

SleepWeaver® élan™ Cleaning and Disinfecting Instructions between Patient Use

This mask should be reprocessed when used between patients. The mask must be cleaned first using the procedure below and then disinfected using one of the three procedures below.

- **Cleaning**
 - Clean the mask using an enzymatic cleaner such as Enzol®
 - Prepare the cleaning solution using the manufacturer's instructions
 - Disassemble and immerse the components in the cleaning solution and allow them to soak for a maximum of 5 minutes.
 - Agitate the components and start the soak time when no bubbles are exiting the components
 - Use a soft bristled brush to remove all visible soil. Pay close attention to hard to reach areas.
 - Remove the components from the cleaning agent and rinse them in cool running tap water for 2 minutes
 - Allow components to dry
- **Disinfecting (CIDEX OPA®)**
 - Equilibrate a water bath of CIDEX OPA® to $\geq 20^{\circ}\text{C}$
 - Disassemble and fully immerse the mask in the solution and ensure all air bubbles are removed from the surface
 - Allow the mask to soak for a minimum of 12 minutes
 - Thoroughly rinse the mask by full immersing in pure water (PURW), agitating and allowing them to set for a minimum of 2 minutes
 - Repeat rinse cycle 2 more times for a total of 3 rinse cycles using a fresh batch of PURW each time
 - Allow product to dry
 - Testing by Circadiance has shown that the mask can withstand up to 10 cycles of chemical disinfection using CIDEX OPA® using the procedure above
- **Disinfecting (CIDEX Plus®)**
 - Equilibrate a water bath of CIDEX Plus® to $25 \pm 2^{\circ}\text{C}$
 - Disassemble and fully immerse the mask in the solution and ensure all air bubbles are removed from the surface
 - Allow the mask to soak for a minimum of 20 minutes
 - Thoroughly rinse the mask by full immersing in pure water (PURW), agitating and allowing them to set for a minimum of 2 minutes
 - Repeat rinse cycle 2 more times for a total of 3 rinse cycles using a fresh batch of PURW each time
 - Allow product to dry
 - Testing by Circadiance has shown that the mask can withstand up to 10 cycles of chemical disinfection using CIDEX Plus® using the procedure above
- **Disinfecting (Thermal Disinfection)**
 - Using a certified hot water disinfection system, perform the following:
 - Disassemble the mask and place in the washer/disinfector
 - Use the following settings:
 - Water Temperature – 82.2°C
 - Recirculation Time – 1 minute
 - Testing by Circadiance has shown that the mask can withstand up to 10 cycles of thermal disinfection using the procedure above

Inspect the mask after each cleaning and disinfecting cycle. Any damaged or worn parts must be replaced.