

Instructions for Healthcare Facilities: Emergency Use Decontamination of Compatible N95 Respirators in Stryker’s STERIZONE VP4 Sterilizer Using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle in STERIZONE VP4 Sterilizers (referred to as “STERIZONE VP4 Sterilizer”) for use in decontaminating compatible N95 respirators in healthcare facilities for single-user reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. Compatible N95 respirators are any non-cellulose containing respirators that do not have an exhalation valve, antimicrobial agents, or a duck-billed design and that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at <https://www.fda.gov/emergency-preparedness-and-response/mcmlegal-regulatory-and-policy-framework/emergency-use-authorization>. Please see FDA’s website for further information on N95 respirators, available at <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks>.

The STERIZONE VP4 Sterilizer contains one (1) pre-programmed cycle. Healthcare personnel (HCP) should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination using the STERIZONE VP4 N95 Respirator Decontamination Cycle in the STERIZONE VP4 Sterilizer.

The STERIZONE VP4 Sterilizer has neither been cleared or approved by FDA, but has been authorized by FDA under an EUA for use in decontaminating compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during the COVID-19 outbreak. The emergency use of the STERIZONE VP4 Sterilizer 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 STERIZONE VP4 N95 Respirator Decontamination Cycle in the STERIZONE VP4 Sterilizer is not authorized for use with the following:**
 - **Respirators containing cellulose-based materials;**
 - **Respirators containing antimicrobial agents;**
 - **Respirators with duck-billed designs;**

- Respirators containing exhalation valves; 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.
- Discard compatible N95 with visible soiling (e.g., blood, dried sputum, makeup, soil) or damage – do not use and do not send for decontamination.
- Compatible N95 respirators may be decontaminated up to 2 times.
- Any compatible N95 respirator with illegible markings to indicate the number of decontamination cycles completed must 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 STERIZONE VP4 Sterilizer:

1. Place a compatible N95 respirator 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 contains 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 decontaminated in the STERIZONE VP4 N95 Respirator Decontamination Cycle. (**Caution:** Do not combine any other medical devices with the 20 pouched, respirator load).



3. Pouches must 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. The 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 the recommendation in 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 the 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 decontaminated, 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, the decontaminated, compatible N95 respirators are loaded back in sterilized trays or containers and placed in a closed case cart following department policy for identifying/labeling processed loads. The department protocol 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 decontaminated, compatible N95 respirators to the original location in the facility for distribution to the original healthcare personnel.

Upon return of the decontaminated, compatible N95 respirators to the appropriate individuals, check the respirator to ensure that the name or other identifier is still legible. If not legible, or the respirator is damaged, the respirator must be discarded.

Marking:

1. Your organization will create a collection station at the point of generation (i.e., hospital floor/unit)
2. Each station will 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 label their own individual compatible N95 respirators with their name, identifiers, and number of decontamination cycles (such as a tick mark).
Note: compatible N95 respirators may be decontaminated a maximum of 2 times.
4. Healthcare personnel follow the instructions provided by Stryker in Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the STERIZONE VP4 Sterilizer Using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle.



Notes:

1. Prior to use, decontaminated, compatible N95 respirators will be inspected for visible damage and/or excessive soil (i.e., blood, dried sputum, makeup, soil). Respirators that are damaged or contain visible soil will be discarded.
 - Examine all parts of the respirators including the filtration media, the straps, the nose foam, the nose clip (parts present will depend on the model design);
 - The respirator should not show physical change, including color and texture;

- Ensure that the straps can still properly maintain the respirator fit;
 - 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-based materials, exhalation valves, antimicrobials, or a duck-billed design must 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 personnel pouch their compatible N95 respirators at the end of use, and label the respirator and pouch with their name or other identifier with a permanent marker. Permanent markers are used with the vapor hydrogen peroxide process to mark decontamination pouches and wrap (used once). To maintain the decontamination cycle count, the healthcare personnel places a tick mark on the respirator each time the healthcare personnel prepares the respirator for decontamination. The healthcare personnel confirms that their name is legible prior to placing the respirator in the pouch and that there is no visible soil or damage to the respirator. If any visible soil or any damage is present, the respirator must be discarded. The healthcare personnel will place the compatible N95 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 pouched, compatible N95 respirators. When the pouched respirators are ready to be transported to the Sterile Processing Decontamination area, transport pouched respirators in a closed case cart to minimize risk of environmental contamination. The case cart will have a hospital-controlled tag or identifier that indicates the location in the hospital where the respirators were utilized.

The case cart is transported to the Sterile Processing Decontamination area by transport personnel assigned by the healthcare facility with training for transport of the material. Unload the pouched respirators in the Sterile Processing Decontamination area. Stryker recommends that the sterile processing staff follow existing processes to decontaminate the case carts and sterilize the transport trays or container for reuse and delivery back to patient areas.

Transfer the pouched respirators through the pass-through window along with the location identifier. Retrieve the pouched respirators and place in the STERIZONE VP4 Sterilizer for decontamination. The sterile processing staff will adhere to department policy for documenting load contents for the sterilizer.

Upon completion of the decontamination cycle, the decontaminated, compatible N95 respirators are loaded back in sterilized trays or containers and placed in a closed case cart following department policy for identifying/labeling processed loads. The department protocol 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 decontaminated, compatible N95 respirators to the original location in the facility for distribution of each decontaminated, compatible N95 respirator to the original healthcare personnel.

Upon return of the decontaminated, compatible N95 respirators to the appropriate individuals, check the respirator to ensure that the name or other identifier is still legible. If not legible, or if the respirator is damaged, the respirator must 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 must 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 must be discarded and not reused if the name or other identifier are illegible or the respirator is visually damaged or soiled.

Healthcare personnel 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.

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