



This guide is intended for multi-patient use of the F&P Nova™ Nasal mask in the hospital, or other clinical settings, where proper disinfection of the device must occur between patients. When using the mask for single-patient use in the home, please refer to your F&P Nova Nasal Instructions for Use under ‘Cleaning Your Mask at Home’.

Mask Components	Thermal Disinfection <i>In line with EN ISO 15883, the uncertainty range for disinfection temperature is -0 °C to +5 °C.</i>			Chemical Disinfection	Sterilization
	1 min at 90 °C (194 °F)	10 mins at 80 °C (176 °F)	30 mins at 75 °C (167 °F)	CIDEX™1 OPA	STERRAD™2
F&P Nova Nasal Mask • Cushion* • Frame Assembly**	Maximum of 25 cycles			Maximum of 25 cycles	-
F&P Nova Nasal Headgear • Headgear*** • Tube Clip***	The Headgear and Tube Clip are not required to be disinfected, thorough cleaning between patients is sufficient. Follow ‘Cleaning the Headgear and Tube Clip’ instructions for a maximum of 25 cycles.			-	-
Diffuser	The Diffuser is not intended for reuse between patients. If used, replace Diffuser between patients.			-	-
Headgear Pad	The Headgear Pad is not intended for reuse between patients and is not removable. If used, replace Headgear between patients.			-	-

\*Replace the cushion if it becomes discolored.

\*\*Frame Assembly includes: Frame, Tube and Swivel.

\*\*\*If contaminated with blood, please replace the contaminated component between patients.




Each cycle is limited to one day of use.

### General Warnings and Cautions

The instructions provided in this guide have been validated as being capable of preparing the masks for reuse. Fisher & Paykel Healthcare does not recommend any deviations from the recommended method of reprocessing.

<b>Warning</b>	Deviations from the recommended methods of reprocessing may result in inadequate disinfection/sterilization and adverse health effects.
<b>Warning</b>	Frequency of cleaning, methods of cleaning or the use of cleaning agents, other than those specified in the accompanying documents or exceeding the number of processing cycles, can have an adverse effect on the mask and consequently the safety or the quality of the therapy.
<b>Caution</b>	Only clean the mask with cleaning products specified in the cleaning instructions of this guide, as any other products may result in an adverse reaction if cleaning residue is left behind.
<b>Caution</b>	Do not clean the mask with products containing alcohol, antiseptic, bleach, chlorine or moisturizer as these may compromise the function of the mask.
<b>Caution</b>	Do not clean the mask in a dishwasher as this may compromise the function of the mask.

## Validated Disinfection and Sterilization Procedures

<b>Point of Use (optional)</b>	Any gross soiling on the mask may be removed by wiping or rinsing with potable water.		
<b>Disassembly</b>	<p>Disassemble the mask according to the 'Disassembling your mask' instructions provided in the F&amp;P Nova Nasal Instructions for Use and these additional steps:</p> <ol style="list-style-type: none"> <li>1. Remove the Back Panel from the Headgear</li> <li>2. Remove the Tube Clip from the Top Strap</li> <li>3. Disconnect the Top Strap</li> </ol> <p> <b>Caution:</b> Failure to fully disassemble the mask may compromise the effectiveness of cleaning and the subsequent disinfection steps which may result in a range of harms, some of which are severe.</p>		
<b>Cleaning</b>	<i>Cleaning the Cushion and Frame Assembly</i>	<p>Masks should always be properly cleaned before further reprocessing.  <b>Warning:</b> Failure to properly clean this device according to these instructions or the use of an automated cleaning method may result in ineffective disinfection/sterilization and adverse health effects.</p> <ol style="list-style-type: none"> <li>1. Soak Cushion and Frame Assembly in a 1% concentration solution of Alconox™<sup>3</sup> (or equivalent mild alkaline anionic detergent) for 5 minutes at 50 °C, ensuring that no air bubbles are present on the device surface.</li> <li>2. Using a soft non-metallic brush (e.g. medium-hard toothbrush), vigorously brush the mask parts until visibly clean but not for less than 30 seconds. An additional narrow bottle brush is required to access the Mask Tube. Brush the components while submerged and out of the solution. Pay close attention to crevices, cavities and corners, such as the joint between the silicone cushion, plastic surrounds and the internal surfaces of the frame.</li> <li>3. Vigorously brush the joint between the frame and tube alternating between the inside and outside surfaces for at least 30 seconds.</li> <li>4. Manually rotate the swivel for at least 10 seconds each, while submerged in the detergent solution.</li> <li>5. Repeat steps 1 to 4 (total soaking time of 10 minutes).</li> <li>6. Rinse by submerging in 5 liters of fresh demineralized water and agitating for at least 10 seconds. Repeat rinse.</li> <li>7. Manually rotate the swivel for at least 10 seconds each, while submerged in the demineralized water.</li> <li>8. Ensure the mask is visibly clean before continuing. If not, repeat steps 1-7.</li> </ol>	
	<i>Cleaning the Headgear and Tube Clip</i>	<ol style="list-style-type: none"> <li>1. Soak the Headgear and Tube Clip Assembly in a 1% concentration solution of Alconox (or equivalent mild alkaline anionic detergent) for 10 minutes at 50 °C, ensuring that no air bubbles are present on the device surface.</li> <li>2. Using a soft non-metallic brush (e.g. medium-hard toothbrush), scrub the parts until visibly clean but not for less than 30 seconds. Pay close attention to crevices, cavities and corners.</li> <li>3. Rinse the parts under running water for at least 30 seconds, intermittently wringing the fabric.</li> <li>4. Submerge in 5 liters of demineralized water while agitating and squeezing for at least 30 seconds.</li> <li>5. Repeat submerged rinse in fresh demineralized water. Ensure that all detergent residue is removed by repeating submerged rinse as many times as necessary.</li> <li>6. Ensure the parts are visibly clean before continuing. If not, repeat steps 1-5.</li> </ol>	
<b>Drying</b>	Make sure mask components are thoroughly dry before continuing by leaving them to air dry out of direct sunlight. Failure to do this may result in ineffective chemical disinfection.		
<b>Disinfection</b>	<b>Thermal Disinfection</b>	<b>Chemical Disinfection</b>	<b>Sterilization</b>
	Run a disinfection cycle in a legally marketed automatic washer-disinfector using one of the time/temperature combinations shown in the reprocessing table. These time/temperature combinations are consistent with EN ISO 15883 and are equivalent in terms of known thermal inactivation kinetics of vegetative microorganisms, meeting an A <sub>0</sub> of 600.	<p><b>For all reprocessible components:</b></p> <ol style="list-style-type: none"> <li>1. Immerse completely in an undiluted bath of CIDEX OPA at 20 °C for 12 minutes, ensuring that no air bubbles are present on the device surface.</li> <li>2. Rinse thoroughly following the manufacturer's rinsing instructions.</li> </ol>	 <b>Caution:</b> The use of STERRAD or Autoclave as a reprocessing method may lead to mask degradation and adverse health effects.
<b>Drying</b>	Allow all components to air dry out of direct sunlight.		
<b>Inspection</b>	Before each use, inspect the mask for deterioration. If any visible deterioration of a mask component is apparent, the mask component should be discarded and replaced.		
<b>Reassembly</b>	Reassemble the mask according to the 'Assembling your mask' instructions provided in the F&P Nova Nasal Instructions for Use. To ensure traceability, mask components belonging to an individual mask must be reassembled back into the same mask after cleaning, excluding the components requiring replacement as marked in the reprocessing table.		
<b>Storage</b>	Ensure the mask is completely dry before storing. Store in clean conditions out of direct sunlight. Storage temperature: -20 °C to 50 °C (-4 °F to 122 °F).		

1. CIDEX is a trademark of ASP Global Manufacturing GmbH.
2. STERRAD is a trademark of ASP Global Manufacturing GmbH.
3. Alconox is a trademark of Alconox, Inc.

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



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