FACT SHEET FOR HEALTHCARE PERSONNEL

ASP STERRAD Sterilizers for Decontaminating Compatible N95 FFR Respirators

April 8, 2020

Coronavirus Disease 2019 (COVID-19)

You have been given a **decontaminated N95 or N95-equivalent respirator** that has been decontaminated using a decontamination system **for reuse by healthcare personnel in a healthcare setting** to help prevent healthcare personnel exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of decontaminated compatible N95 respirators. These compatible N95 respirators have been decontaminated using the one of the following *ASP vaporized hydrogen peroxide (VHP) STERRAD Cycles:*

- STERRAD® 100S Short Cycle
- STERRAD NX Standard Cycle, or
- STERRAD 100NX Express Cycle

(hereafter referred to as "**decontaminated compatible N95 respirators**" and "**ASP STERRAD Cycle**" throughout this Fact Sheet).

Decontaminated compatible N95 respirators that have been decontaminated using an ASP STERRAD Cycle are authorized for use by healthcare personnel in a healthcare setting during the COVID-19 pandemic.

Whether or not you use a respirator, always follow infection control measures: wash hands, cover coughs and sneezes, stay home if you may be sick.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of decontaminated compatible N95 respirators?

- The STERRAD 100S Short Cycle, STERRAD NX Standard and STERRAD 100NX Express Cycles have been identified as a method to decontaminate the respirators between use. **Testing was conducted with 3M models 8210 and 1860 and 1860S N95 Particulate Filtering Facemask Respirators (FFR).**

- Validation testing has been completed to ensure that the process is able to demonstrate acceptable performance of 2x decontamination cycles which also include functional properties of the respirator**.**

- **Use of decontaminated compatible N95 respirators:**
  - ✓ Do not use decontaminated N95 Respirators during surgical procedures
  - ✓ Only use for outpatient and patient examination procedures.
  - ✓ Decontaminated N95 Respirators are not Sterile.
  - ✓ Inspect respirators after each use prior to submission for decontamination
  - ✓ Discard respirators with visible soiling (e.g., blood, dried sputum, makeup, soil) or damage – do not use and do not send for decontamination
  - ✓ N95 respirators with cellulose or paper should not be processed in the STERRAD Sterilizer
  - ✓ The number of times a respirator has been decontaminated should be written on the respirator (maximum 2 times)
  - ✓ Report problems with decontaminated N95 respirators to your healthcare facility
  - ✓ Respirators may be safely stored in pouches
  - ✓ It is strongly recommended to maintain chain of custody on the respirator to minimize the risk of cross-contamination

- **Monitor healthcare personnel for signs and symptoms** of potential infection with SARS-CoV-2 or other respiratory infection for up to and including 14 days after last contact with the SARS-CoV-2 virus and related material, and promptly report such information to ASP.

- **Report damage or discoloration** observed upon receipt of the decontaminated compatible N95 respirators, and potential exposure of healthcare personnel from breaks in or other damage to or degradation of the decontaminated compatible N95 respirators.

ASP recommends that healthcare workers pouch their respirators at the end of use with their name or other identifier written on the respirator and pouch. Please note that ASP has used Sharpie markers in VHP for over 15 years. These markers have been used to mark sterilization pouches (used once) and medical devices such as sterilization trays (processed for hundreds of cycles) with no issues observed.

To maintain the reprocessing cycle count, the healthcare worker should place a tick mark on the respirator each time the healthcare worker prepares the respirator for reprocessing. The healthcare worker should confirm that their name is legible prior to placing the respirator in the bag and that there is no visible soil or damage to the respirator. If any visible soil or any damage is present, the respirator should be discarded.

The healthcare worker should place the respirator in the Tyvek pouch and seal it in accordance with healthcare center policies. ASP recommends that each department utilize trays or containers that are normally utilized to deliver surgical instruments to the OR to collect the respirators. When the pouched respirators are ready to be transported to the Sterile Processing decontamination area, they should be transported in a closed case cart to minimize risk of environmental contamination. The case cart should have a hospital -controlled tag or identifier that indicates the location in the hospital where the respirators were utilized.

The Case Cart should be transported to Sterile Processing to the decontamination area by transport personnel assigned by the healthcare facility with training for transport of the material. Unload the respirators in the decontamination area. ASP recommends that the Sterile processing staff following existing processes to decontaminate the case carts and sterilize the transport trays or container for re-use and delivery back to patient areas.

Transfer the pouched respirators through the pass-through window along with the location identifier. Retrieve the pouched N95 respirators and place in the STERRAD for processing. The Sterile Processing staff should adhere to department policy for documenting load contents for the STERRAD Sterilizer.

Use appropriate personal protective equipment (PPE) when caring for individuals suspected of having COVID-19 as outlined in the CDC webpages, including *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID- 19 in Healthcare Settings, Infection Control, and FAQ about PPE.*

Current information on COVID-19 for healthcare personnel is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of using decontaminated N95 respirators?

Potential benefits include:

- May help prevent exposure to airborne pathogens, and therefore risk of infection or illness
- Extends the usability of compatible N95 or N95-equivalent respirators by allowing for decontamination and reuse. The availability of N95 respirators are critical to healthcare workers in the diagnosis and treatment of patients with COVID-19
    - Please note that visibly soiled respirators are excluded from this process and should be discarded immediately

Potential risks include:

- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit
- Reused respirators may not have been effectively decontaminated of SARS- CoV-2 or other pathogens

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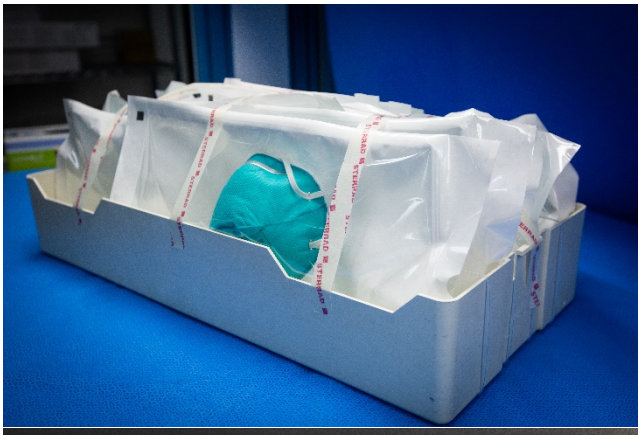
Overview of the ASP STERRAD Sterilizers for Decontaminating Compatible N95 FFR Respirators

The ASP STERRAD Sterilizers are self-contained devices that use vapor phase hydrogen peroxide (VPHP) and plasma phase for decontamination of compatible N95 or N95-equivalent respirators that are contaminated or potentially contaminated with SARS-CoV-2. N95 or N95-equivalent respirators containing paper or cellulose-based materials are incompatible with the ASP STERRAD Sterilizers.



Materials Needed:

- Tyvek® pouch identified for use in vaporized hydrogen peroxide, for example ASP Tyvek Pouch with STERRAD Chemical Indicator.
- Type 1 chemical indicator for vaporized hydrogen peroxide, for example ASP STERRAD Chemical Indicator Strips or SEALSURE® Chemical Indicator Tape.

To decontaminate compatible N95 respirators in a STERRAD 100S Short, STERRAD NX Standard or STERRAD 100NX Express cycle:

- Place Individually pouched compatible N95 respirators in a STERRAD cycle up to the weight and loading limits identified for each cycle in the STERRAD Sterilizer User's Guide.
- A specific orientation of the respirator in the Tyvek pouch or pouches in the sterilizer is not required.
- Pouches should not overlap or cover other pouches.
- A Type 1 indicator for vaporized hydrogen peroxide (for example a chemical indicator or chemical indicator tape) may be used to monitor the cycle. The indicators may be place on the pouch, inside a pouch or within the chamber to provide an indicator that sterilant has been delivered. One indicator per cycle is recommended.
- Follow STERRAD Sterilizer User's Guide instructions on how to initiate a cycle and verify successful cycle completion.
- Upon completion of the cycle, the compatible N95 respirators should be aerated in an opened pouch for 1 hour after which they are ready for use.
- A compatible N95 Respirator may be processed a maximum of 2 times.

Upon completion of the cycle required to reprocess the respirators, the respirators should be loaded back in sterilized trays or containers and placed in a closed case cart following department policy for identifying/labeling processed loads. The department should follow similar protocol for identifying processed loads to transport to the OR for surgical cases. The documentation needs to include a clean copy of the location identifier to ensure return of the respirators to the original location in the facility for distribution to healthcare workers.

Upon return of the respirators to the appropriate individuals, the respirators should be checked to ensure that the name or other identifier is still legible. If not legible, or the respirator is damaged, the respirator should be discarded.

Notes:

- Prior to use, respirators should be inspected for visible damage and/or excessive soil (i.e. blood, dried sputum, makeup, soil). Respirators that are damaged or contain visible soil should be discarded.
- N95 respirators with cellulose or paper should not be processed in the STERRAD Sterilizer.
- Respirators may be safely stored in pouches.
- It is strongly recommended to maintain chain of custody on the respirator to minimize the risk of cross-contamination.

What is an Authorization under an *Interim Order*?

Health Canada has made the emergency use of the ASP STERRAD Sterilizers to decontaminate compatible N95 or N95-equivalent respirators available under an emergency access mechanism called an Interim Order (IO). The IO is supported by Health Canada's declaration that circumstances exist to justify the emergency use of medical devices, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic.

The ASP STERRAD Sterilizers for decontamination of compatible N95 respirators have been made available under an IO and have not undergone the same type of review as a licensed device. Health Canad may issue approval under an IO when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the ASP STERRAD Sterilizers may be effective at preventing healthcare personnel exposure to pathogenic airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by decontaminating, for a maximum of 2 decontamination cycles per compatible N95 or N95-equivalent respirator that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The IO for the ASP STERRAD Sterilizers is in effect for the duration of the COVID-19 declaration justifying emergency use of medical devices, unless terminated or revoked (after which the products may no longer be used for this purpose).

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html
FAQ on Personal Protective Equipment: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations