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Checklist

Organizational and Structural Activities for Reprocessing Medical Devices

This checklist is intended to support the organization and structure of activities which are necessary to reprocess medical devices. It also can be used as a self-check before an inspection by relevant authorities. This checklist does not claim to be complete.

Manual Cleaning and Disinfection	Yes	No	Not applicable
Definition of interfaces regarding manual pre-cleaning that might be necessary after surgical/endoscopic procedure	○	○	○
Definition and observance of time intervals between end of procedure and starting reprocessing as described in guidelines (e.g., organizing pickup and delivery service)	○	○	○
Are suitable cleaning/disinfection sinks available and are they used and reprocessed correctly?	○	○	○
Is the cleaning/disinfectant solution prepared and used correctly?	○	○	○
Is the exposure time according to the manufacturer's instructions observed and documented?	○	○	○
Is the cleaning/disinfectant solution renewed at regular intervals according to the manufacturer's instructions?	○	○	○
Are all necessary cleaning utensils (e.g., adapters, brushes, tubes) as required by the instructions for use (IFU) available and reprocessed (if not single-use items)?	○	○	○
If an ultrasonic cleaner is used to support the cleaning process, is it regularly tested?	○	○	○

Automated Cleaning and Disinfection	Yes	No	Not applicable
Is there an endoscope washer disinfector (EWD/AER) manufacturer's confirmation for all instruments/endoscopes which should be reprocessed in the EWD/AER and are all necessary adapters available?	○	○	○
Are the correct baskets/racks available for all instruments which have to be reprocessed in the washer disinfector (WD)?	○	○	○
Are all WDs and EWDs/AERs serviced regularly?	○	○	○
Are the reprocessing processes validated regularly?	○	○	○
Are the recommended routine tests based on the validation report carried out?	○	○	○
Has anyone who is working with the WD/EWD/AER undertaken documented training on it (including daily routine tests, adapters, programs, hygiene program, chemical replacement, release parameters, etc.)?	○	○	○

Packaging

	Yes	No	Not applicable
Are all instruments completely dry before packaging (maybe a drying cabinet is to be used)?	○	○	○
Are the instrument manufacturer's IFU followed in the functional check, care and assembling of the instruments?	○	○	○
Has the correct type of packaging been selected for the respective sterilization process?	○	○	○
If a sealing device is used for packaging, is it maintained (e.g., serviced) and validated regularly according to the IFU / manufacturer´s specifications?	○	○	○
Are the instruments properly packed and labeled?	○	○	○
Are the filters changed regularly when using containers?	○	○	○
Has anyone who is working with the sealing device undertaken documented training on it?	○	○	○

Sterilization

	Yes	No	Not applicable
Is the used sterilizer (method and program) suitable for the instruments which have to be sterilized?	○	○	○
Is the sterilizer serviced regularly?	○	○	○
Is the sterilization process validated regularly?	○	○	○
Are the recommended routine tests based on the validation report carried out?	○	○	○
Are chemical indicators used for routine tests?	○	○	○
Are biological indicators used for routine tests?	○	○	○
Has anyone who is working with the sterilizer undertaken documented training on it (including daily routine tests, programs, release parameters, etc.)?	○	○	○
Is the releasing decision for each batch/cycle documented?	○	○	○

Storage

	Yes	No	Not applicable
Are cleaned and disinfected instruments completely dry before storage (e.g., by using compressed air and considering the allowed pressure based on the IFU / manufacturer´s specifications)?	○	○	○
Are the storage conditions in line with the instruments to be stored (e.g., dust-free, defined humidity, by using a storage cabinet with controlled environment for processed thermolabile endoscopes (EN 16442:2015))?	○	○	○
Do the storage periods correspond to packaging and environmental conditions? (First in / first out principle needs to be considered.)	○	○	○
Is there a standard operating procedure (SOP) for cleaning/disinfection of the storage area?	○	○	○
Has a risk assessment been performed to determine maximum storage time of a disinfected or sterilized scope before it must be reprocessed again?	○	○	○

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