




Document #: CO-6	 Standard Operating Procedure (SOP)	Status: v 0.0 Revised: June 01, 2020 Owner: Shared Health
Reprocessing Single Use N95 respirators due to COVID-19 using STRYKER STERIZONE VP4 Sterilizer		Page 1 of 5

Purpose	<p>To disinfect single use N95 respirators using STERIZONE VP4 Sterilizer throughout the health care site to a maximum of two (2) reprocessing cycles. These will be stored and used as a backup supply to regular inventory on the direction of the Provincial Ministry or Health Authority.</p>
Background	<p>The STERIZONE VP4 uses dual sterilant; vaporized hydrogen peroxide (H₂O₂) and ozone (O₃), in a multiphase process, at low temperature. It uses a single pre-set cycle of hydrogen peroxide and ozone to achieve terminal sterilization of medical devices loads in its 125L chamber. The injection of vaporized hydrogen peroxide is followed by the injection of ozone, which reacts with residual hydrogen peroxide to form hydroxyl radicals. N95 respirators may be reprocessed a maximum of two (2) times.</p>  <ul style="list-style-type: none"> • Visibly soiled (blood, dried sputum, makeup, soil, bodily fluids, etc.) or damaged N95 respirators must be discarded and not reused or disinfected. Furthermore, do not reprocess if the respirator is wet or contains excessive moisture, as this can lead to residual hydrogen peroxide in the N95 respirator which causes a respiratory risk to the user. • N95 respirators should be packaged for processing following the STERIZONE VP4 sterilizer Instructions for Use (IFU). • Do not stack multiple N95 respirators together or process without packaging and chemical indicators. • Do not mix N95 respirators with other instruments in the STERIZONE VP4 Sterilizer. • Wait for an aeration time of at least 24 hours post-sterilizing before using the N95 respirators. • Disinfected N95 respirators are not sterile. • Refer to STERIZONE VP4 User Manual and supplemental documentation for complete operating instructions. • Follow existing policies and CSA standards for proper operating documentation.
Types of N95 respirators	<ul style="list-style-type: none"> • N95 respirators that do not contain cellulose-based or paper materials, natural rubber, latex or activated carbon. (Refer to CO-4 N95 Respirator Content Information from Vendors). • N95 respirators that have either not been reprocessed before or have been reprocessed using the STERIZONE VP4 Sterilizer are compatible.
Required Materials	<ul style="list-style-type: none"> • Black permanent marker (e.g. Sharpie) that conforms to ASTM D-4236 (avoid fine points). • STERIZONE VP4 compatible Tyvek pouches/rolls. • STERIZONE CI+ chemical indicator. • STERIZONE BI+ Self-contained Biological Indicator². • STERIZONE CI+ Chemical Indicator³.

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The Process:

Step	1) Collecting N95 respirators
1.1	Refer to <i>CO-1 N95 Respirator and Eye Protection Collection for Sterilization and Reuse</i> .


Step	2) Sorting
2.1	Refer to <i>CO-3 Sorting Compatible N95 Respirators for Reprocessing</i> .

Step	3) Packaging
3.1	Use PPE (gown, gloves, mask, eye protection) when packaging respirators for reprocessing.
3.2	<p>Confirm that there is no visible damage or soil/contamination prior to prepping the N95 respirator for reprocessing.</p> <p>Use a black permanent marker (e.g. Sharpie) that conforms to ASTM D-4236 (avoid fine points) for all labelling on respirator.</p> <ul style="list-style-type: none"> • Respirators that are unmarked have not been reprocessed. <ul style="list-style-type: none"> ○ Place an “X” on the respirator to indicate this was reprocessed through the STERIZONE VP4 STERILIZER. ○ Place a small line on the N95 respirator to indicate the current reprocessing cycle in order to maintain the reprocessing cycle count. • If the respirator has an “X” and one (1) line marked on it, <ul style="list-style-type: none"> ○ Place a second small line on the N95 respirator to indicate the current reprocessing cycle in order to maintain the reprocessing cycle count. • If the respirator already has an “X” and two (2) lines marked on it, <ul style="list-style-type: none"> ○ The respirator has already reached the maximum number of reprocessing cycles and should be discarded. • Respirators labelled with an “A”, “X”, or “N” have been reprocessed through other equipment and should be returned to sites that have the appropriate equipment for reprocessing. <ul style="list-style-type: none"> ○ Place respirators into clearly labelled bins for possible return


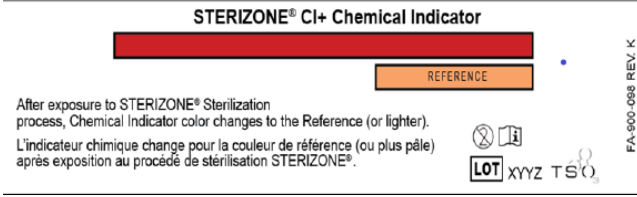


One (1) reprocessing cycle

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<p>3.2</p>	<p>to a site that has the equipment to reprocess the respirator.</p> <ul style="list-style-type: none"> ▪ “C” = Clēan Flow Health Care Mini ▪ “A” = STERRAD 100S, NX, 100NX ▪ “N” = STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 <ul style="list-style-type: none"> • If labelling is not legible or does not conform to labelling conventions, place the respirator aside for further review and consideration of reprocessing. <p>NOTE: The respirator may be reprocessed up to a maximum of two (2) times through the STERIZONE VP4 Sterilizer. Respirators already reprocessed to the maximum two (2) times will be discarded.</p>	 <p><i>Two (2) reprocessing cycles</i></p>
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<p>3.3</p>	<p>Using Tyvek pouches/roll or equivalent product compatible with STERIZONE VP4 Sterilizer, place one N95 respirator in each pouch.</p>
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<p>3.4</p>	<p>Ensure that a STERIZONE CI+ or compatible chemical indicator is contained within each pouch.</p> <div style="display: flex; align-items: center;">  <div style="margin-left: 20px;">  </div> </div>
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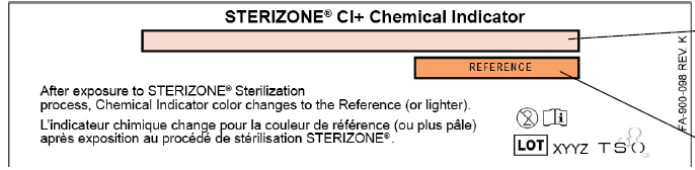
<p>3.5</p>	<p>Make sure both ends of the Tyvek pouches are sealed.</p>
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<p>Step</p>	<p>4) Reprocessing using STERIZONE VP4 Sterilizer</p>
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<p>4.1</p>	<ul style="list-style-type: none"> • Place the pouches onto the loading rack. Using two pouch holders on the bottom shelf will help maximize the rack capacity. • Pouches should not overlap each other. • Loading rack has enough weight and surface area to reach 3:30 minute hydrogen peroxide injection time • Ensure sterilizer is loaded to allow for free flow of vaporized hydrogen peroxide vapor. • Up to 20 respirators can be processed in a sterilization load. 	
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	<ul style="list-style-type: none"> Load temperature should be between 20-26°C (68-78°F). 	
4.2	<p>When running consecutive cycles, ensure the loading rack and pouch holders are cooled down between cycles (approximately 15 minutes) back to a temperature between 20° - 26°C (68° - 78°F). Use of an infrared temperature gun is advised.</p>	
4.3	<p>Place a Test Pack1 containing a STERIZONE BI+ Self-contained Biological Indicator2 (or STERIZONE VP4 compatible biological indicator), and a STERIZONE CI+ Chemical Indicator3 (or STERIZONE VP4 compatible chemical indicator) on the top shelf of the loading rack, as per recommendation of the STERIZONE VP4 Sterilizer User Manual.</p> 	
4.4	<p>Initiate a cycle and once cycle is completed, verify successful completion following the STERIZONE VP4 Sterilizer User Manual.</p>	
4.5	<p>Once cycle is complete, inspect each respirator and discard any damaged ones.</p>	
4.6	<p>Check that the indicator color stripe of the CI+, contained in each package, to ensure it is a lighter color than the reference stripe. If the color is darker than the reference, return respirator to decontamination to be repacked and reprocessed. If the respirator has already been reprocessed twice (2 black lines), discard respirator.</p>  <p>STERIZONE® CI+ Chemical Indicator</p> <p>REFERENCE</p> <p>After exposure to STERIZONE® Sterilization process, Chemical Indicator color changes to the Reference (or lighter). L'indicateur chimique change pour la couleur de référence (ou plus pâle) après exposition au procédé de stérilisation STERIZONE®.</p> <p>LOT xyz TSO</p> <p>FA-600-088 REV. K</p>	
4.7	<p>Keep respirators in Tyvek pouches until next use.</p>	
4.8	<p>Wait for an aeration time of at least 24 hours post-reprocessing before using the N95 respirators.</p>	
4.9	<p>Healthcare facilities should report any discoloration or other signs of degradation with a disinfected, compatible N95 respirator to Shared Health Logistics and STRYKER, and the healthcare facility should discard the respirator.</p>	

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<p>Step</p>	<p>5) Re-issue of N95 respirators</p>
<p>5.1</p>	<p>Return disinfected N95 respirators to Materials Management for entry into inventory, secure storage and re-issue according to PPE policies.</p>