

Recommendations by the Quality Task Group (64): Decontamination of Containers

In principle, the establishment’s authorities are responsible for reprocessing medical devices (MDs), while taking account of the requirements for the protection of patients, users and third parties. This also applies to the containers used for delivery of sterile medical devices and collection of the used supplies (instruments).

The containers used for delivery of sterile supplies constitute a preformed rigid sterile barrier system (ISO 11607). Containers are generally classified as non-critical medical devices, but preference should be given to automated methods to reprocess them (see recommendation jointly drafted by the Robert Koch Institute (RKI) and German Federal Association for Drugs and Medical Devices or the Technical Regulation for Biological Substances (TRBA 250)).

This present recommendation focuses on the hygiene requirements for container decontamination. It will not address any issues related to material compatibility vis-à-vis the decontamination process (containers are generally made of aluminium, stainless steel or plastic). That topic is covered in Quality Task Group Recommendations 48 and 49.

Using containers

Containers are classified as follows in accordance with their intended use:

1. Sterile barrier system (sterile supply delivery containers)
2. Transport containers
3. Containers used to collect used supplies

Based on this distinction, the decontamination requirements may differ, but mixed use is also possible. → **RISK ASSESSMENT** must be performed to determine which decontamination requirements apply.

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Risk assessment, classification and hygiene requirements

Risk analysis and risk assessment are carried out in line with quality management dictates so as to identify whether, within the respective establishment, the containers pose a → **RISK OF INJURY** to personnel once they have been cleaned and disinfected and whether there is a risk of transmission of (facultative) pathogenic microorganisms. Another point to be clarified is whether the probability of such an injury is high, low or whether this can be ruled out.

→ **THE RISK OF INJURY** for personnel has to be identified during risk assessment.

Table 1 will help decide which minimum spectrum of action is needed for a disinfection process and at what level of expected contamination or which A_0 value is to be used. This takes account of the main type of hazards.

Decontamination methods (cleaning and disinfection)

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1. Automated cleaning with thermal disinfection

Cleaning and thermal disinfection are carried out in washer-disinfectors (WDs). On using an A_0 value of 3000 (e.g. 5 min 90 °C), bactericidal, yeasticidal, fungicidal, mycobactericidal, limited virucidal and virucidal activity is assured. With an A_0 value of 600 (e.g. 1 min 90 °C), bactericidal, yeasticidal, fungicidal and mycobactericidal activity is assured.

2. Automated cleaning with chemothermal disinfection

In decontamination machines or WDs that use chemothermal cleaning and disinfection processes, the required spectrum of activity can be assured if a disinfectant or disinfectant process with the corresponding spectrum of activity is used (see table 1).

→ **FOR MANUAL DECONTAMINATION** additional rules have to be observed.

3. Manual cleaning and disinfection

→ **MANUAL DECONTAMINATION** methods are not recommended because of the high risk of endangerment of personnel (see TRBA 250)

If, in certain justified cases, manual decontamination is used, wipe methods with surface disinfectants or immersion methods with instrument disinfectants are used. The following should be borne in mind:

- Select the disinfectant spectrum of action in accordance with the type of contamination expected and the probability of injury (see table).
- A (standard) operating procedure must be available for all working steps.
- This operating procedure must give detailed information on all working steps.
- Virucidal processes, in particular, can call for more stringent workplace demands because of the substances needed (e.g. aldehydes). Appropriate precautions must be taken as needed.

Manual decontamination is time-consuming and relatively expensive because of the manpower needed. Moreover, there is a risk that not all parts of the containers will be properly decontaminated (see workshop report from the German Society of Sterile Supply Conference (DGSV) in 2009 /Recommendation 62, *Central Service* 5/2009).

The requirements outlined here are minimum requirements based on the nature of the contamination and risk of injury expected. Under certain conditions or circumstances more stringent requirements can be imposed temporarily or for certain departments by the hospital's infection control team. ◆

Table 1

Disinfection process	Infection risk in the event of injury and spectrum of action required		
	Bacteria	Bacteria and enveloped viruses (e.g. HBV, HCV, HIV)	Bacteria, enveloped viruses (e.g. HBV, HCV, HIV) and non-enveloped viruses (e.g. papilloma viruses)
Thermal	A ₀ 600	A ₀ 3000**	A ₀ 3000**
Chemothermal (automated)	Bactericidal	Bactericidal and limited virucidal activity	Bactericidal and virucidal
Chemical (manual)	Bactericidal	Bactericidal and limited virucidal activity	Bactericidal and virucidal

If there is also a risk of contamination, and hence a risk of infection posed to personnel, by mycobacteria* and / or yeasts and /or moulds, yeasticidal and /or mycobactericidal and /or fungicidal efficacy is required additionally. This is assured by A₀ 600.

*Note: efficacy against mycobacteria may be needed e.g. for laundry containers used for a tuberculosis ward.

** Note: in the case of thermal disinfection no distinction can be made between limited virucidal activity and virucidal activity. Hence an A₀ value of at least 3000 is always needed to kill viruses.

If risk analysis shows that a risk of injury can be reliably ruled out, for reasons of general infection prophylaxis cleaning and bactericidal decontamination are needed as a minimum.

Note: as borne out by experiences from everyday practice, the risk of injury when handling containers cannot be ruled out.