Recommendations by the Quality Task Group (90)

Protection of disinfected medical devices against recontamination

B. Amann, T. Appel, P. Bröcheler, D. Diedrich, S. Fiedler, A. Forster, B. Früh, M. Kamer, G. Kirmse, S. Krüger (Coordinator), M. Schick-Leisten, C. Schmid, U. Zimmermann (Coordinator), A. Schlepp + Packaging Subgroup

E-mail: qualitaet@dgsv-ev.de

Requirements for handling semi-critical medical devices

The KRINKO/BfArM Recommendation [1] explicitly states that when handling medical devices (MDs) that have been cleaned, disinfected, but not packed or/and not generally sterilized, measures must be taken to ensure that recontamination will not occur and that the disinfected state is preserved.

Before MDs are reprocessed they must undergo risk assessment and classification in accordance with the KRINKO/BfArM Recommendation, while taking account of constructional features, previous use and intended reuse; see the flow chart compiled by the German Society of Sterile Supply (DGSV) in Recommendation No. 77 by the Quality Task Group.

MDs that come into contact with mucous membranes or pathologically altered skin can be classified as semi-critical and should preferably be reprocessed in an automated washer-disinfector (WD); see Recommendation No. 51 "Decontamination of Anaesthesia and Respiratory Accessories" by the Quality Task Group. If the MDs present a higher ➜ **RISK**, they are classified as critical A or B, packed after being reprocessed and preferably sterilized with moist heat. Please refer to Recommendation No. 85 by the Quality Task Group for storage details of packed sterile MDs

Semi-critical MDs may also be manually reprocessed [2]. For the semi-critical B group KRINKO recommends that preference be given to ➜ **AUTOMATED CLEANING AND DISINFECTION** because these MDs are amenable only to a certain extent to visual inspection for cleanliness.

The MDs must be dried before they are stored, and should be reused as soon as possible.

➜ **IF THERE IS A HIGHER RISK** MDs are classified as critical A or B (critical B if the mucous membrane is breached, e. g. endoscopic accessories).

➜ **AUTOMATED CLEANING AND DISINFECTION** is also recommended for the semi-critical B group.

Anaesthesia and respiratory accessories

Reusable anaesthesia accessories are mainly classified as semi-critical B devices and are cleaned, disinfected and dried in a WD. After redrying, if necessary, they are placed in "protective packaging", e. g. plastic boxes with a lid, for storage and transportation and should be reused as soon as possible.

Flexible endoscopes

The majority of flexible endoscopes, e. g. gastroscopes, are classified as semi-critical B devices. Following cleaning and disinfection they must not contain any more than 1 cfu/ml per 20 ml rinse solution/channel [3]. Based on the KRINKO/BfArM Recommendation, reprocessed endoscopes may be stored for up to 14 days when hanging in an ➜ **ENDOSCOPE CABINET** [1].

Flexible bronchoscopes are being used increasingly for diagnosis and treatment of mechanically ventilated patients as well as for emergency intubation. Since these endoscopes are used in different departments they must be ➜ **TRANSPORTED** in suitable containers that protect them against recontamination. Because endoscopes vary in terms of design, size and length the containers recommended by the manufacturer, or appropriate transport containers that can be closed, should be used for routine purposes.

➜ **IN THE ENDOSCOPE CABINET** endoscopes reprocessed as directed can be stored for up to 14 days .

➜ **TRANSPORT** of endoscopes must be effected in suitable containers while protected against contamination.

One important aspect is to ensure that flexible bronchoscopes are also properly dried with medical compressed air after being reprocessed in the endoscope washer-disinfector (EWD) and before they are transported.

Drying

The KRINKO/BfArM Recommendation draws attention to the risk of microbial growth, e. g. of *Pseudomonas*, if endoscopes are stored under moist conditions [1].
Besides, when ➜ **STORED UNDER MOIST CONDITIONS** there is also a risk of material rusting or alteration.
Drying is carried out using a final drying step in an EWD. Some EWDs have facilities to optimally set the drying step. Filters, e. g. HEPA filters, are generally used to prevent airborne recontamination. For synthetic MDs, or devices with synthetic components, the drying time must be prolonged as needed or the device redried with compressed air. The compressed air must be virtually free of oil (0.1 mg/m^3). The KRINKO/BfArM Recommendation advocates the use of compressed air of medical quality.
To verify dryness the MDs are placed on coloured crepe paper. WATESMO paper can also be used to detect moisture. For hollow devices dry air is blown through the lumen onto a mirror to detect any residual moisture.

➜ **STORAGE UNDER MOIST CONDITIONS** can lead to microbial growth and material changes.

Protective packaging, transport, labelling and storage

EN ISO 11607-1:2009 defines ➜ "**PROTECTIVE PACKAGING**" as "the packaging configuration designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use", e. g. to protect against dust [4]
To avoid confusion, it is recommended that ➜ **DISINFECTED DEVICES** be packed in suitable full-plastic packaging, e. g. dust cover or plastic pouches with adhesive seals or adhesive tapes, rather than in sterile supply packaging.
Endoscopes must be transported in suitable containers/toolboxes that protect them against recontamination. Because endoscopes vary in terms of design, size and length, suitable closed transport containers should be used; see above.
Endoscope cases should only be used to transport the devices to the manufacturer for repair.
Pursuant to the KRINKO/BfArM Recommendation, for medical devices for which disinfection is the final decontamination step the user must be able to ascertain that disinfection was, indeed, carried out, i. e. certain details of the disinfection process must be available at all times to the user, e. g.:

– the medical device designation,
– details of MD release as well as
– data on which the safe storage period for the MD was based.

Clear ➜ **LABELLING** must be used to rule out mix-ups.
In dentistry semi-critical MDs are stored in boxes, cabinets or drawers after cleaning, disinfection and drying. MDs that are stored in an unpacked state should be reused as soon as possible for patients.
(Details available in German language in the Hygieneleitfaden (Guide to Hygiene) compiled by the German Workgroup for Hygiene in Dentistry [DAHZ], 9th edition 2014 [6] and in the Hygieneleitfaden, BG en/BGBW [7]).

➜ **THE PROTECTIVE PACKAGING** prevents damage to the sterile barrier system.

➜ **DISINFECTED DEVICES** should be packed in suitable full-plastic packaging and not in sterile supply packaging.

➜ **THE LABELLING** used for disinfected devices must show that such a disinfection process was carried out.

Storage periods

Based on DIN 58953 Part 8 [5] the storage periods must be set out in writing by the user's infection control team.
As such, ➜ **STORAGE PERIODS** for MDs that were only disinfected should also be defined by the infection control committee and documented accordingly in the QM system.
Medical devices with only a low microbial count (semi-critical) must be stored such that recontamination during storage is prevented. The storage period is determined on the basis of risk assessment, while taking account of the points mentioned above. This decision is taken jointly with infection control specialists.
The storage conditions must be checked regularly by the infection control team, e. g. using contact plating methods.

➜ **STORAGE PERIODS** for disinfected devices, too, should be defined by the infection control committee.

Recontamination sources and recommended measures to avoid recontamination

Recontamination source	Recommended measures
Touching with non-disinfected hands or gloves that do harbour more than a low microbial count	Contact only with disinfected hands or gloves containing, at most, only a low microbial count
Contact with medical devices that have not been cleaned – cross contamination Aerosol transmission	Provide for spatial or organizational separation of the Reprocessing Unit for Medical Devices (RUMED)
Unclean work surfaces, e. g. dust	Improve and check occupational hygiene practices in accordance with the cleaning and disinfection policy
Contaminated packaging and transport materials	Use packaging material with only a low microbial count (observe storage conditions and storage periods specified by manufacturer) Reusable packaging and transport materials must be cleaned and disinfected (suitable transport containers)
Storage of unpacked medical devices (loose storage in drawers, cabinets)	More rigorous demands must be met by personnel for loose, unpacked storage of medical devices (hand and glove hygiene). Clean and disinfect drawers and cabinets regularly (as per the cleaning and disinfection policy) Uncontrolled removal of sterile items from their sterile store, e. g. during treatment, must be avoided
Non-disinfected storage surfaces (prolonged storage periods)	All surfaces used to store packed and unpacked medical devices must be cleaned and disinfected regularly (as per the cleaning and disinfection policy).
Transport routes	Personnel entrusted with logistical activities must undergo regular training. The training measures must be documented. Unpacked medical devices should not be transported.
Failure to observe "First in/First out" principle	This must be incorporated as a standard operating procedure (SOP) into the QM system.
No labelling	On the basis of labelling, it must be possible to clearly distinguish MDs that have only been disinfected from sterilized MDs.
Untrained staff	Regular personnel training and awareness measures. The training measures must be documented.
Moist/wet medical devices	Visual inspection, crepe paper, WATESMO paper Drying programme – EWD, check EWD If necessary dry with sterile compressed air or with disposable microfiber cloths

References

[1] KRINKO/BfArM Recommendation: Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM), 2012, 2.2.2 Drying; 2.2.4 Packaging; Annex 8 (3.7)
[2] Guideline for validation of manual cleaning and manual chemical disinfection of medical devices compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV), Working Group Instrument Preparation (AKI) and the Association of Applied Hygiene (VAH). Central Service Suppl. 2013
[3] Guideline for validation of automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes compiled by the DGKH, DGSV and AKI. Central Service Suppl. 2011
[4] EN ISO 11607 Validation of packaging systems
[5] DIN 58953 Part 8: Sterile medical device logistics
[6] Guide to Hygiene compiled by the German Workgroup for Hygiene in Dentistry (DAHZ) 9th edition 2014
[7] Hygiene in medical practitioners' offices – Centre of Competence for Hygiene and Medical Devices of the National Association of Statutory Health Insurance Accredited Physicians