



## Notice Regarding Disinfection/Sterilization of Löwenstein-Medical-Masks in Hospital Use

This notice concerns all mask types and mask parts which are to be disinfected/sterilized for use. Please observe also the instructions for use for each mask type or part. The information is presented as follows: Table 1, Mask parts to be disinfected/sterilized; Table 2, Our recommended and validated disinfecting and sterilization procedures; and Table 3, List of active ingredients used and ingredient groups. In rare cases the forehead support may become detached from the mask body during the disinfection/sterilization procedure. We tell you how to reassemble the parts in Table 4.

Important instructions:

- ▶ If the institution responsible for processing (e. g., hospital) uses a different procedure or exceeds the disinfection or sterilization cycles, the institution assumes the responsibility for any effect on the masks.
- ▶ Discoloration of the forehead cushion and mask seal can occur. These changes do not impair the mask's function.
- ▶ Pay strict attention to the manufacturer's instructions when using cleansing, disinfecting or sterilizing agents.
- ▶ Please observe the instructions for use and safety data sheet.
- ▶ The following should be considered when choosing a cleansing or disinfecting material:
  - that it is suitable for the cleaning or disinfecting of synthetic materials,
  - that a disinfectant with certified effectiveness (e.g., VAH/DGHM- or FDA approval or CE sign) is used and that it is compatible with the cleansing agent used.

- ▶ The concentration and contact time provided by the manufacturer of the cleansing or disinfecting agent must be strictly observed.
- ▶ The Sterility Assurance Level (SAL) of the reusable mask components is 10<sup>-6</sup> or one in a million when the mask components are disinfected or sterilized as described in the following procedures.

Our recommended and validated procedures for disinfection/sterilization

We recommend the disinfectants Gigasept FF, Cidex OPA and Aniosyme DDI. An independent and accredited test laboratory has proven the compatibility and effectiveness for these disinfectants. Please observe the manufacturers' instructions for these products.

The procedure described is based on DIN EN ISO 17664 "Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices".

Table I

Overview of mask parts to be disinfected/sterilized						
Mask type: ■ JOYCEone-family ■ JOYCEeasy-family ■ JOYCE-family ■ NP 15						
Disinfection/sterilization procedures validated by Löwenstein Medical						
Part	Chemical disinfection	Number of cycles	Thermal disinfection	Number of cycles	Sterilization	Number of cycles
Mask cushion silicone	Yes	30	Yes	30	Yes	30
Mask cushion GEL / SilkGel	Yes	30	No	—	No	—
Forehead cushion silicone	Yes	30	Yes	30	Yes	30
Forehead cushion GEL /SilkGel	Yes	30	No	—	No	—
Plug	Yes	30	Yes	30	Yes	30
Mask body	Yes	30	Yes	30	No	—
Forehead support one <sup>2</sup> /easy	Yes	30	Yes	30	No	—
Coarse adjustment Forehead support	Yes	30	Yes	30	No	—
Fine adjustment Forehead support	Yes	30	Yes	30	No	—
Elbow vented nasal	Yes	30	Yes	30	No	—
Anti-asphyxia valve (AAV)	Yes	30	No	30	No	—
Elbow vented full face without AAV	Yes	30	Yes	30	No	—
Elbow non vented	Yes	30	Yes	30	No	—
Rotating sleeve vented and non vented	Yes	30	Yes	30	No	—
Retaining ring vented and non vented	Yes	30	Yes	30	No	—
Headgear clip	Yes	30	Yes	30	No	—
Quick-release cord	Yes	30	Yes	30	No	—
Headgear	No <sup>3</sup>	—	No <sup>3</sup>	—	No <sup>3</sup>	—
Headgear: JOYCEstrap	No <sup>4</sup>	—	No <sup>4</sup>	—	No <sup>4</sup>	—
NP 15 nasal pillows	Yes	30	Yes	30	Yes	30
NP 15 elbow	Yes	30	Yes	30	No	—
NP 15 headgear	No <sup>3</sup>	—	No <sup>3</sup>	—	No <sup>3</sup>	—
Mask tube	Yes	30	Yes	20	No	—
Tube anchoring clip	Yes	30	Yes	30	No	—
Tube anchoring strap	No <sup>3</sup>	—	No <sup>3</sup>	—	No <sup>3</sup>	—

<sup>1</sup> These mask parts have been validated with the disinfectant Gigasept FF (new). In addition, mask parts in the JOYCE family have been validated with the disinfectants Cidex OPA and Aniosyme DDI.

<sup>2</sup> Note about cleaning: It is not necessary to disassemble the forehead support including the silicone springs in order to clean JOYCEone. A cleaning validation for the assembled mask was conducted with positive findings (sufficient germ reduction).

<sup>3</sup> These mask parts are to be replaced at change of patient because they cannot be disinfected/sterilized.

<sup>4</sup> The headgear does not have to be disinfected or sterilized. It suffices to wash the headgear in a clothes washer before use by the new patient.

The headgear should be cleaned at a maximum temperature of 30 °C and only up to 30 cycles with commercially available detergent. Protect the headgear from exposure to direct sunlight and heat and allow it to air-dry. Do not iron the headgear; doing so could damage the material.

Table 2

Our recommended and validated procedures for disinfection/sterilization			
Disinfection/sterilization procedures			
Procedure	Chemical disinfection	Thermal disinfection <sup>5</sup>	Sterilization <sup>6</sup>
1. Mask disassembly	Take apart the mask as described in the instructions for use.		
2. Cleaning	Clean the mask parts separately and thoroughly with a soft brush in a sudsy solution or with cleansing/disinfecting agent <sup>1</sup> . Make sure to clean all the folds and cavities. Then rinse all the parts thoroughly with drinking water.		
3. Drying	If disinfection is continued immediately, the drying step is not required. Otherwise, refer to the drying instructions under "Thermal disinfection".	After the parts have been cleaned, they should be air-dried away from direct sunlight and sources of heat.	
4. Disinfection	<p>Procedure and concentration with Gigasept FF: Submerge the mask components in a Gigasept FF solution with a concentration of 5% for 15 minutes. There should be no air bubbles on the mask parts.</p> <p>Procedure and concentration with Cidex OPA: Submerge the mask components in a concentrated (undiluted) solution of Cidex OPA for 5 minutes. There should be no air bubbles on the mask parts.</p> <p>Procedure and concentration with Aniosyme DDI: Submerge the mask components in a 0.5% solution of Aniosyme DDI for 15 minutes. There should be no air bubbles on the mask parts.</p>	<p>For disinfection of mask components with a certified thermal disinfection system<sup>5</sup>, the time and temperature combinations (below) should be observed.</p> <p>The mask components were tested in accordance with DIN EN ISO 15883-1 at the following time and temperature combinations:</p> <p>70 °C - 100 minutes 75 °C - 30 minutes 80 °C - 10 minutes 90 °C - 1 minute 93 °C - 10 minutes</p> <p>(RKI program Effective range A/B)</p> <p>Lastly, the drying process takes place in the disinfection system<sup>4</sup>.</p>	Please observe the manufacturer's directions when using the sterilization system <sup>6</sup> .
5. Functional check	Carry out a functional check before each use, as described in the instructions for use.		
6. Packaging and storage	The masks should be stored in a dry and dust-free place away from heat and direct sunlight at temperatures between -20 °C and + 70 °C.		

<sup>5</sup> For example, the cleaning/disinfecting device from Miele with Vario TD program. An A0 value of at least 3000 (semi-critical) must be achieved.

<sup>6</sup> The number of cycles has been validated by Löwenstein Medical with use of the steam sterilizer A35 EN, from WEBECO.

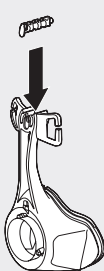
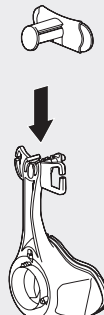
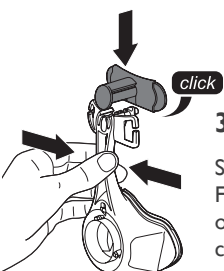
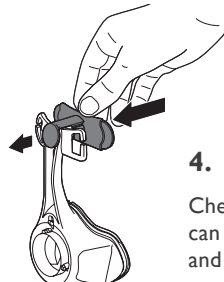
Table 3

Active ingredients and ingredient groups	
Active ingredients in the disinfectant Gigasept FF (new) and Cidex OPA. This information is based on the list of disinfecting agents issued by VAH.	
Active ingredient	Ingredient group
Aldehyde	2-Ethyl-1-hexanal, formaldehyde, glutardialdehyde, glyoxal, o-phthalaldehyde, succinaldehyde
Aldehyde separator	2-alkoxy-3, 4-dihydro-2H-pyran, 1,6-Dihydroxy-2,5-dioxohexane, formacetal, dimethoxytetrahydrofuran, ethylenglycolbis formaldehyde, polymethylolurea derivative

Table 4

**JOYCEone-family – Assemble forehead support**

In rare cases the forehead support may become detached from the mask body during the disinfection/sterilization procedure. To reassemble the parts, follow these instructions:

	<p><b>1.</b></p> <p>Insert the silicone spring in the mask body. Be sure that the flat side of the silicone spring is pointed towards the front.</p>
	<p><b>2.</b></p> <p>Pull the forehead support over the silicone spring. The rear part of the spring should be inserted through the rear recess of the forehead support.</p>
	<p><b>3.</b></p> <p>Squeeze the mask body tightly. From the rear, put the forehead support onto the mask body and push until it audibly clicks into place.</p>
	<p><b>4.</b></p> <p>Check whether the forehead cushion can be moved and can be pushed forward and backward.</p>

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Löwenstein Medical Technology  
 Kronsaalsweg 40, 22525 Hamburg  
 Germany  
 T: +49 40 54702-0  
 F: +49 40 54702-461  
 info@loewensteinmedical.de  
 www.loewensteinmedical.de

Löwenstein Medical UK  
 1 E-Centre, Easthampstead Road  
 RG12 1 NF Bracknell  
 United Kingdom  
 T: +44 1344 830023  
 info@loewensteinmedical.uk  
 www.loewensteinmedical.uk

