

Instructions for Healthcare Personnel & Healthcare Facilities:

Preparation of Compatible N95 Respirators for Decontamination by Stryker Sustainability Solutions

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Stryker Sustainability Solutions VHP N95 Respirator Decontamination System (hereafter referred to as “SSS Decontamination System”) for use in decontaminating compatible N95 respirators for multiple-user reuse 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 by Stryker Sustainability Solutions (SSS) using the SSS Decontamination System.

The SSS Decontamination System has been authorized by FDA under an EUA for use in decontaminating compatible N95 respirators for multiple-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during the COVID-19 outbreak. The SSS Decontamination System has neither been cleared nor approved for this use. The SSS Decontamination System 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 the authorization is revoked sooner.

Respirators that are NIOSH-approved before decontamination (<https://www.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 SSS Decontamination System is not authorized for use with the following:**
 - Respirators containing cellulose-based materials;
 - Respirators containing exhalation valves;
 - Respirators containing antimicrobial agents;
 - Respirators containing 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 provided to Stryker Sustainability Solutions must be free of any visible soiling or contamination (e.g., blood, bodily fluids, makeup).**
- **Do not collect compatible N95 respirators that are visibly soiled or damaged for decontamination. Any visibly soiled or damaged respirators that have been collected will be disposed of by Stryker Sustainability Solutions.**



- Discard compatible N95 respirators after exceeding 3 decontamination cycles.
- Decontaminated, compatible N95 respirators are not sterile.
- The SSS Decontamination System 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 multiple-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;
- The SSS Decontamination System 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.
- Healthcare facilities must ensure that HCP receive the same model of decontaminated compatible N95 respirator for which they have been fit tested. If such model of respirator is unavailable, then healthcare facilities must provide HCP with fit testing prior to using an alternative model of decontaminated, compatible N95 respirator.

Compatible N95 Respirator Collection:

- Your local Stryker Service Representative will provide you with the collection materials needed to maximize the collections at your healthcare facility; i.e., hamper stands, individual respirator collection bags, hamper stand collections bags, boxes, and more.
- N95 respirator hamper stands are designated with a sticker on the lid stating “N95 respirators ONLY”. They are located in critical care units, emergency departments, and patient floors.

NOTE: Collection bags are for compatible N95 respirators only; do not throw other personal protective equipment (such as gloves, face masks, and surgical masks), paper towels, or waste in the collection bags.

Note: Please follow either instruction set A (Collection and Packaging) or B (Collection ONLY) below, depending on your healthcare facility’s policy.

A. Hospital Completing Collection and Packaging:

1. Hospital staff place compatible N95 respirators in a designated hamper stand.
2. Remove the teal bag from the hamper stand.
3. Tightly tie the top of the bag in a knot.
4. Place bag into a second teal bag and tie the top of second bag in a knot.
5. Replace the bag in the hamper stand with a new empty bag.
6. Spray or wipe the second bag with disinfectant.
7. Place the bag into the large shipping box.
8. Place the customer bar code label on the top of the inside small flap. The bar code label should not be visible once the box is sealed. **Avoid placing the bar code label in the cut line.**
9. Tape the box securely closed.
10. Place a white, Phoenix UPS label on the top exterior of the shipping box.
11. Take the sealed box to a designated shipping area for UPS pick-up.

B. Hospital Completing Collections (Stryker Completing Packaging):

1. Hospital staff place compatible N95 respirators in a designated hamper stand.
2. Remove the teal bag from the hamper stand.
3. Tightly tie the top of the bag in a knot.
4. Place bag into a second teal bag and tie the top of second bag in a knot.
5. Spray or wipe the second bag with disinfectant.
6. Replace the bag in the hamper stand with a new empty bag.
7. Place tied bags in a location that is consistent with your current patient care collections, for SSS pick up.

Stryker Sustainability Solutions personnel will complete the following steps:

8. Spray or wipe the second bag with disinfectant.
9. Place the bag into the large shipping box.
10. Place the customer bar code label on the top of the inside small flap. The bar code label should not be visible once the box is sealed. **Avoid placing the bar code label in the cut line.**
11. Tape the box securely closed.
12. Place a white, Phoenix UPS label on the top exterior of the shipping box.
13. Take the sealed box to a designated shipping area for UPS pick-up.

Any problems should be immediately reported to Stryker Sustainability Solutions

SSS Contact: 888-888-3433 or chsteam@stryker.com