

EasyFit® SilkGel Nasal Mask

Cleaning and Disinfecting Instructions for Multiple-Patient Use (for Sleep Laboratory Applications only)

Caution:

Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician

Latex Free

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1 Cleaning and Disinfecting Instructions

- Before using the mask for another patient, first subject it to appropriate hygiene measures. Disassemble the mask and clean it, then disinfect all parts as described.
- Discard and replace mask components if they show signs of wear such as rips, tears or cracks.
- When used for multiple patients, these instructions supersede the cleaning and disinfecting instructions in the instructions for use provided with each mask.
- See instructions for use included with each mask for Warnings and Cautions as well as for general directions for use and reordering information.

2 Procedures allowed

 **CAUTION**

Risk of injury if headgear is used for multiple patients!

The headgear is not intended for multiple patient use due to risk of patient cross infection.

⇒ Always supply a new headgear when using the mask for a new patient.

NOTICE

Material damage from abrasion!

Rubbing the mask cushion and forehead cushion can damage the coating.

⇒ Only clean mask cushion and forehead cushion when wet.

⇒ Do not rub mask cushion or forehead cushion when dry.

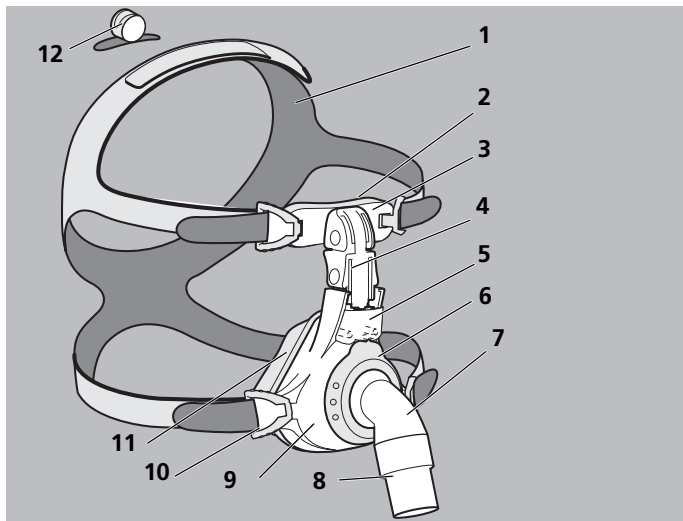
NOTICE

Material damage due to sterilization!

Sterilization can damage the materials of the mask. The materials of the mask are not validated for use after sterilization.

⇒ Do not sterilize the mask.

The following procedures are allowed:



Procedures	No.	Hand wash	Disinfect ¹
Parts			
Headgear	1	X	
Forehead cushion	2	X	X
Fine adjustment component	3	X	X
Coarse adjustment component	4	X	X
Ports for pressure measurement	5	X	X
Retaining ring	6	X	X
Elbow	7	X	X

Procedures	No.	Hand wash	Disinfect¹
Parts			
Rotating sleeve	8	X	X
Mask frame	9	X	X
Headgear clip	10	X	X
Mask cushion	11	X	X
Tube anchoring strap	12	X	

¹ We recommend using undiluted high-level disinfectant CIDEX[®] OPA Solution (0.55% orthophthaldehyde) only. Tolerance of this disinfectant has been proven. Carefully follow the manufacturer's instructions for use.

3 Description of procedures

Process	Description
Hand wash	Wash mask in warm water using Palmolive® Ultra Original dishwashing liquid soap or a comparable mild detergent. Then carefully rinse off all parts with clean water. Allow to air-dry.
Disinfect ¹	Clean manually first as described under "Hand wash." Immerse parts completely into disinfectant solution ¹ , filling all lumens and eliminating air pockets, according to the manufacturer's disinfecting guidelines. After disinfecting, rinse the parts thoroughly with distilled water and dry them completely with a clean lint-free cloth before reassembling the mask.

¹ We recommend using undiluted high-level disinfectant CIDEX® OPA Solution (0.55% orthophthaldehyde) only. Tolerance of this disinfectant has been proven. Carefully follow the manufacturer's instructions for use.

4 After cleaning and disinfecting

1. Thoroughly dry all parts following the hygiene treatment: Allow parts to air-dry.
2. Check all parts for residues. Repeat the hygiene treatment if residues are still present.
3. Check all parts for damage. Replace parts if damaged.
4. Assemble the mask as described in the instructions for use.

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