

Recommendation of the Quality Task Group (119)

Process chemicals in the medical device (MD) reprocessing process

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The aim of the reusable MD reprocessing process is to prevent infection risks that could arise from the devices. An entire reprocessing process is generally comprised of several subprocesses such as transport, cleaning, disinfection, sterilization, storage, etc. depending on the requirements applicable to the individual MDs and their site of use.

This recommendation is intended as a guide to choosing process chemicals that can be used in cleaning and disinfection processes. It is advisable to contact the chemical products' manufacturer when selecting products because it is not possible to make a generalized statement about the choice of process chemicals due to the heterogeneous nature of the MD and the reprocessing requirements to be met.

Process chemicals for cleaning and disinfection of medical devices	
Pretreatment, precleaning at the site of use	Non-fixing pretreatment agents and/or detergents*
Transport	Preferably in a dry state
Pretreatment, precleaning, manual cleaning at the reprocessing site	Detergents (possibly disinfectant detergent)*
Ultrasound	Use detergents/disinfectants tailored to ultrasonic cleaning*
Automated cleaning	Preferably use alkaline detergents as per the KRINKO/BfArM Recommendation [1]; other detergents are needed for MDs that do not tolerate alkaline cleaning
Automated neutralization	Neutralizing agents tailored to the detergent and process conditions (observe instructions supplied by chemical products' manufacturer)
Automated disinfection	Thermal disinfection process without disinfectant or chemothermal disinfection process with disinfectant Note: For semi-critical MDs not undergoing subsequent sterilization, at least the following efficacy levels must be assured: <ul style="list-style-type: none"> ▪ virucidal ▪ bactericidal ▪ fungicidal ▪ mycobactericidal
Automated drying	Rinse aid tailored to the process conditions and to the use of the MD
Manual chemical disinfection	Chemical disinfectant Note: For semi-critical MDs not undergoing subsequent sterilization, at least the following efficacy levels must be assured: <ul style="list-style-type: none"> ▪ virucidal ▪ bactericidal ▪ fungicidal ▪ mycobactericidal



Note: The chemical products' manufacturer must supply the following:

- Product information
- Safety data sheet

(Use instruction templates are often provided.)

Note: When reprocessing observe the instructions supplied by chemical products' manufacturer, MD manufacturer as well as those given in the chemical product information sheets.

Note: There are separate detergents and disinfectants as well as certain products marketed as combination products that can be used for both manual cleaning and manual disinfection.

The use of combination products can underpin personnel protection, obviate the need for purchasing a second chemical product and help to avoid confusion of products. However, separate cleaning and disinfection steps must also be carried out when using combination products.

Note: Disinfectants for manual use are featured on the approved List of Disinfectants of the Association of Applied Hygiene (VAH).

*Note: The compatibility of the different process chemicals must be assured to avoid interactions between process chemicals that could negatively impact the ensuing reprocessing steps.

[1] KRINKO/BfArM Recommendation: Hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM)