



Document #: CO-5	 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 ASP STERRAD 100S, NX, 100NX Sterilization Systems.		Page 1 of 6

Purpose	To disinfect single use N95 respirators using STERRAD 100S, NX, 100NX Sterilization Systems 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.
Background	<ul style="list-style-type: none"> • The STERRAD Sterilization System disinfects using hydrogen peroxide vapor. • Compatible N95 respirators are those that are compatible with vaporized hydrogen peroxide gas sterilization and can safely and effectively be reprocessed two (2) times after initial use without detrimentally impacting respirator form, fit, or function. • Cellulose-based materials are incompatible with the STERRAD 100S, NX, 100NX Sterilization Systems. • Discard any N95 respirators that are visibly soiled (e.g.: blood, dried sputum, makeup, soil, bodily fluids) or damaged. • Disinfected N95 Respirators are not sterile. • Refer to STERRAD 100S, NX, 100NX User Manuals 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 are compatible. <ul style="list-style-type: none"> ○ Refer to <i>CO-4 N95 Respirator Content Information from Vendors.</i> • N95 respirators that have either not been reprocessed before or have been reprocessed using the STERRAD 100S, NX, 100NX Sterilization Systems 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). • Tyvek and compatible pouches/rolls identified for use in STERRAD 100S, NX, 100NX Sterilization Systems. • Type 1 chemical indicator for vaporized hydrogen peroxide, such as ASP STERRAD Chemical Indicator Strips or SEALSURE® Chemical Indicator Tape. • Velocity biological indicator / process challenge device or CYCLESURE Biological Indicator.

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>

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<p>Step</p>	<p>3) Packaging for Reprocessing</p>
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<p>3.1</p>	<p>Use PPE (gown, gloves, mask, eye protection) when packaging respirators for reprocessing.</p>
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<p>3.2</p>	<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 “A” on the respirator to indicate this was reprocessed through the STERRAD 100S, NX, 100NX Sterilization Systems. ○ 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 “A” 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 “A” 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 a “C”, “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 to a site that has the equipment to reprocess the respirator. <ul style="list-style-type: none"> ▪ “C” = Clēan Flow Health Care Mini ▪ “X” = STERIZONE VP4 ▪ “N” = STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 • If labelling is not legible or does not follow 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 STERRAD 100S, NX, 100NX Sterilization Systems. Respirators already reprocessed to the maximum two (2) times will be discarded.</p>
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One (1) reprocessing cycle



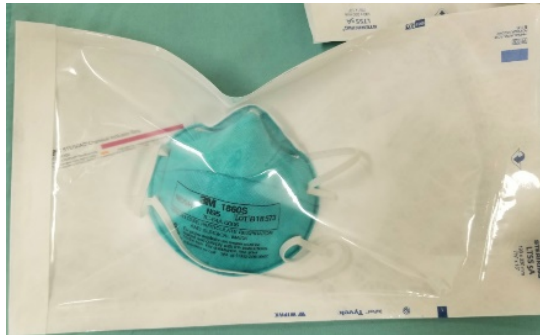
Two (2) reprocessing cycles

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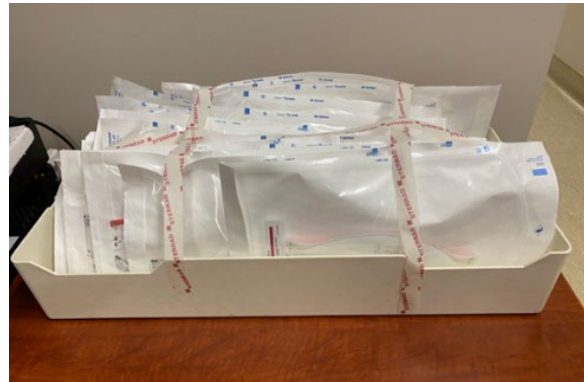
3.3 Using Tyvek pouches/roll or equivalent product compatible with STERRAD 100S, NX, 100NX Sterilization Systems. place one N95 respirator in each pouch.


3.4 Place one STERRAD compatible chemical indicator in each pouch and seal the opening.



3.5 Place the pouched respirators into a STERRAD compatible tray. Ensure the respirators are on the long edge so that they are not layered on top of each other and secure the load using STERRAD compatible tape. The tape will ensure the pouches stay in place and do not touch the sides of the sterilization chamber.

A STERRAD compatible Biological Indicator should be used in accordance with operational protocols for STERRAD Sterilizers.



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Disinfection:


There are 3 different models of STERRAD sterilizers that can be used to disinfect N95 respirators, each with their own specific cycle.


ASP System	Cycle	Cycle Time	Placement
STERRAD 100S System	Short	55 Minutes	Both shelves
STERRAD NX System	Standard	28 Minutes	Both shelves
STERRAD 100NX System	Express	24 Minutes	Bottom shelf only


Failure to use the specific cycle and STERRAD sterilizer will result in an aborted load and reprocessing life.


Important Reminder:


- Do not mix N95 respirators with other instruments in the STERRAD.

Step	4) Reprocessing using STERRAD 100S System
4.1	<ul style="list-style-type: none"> • Load and evenly distribute ten (10) N95 respirators onto both shelves. • Do not overcrowd, overlap, or crush respirators during loading. • Both shelves must be used, or the cycle will abort. • Use a STERRAD compatible Biological Indicator in accordance with operational protocols for STERRAD Sterilizers. 
4.2	Set the cycle to Short and the cycle time to 55 minutes .
4.3	Following completion of the cycle in the STERRAD Sterilizer, the chemical indicator’s color should be compared to the “PASS” reference color. If the colors matched or the color present is lighter, the compatible N95 respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the “PASS” criteria, the compatible N95 respirators should not be considered disinfected and either re-run through the cycle in the STERRAD Sterilizer or discarded.
4.4	Once cycle is complete, inspect each respirator and discard any damaged ones.
4.5	Open each pouch and let sit for 1 hour before using the respirators.
4.6	Healthcare facilities should report any discoloration or other signs of degradation with a disinfected, compatible N95 respirator to Shared Health Logistics and STERRAD, and the healthcare facility should discard the respirator.

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Step	5) Reprocessing using STERRAD NX System
5.1	<ul style="list-style-type: none"> • Load and evenly distribute ten (10) N95 respirators onto both shelves. • Do not overcrowd, overlap, or crush respirators during loading. • Both shelves must be used, or the cycle will abort. • Use a STERRAD compatible Biological Indicator in accordance with operational protocols for STERRAD Sterilizers. 
5.2	Set the cycle to Standard and the cycle time to 28 minutes .
5.3	Following completion of the cycle in the STERRAD Sterilizer, the chemical indicator's color should be compared to the "PASS" reference color. If the colors matched or the color present is lighter, the compatible N95 respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the "PASS" criteria, the compatible N95 respirators should not be considered disinfected and either re-run through the cycle in the STERRAD Sterilizer or discarded.
5.4	Once cycle is complete, inspect each respirator and discard any damaged ones.
5.5	Open each pouch and let sit for 1 hour before using the respirators.
5.6	Healthcare facilities should report any discoloration or other signs of degradation with a disinfected, compatible N95 respirator to Shared Health Logistics and STERRAD, and the healthcare facility should discard the respirator.

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Step	6) Reprocessing using STERRAD 100NX System
6.1	<ul style="list-style-type: none"> Place the tray within sterilization chamber bottom shelf and remove the top shelf. Important: Load cannot touch the walls of the sterilization chamber, door, electrode, or block the ultraviolet lamp beam in the front right side of the chamber. Use a STERRAD compatible Biological Indicator in accordance with operational protocols for STERRAD Sterilizers. 
6.2	Set the cycle to Express and the cycle time to 24 minutes .
6.3	Disable All Clear Technology. Refer to STERRAD 100NX User Manual for complete instructions.
6.4	Following completion of the cycle in the STERRAD Sterilizer, the chemical indicator's color should be compared to the "PASS" reference color. If the colors matched or the color present is lighter, the compatible N95 respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the "PASS" criteria, the compatible N95 respirators should not be considered disinfected and either re-run through the cycle in the STERRAD Sterilizer or discarded.
6.5	Once cycle is complete, inspect each respirator and discard any damaged ones.
6.6	Open each pouch and let sit for 1 hour before using the respirators.
6.7	Healthcare facilities should report any discoloration or other signs of degradation with a disinfected, compatible N95 respirator to Shared Health Logistics and STERRAD, and the healthcare facility should discard the respirator.

Step	7) Re-issue of N95 respirators
7.1	Return disinfected N95 respirators to Materials Management for entry into inventory, secure storage and re-issue according to PPE policies.