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.

In ➜ **OPHTHALMOLOGY** the most commonly used devices are microsurgical instruments, most of which have lumens. Certain instruments that are particularly difficult to clean, e.g. Sauter cannulas with very narrow lumens, are now available on the market as single-use instruments. But many instruments continue to be supplied for reuse. The instrument manufacturer is obliged to provide detailed instructions for reprocessing. Standard DIN EN ISO 17664 (1) gives an overview of this topic.

➜ **VALIDATED REPROCESSING** is stipulated in the Medical Devices Operator Ordinance.

The Medical Devices Operator Ordinance (2) stipulates ➜ **VALIDATED REPROCESSING**, i. e. validated processes for cleaning, disinfection and sterilisation.

Medical devices that penetrate the skin or mucous membranes, thus coming into contact with blood, tissue or organs, which are inserted into a wound, have lumens or complex geometries (e. g. instruments with joints or closure mechanisms) must be classified as per the Recommendation by the Robert Koch Institute (RKI) (3) as ➜ **CRITICAL B INSTRUMENTS** and be reprocessed using automated cleaning and disinfection followed by sterilisation in a steam steriliser. In ophthalmology instruments with uncomplicated geometries are also used and these must be classified as critical A or semi-critical A (contact with mucosa).

➜ **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.

The ➜ **OCULAR FUNDUS** is categorised as risk tissue since it could harbour prions with the potential to cause Creutzfeldt-Jakob disease (CJD) or variant CJD (vCJD). The relevant instructions set out in the RKI Recommendation (4) must be observed.

Table 11 of the Recommendation advocates the use of an automated, validated cleaning/disinfection process, which includes an alkaline cleaning step, for heat-resistant medical devices that tolerate steam sterilisation. Critical medical devices are subjected to steam sterilisation at 134 °C, using a holding time of at least 5 minutes.

If automated alkaline cleaning is not safely tolerated, final steam sterilisation at 134 °C with a holding time of 18 minutes is recommended, in particular, in the ophthalmology setting.

To facilitate implementation, the vCJD Task Force advocates that as a standard procedure one of the above processes be used for all instruments (4).

The RKI has described methods suitable for testing detergents in respect of their prion-stabilising, prion-activating and prion-decontaminating properties (5). The manufacturers of process chemcials should provide information on this topic.

The Transmissible Spongiform Encephalopathy (TSE) Reference Centre at Göttingen University understands the fundus of the eye as comprising the retinal tissue, subretinal fluid and optic nerve. In principle, vitreous bodies are not classified as critical, therefore e. g. ablation of vitreous bodies during cataract surgery is not deemed to involve instrument contact with the fundus of the eye.

But among the instruments used for surgery of the posterior section of the eye are also heat-sensitive medical devices that do not tolerate steam sterilisation (6) and must therefore be sterilised with a low-temperature process.

➜ **OPHTHALMOLOGIC INSTRUMENTS** should preferably be reprocessed using alkaline detergents in an automated validated process followed by steam sterilisation.

From the above legal requirements and recommendations can be concluded that ➜ **OPHTHALMOLOGIC INSTRUMENTS** should preferably be reprocessed using alkaline detergents in an automated validated process followed by steam sterilisation.

2. General information for handling ophthalmologic instruments

➜ **THE FILIGREE CONSTRUCTION of** ophthalmologic instruments ncessitates special care.

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 precleaning 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.

➜ **CERTAIN STEPS** must be taken already at the site of use to avoid drying of proteins and residues and blockage of lumens.

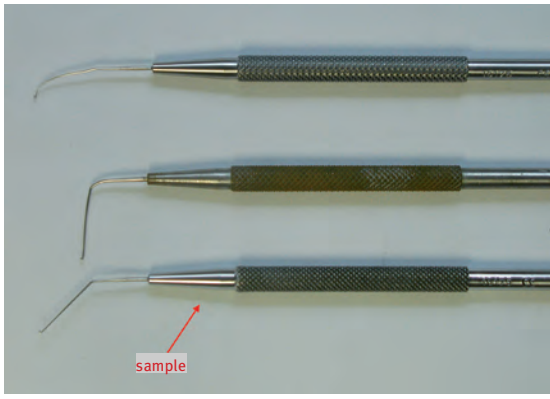

Fig. 1: Mechanical damage to iris hooks
Geuder factory photo

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 precleaning 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

➜ **SECURE TRAY SYSTEMS** must be used to prevent mechanical damage.

➜ **UNLOADING AND RELOADING THE INSTRUMENTS** should be avoided, therefore systems should be used which can also be used in an ultrasonic basin as well as in the WD and steriliser.

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.

➜ **THE CHROMIUM OR NICKEL LAYER** of the instruments must be intact, because otherwise corrosion of stainless steel or titanium instruments may occur.

➜ **MANY FUNCTIONAL TESTS** can only be performed in the OR.

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 multicentre trial conducted in 2009, whose participants included the manufacturers of ophthalmologic instruments, process chemicals and washer-disinfectors, materials were tested under everyday conditions.

➜ **SUITABILITY OF THE REQUIRED PROCESSES** must be established for the instruments in use.

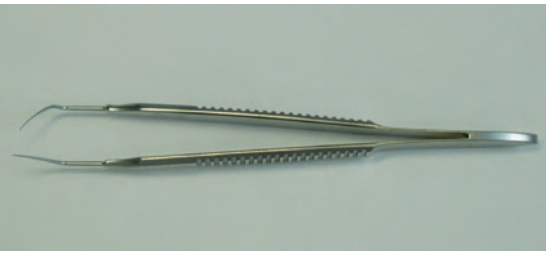

Fig. 2: Mechanical damage to capsulorhexis forceps *Geuder factory photo*

➜ **FOR THE FINAL RINSE** demineralised water must be used.

➜ **SPECIALIST TRAINING COURSES** are absolutely necessary for personnel to ensure orderly reprocessing in line with quality assurance dictates.

No material damage or surface changes were detected on instruments made of polyoxymethylene (POM), polytetrafluorethylene (PTFE), silicone or on instruments with brass coating or composed of titanium, stainless steel with material numbers 1.4301, 1.4404, 1.4024, 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 stainless 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 expertise. 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 Wiederaufbereitung von resterilisierbaren Medizinprodukten – Anforderungen
2 Verordnung über das Errichten, Betreiben und Anwenden von Medizinprodukten (Medizinprodukte-Betreiberverordnung MPBetreibVO) vom 21. 8. 2002; zuletzt geändert durch Art. 4 G v. 29. 7. 2009 BGBl. I S. 2326
3 Empfehlung von RKI und BfARM: Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten BGBl 2001; 44: 1115–1126.
4 Empfehlung von RKI und BfARM: Die Variante der Creutzfeldt-Jakob-Erkrankung (vCJK) Prävention einer Übertragung. BGBl 45 2002; 4, S. 376–394.
5 Bertram et al. BGBl 47 (2004) : 36–40.
6 M. Knoche, S. Grisanti, K.-D. Lemmen: Aktuelle Hygienestandards in der Ophthalmochirurgie Teil 2: Aufbereitung der Instrumente – Schritt für Schritt. Ophthalmo-Chirurgie 2006; 18: 252–259.
7 Wiederaufbereitungsanleitung für Produkte der GEUDER AG (2007)
8 Kommission «vCJK-Ophtha» der Deutschen Ophthalmologischen Gesellschaft DOG) und Arbeitskreis Instrumentenaufbereitung (AKI) unter Mitwirkung der Geuder AG: Prüfung alkalischer Reiniger zur maschinellen Aufbereitung augenchirurgischer Instrumente im Hinblick auf das Materialverhalten und alkalische Rückstände. Zentr Steril 2009; 17 (4):245–256.
9 Arbeitskreis Instrumentenaufbereitung (AKI): Instrumentenaufbereitung – richtig gemacht (Rote Broschüre), 9. Ausgabe 2009 bestellung@a-k-i.org
10 Leitlinie von DGKH, DGSV und AKI für die Validierung und Routineüberwachung maschineller Reinigungs- und Desinfektionsprozesse für Medizinprodukte und zu Grundsätzen der Geräteauswahl. Zentr Steril 2008; Suppl. 2. Download unter: www.dgsv-ev.de (Leitlinien)

Remark

Part 2 will address manual and automated reprocessing as well as sterilisation, validation of processes, routine checks and special aspects of the media used.