

1.8 Storage

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

1.9 Reusability

PMS instruments can be reprocessed up to 500 times and thus reused, provided they are undamaged and uncontaminated.

1.10 Service, repair and return transport

⚠ **Service and repair**

Do not carry out any repairs or modifications to the product yourself. Only authorised personnel of the manufacturer are responsible for and intended for this. If you have any complaints, claims or comments regarding our products, please contact us.

⚠ **Return transport**

Defective or non-compliant medical devices must have undergone the entire reprocessing process before being returned for repair/service. In addition, the medical devices must be labelled accordingly with "hygienically safe" or "not decontaminated".

1.11 Waste disposal

If the instruments can no longer be repaired, they should be disposed of in accordance with standard hospital practice.

1.12 Guarantee

The products are manufactured from high-quality materials and undergo quality control before delivery. Should material or manufacturing defects nevertheless occur, please contact our service department (phone: +49 (0) 7461 13131, e-mail info@pms-tuttlingen.de). However, we cannot guarantee that the instruments are suitable for the respective procedure. This must be determined by the user.

1.13 Liability

PMS GmbH, as the distributor of these products, accepts no liability for accidental or consequential damage caused by improper use and handling, in particular by failure to observe the instructions for use or by improper care or maintenance.

1.14 Guarantee declaration

PMS Präzisions Medizinische Spezialitäten GmbH is only responsible for ensuring that each individual product has been manufactured, inspected and packaged with the greatest possible care. As *PMS* has no influence or control over indications and/or applications, *PMS* cannot be held responsible for complications or the failure of an application. *PMS* individual

products and sets are compatible with each other. Nevertheless, the user is requested to ensure that the products are compatible with each other before use. This applies in particular if the user uses *PMS* products in conjunction with products from other manufacturers. Employees of *PMS* are not authorised to modify the aforementioned conditions or to extend liability or to enter into additional product-related obligations.

1.15 Reporting of Serious Incidents

All serious incidents that have occurred in connection with this product must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is located.

1.16 Reprocessing (cleaning, disinfection and sterilisation)

1.16.1 ⚠ *General information*

The instruments must be cleaned, disinfected, sterilised and checked for correct function before each use; this also applies in particular to the first use after delivery, as PMS instruments are generally supplied non-sterile.

As part of your responsibility for the sterility of the instruments during use, please always ensure that only sufficiently device- and product-specific validated procedures are used for cleaning/disinfection and sterilisation, that the devices used (disinfector, steriliser) are regularly maintained and checked and that the validated parameters are adhered to for each cycle.

The following guidelines should be observed:

- Recommendation of the AK “Quality” (70) Reprocessing of ophthalmologic medical devices [AK-Q-70 3-2011]

and

- Hygiene requirements for the reprocessing of medical devices Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) [Bundesgesundheitsblatt 2012 - 55:1244-1310]

Please also observe the legal regulations applicable in your country and the hygiene regulations of the doctor's surgery or hospital. This applies in particular to the different requirements regarding effective prion inactivation.

The working ends of instruments (cutting edges, tips, etc.) are highly sensitive to mechanical contact, which is why manipulation must be avoided at all costs, especially during cleaning and storage. This happens when the instruments touch each other or come into contact with other hard materials.

1.17 ⚠ Warnings

-City water to be used must be of drinking water quality.
-VE Water should be low in germs (<100 CFU/ml) and have an elect. conductivity <10 µS/cm have.
-Dismantle products before cleaning, if possible.

-Reassemble disassembled products before sterilisation.
No use of chloride-containing cleaning agents to avoid attacking the passive layer

1.18 ⚠ Place of use

Coarse soiling, residues of e.g. haemostatic agents, skin disinfectants and lubricants as well as corrosive medicines should be removed,
removed, if possible, before placing the instruments.
Wherever possible, dry disposal (moisturised, closed system) should be preferred. Residues must be prevented from drying!
Long waiting times before reprocessing, e.g. overnight or over the weekend, should be avoided for both types of disposal (<6 hours).

1.19 Cleaning and disinfection

Effective cleaning and disinfection is an essential prerequisite for effective sterilisation.

1.19.1 Basics

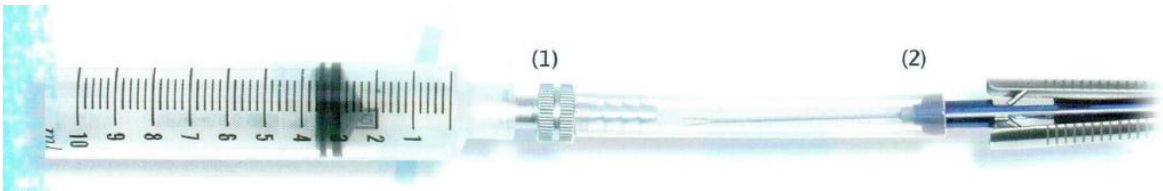
In principle, all sterile instruments used should be reprocessed mechanically. However, due to their design, not all instruments can be reprocessed by machine without manual pre-cleaning, as residual soiling remains, particularly in areas that are not visible, i.e. joints, tube shafts and crevices. Pre-treatment is recommended in both cases.

1.19.2 Pre-treatment

Remove surface soiling with a disposable cloth/paper towel. Immediately after use (within max. 2 h), coarse soiling must be removed from the instruments. Use running tap water (drinking water quality <40°C) or a detergent solution; the detergent should be compatible with the instruments.

If instruments can be disassembled, disassemble them before reprocessing. Ensure that scissors, clamps, needle holders and other forceps-like constructions are open during cleaning/sterilisation.

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



1. VR (vitreoretinal) products
Pre-cleaning with rinsing attachment

- After use, slide the rinsing attachment onto the working end.
- Rinse the end of work at least 2-3 times with 10 ml deionised water (<40°C).

- Then rinse the end of the work 2-3 times with 10 ml of 100% isopropyl alcohol to remove the water residue.
- Remove the alcohol residue 1-2 times with a syringe using air.

2. rinse the products under cold tap water (drinking water quality <40°C) until all visible dirt has been removed. Stubborn dirt should be removed with a soft brush. Cavities and lumens must be rinsed intensively (>60 sec) with cold city water (drinking water quality <40°C) using a pressurised water gun (or similar).

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

- After use, clean instruments immediately with a soft cloth, sponge and suitable soft brushes in a detergent solution.
- The cleaning solution used must be suitable for cleaning steel, titanium, aluminium and plastic materials.
- Observe the concentration and contact time of the cleaning solution according to the manufacturer's instructions; the cleaning agent should be a non-foaming solution.
- Remove instruments from the detergent solution using disposable gloves. Thoroughly rinse channels and cavities with tap water (drinking water quality <40°C) or wet steam.
- After rinsing with clear, running city water (drinking water quality <40°C), dry well.

Manual cleaning/disinfection effectively complements automated reprocessing. Nevertheless, automated cleaning and disinfection is recommended due to its significantly better effectiveness and reproducibility.

A-1) Manual cleaning process
- Soak 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 at <40°C. The instructions of the cleaning agent manufacturer must be followed
- Clean the products completely with a soft brush. Flush cavities and lumens, if present, intensively (>30 sec) with city water (drinking water quality <40°C) using a pressurised water gun (or similar)
- Rinsing the products under running city water (drinking water quality <40°C) to remove the cleaning agent (>15 sec).

A-2) Manual disinfection
- Immerse products in an RKI or VAH-listed disinfectant in an ultrasonic bath. The instructions of the disinfectant manufacturer must be followed. It must be ensured that the disinfectant really reaches all areas of the product. In the case of cavities, lumens, gaps and slits, these areas are carefully rinsed with the disinfectant using a syringe and a fine cannula (3 x 10 ml)
- The process is validated with the following disinfectant: 1% Bomix Plus, 15 minutes.

- Rinsing the products (complete rinsing inside, outside and cavities) in demineralised water (<40°C) >15 sec.

A-3) Manual drying

Manual drying with a lint-free disposable cloth. To largely avoid water residues in cavities, we recommend blowing them out using sterile, oil-free compressed air.

B) Automatic cleaning/disinfection

When selecting the disinfection washer-disinfector (WD), this must be taken into account,

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

This must be taken into account when selecting the cleaning agent system used,

- that they are generally suitable for cleaning instruments made of steel, aluminium alloy, titanium and plastic materials,
- that - if thermal disinfection is not used - a suitable disinfectant with tested effectiveness (e.g. DGHM or FDA approval or CE labelling) is also used and that this 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, the disinfectant must be strictly adhered to.

Procedure:

1. place the instruments in the disinfector. Ensure that the instruments do not touch each other.
2. close the machine, select and start the programme.
3. open the disinfector, remove the instruments with disinfected hands or fresh disposable gloves.
4. dry channels and cavities with compressed air; if necessary, dry the instrument with a lint-free cloth

5 Check and pack the instruments as soon as possible after removal; if necessary, after additional post-drying in a clean place.

B-1) Automatic cleaning process (WD according to EN ISO 15883-1,-2;): (after manual pre-cleaning)

- 1 min. pre-cleaning with cold city water (drinking water quality <40°C)
- Water drainage
- 3 min. pre-cleaning with cold city water (drinking water quality <40°C)
- Water drainage
- 5 min. cleaning at 55°C ± 5°C with 0.5% alkaline cleaning agent (neodisher® MediClean forte)
- Water drainage
- 3 min Neutralisation (neodisher® Z, 0.1%) with warm city water (drinking water quality >40°C)
- Water drainage
- 2 min. rinse with demineralised water (>40°C)
- Water drainage

The special instructions of the manufacturer of the cleaning machine must be observed

B-2) Automatic disinfection (washer-disinfector according to EN ISO 15883-1,-2;)

Automatic thermal disinfection in washer-disinfector, taking into account the national requirements for the A0 value; e.g. A0 value 3000;
>5 minutes at 92°C±2°C with deionised water

B-3) Automatic drying

Automatic drying according to the automatic drying process of the washer-disinfector 30 minutes at 60°C±5°C (programme parameters) If necessary, subsequent manual drying with a lint-free cloth and blowing out of lumens using sterile, oil-free compressed air.

1.19.4 Control

After cleaning or cleaning/disinfection, check the instruments for corrosion, damaged surfaces, chipping and soiling as well as correct function. After cleaning, no soiling, incrustations, deposits or films should be visible with normal or corrected vision at 10x magnification. Instruments that are still dirty must be cleaned and disinfected again.

Inspect visibly damaged instruments with cracks in the surface, on the closure, dents or nicks on the cutting edges. Send damaged instruments to the manufacturer for repair. The instruments must be cleaned, disinfected and/or sterilised before dispatch.

1.19.5 Maintenance

If possible, instrument oils should not be used. If use is nevertheless desired (e.g. joint, screw and sliding constructions), these instruments must be treated before sterilisation with a special physiologically safe surgical oil (paraffin oil) on the surfaces that are difficult to access and concealed, which is approved for steam sterilisation - taking into account the maximum sterilisation temperature used - and has been tested for biocompatibility. The paraffin oil must comply with the applicable pharmacopoeia and be physiologically safe in accordance

with the "German Pharmacopoeia" or "European Pharmacopoeia (Ph. Eur.)" or the "United States Pharmacopeia (USP)".

1.19.6 Packaging

The instruments should be packed in a suitable container or suitable sterilisation packaging in accordance with DIN EN ISO 11607 or DIN EN 868 before sterilisation. In practice, the following packaging is referred to as sterile barrier systems (SBS):

- Bags and tubes closed by sealing
- Sealed, reusable containers (reusable containers)
- Folded sterilisation wipes (wrapping)

The sterilisation packaging depends on the sterilisation process, transport and storage. The packaging must be selected so that the products fit into the packaging, do not touch each other and are adequately protected against tampering and mechanical damage.

The traditionally used instrument tray or sieve for indiscriminate storage is definitely not suitable for microsurgical instruments and ophthalmic instruments. The ideal container must be made of metal-friendly materials and be divided or fitted with silicone inserts (mats, plates, backrests) in such a way that the delicate instruments do not touch each other and the sensitive working ends do not come into contact.

1.19.7 Sterilisation

Steam sterilisation is also effective in instruments that are relatively difficult to access, does not use any hazardous substances and is toxicologically safe. We recommend the following sterilisation procedure for sterilising instruments.

Steam sterilisation

Sterilisation of the products using the fractionated pre-vacuum process (in accordance with DIN EN ISO 17665-1), taking into account the respective national requirements. Sterilisation of the medical devices must be carried out in suitable sterilisation packaging and has been validated with double-wrapped Steriking® film.
Sterilisation must be carried out using a fractionated pre-vacuum process with the following parameters:

- 134°C / 273,2°F,
- ≥5 minutes holding time,
- 3 pre-vacuum cycles
- Drying in a vacuum for at least 20 minutes
- Check the integrity of the sterile packaging after sterilisation
- Regularly check sterilisers with bioindicator

Use a sterilisation indicator for the packaging and note the sterilisation and expiry date on it. An additional safety seal protects against unauthorised removal and guarantees sterility until the time of use.

The autoclave manufacturer's instructions for use and the recommended guidelines for the maximum load of sterilisation material must be observed. The autoclave must be installed, maintained, validated and calibrated in accordance with the regulations.

Do not use hot air, radiation or plasma sterilisers for the sterilisation of anodised aluminium and titanium instruments, as the coated surfaces will be destroyed or eroded and may then look unsightly.

⚠**Hint**
The reprocessor is solely responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the results required by law. This normally requires validation and routine monitoring of the process

1.19.8 *Literature*

"Instrument reprocessing done right" AKI (Instrument reprocessing working group)
"Hygiene requirements for the reprocessing of medical devices" RKI (Robert Koch Institute)

1.19.9 For further information and assistance, please contact us:

Manufacturer and service address
Precision Medical Specialities GmbH
Kreuzstrasse 5
78532 Tuttlingen
Germany

Phone: +49 (0) 7461 13131
Fax: +49 (0) 7461 76698

E-mail: info@pms-tuttlingen.de
http:/www.pms-tuttlingen.de

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