

Cleaning and disinfection instructions

NOTICE

- Only use products that are approved for reprocessing of medical devices according to the regulations of the responsible authorities.
- Wear appropriate protective equipment during all work to protect yourself from contamination and harmful effects of the substances used.
- Observe the manufacturer's instructions for use regarding dosage, exposure time and water quality for the required mode of action.
- Components for single use must not be reprocessed. They must be disposed of after use.

All prepared components are divided into risk classes according to the type of patient contact. For the most part, the components of the CORTEX systems are classified as „uncritical“.

Only the following components of the CORTEX systems fall into the class „semi-critical“ (A), as they have indirect contact to mucous membranes via respiration:

- Mask adapter
- Volume flow sensor housing
- Turbine

In general, you should always apply the three essential steps to all components of CORTEX systems:

- 1. cleaning
- 2. disinfection
- 3. check for any residues or damage

For „uncritical“ system components you can use cleaning wipes with a disinfectant effect. For „semi-critical“ system components, manual chemical treatment is recommended, as some components are thermolabile.

We recommend that the following steps are executed correctly:

Preparation:

- Disassemble the components as far as possible
- Washing off coarse impurities
- If necessary, store in cleaning liquid if preparation can only take place later

Cleaning:

- Use of a pH-neutral enzyme cleaner, alternatively disinfectant with cleaning effect
- Prepare a cleaning solution according to the manufacturer's instructions
- Inserting the components for the prescribed exposure time
- Rinse with cold, clean water of at least drinking water quality to remove all residues

Disinfection:

- Use of a listed product with a bactericidal (including mycobacterial), fungicidal and virucidal or high level disinfectant activity
- Note known material incompatibilities (see below)
- Prepare a disinfectant solution according to the manufacturer's instructions
- Inserting the components for the prescribed exposure time
- Flush with cold, clean water of at least drinking water quality to remove all residues

Drying:

- Air drying in clean, germ-free/low-germ environment
- (alternative) Drying with a sterile/low-germ wipe

Checking:

- Check for residues or damage

Storage:

- Storage in a clean, aseptic/low germ packaging

Due to the variety and the partly limited local availability of the different cleaning and disinfection products, a validation of these is only possible to a very limited extent for CORTEX. The following active ingredients are known to be incompatible with materials:

Active ingredient	Components	Type of incompatibility
Alkylamine	Turbine	Damage to the plastic material
Peracetic acid	Turbine	Increased wear of the plastic material with intensive use

Active ingredients that are highly compatible with all components are well-known:

Active ingredient	Example	Manufacturer
Active oxygen / caroate	Descogen I Oxygenon I	ANTISEPTICA Dr. Hans-Joachim Molitor GmbH

Further information:

Processing of medical devices:

https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Medprod_Rili_2012.pdf?__blob=publicationFile (german)

https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Hygiene_Requirements_Medical_Devices_2012.pdf?__blob=publicationFile (english)

<https://www.cdc.gov/infectioncontrol/guidelines/disinfection/rational-approach.html> (english)

List of disinfectant:

<https://vah-liste.mhp-verlag.de/> (german)

<https://vah-online.de/en/vah-list> (english)

https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Desinfektionsmittel/Desinfektionsmittellist/Desinfektionsmittelliste_node.html (german)

<https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and> (english)