

Sleepnet Innova Nasal Mask High Level Disinfection Procedure

- Where multiple users are anticipated, the correct high level disinfection procedure must be followed. ACCEPTABLE RESULTS CANNOT BE ASSURED IF THERE ARE DEVIATIONS FROM THIS PROTOCOL.
- This procedure includes instructions for disassembly of the mask and disinfection according to manufacturer's recommendations.
- The approved disinfectant is CIDEX OPA® (registered trademark of Advanced Sterilization Technologies.)

Innova Vented Nasal Mask Disassembly and Disinfection Protocol

1. Detach mask from headgear and CPAP/ Bi-level tubing. Discard tubing (Figure 1).

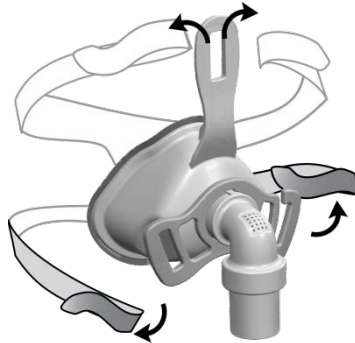


Figure 1

2. Hand wash the mask and components in warm water using a mild detergent before disinfection. Rinse the mask thoroughly after washing.
3. Read CIDEX OPA® manufacturer's instructions and warnings carefully before use.
4. Immerse mask completely, filling all lumens, in CIDEX OPA® solution.
5. **The mask must be soaked for a minimum of 20 minutes at 20°C (68°F).**
6. Remove the mask from the CIDEX OPA Solution and thoroughly rinse by immersing it completely in a large volume (e.g. 2 gallons) of water. Use sterile water. See CIDEX OPA Instructions for further information.
7. Keep the device totally immersed for a minimum of 1 minute.
8. Manually flush all lumens with large volumes (not less than 100 mL) of rinse water.
9. Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
10. Repeat steps 6 through 9, TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove CIDEX OPA Solution residues.

NOTE: Residues may cause serious side effects. See manufacturer's warnings. Three (3) separate, large volume water immersion rinses are required.

11. Allow mask to completely air dry.
12. Reassemble mask by attaching new CPAP tubing to swivel tubing adapter (Figure 2)

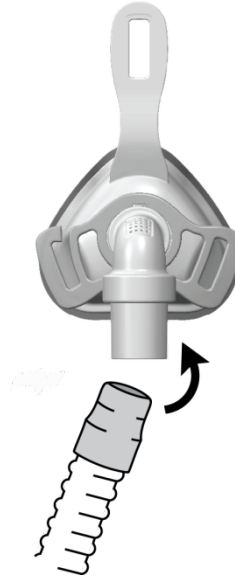


Figure 2

13. Inspect gel cushion for damage. If any damage is observed, do not use the mask.

NOTE: This procedure has been validated for ten (10) disinfection cycles.