**Instructions for Healthcare Facilities: Emergency Use Decontamination of Compatible N95 or N95-equivalent Respirators in Stryker's STERIZONE VP4 Sterilizer Using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle**

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of the Stryker's STERIZONE VP4 N95 Respirator Decontamination Cycle for use in decontaminating compatible N95 or N95-equivalent respirators (hereafter referred to as the "compatible N95 respirators") in healthcare facilities for single-user reuse by healthcare personnel. The STERIZONE VP4 Sterilizer contains one (1) pre-programmed cycle. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination by the STERIZONE VP4 N95Respirator Decontamination Cycle.

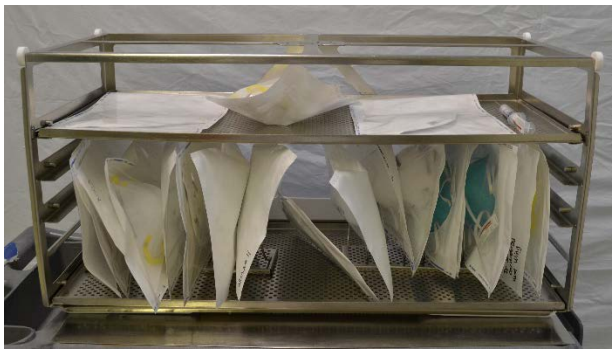
- **Due to incompatibility, the STERIZONE VP4 N95 Respirator DecontaminationCycle is not authorized for use with respirators containing cellulose-based or paper materials, natural rubber, or latex.**
- **Discard compatible N95 with visible soiling (e.g., blood, dried sputum, makeup, soil) or damage – do not use and do not send for Decontamination.**
- **If compatible N95 respirators are soiled or damaged, they should be discarded.**
- **Decontaminated compatible N95 respirators are Not Sterile.**

**Materials Needed**:

- Tyvek pouch (non-woven polyethylene with polyester/LDPE transparent film) identified for use in Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle
- STERIZONE Test Pack for Stryker STERIZONE VP4 Sterilizers – It is recommended to place a test pack containing a STERIZONE® BI+ Self-contained Biological Indicator each day the sterilizer is used but preferably in every decontamination cycle load.

**To use the Stryker's STERIZONE VP4 Sterilizer:**

1. A compatible N95 Respirator should be placed in a Tyvek pouch with a STERIZONE CI+ Chemical Indicator. Follow the STERIZONE CI+ Chemical Indicator Instructions for Use (MA-900-044).
   - Do not decontaminate a respirator that is wet or contain excessive moisture.
   - Be careful not to deform the respirator as it could negatively impact its fit.
2. A maximum of 20 pouched compatible N95 Respirators (17 pouches on lower shelf, 3 on top shelf) can be processed in STERIZONE VP4 N95 Respirator Decontamination Cycle. (**Caution:** Do not combine any other medical devices with the 20 pouched N95 Respirator Load).



3. Pouches should not overlap each other.
4. It is recommended that a pouch holder (Stryker part number 41303) be used to hold the pouches in a vertical configuration but is not required for adequate decontamination.
5. STERIZONE Test Pack is used for routine monitoring of the sterilizer cycle. The STERIZONE Test pack shall be placed on the top shelf of the load as per recommendation of the STERIZONE VP4 Sterilizer User Manual. It is recommended to place a test pack containing a STERIZONE® BI+ Self-contained Biological Indicator each day the sterilizer is used but preferably in every decontamination cycle load. Follow the STERIZONE VP4 Test Pack Instructions for Use (MA-900-066) and the STERIZONE BI+ Indicator Instructions for Use (MA-900-043).
6. Follow Stryker STERIZONE VP4 Sterilizer User Manual instructions on how to initiate a cycle and to verify a successful cycle completion (MA-200-051).
7. Upon completion of the cycle, and after a 24-hour aeration period, the compatible N95 respirators are ready for use.
8. Compatible N95 Respirators may be decontaminated a maximum of two (2) times.

Upon completion of the cycle, respirators should be loaded back in sterilized trays or containers and placed in a closed case cart following department policy for identifying/labeling processed loads. The department should follow a protocol that is similar to the protocol for identifying processed loads to transport to the Operating Room for surgical cases. [Note: decontaminated respirators are not sterile.] 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 the original healthcare workers.

Upon return of the respirators to the appropriate individuals, the respirator should be checked to ensure that the name or other identifier is still legible. If not legible, or the mask is damaged, the mask should be discarded.

**Marking:**

1. Your organization should create a collection station at the point of generation (i.e., hospital floor/unit)
2. Each station should have a bag provided by the healthcare facility to collect compatible N95 respirators with the following note.
   **NOTE: Bags are for compatible N95 respirators only. Do not throw other personal protective equipment (such as gloves), paper towels, or waste in the collection bag.**
3. With a permanent marker, the healthcare personnel should label their own individual compatible N95 respirators with their name, identifiers, and number of reprocessing cycles (such as a tick mark). Note: the compatible N95 respirators may be decontaminated a maximum of 2 times.
4. Healthcare personnel should follow the instructions provided by Stryker in Instructions for Healthcare Personnel: Preparation of compatible N95 Respirators or N95-equivalent Respirators for Decontamination by the STERIZONE VP4 Sterilizer Using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle.


**Notes:**

1. Prior to use, respirators should be inspected for visible damage and/or excessive soil (i.e. blood, dried sputum, makeup, soil). Respirators that are damaged or contain visible soil should be discarded.
    - Examine all parts of the respirators including the filtration media, the straps, the nose foam, the nose clip, the exhalation valves (parts present will depend on the model design);
    - The respirator should not show physical change, including color and texture;
    - Attention should be paid to the straps to ensure that they can still properly maintain the respirator fit;
    - If the respirator model has an exhalation valve, verify that it can properly open and close;
    - If a respirator model consistently shows material degradation after decontamination, discontinue the practice of respirator decontamination for that model and notify Stryker.
2. Do not decontaminate a respirator that is wet or contains excessive moisture.
3. N95 respirators with cellulose, paper, natural rubber, or latex should not be processed in the STERIZONE VP4 Sterilizer.
4. It is recommended to perform an evaluation of the respirator facial fit after decontamination following the recommendation of the manufacturer, or the facility policy.
5. Respirators may be safely stored in pouches.
6. Maintain chain of custody on the respirator to minimize the risk of cross-contamination.

**Chain of Custody:**

Stryker recommends that healthcare workers pouch their respirators at the end of use with their name or other identifier written on the mask and pouch with a permanent marker. Permanent markers are used with the VHP process to mark decontamination pouches and wrap (used once).

To maintain the decontamination cycle count, the healthcare worker should place a tick mark on the respirator each time the healthcare worker prepares the respirator for decontamination. The healthcare worker should confirm that their name is legible prior to placing the respirator in the bag and that there is no visible soil or damage to the respirator. If any visible soil or any damage is present, the respirator should be discarded.

The healthcare worker will place the respirator in the Tyvek pouch, ensure that a STERIZONE CI+ chemical indicator strip is included in the bag, and seal it. Stryker recommends that each department utilize clean trays or containers that are normally utilized to deliver surgical instruments to the Operating Room to collect the masks. When the pouched respirators are ready to be transported to the Sterile Processing Decontamination area, they should be transported in 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.

The case cart should be transported to Sterile Processing to the decontamination area by transport personnel assigned by the healthcare facility with training for transport of the material. Unload the respirators in the decontamination area. Stryker recommends that the sterile processing staff following existing processes to decontaminate the case carts and sterilize the transport trays or container for re-use and delivery back to patient areas.

Transfer the pouched respirators through the pass-through window along with the location identifier. Retrieve the pouched N95 respirators and place in the STERIZONE VP4 Sterilizer for processing. The sterile processing staff should adhere to department policy for documenting load contents for the sterilizer. Upon completion of the decontamination cycle, the masks should be loaded back in sterilized trays or containers and placed in a closed case cart following department policy for identifying/labeling processed loads. The department should follow a protocol that is similar to the 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 of each respirator to the original healthcare worker.

Upon return of the respirators to the appropriate individuals, they should be checked to ensure that the name or other identifier is still legible. If not legible, or if the respirator is damaged, the respirator should be discarded.

**Single-User Reuse Information:**

Following decontamination, you will be provided **decontaminated compatible N95 respirators** that have been processed through a decontamination system for single-user reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic. Before reuse, healthcare personnel should inspect each decontaminated, compatible N95 respirator for:

1. Numeric indication of the decontamination cycle number.
   **NOTE: Compatible N95 respirators will be disposed of after 2 decontamination cycles.**
2. Legible identifier, visible damage or soiling.
   **NOTE**: **Compatible N95 respirators should be discarded and not reused if the name or other identifier are illegible or the mask is visually damaged or soiled.**

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