Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination in ASP STERRAD Sterilization Systems

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of ASP STERRAD Sterilization Systems are to be used in the following cycles to decontaminate compatible N95 respirators: the ASP STERRAD 100S Sterilization System is operated in the 100S cycle, the ASP STERRAD NX Sterilization System is operated in the Standard cycle, or the ASP STERRAD 100NX Sterilization System is operated in the Express cycle (hereafter referred to as the "STERRAD Sterilization Systems") for use in decontaminating compatible N95 respirators for single-user reuse (i.e., the same respirator is returned for reuse to the same healthcare personnel following its decontamination) by healthcare personnel to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination using the STERRAD Sterilization Systems.

The STERRAD Sterilization Systems have neither been cleared or approved by the FDA, but have been authorized for emergency use by FDA under an EUA for decontamination of compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates. The emergency use of the STERRAD Sterilization Systems 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.

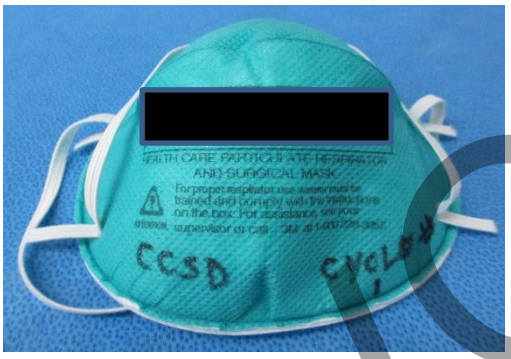
Respirators that are NIOSH-approved before decontamination (https://wwwn.cdc.gov/niosh-cel/) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH 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.

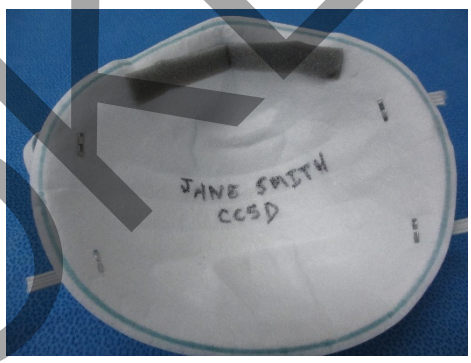
- **The STERRAD Sterilization Systems are not authorized for use with the following:**
  - **Respirators or pouches containing cellulose-based materials;**
  - **Respirators that have exhalation valves;**
  - **Respirators containing antimicrobial agents;**
  - **Respirators with duck-billed designs; and**
  - **Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.**
- **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 STERRAD Sterilization Systems must be free of visible damage and soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids).**

- **Do not collect compatible N95 respirators that are visually soiled or damaged for decontamination, and discard such respirators.**
- **Discard compatible N95 respirators after exceeding 2 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.**

<u>Compatible N95 Respirator Marking, Collection, and Return</u>:

1. ASP recommends maintaining chain of custody on the compatible N95 respirators to minimize the risk of cross-contamination. Pouch your own individual compatible N95 respirator in Tyvek or compatible sterilization pouches, at the end of use. Label with your name and/or other identifier using a permanent marker. Labeling should be legibly written on the outside OR inside of each compatible N95 respirator, as shown below .





2. Place a tick mark on your compatible N95 respirator and Tyvek pouch each time to maintain the decontamination cycle count. <u>NOTE</u>: **your respirator and Tyvek pouch may be decontaminated up to a maximum of 2 times.**

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 compatible N95 respirator in the Tyvek pouch provided by your healthcare facility and seal it. Place the pouched, compatible N95 respirator at the healthcare facility's designated collection station.

5. After receiving your decontaminated, compatible N95 respirator, check that the appropriate respirator was returned to you.

6. If at any time the labeling is not legible or there is visible soil or damage, discard the respirator. Discard the respirator and Tyvek pouch after 2 decontamination cycles.

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