#### 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. 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).



- Due to incompatibility, the Stryker Sustainability Solutions Decontamination System is not authorized for use with respirators containing cellulose-based materials.
- 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 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 has been authorized by FDA under an EUA;
- 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 unless the authorization is terminated or revoked sooner.

## **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. <u>Hospital Completing Collection and Packaging:</u>

- 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. <u>Hospital Completing Collections (Stryker Completing Packaging):</u>

- 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