Instructions for Healthcare Facilities: Emergency Use of Sterilucent Sterilization System to Decontaminate Compatible N95 Respirators

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Sterilucent HC 80TT Vaporized Hydrogen Peroxide Sterilizer (hereafter referred to as the "Sterilucent Sterilization System") to be used on the Sterilucent N95 Respirator Decontamination Cycle ("Flexible" Pre-Programmed Sterilization Cycle) for use in decontaminating compatible N95 or N95-equivalent respirators (hereafter referred to as "compatible N95 respirators") for single-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 using the Sterilucent Sterilization System.

- **Due to incompatibility, the Sterilucent Sterilization System is not authorized for use with respirators or pouches containing cellulose-based materials.**
- **Use proper hand hygiene and gloves when removing or handling potentially contaminated N95 respirators.**
- **All compatible N95 respirators used in the Sterilucent Sterilization System must be free of visible damage and visual soil/contamination (e.g. blood, dried sputum, makeup, soil, bodily fluids).**
- **Compatible N95 respirators that are visually soiled or damaged should not be collected for decontamination and should be discarded.**
- **Each compatible N95 respirator should be individually packaged in a Tyvek Self-seal pouch, or equivalent pouch.**
- **Compatible N95 respirators should be discarded after 10 decontamination cycles.**
- **Any compatible N95 respirator whose traceability was lost or number of decontamination cycles was not able to be identified should be discarded.**
- **Decontaminated compatible N95 respirators are not sterile.**

Materials Needed:

- Tyvek pouch identified for use in vaporized hydrogen peroxide, for example, a Tyvek Self-seal pouch, or equivalent pouch
- Sterilucent VH_2O_2 Chemical Indicator (Class 1/Type 1 process indicator)
- Sterilucent "Flexible Cycle" Process Challenge Device (PCD-F) Test Pack (containing a Self-contained Biological Indicator)

Compatible N95 Respirator Marking:

The healthcare facility should ensure that the chain of custody is maintained to minimize risk of cross-contamination. Prior to collection by the healthcare facility personnel, the healthcare personnel should label their own individual compatible N95 respirator with their name and/or identifier, and number of decontamination cycles (as shown below) with a permanent marker, such as a permanent marker. The healthcare personnel should pouch the compatible N95 respirator in a Tyvek pouch, label the pouch with the decontamination cycle count, and seal it. The compatible N95 respirator in the Tyvek pouch should be placed at a designated collection station. See the *"Instructions for Healthcare Personnel"* for details.

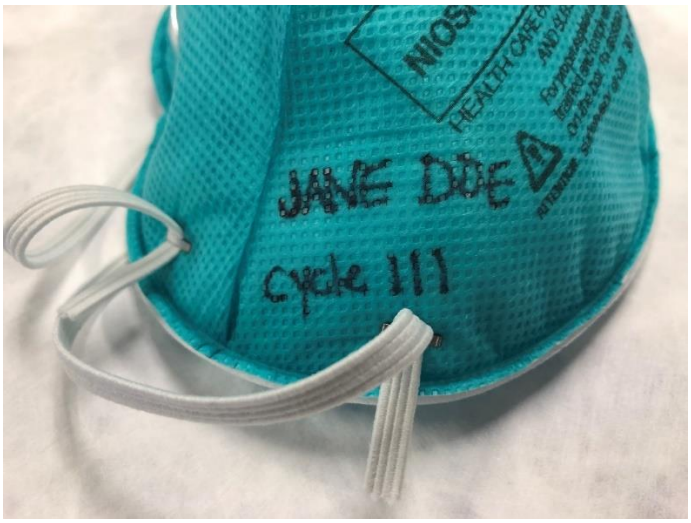

Figure 1: Chain of custody identification of N95 compatible respirators

Compatible N95 Respirator Collection and Transportation:

1. The healthcare facility should create a collection station at the point of generation (i.e., hospital floor/unit). Each station should have a basket or container provided by the healthcare facility to collect the pouches containing the compatible N95 respirators for decontamination with the following note:
   NOTE: Only compatible N95 respirators in Tyvek, or equivalent, pouches should be placed at this collection station for decontamination. No other items will be decontaminated in the same decontamination cycle.
2. The healthcare personnel who are assigned to decontamination (i.e., those with training for collection/transport of such materials) should collect the Tyvek pouches containing the compatible N95 respirators at the collection stations, and place them into the appropriate container for transportation, such as a closed case cart, to minimize risk of environmental contamination. The case cart should have a hospital-controlled tag or identifier that indicates the location in the hospital where the respirators were utilized.
3. The case cart should be transported to healthcare facility's decontamination area.

Use of the Flexible Cycle in the Sterilucent Sterilization System:

1. Prior to sterilization, compatible N95 respirators should be individually packaged in a Tyvek® Self-Seal pouch or equivalent pouch (Figure 2). A Sterilucent VH_2O_2 Chemical Indicator (Class 1/Type 1 process indicator) should be used in or on every pouch.

2. A maximum of 12 respirators should be loaded on edge, side-by-side, in a sterilization basket (Figure 3). Tyvek pouches should never be stacked on top of one another. Ensure that respirators are not crushed or damaged when packaged and placed in the sterilization basket. (Caution: Do not combine any other load with the 12-pouch N95 respirator load).

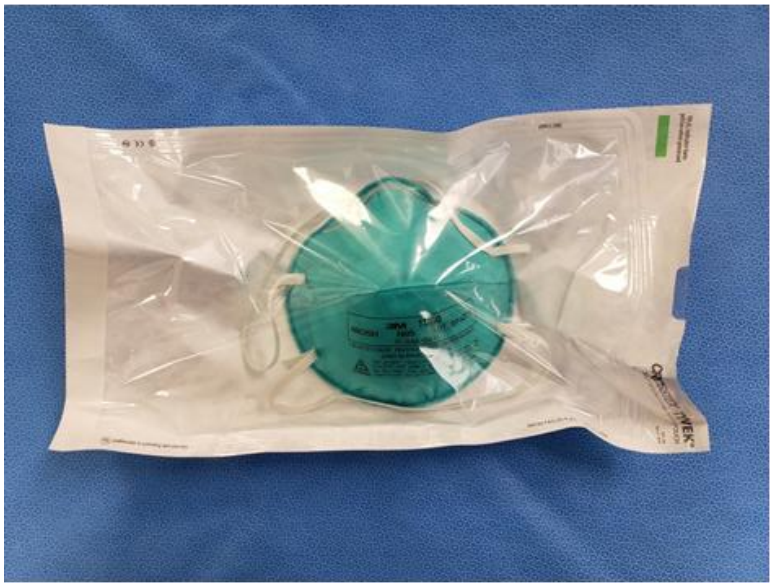

Figure 2: Single compatible N95 respirator packaged in a Tyvek pouch.

Figure 3: Up to twelve (12) individually packaged respirators placed side-by-side in a sterilization basket.

3. A Sterilucent "Flexible Cycle" Process Challenge Device (PCD-F) Test Pack (containing a Self-contained Biological Indicator) should be used at least daily, but preferably in every sterilization

cycle, to provide an indicator that sterilant has been delivered. The Test Pack should be placed in the rear corner of the sterilization basket.

4. A single basket should be placed inside on the lower shelf of the sterilizer chamber (Figure 4).

Figure 4: Sterilization basket with up to 12 individually packaged respirators, placed inside of the Sterilucent sterilizer.

5. After closing the sterilizer door, select the "Flexible Cycle", using the Instructions for Use for the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer, which will run for approximately 35 minutes.

After the Flexible Cycle in the Sterilucent Sterilization System is complete:

1. Upon completion of the cycle, the sterilization basket should be removed from the chamber and allowed to aerate for a minimum of 6 hours before use.
2. Following completion of the Flexible Cycle in the Sterilizer, the chemical indicator's color should be compared to the "PASS" reference color (Figure 5). If the indicator color matches the reference color or is lighter, the respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the "PASS" criteria, the compatible N95 respirator should not be considered decontaminated and either repackaged and decontaminated through another Flexible Cycle in the Sterilucent Sterilization System or discarded. Please note that successful completion of the cycle and passing chemical indicator signifies appropriately decontaminated, compatible N95 respirators. These results do not indicate sterility of the decontaminated, compatible N95 respirators. Any respirators with visible damage should be discarded.

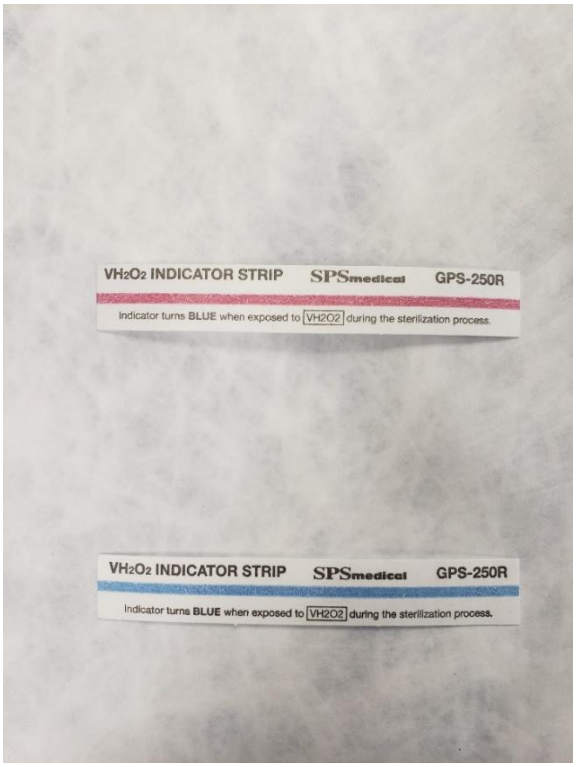

Figure 5: Chemical indicator control color (pink) and processed "PASS" color (blue).

3. Process the Sterilucent Test Pack in accordance with the PCD-F Instructions for Use.
4. Healthcare facilities should utilize existing processes to decontaminate the case carts and sterilize the transport basket or container for reuse and delivery of decontaminated, compatible N95 respirators back to patient areas.
5. Decontaminated, compatible N95 respirators that match the "PASS" criteria should be loaded back into the sterilized basket or containers and placed in a closed case cart following the healthcare facility's policy for identifying/labeling processed loads. The healthcare facility should follow similar protocol for identifying processed loads to transport to the operating room for surgical cases. The documentation needs to include a clean copy of the location identifier to ensure return of the respirators to the original location in the facility for distribution to healthcare workers.
6. The healthcare facility should ensure that the chain of custody is maintained to minimize risk of cross-contamination. Upon return of the decontaminated, compatible N95 respirators to the appropriate individuals, the respirator should be checked for the following:
    a. Ensure that the name or other identifier and number of decontamination cycles is still legible. Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified should be discarded.
    b. Any compatible N95 respirator that is visually damaged or soiled should be discarded.
    c. Any compatible N95 respirator that has exceeded 10 decontamination cycles should be discarded.
    d. Ensure that the compatible N95 respirator is returned to its previous user.
7. The healthcare facility should make available the "Fact Sheet for Healthcare Personnel:

Sterilucent Sterilization System for Decontaminating Compatible N95 Respirators" upon return of the decontaminated, compatible N95 respirators.

Additional Information:

1. Prior to use, healthcare personnel should inspect decontaminated, compatible N95 respirators for visible damage and soil/contamination (i.e., blood, dried sputum, makeup, soil, bodily fluids, excessive odor). Respirators that are damaged or contain visible soil should be discarded.
2. N95 respirators or pouches containing cellulose should not be processed in the Sterilucent Sterilization System.
3. N95 respirators may be safely stored in pouches.
4. It is strongly recommended to maintain chain of custody on the compatible N95 respirator to minimize the risk of cross-contamination between individuals.

Reporting to Sterilucent, Inc.:

Healthcare facilities should report any damage, discoloration, excessive odor, or other signs of degradation with a decontaminated, compatible N95 respirator to healthcare facility management and Sterilucent, Inc., and the healthcare facility should discard the respirator.

Healthcare facilities using the decontaminated, compatible N95 respirators should monitor healthcare personnel who use such respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and promptly report such information to Sterilucent, Inc., so that Sterilucent can provide a weekly report to FDA. Reports of adverse events should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.

Complaints or Adverse Event Reporting may be submitted to Sterilucent, Inc. as follows:

Phone: 877-721-8405
Email: customer.care@sterilucent.com