Information on hygiene treatment

This information describes the hygiene treatment for all types and parts of Löwenstein Medical Technology masks in a hospital environment. The following information is included:

- **Permitted processing methods for mask parts**
- **Performing the hygiene treatment**
- **Packing and storing**
- **Composition of the disinfectant Sekusept® Aktiv**
- **Composition of detergents for thermal disinfection**

Important information

- Follow the information in the respective instructions for use and safety data sheets.
- If the person performing the hygiene treatment (in the hospital) uses a different hygiene treatment method or exceeds the number of disinfection cycles, the person performing the hygiene treatment accepts responsibility for the effect on the masks.
- National authorities may permit or demand the use of an alternative method. In this case, these methods must be validated by the person performing the hygiene treatments.
- The silicone mask parts may discolor and emit a slight odor. These characteristics do not impair function.
- When using detergents and disinfectants, follow the manufacturer's instructions.
- Detergents and disinfectants must be suitable for cleaning/disinfecting plastics, silicone and textile.
- The efficacy of disinfectants must have been tested (e.g. VAH/DGHM or FDA license/CE marking) and be compatible with the detergent used.
- Comply with the concentrations and times to take effect quoted by the manufacturer.
- A narrow soft brush (maximum diameter 10 mm) is required to clean and disinfect the inside of full-face masks.

Recommended and validated disinfectants

- The disinfectant Sekusept® Aktiv is recommended. Evidence of the efficacy of this products has been provided by an independent accredited test laboratory.
- This document is based on EN ISO 17664-*1 Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices.*

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Permitted processing methods for mask parts

MATERIAL OF MASK PARTS	PROCESSING METHODS VALIDATED BY LÖWENSTEIN MEDICAL TECHNOLOGY					
	Chemical disinfection[1]	Max. number of cycles	Thermal disinfection (Vario TD)	Max. number of cycles	Thermal disinfection (autoclave)	Max. number of cycles
CARA family						
Plastic	Yes	30	Yes	30	No	-
Silicone	Yes	30	Yes	30	Yes	30
Textile[3]	No	-	No	-	No	-
LENA family						
Plastic	Yes	30	Yes	30	No	-
Silicone	Yes	30	Yes	30	Yes	30
Textile[3]	No	-	No	-	No	-
JOYCEone family[2]						
Plastic	Yes	30	Yes	30	No	-
Silicone	Yes	30	Yes	30	Yes	30
Textile[3]	No	-	No	-	No	-
JOYCEeasy family						
Plastic	Yes	30	Yes	30	No	-
Silicone	Yes	30	Yes	30	Yes	30
Textile[3]	No	-	No	-	No	-
JOYCE family						
Plastic	Yes	30	Yes	30	No	-
Silicone	Yes	30	Yes	30	Yes	30
Silicone gel	Yes	30	No	-	No	-
Textile[3]	No	-	No	-	No	-

[1] Cleaning of these mask parts was validated using the disinfectant Sekusept® Aktiv.
[2] It is not necessary to remove the forehead support including the silicone springs for cleaning.
[3] Replace mask parts in the event of a change of patient.

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Performing the hygiene treatment

<table>
<tr><th></th><th>CHEMICAL DISINFECTION</th><th colspan="2">THERMAL DISINFECTION</th></tr>
<tr><td>DISMANTLE THE MASK</td><td colspan="3">Dismantle the mask in accordance with the illustrations in the instructions for use.</td></tr>
<tr><td>CLEAN THE MASK</td><td colspan="3">Wash mask parts in hot water (min. 30 °C) and mild detergent (1 ml detergent to 1 l water) for 15 minutes.
1. Wash the immersed mask parts with a soft brush for at least 3 minutes.
2. Pay attention to all creases and cavities.
3. Rotate and swivel rotating mask parts which cannot be removed (ball element) in order to access the whole surface of the ball element.
4. For full-face masks only: Clean the openings in the emergency exhalation valve using a narrow, soft brush.
5. For full-face masks only: Lift and wash the inner valve membrane using a narrow, soft brush. Carefully wash the bearing web on both sides.
6. Rinse all parts with clean water.</td></tr>
<tr><td>DISINFECT THE MASK</td><td>Immerse mask parts in Sekusept® Aktiv solution at a concentration of 2 % for 15 minutes.[5]
1. Ensure that there are no air bubbles on the mask parts.
2. Wash the immersed mask parts with a soft brush for at least 3 minutes.
3. Pay attention to all creases and cavities.
4. Rotate and swivel rotating mask parts which cannot be removed (ball element) in order to access the whole surface of the ball element.
5. For full-face masks only: Disinfect the openings in the emergency exhalation valve using a narrow, soft brush.
6. For full-face masks only: Lift and disinfect the inner valve membrane using a narrow, soft brush. Carefully disinfect the bearing web on both sides.
7. Rinse the mask parts with water (at least drinking water quality, sterile distilled water or fully demineralized water)[6] for at least a minute.</td><td>When disinfecting with a certified thermal disinfection system[7], comply with the following time/ temperature combinations:
90 °C to 94 °C
for 5 minutes
(Range of efficacy in Robert Koch Institute program: A/B)</td><td>When disinfection with an autoclave[8], comply with the following time/ temperature combinations:
134 °C
for 5 minutes
(Range of efficacy in Robert Koch Institute program: A/B)[8]</td></tr>
<tr><td colspan="4">[4] A bactericidal, levurocidal, tuberculocidal and mycobactericidal effect is achieved at this concentration and time to take effect.
[5] A bactericidal, levurocidal, tuberculocidal, mycobactericidal, sporicidal, fungicidal (clean cond.) and virucidal effect is achieved at this concentration and time to take effect.
[6] Recommendations of KRINKO BfArM [Kommission für Krankenhaushygiene und Infektionsprävention - Commission for Hygiene and Infection Prevention at the Robert Koch Institute/Bundesinstitut für Arzneimittel und Medizinprodukte - Federal Institute for Drugs and Medical Devices] (pages 1252/1254).
[7] For example, a Miele cleaning and disinfecting machine with the Vario TD hygiene treatment program, with the following detergents, concentrations, and program times: Dr. Weigert neodisher® Z neutralizing agent at a concentration of 0.1 %. Dr. Weigert neodisher® MediClean forte universal cleaning agent at a concentration of 0.5 %
Pre-rinse and clean: approx. 15 minutes, neutralize and rinse: 10 minutes, disinfect (total): 25 minutes
Disinfect (T_{max}): 5 minutes, dry: 40 minutes
[8]An A0 value of at least 3000 must be achieved. Only disinfect the product with an autoclave in case of a change of patient. Only sterile packaging contains a sterile product.</td></tr>
<tr><td>VISUAL INSPECTION</td><td colspan="3">Perform a visual inspection in line with the instructions for use before every use.</td></tr>
</table>

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Packing and storing

Keep masks in a dry, dust-free location away from heat and the effect of direct sunlight within a temperature range from -20 °C to +70 °C

Composition of the disinfectant Sekusept® Aktiv

The following information is based on the disinfectant list from VAH.

DISINFECTANT	ACTIVE INGREDIENT BASIS	INDIVIDUAL ACTIVE INGREDIENTS
Sekusept® Aktiv	Peroxide compounds	Contains as active ingredient a reaction product of peracetic acid which corresponds to sodium percarbonate, non-ionic surfactants, and phosphonates.

Composition of detergents for thermal disinfection

The following list is based on the manufacturer's information.

DETERGENT	TYPE OF AGENT	INGREDIENTS
Neodisher Z	Neutralizing agent	Phosphoric acid Citric acid
Neodisher MediClean forte	Mildly alkaline cleaner	Non-ionic and anionic surfactants Enzymes

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