FACT SHEET FOR HEALTHCARE PERSONNEL

STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers for Decontaminating Compatible N95 Respirators

May 21, 2020

Coronavirus Disease 2019 (COVID-19)

You have been given a 3M 1860, 3M 1860S, or 3M 1804 NIOSH approved N95 **respirator** ("compatible N95 respirator") that has been decontaminated **for single-user reuse by healthcare personnel in a healthcare setting** to help prevent healthcare personnel exposure to pathogenic biological 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 *STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers* (hereafter referred to as "**decontaminated N95 respirators**" and "**STERIS STEAM Decon Cycle**" throughout this Fact Sheet).

Whether or not you use a surgical mask, respirator, or face shield, 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). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, or new loss of taste or smell. 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.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, 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 N95 respirators?

- The STERIS STEAM Decon Cycle has been authorized 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 biological airborne particulates.
- **The STERIS STEAM Decon Cycle is currently limited to the decontamination of 3M 1860, 3M 1860S, and 3M 1804 NIOSH-approved N95 respirators only. These N95 respirators are labeled with their model numbers. Other N95 or N95-equivalent respirators have not yet been demonstrated to be compatible with the STERIS STEAM Decon Cycle.**
- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through 10 decontamination cycles for sporicidal activity, material compatibility, fit testing, and filtration performance.
- **Preparing compatible N95 respirators for decontamination:**
  - ✓ Place the compatible N95 respirator at the end of use into its own sterilization pouch. Respirators should not share pouches.
  - ✓ Write name and/or other identifier using a permanent marker so the respirator may be returned after successful decontamination.
  - ✓ Place a tick mark on respirator each time a respirator is prepared for decontamination. **If there are already 10 tick marks, discard the respirator.**
  - ✓ Seal the respirator in the sterilization pouch, and place it into area for subsequent decontamination per your healthcare facility's procedures.
  - ✓ **Discard if decontaminated 10 times** or if visibly soiled or damaged.

Report Adverse events, including problems with device performance, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

- **Use of decontaminated N95 respirators:**
  - ✓ Decontaminated N95 respirators are not sterile.
  - ✓ Inspect respirators after each use prior to submission for decontamination.
  - ✓ If decontaminated N95 respirators are soiled or damaged, discard them.
  - ✓ The number of times a respirator has been decontaminated will be written on the respirator (maximum 10 times).
  - ✓ Report problems with decontaminated N95 respirators to your healthcare facility.
  - ✓ Check decontaminated N95 respirators for fit and breathability before use.
  - ✓ 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, and promptly report such information to your healthcare facility.

- **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 to your healthcare facility.

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 reduce the 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 STERIS STEAM Decon Cycle

The STERIS Medium Steam Sterilizers, specifically the AMSCO 400 Series Medium Steam Sterilizers (36H, 48H, 60H, 36SL, 48SL, 60SL, 36CH, 48CH, 60CH, 36CSL, 48CSL, 60CSL) or AMSCO Century Medium Steam Sterilizers 26" x 37.5" (x 36", 48", or 60"), are FDA-cleared for sterilization of heat and moisture-stable materials used in healthcare facilities and contain pre-programmed sterilization cycles. For this emergency use, STERIS Corporation developed a new cycle, the STERIS STEAM Decon Cycle, to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms.

In the STERIS STEAM Decon Cycle, the temperature inside the sterilization chamber is increased to 65°C and 21 in mercury (Hg) exposure pressure. Once the temperature and pressure reach the set point, the cycle is held for 30 minutes, followed by a one-minute dry time.

The STERIS STEAM Decon Cycle 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 reused or decontaminated.

What is an EUA?

The United States FDA has made the emergency use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers to decontaminate compatible N95 respirators available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices due to insufficient supply during the COVID-19 pandemic.

The STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers is authorized to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms, for a maximum of 10 decontamination cycles per respirator, for single-user reuse by healthcare personnel. The STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers has not been FDA-approved or -cleared for this use. The STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers has been made available under an EUA and has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA 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 STERIS STEAM Decon Cycle may be effective at preventing healthcare personnel exposure to pathogenic biological airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by decontaminating, for a maximum of 10 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms.

The EUA for the STEAM Decon Cycle in AMSCO Medium Steam 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).

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