

Recommendations by the Quality Task Group (40) Automated Processing of Ophthalmologic Instruments

Delicate microinstruments are used in ophthalmology. Up till now, the users and manufacturers of these medical devices therefore believed that only separate manual processing could be used.

The Task Force at the Robert Koch Institute classifies the fundus of the eye as belonging to the risk tissues, i.e. these tissues pose a risk of transmission of the prions causing vCJD. Therefore reliable cleaning and steam sterilisation must be conducted with validated processes as per the provisions of the Task Force. For reasons dictated by practicability and safety, all ophthalmologic instruments are processed in the same manner.

In the meantime, ophthalmologic instruments undergo automated processing both in medical practitioners' establishments and in the CSSD.

General Preconditions

- Trained staff with expertise and specialist qualifications
- Suitable premises, with clean and unclean side
- Quality management system
- Manufacturer's instructions or in-house guidelines

Special Preconditions (Instrument Protection) (Fig. 1 – 5)

- Special instrument storage systems for processing, transport, storage and use
- Containers
- Punched, silicone burled strips
- Silicone internal side corners to protect against impact
- Flat mesh trays with lid/cover
- Special containers for small, non-lumened components (corneal burr, lenses, trepans)
- Protective transport caps for delicate instruments
- Special loading trolley with connections for phaco handpieces and accessories, connection tubes should be replaced at regular intervals

Collection of Used Instruments and Precleaning by the User

- Removal of secretions, blood, lens residues, drug residues by rinsing in the direction of flow immediately after use
- Check integrity of instruments (microscope)
- Dismantle, if necessary
- Place carefully in transport system
- Always lift, carry and transport the transport containers horizontally
- Provide for vibration-free transport – make sure there are no uneven surfaces

Decontamination

- Organisational separation from instruments of other disciplines
- Decontaminate in suitable washer-disinfector (WD)
- No mixed loads, risk of blockage due to lint, paper fibres from container labels, etc.
- Run empty load before use, if necessary
- Check outflow trays
- Use filter systems as per manufacturer's instructions, if necessary (reduce rinsing pressure)
- If the WD is also being used for other disciplines, ensure that all instruments are properly prepared for processing, as there can be particle entrainment over many loads
- Do not place surgical shoes in the same WD!!

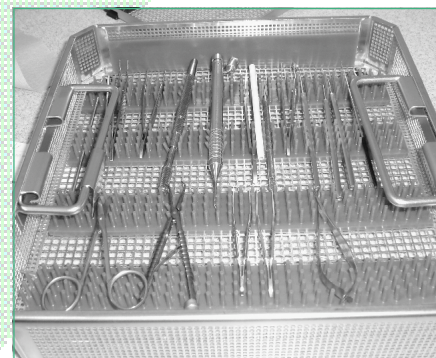


Fig. 1

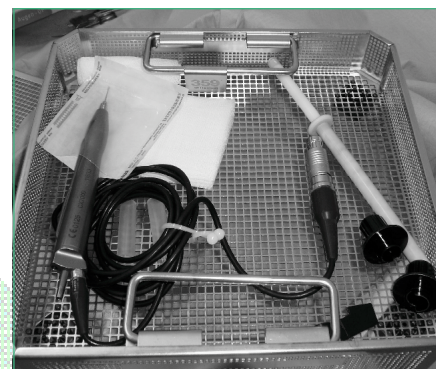


Fig. 2

Fig. 1 + 2: Examples for mesh trays

Precleaning by the user

Preconditions for decontamination

Process Chemicals

- Preference must be given to surfactant-free detergents
- If alkaline detergents are used, use neutralising agent immediately after cleaning
- Define number of subsequent rinses while bearing in mind the possibility of entrainment (check at the time of validation)
- Rinse with demineralised water, if necessary, final rinse < 5 µS
- Check pH value for control purposes
- Do not use any care or wetting agents
- If a neutral detergent is used, prolong steam sterilisation to 18 minutes

Requirements for process chemicals

Drying

- Drying is a precondition for reliable sterilisation
- Drying is conducted in either the WD or in a drying cabinet. To dry the channels or other lumens, medical compressed air (reduced pressure as per manufacturer's instruments) can be used
- Manual drying damages microinstruments

Drying

Inspection/Maintenance

- Functional test carried out in OR
- Avoid care agents

Inspection Maintenance

Packing

- Must be free of particles, i.e. non-linting (no cotton)
- Sterilise foil-packed individual instruments separately from other materials to avoid damage

Packing

Sterilisation

- For alkaline cleaning with pH > 10 134 °C 5 minutes,
- For cleaning with pH < 10 or manual decontamination 134 °C 18 minutes.

134° C – 5 minutes
134° C – 18 minutes

Routine Inspection

- The pH value of the last rinse water must be between pH 5 and 7.
- The conductance of the last demineralised water supplied must not exceed the specified limit value, e.g. 5 µS cm⁻¹.

Water quality
Conductance
pH value

Instrument Requirements

- There should be reliable facilities for connecting lumened instruments
- Materials should be amenable to alkaline processing

Instrument design

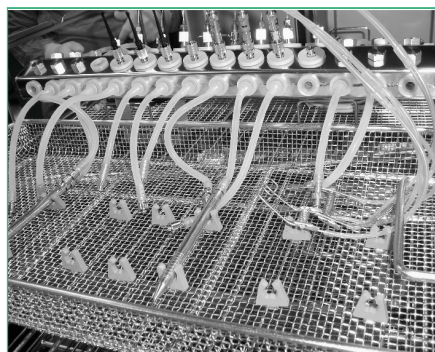


Fig. 3 – 5: Different loading trolleys with connections and adaptors for ophthalmologic instruments