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Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination Using the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers (hereafter referred to as the "STERIS STEAM Decon Cycle") for use in decontaminating **3M N95 respirator models 8210, 1860, 1860S, and 1804** (hereafter referred to as "compatible N95 respirators") for single-user reuse by healthcare personnel (HCP) to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. HCP should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination by the STERIS STEAM Decon Cycle.

The STERIS STEAM Decon Cycle 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 4 decontamination cycles per respirator, for single-user reuse by healthcare personnel. The STERIS STEAM Decon Cycle has neither been cleared or approved for this use. The STERIS STEAM Decon Cycle is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Respirators that are NIOSH-approved before decontamination (https://wwwn.cdc.gov/niosh-cel/) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated NIOSH-approved respirator, please check with the respirator manufacturer and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.

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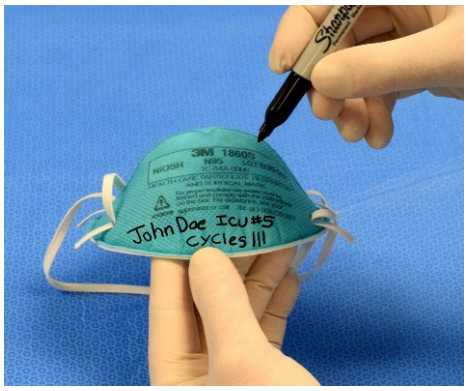
- **The STERIS STEAM Decon Cycle is currently limited to the decontamination of 3M 8210, 3M 1860, 3M 1860S, and 3M 1804 N95 NIOSH-approved respirators only.**
- **HCP must perform a user seal check of the decontaminated, compatible N95 respirator according to OSHA standards prior to beginning a shift. If the user seal check does not pass, discard the respirator.**
- **All compatible N95 respirators used in the STERIS STEAM Decon Cycle must be free of visible damage and soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids).**
- **Discard and do not collect compatible N95 respirators that are visually soiled or damaged.**
- **Discard compatible N95 respirators after exceeding 4 decontamination cycles.**
- **Discard any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified.**
- **Decontaminated, compatible N95 respirators are not sterile.**
- **The STERIS STEAM Decon Cycle has neither been cleared or approved by FDA but has been authorized for emergency use by FDA under an EUA for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates.**
- **The emergency use of the STERIS STEAM Decon Cycle is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.**

Compatible N95 Respirator Marking, Collection, and Return:

1. Maintain chain of custody on your compatible N95 respirator to minimize the risk of cross-contamination. Label with your name and/or other identifier using a permanent marker. Labeling should be legibly written on the outside OR inside of each N95 respirator, as shown below.
2. Place a tick mark on your compatible N95 respirator each time to maintain the decontamination cycle count. NOTE: **Your respirator may be decontaminated up to a maximum of 4 times. If your respirator already contains 4 tick marks, discard the respirator.**
3. Confirm that the labeling is legible, and that there is no visible damage or soil/contamination prior to pouching the compatible N95 respirator.
4. Place your respirator in the sterilization pouch provided by your healthcare facility and seal it. Place the pouched respirator at the healthcare facility's designated collection station.



5. After receiving your decontaminated, compatible N95 respirator, please check to ensure that the respirator returned to you has your name and/or appropriate identifier on it. Check for fit and breathability, and look for any signs of degradation.
6. If at any time the labeling is not legible or there is visible soil or damage, discard the respirator. Discard the respirator after exceeding 4 decontamination cycles.

NOTE: Only compatible N95 respirators in sterilization pouches can be placed at this collection station for decontamination. No other items will be decontaminated in the same cycle.