Reprocessing of medical devices in exceptional situations, e.g. the COVID-19 pandemic

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In an exceptional situation, such as the COVID-19 crisis, a CSSD may be faced with the need to reprocess medical devices that are normally not intended for reprocessing. For example, the reprocessing of disposable respiratory masks, tubes, etc. may be necessary because new goods are not available in time.

Legal evaluation

Single-use medical devices are designed not to be reused. If reprocessed, it is done at the user's own risk, but can be justified in a crisis situation after a risk assessment [1] is carried out, see EN ISO 14937 [2]. These reprocessing processes are carried out outside of validated procedures and can only be justified during an exceptional situation. Additional personnel protection is not necessary in a CSSD, since the personnel must always poise infection risks from contaminated goods, even outside of crisis periods, and always secure themselves with protective gear.

Disinfection

The disinfection of e.g. respiratory equipment and other devices should be carried out in a WD by thermal disinfection with hot water with an A_0-value of 3000 – 5000 (90–93 °C, 5 min) [3]. Hot water is the best disinfectant available in the hospital and protects CSSD employees during packing. The A_0-value is monitored reliably by recording the temperature-time-integral inside the WD. If older equipment has no built-in temperature-time recording system, a data logger should be used.

Sterilization

Sterilization should be carried out in a standard steam sterilization process at 121 °C, 15 min, under the condition that the goods can withstand temperatures of at least 125 °C [4, 5, 6]. We warn to use shortened sterilization processes to achieve higher throughput. Shortened processes reduce the fractional air removal required to safely remove air from hollow instruments, such as respiration tubes. Especially longer tubes with a large diameter are much more difficult to sterilize inside than shorter ones with a smaller diameter [7]. For safe sterilization, the temperature-time integral (F_0-value) > 15 min is not sufficient, and also all inner and outer surfaces must be covered at least with a condensate film of steam. This is only fulfilled in hollow lumens and tubes if the air has been removed and replaced by steam before sterilization [7].

If products cannot withstand temperatures above 90 °C, low-temperature sterilization processes, such as LTSF, ethylene oxide (EO) are used. EO sterilization processes are quite suitable for plastic materials, since the sterilizing gas ethylene oxide penetrates plastic materials and therefore ensures effective sterilization even in hollow lumens. The major disadvantage in hospitals however is, that EO gas dissolves in plastic material and requires several days after sterilization to be desorbed again. Therefore, a validated desorption has to be carried out before use. Inhaled EO gas leads to mutation of body cells and later on cancer, so this procedure is not recommended in hospitals. The formaldehyde (LTSF) sterilization procedure, which has been used for a long time and for which EN and ISO standards exist, is a safe procedure [8, 9].

The use of low temperature hydrogen peroxide (VHPO) sterilization processes is not recommended. These processes today still have the following disadvantages:

- There are no standards yet, since the procedures have not yet been fully understood.
- There is still a lack of sufficient experience to safely sterilize long tubes and tubes with large diameters.
- The inactivation speed of viruses is largely dependent on the material and roughness of the surface they are located on.

Sterilization monitoring

All sterilization processes must be monitored to ensure that all critical variables and their parameters are present at all locations inside the sterile goods [6, 7, 9].

Unfortunately, during routine operations the most critical areas within hollow lumens cannot be monitored by biological or chemical indicators [10, 11], because no indicators can be placed there and they also cannot be removed and evaluated after sterilization before use. These areas can be only safely monitored with Type 2 indicator systems [11]. The indicator systems used there must have more difficult air removal and steam penetration characteristics than the instruments themselves. Industry offers various Type 2 indicator systems with different steam penetration characteristics fulfilling this requirement.

References

1 EN ISO 14971: Medical devices – Application of risk management to medical devices
2 EN ISO 14937: Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
3 EN ISO 15883-1: Washer-disinfectors – Part 1: General requirements, terms and definitions and tests
EN ISO 15883-2: Washer-disinfectors – Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
4 EN 285: Sterilization – Steam sterilizers – Large sterilizers
5 EN 13060: Small steam sterilizers
6 EN ISO 17665-1: Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
7 U. Kaiser, J. Gömann: Investigation of Air Removal from Hollow Devices in Steam Sterilization Processes; Central Service 1998; 6: 401–413.

8 EN 14180: Sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing

9 EN ISO 25424: Sterilization of health care products – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilization process for medical devices

10 EN ISO 11138-1: Sterilization of health care products – Biological indicators – Part 1: General requirements
EN ISO 11138-2: Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11138-3: Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes
EN ISO 11138-4: Sterilization of health care products – Biological indicators – Part 4: Biological indicators for dry heat sterilization processes
EN ISO 11138-5: Sterilization of health care products – Biological indicators – Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes

11 EN ISO 11140-1: Sterilization of health care products – Chemical indicators – Part 1: General requirements
EN ISO 11140-3: Sterilization of health care products – Chemical indicators – Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
EN ISO 11140-4: Sterilization of health care products – Chemical indicators – Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration