FACT SHEET FOR HEALTHCARE PERSONNEL

SciCan BRAVO Chamber Autoclave for Decontaminating Compatible Flat-Fold Style N95 Respirators **January 08, 2021**

Coronavirus Disease 2019 (COVID-19)

You have been given a **compatible flat-fold style N95 respirator** (3M 1870+, 9210+ models only) that has been decontaminated **for single-user reuse by healthcare personnel in a healthcare setting** to help prevent 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. Please note that compatible respirators are 3M 1870+ and 9210+ models only. These compatible N95 respirators have been decontaminated using the **121°C Porous Wrapped Cycle** of the **BRAVO 17V or BRAVO 21V Chamber Autoclaves** (hereafter referred to as "**decontaminated N95 respirators**" and "**SciCan BRAVO Autoclaves**" throughout this Fact Sheet).

Decontaminated N95 respirators that have been decontaminated using SciCan BRAVO Autoclaves are authorized for single-user reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic. The BRAVO Chamber Autoclaves are not compatible for respirators that are the moulded/cup style, have exhalation valves or authorized in the Non-NIOSH approved disposable filtering facepiece respirators manufactured in China EUA.

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), while others show mild symptoms like the flu, or none at all. 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 pandemic, 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 from 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including Canada, which may pose risks for public health. For up-to-date information relating to the COVID-19 pandemic, please refer to your Public Health Office website (e.g., Ontario – Public Health Ontario) or Health Canada. Some general links are provided at the end of this Fact Sheet.

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

- The SciCan BRAVO Autoclaves has been authorized by the Interim Order for emergency use to decontaminate compatible N95 respirators for single-user reuse by healthcare personnel during the COVID-19 pandemic to prevent exposure to pathogenic airborne particulates.
- Successful testing demonstrated a 6-log reduction of bacterial spores (which are less susceptible to decontamination than viruses, thereby suggesting support that the decontamination method can safely inactivate viruses), material compatibility, and filtration performance on decontaminated compatible N95 respirators and demonstrated acceptable performance through a maximum of 10 decontamination cycles.

- **Preparing compatible N95 respirators for decontamination:**
  - ✓ At the end of use, write name and/or other identifier using a permanent marker on the respirator so that it may be returned after successful decontamination
  - ✓ Place a tick mark on respirator each time the respirator is prepared for decontamination
  - ✓ Inspect respirators after each use prior to submission for decontamination
  - ✓ Place compatible N95 respirators into a plastic-paper pouch that allows the respirator to lay flat, such as (e.g., Chex-all II SKU 024010).
  - ✓ Seal the respirator in the pouch, and place in designated area for subsequent decontamination per your healthcare facility's procedures
  - ✓ After receiving the decontaminated compatible N95 respirator, perform a seal check to ensure its integrity prior to use. For detailed steps, please refer to the respirator manufacturer's User Instructions.
  - ✓ Discard the compatible N95 respirator after a maximum of 10 decontamination cycles, and if soiled or visibly damaged.

- **Use of decontaminated N95 respirators:**
  - ✓ Decontaminated N95 respirators are not sterile
  - ✓ Do not use decontaminated, compatible N95 respirators in surgical procedures.
  - ✓ Report problems with decontaminated N95 respirators to your healthcare facility

Submit Mandatory Medical Device Problem Reporting, including problems with test performance or results, to Health Canada (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/medical-device.html

✓ N95 respirators may be safely stored in pouches after decontamination
✓ Maintain chain of custody on the N95 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; promptly report such information to SciCan Ltd.

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

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 on the 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 respirators by allowing for decontamination and single-user reuse

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

Overview of the BRAVO Chamber Autoclaves
The SciCan BRAVO Chamber Autoclaves are fractionated vacuum steam autoclaves, which contain a pre-programmed **121°C Porous Wrapped Cycle**, in addition to other cycles intended for terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in healthcare facilities. For this Interim Order, SciCan BRAVO Autoclaves must be operated in the **121°C Porous Wrapped Cycle** to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms.

When the **121°C Porous Wrapped Cycle** starts, air is removed, and steam is injected to penetrate the material through a series of vacuum (extracting air from the sterilization chamber) and pressure (injecting steam into the chamber) phases. This raises the pressure, with the consequent increase in the temperature of the steam, until the autoclave reaches the conditions required for decontamination. Once the decontamination parameters are met, the chamber depressurizes, and the vacuum drying phase begins.

SciCan BRAVO Autoclaves enables single-user reuse of compatible N95 respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled must be discarded and not decontaminated or reused.

What is an Interim Order?
Health Canada has made the emergency use of the SciCan BRAVO Autoclaves to decontaminate compatible N95 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 supplies during the COVID-19 pandemic.

This extended use of the SciCan BRAVO Autoclaves have been made available under the IO and have not undergone the same type of review as a Health Canada-approved or cleared device. Health Canada may issue an IO when certain criteria are met, which includes that there are no adequate, approved, available alternatives. Successful testing demonstrated a 6-log reduction of bacterial spores (which are less susceptible to

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decontamination than viruses, thereby suggesting support that the decontamination method can safely inactivate viruses), material compatibility, and filtration performance on decontaminated compatible N95 respirators and demonstrated acceptable performance through a maximum of 10 decontamination cycles.

The IO for this extended use of the SciCan BRAVO Autoclaves is in effect for the duration of the COVID-19 pandemic, justifying the emergency use of this extended use of the BRAVO Chamber Autoclaves, 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?

Health Canada webpages:

General: https://www.canada.ca/en/health-canada.html
COVID-19: https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html
Interim Order (IO): https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/what-new.html

If you have specific questions, please contact your SciCan Territory Manager, or submit your questions to customerservice@scican.com.

CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html
Infection Control: https://www.cdc.gov/infectioncontrol/index.html
FAQ on Personal Protective Equipment: https://www.cdc.gov/oralhealth/infectioncontrol/faqs/personal-protective-equipment.html

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