Recommendations by the Quality Task Group (70)
Reprocessing ophthalmologic medical devices (Part 1)

1. Requirements

In ophthalmology the most commonly used devices are microsurgical instruments.

Validated reprocessing is stipulated in the Medical Devices Operator Ordinance.

Critical B instruments must be reprocessed using automated cleaning and disinfection followed by steam sterilisation according to the RKI recommendation.

The ocular fundus is categorised as risk tissue with regard to CJD/vCJD.

Ophthalmologic instruments should preferably be reprocessed using alkaline detergents in an automated validated process followed by steam sterilisation.

Filigree construction of ophthalmologic instruments necessitates special care.

2. General information for handling ophthalmologic instruments

Because of the filigree construction used in certain cases, special care is needed during cleaning, disinfection and sterilisation as well as transport of these instruments to prevent mechanical damage.
Experience has shown that mechanical damage can occur when handing such devices, in particular during manual reprocessing, because of inappropriate methods used for transportation or for loading them into the washer-disinfector (WD). Therefore all persons entrusted with the reprocessing of ophthalmologic instruments must undergo special training.

2.1 Preparation in the OR

Already at the site of use ➔ CERTAIN STEPS must be taken, e.g. rinsing and pre-cleaning especially of hollow instruments. In addition to protein residues, any traces of silicone oil, viscoelastics, tissues or drugs must be removed before they become dry and/or block the lumens.

- After use rinse out/aspirate hollow instruments and tubular instruments with liquid substances recommended by the instrument manufacturer. To flush out lumened instruments use distilled or demineralised water (< 10 cfu/ml) or other liquids as instructed by the instrument manufacturer. The ports for aspiration and/or irrigation lines should be rinsed 5 times in the direction of flow, using in each case 10 ml (7)
- Wipe off soils from external surfaces with a non-linting single-use cloth
- If necessary, dismantle instruments if this is possible
- If necessary, fit suitable protective caps
- Place instruments carefully in a suitable tray
- Remove any particle-emitting materials
- Secure by fitting an appropriate lid to the tray

All measures must be precisely set out in standard operating procedures.

2.2 Transport

To prevent mechanical damage ➔ SECURE TRAY SYSTEMS must be used for the entire medical device circuit from the time the instruments are used until they are reused. The ideal solution here is to use systems which, after transport, can also be used for pre-cleaning in an ultrasonic basin, for use in the WD and steriliser so as to avoid having to ➔ UNLOAD AND RELOAD the instruments.

- Place tray in a closed, secure transport system
- Dispatch as quickly as possible
- Avoid vibration during transport to prevent damaging the instruments
- Containers should be lifted horizontally and carried/transported by specially trained staff

2.3 Inspection

Visual inspection can be carried out in the Central Sterile Supply Department (CSSD) after reprocessing using magnifying instruments such as magnifying lamps, microscopes, etc. In this way it may be possible to detect any course soils or surface damage. Special instruments whose ➔ CHROMIUM OR NICKEL LAYER has peeled off (possibly older instruments) must be withdrawn since they can lead to discoloration or corrosion of stainless steel or titanium instruments.

On the other hand, many ➔ FUNCTIONAL TESTS can only be performed in the OR since e.g. a control device is needed for this purpose or the integrity and sharpness of cutting surfaces or the functional capabilities/absence of burrs on cutting instruments must be assessed. Any shortcomings in functional capabilities must be reported by the OR team.

2.4 Material inspection

Since all instruments should preferably be cleaned and disinfected in suitable washer-disinfectors using alkaline detergents and a validated process, a check must be carried out to establish whether the instruments in use lend themselves to such ➔ PROCESSES.

The medical device manufacturers must provide information in their documentation on processes whose suitability has been verified.

In a mult centre trial conducted in 2009, whose participants included the manufacturers of ophthalmologic instruments, process chemicals and washer-disinfectors, materials were tested under everyday conditions.
No material damage or surface changes were detected on instruments made of poly- 
oxymethylene (POM), polytetrafluoroethylene (PTFE), silicone or on instruments with 
brass coating or composed of titanium, stainless steel with material numbers 1.4301, 
1.4404, 1.4204, 1.4310, 1.4034 and 1.4401 on using alkaline detergents. Only in the 
case of colour anodised aluminium was fading of colour noted, and this was also seen 
for the series of tests carried out without a detergent (8). The manufacturers draw attention to the fact that surgical instruments made of stain-
less steel or titanium lend themselves in principle to a large number of reprocessing 
cycles, but point out that every chemical and thermal treatment will adversely affect 
and cause ageing of materials. Stainless steel instruments must not be exposed for long periods of time to chlorides (e.g. physiological saline or Ringer’s solution) since this could trigger pitting corrosion. 
Demineralised water must always be used for the ➜ FINAL RINSE to avoid deposits 
and marks on the medical instruments, because the latter can detract from the efficacy 
of the sterilisation process and lead to corrosion (9).
The water quality to be used for the final rinse in the WD is specified in the validation 
guideline (10).

2.5 Personnel training
The persons entrusted with medical device reprocessing must have the necessary ex-
pertise. This expertise is imparted in ➜ SPECIALIST TRAINING COURSES run at 
centres accredited by the German Society of Sterile Supply (DGSV) (www.dgsv-ev. 
de). Such expertise is needed, on the one hand, to ensure orderly reprocessing in line with 
quality assurance dictates and, on the other hand, to prevent damage to valuable 
instruments.

3. References
1 Norm DIN EN ISO 17664 Vom Hersteller zur Verfügung zu stellende Informationen zur Wied-
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7 Wiederaufbereitungsanleitung für Produkte der GEUDER AG (2007)
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beitskreis Instrumentenaufbereitung (AKI) unter Mitwirkung der Geuder AG: Prüfung alka-
lischer Reiniger zur maschinellen Aufbereitung augenchirurgischer Instrumente im Hinblick
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10 Leitlinie von DGKH, DGSV und AKI für die Validierung und Routineüberwachung maschin-
eller Reinigungs- und Desinfektionsprozesse für Medizinprodukte und zu Grundsätzen der 
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Remark
Part 2 will address manual and automated reprocessing as well as sterilisation, valida-
tion of processes, routine checks and special aspects of the media used.