VPRO (Steris) Reprocessing of N95 Respirators – Procedure

Updated June 18, 2020

KN95 respirators and N95 respirators with exhalation valves may not be reprocessed, per updated Emergency Use Authorizations (EUA) from the FDA.

The purpose of this document is to provide guidance for the reprocessing and sterilization of the N95 (non-cellulose containing) respirators in VPRO (Steris) low temperature sterilizers.

Key Considerations

1. Availability of equipment
   a. Recommend scheduling processing of N95 respirators in Sterile Processing Department (SPD) during periods when reusable surgical instruments are not being processed to prevent cross contamination with surgical instruments. Other important aspects include:
2. Follow FDA EUA clearance – see fact sheet and instructions for personnel and facility later in this document.
   a. Due to incompatibility, the STERIS Sterilization System is not authorized for use with respirators or pouches containing cellulose-based or paper materials.
   b. All compatible N95 respirators used in the STERIS Sterilization System must be free of visible damage and soil/contamination (e.g. blood, dried sputum, makeup, soil, bodily fluids).
   c. Compatible N95 respirators that are visually soiled or damaged should not be collected for decontamination and should be discarded.
   d. Compatible N95 respirators should be discarded after 10 decontamination cycles.
   e. Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified should be discarded.
3. Reprocessing of KN95 respirators and N95 respirators with exhalation valves is not permitted. If unable to process N95s when normal operations are underway, schedule this work after surgical instrument processing is complete.
4. Process 10-20 masks/load
5. Discourage colleagues being provided N95s from wearing cosmetics below their eyes (cosmetics stain the N95)
6. Allow enough SPD and other colleagues to permit inspection of N95s before and after processing, e.g. 2-4 colleagues per shift, depending on volume.
7. Urgent Cares and outlying facilities may transport used N95s to centralized location designated by SPD leaders for drop off.
8. Compatible N95 respirators may be processed a maximum of 10 times.
9. Assure N95s include original wearer identification and return processed N95s to this same user.
Process:

1. Place collection bins in centralized areas on clinical units/areas where N95s are in use with clearly marked signage. At the end of the shift for which the colleague used the N95, place in a sterilization pouch - Do not attempt to seal the sterilization pouch - and then place in the collection bin or container labeled with the following:
   a. NOTE: Only compatible N95 respirators in Tyvek pouches should be placed at this collection station for decontamination. No other items will be decontaminated in the same decontamination cycle
   b. Tyvek pouch identified for use in vaporized hydrogen peroxide, for example an 8” x 12” STERIS Vis-U-All pouch 886812 or 885812, will be provided near the collection station.

2. SPD colleague or designee will pick up the N95s in pouches approximately every 4 hours and transport back to SPD for processing. The colleague picking up N95s can wear gloves for transfer of pouched N95s into a transport container with a lid or use a closed case cart and clean hands after unprotected handling of used N95s and/or after the initial sorting and packaging process below.

3. Transport to SPD Decontamination area.
   a. Unload the pouched, compatible N95 respirators and place them into the STERIS Sterilization System for decontamination. Healthcare facility staff should adhere to the healthcare facility’s policies for documenting load contents for and use of the STERIS Sterilization System.
   b. A maximum of 10 pouched, compatible N95 respirators (5 pouches per shelf) can be processed in a Non-Lumen Cycle in the sterilizer. (Caution: Do not combine any other load with the 10-pouched N95 respirator load).
   c. A specific orientation of the mask in the Tyvek pouch or pouches in the sterilizer is not required, however, pouches should not overlap or cover other pouches.
   d. A Type 1 chemical indicator for vaporized hydrogen peroxide (for example, a chemical indicator or chemical indicator tape) may be used to monitor the cycle. The indicators may be placed on the pouch, inside a pouch, or within the chamber to provide an indicator that sterilant has been delivered. One indicator per cycle is recommended.
   e. Use the STERIS V-PRO Sterilizer Operator Manual instructions on how to initiate the Non-Lumen Cycle and to verify a successful cycle completion.
   f. Upon completion of the cycle, the decontaminated, compatible N95 respirators are ready for use. Compatible N95 respirators may be processed a maximum of 10 times.

4. After the Non-Lumen Cycle in the STERIS Sterilization System is complete:
   a. Following completion of the Non-Lumen Cycle in the Sterilizer, the chemical indicator’s color should be compared to the “PASS” reference color. 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 Non-Lumen Cycle in the STERIS 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.

5. Healthcare facilities should utilize existing processes to decontaminate the case carts and sterilize the transport trays or container for reuse and delivery of decontaminated, compatible N95 respirators back to patient areas.

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:

7. Ensure that the name or other identifier and number of decontamination cycles is still legible. (see Image 1 for example of identifying user and number of cycles. Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified should be discarded.

Return processed N95s to Supply Chain or other designated area for transport back to unit/areas from which they came.

- Inspect N95s for damage
- Place into paper bag with colleague’s name on exterior.
- Transport N95s back to appropriate unit and area and provide to the original mask user.

8. Original User Instructions Prior to Use:

- Prior to use, the colleague should inspect decontaminated, compatible N95 respirators for visible damage and soil/contamination (i.e., blood, dried sputum, makeup, soil). Respirators that are damaged or contain visible soil should be discarded.
- Check the N95 to make sure it has not been processed more than 10 times. If 10 cycle indicator marks are on the N95 – discard.
- Colleagues must perform a Fit Seal prior to use.
- If the N95 needs to be removed during the shift, e.g. break, store in paper bag with the colleague’s name on the exterior of the bag.
Image 1. Example of labeling N95 with Identity of User and number of sterilization cycles
Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination Using the STERIS Sterilization Systems

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of the STERIS N95 Respirator Decontamination Cycle (Non-Lumen Cycle) in STERIS V-PRO 1 Plus, maX, and maX2 Sterilizers (hereafter referred to as the “STERIS Sterilization System”) 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 STERIS Sterilization System.

Compatible N95 Respirator Marking and Collection:

1. STERIS recommends maintaining chain of custody on the compatible N95 respirators to minimize the risk of cross-contamination. Pouch your own individual compatible N95 respirator in Tyvek pouches at the end of use. You should label with your name and/or other identifier using a permanent marker. Labeling should be legibly written on the outside OR inside of each compatible N95 respirator, as shown below.

2. Place a tick mark on your compatible N95 respirator and Tyvek pouch each time to maintain the decontamination cycle count. NOTE: your respirator and Tyvek pouch may be decontaminated up to a maximum of 10 times.

3. Confirm that the labeling is legible, and that there is no visible damage or soil/contamination prior to pouching the compatible N95 respirator.

4. Place your compatible N95 respirator in the Tyvek pouch provided by your healthcare facility and seal it. Place the pouched, compatible N95 respirator at the healthcare facility’s designated collection station.

5. After receiving your decontaminated, compatible N95 respirator, please check the respirator to ensure you are the appropriate individual.

- Due to incompatibility, the STERIS Sterilization System is not authorized for use with respirators or pouches containing cellulose-based or paper materials.
- All compatible N95 respirators used in the STERIS Sterilization System must be free of visible damage and 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.
- Compatible N95 respirators should be discarded after 10 decontamination cycles.
- Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified should be discarded.
- Decontaminated, compatible N95 respirators are not sterile.
6. If at any time the labeling is not legible or there is visible soil or damage, discard the respirator. Discard the respirator and Tyvek pouch after 10 decontamination cycles.

**NOTE:** Only compatible N95 respirators in Tyvek pouches should be placed at this collection station for decontamination. No other items will be decontaminated in the same decontamination cycle.
**Instructions for Healthcare Facilities: Decontamination of Compatible N95 Respirators Using the STERIS Sterilization Systems**

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of the STERIS N95 Respirator Decontamination Cycle (Non-Lumen Cycle) in STERIS V-PRO 1 Plus, maX, and maX2 Sterilizers (hereafter referred to as the “STERIS Sterilization System”) for use in decontaminating compatible N95 or N95-equivalent respirators (“compatible N95 respirators”) for single-user reuse by healthcare personnel in healthcare facilities. The STERIS Sterilization System contains three models: V-PRO 1 Plus, V-PRO maX, and V-PRO maX2. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to decontaminate compatible N95 respirators using the STERIS Sterilization System.

- Due to incompatibility, the STERIS Sterilization System is not authorized for use with respirators or pouches containing cellulose-based or paper materials.
- All compatible N95 respirators used in the STERIS 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 by healthcare providers.
- Compatible N95 respirators should be discarded after 10 decontamination cycles.
- Any compatible N95 respirator whose traceability was lost or number of decontamination cycles 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 an 8” x 12” STERIS Vis-U-All pouch 886812 or 885812.
- Type 1 chemical indicator for vaporized hydrogen peroxide: STERIS Celerity Chemical Indicator PCC075 or VERIFY H2O2 Indicator Tape PCC071. In the event of Chemical Indicator Shortage, please see the Parametric Instructions section below.

**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. 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.
**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 tray 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 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 Non-Lumen Cycle in the STERIS Sterilization System:**

1. Unload the pouched, compatible N95 respirators and place them into the STERIS Sterilization System for decontamination. Healthcare facility staff should adhere to the healthcare facility’s policies for documenting load contents for and use of the STERIS Sterilization System.
2. A maximum of 10 pouched, compatible N95 respirators (5 pouches per shelf) can be processed in a Non-Lumen Cycle in the sterilizer. **(Caution: Do not combine any other load with the 10-pouched N95 respirator load).**
3. A specific orientation of the mask in the Tyvek pouch or pouches in the sterilizer is not required, however, pouches should not overlap or cover other pouches.
4. A Type 1 chemical indicator for vaporized hydrogen peroxide (for example, a chemical indicator or chemical indicator tape) may be used to monitor the cycle. The indicators may be placed on the pouch, inside a pouch, or within the chamber to provide an indicator that sterilant has been delivered. One indicator per cycle is recommended.
5. Use the STERIS V-PRO Sterilizer Operator Manual instructions on how to initiate the Non-Lumen Cycle and to verify a successful cycle completion.
6. Upon completion of the cycle, the decontaminated, compatible N95 respirators are ready for use. **Compatible N95 respirators may be processed a maximum of 10 times.**

**After the Non-Lumen Cycle in the STERIS Sterilization System is complete:**

1. Following completion of the Non-Lumen Cycle in the Sterilizer, the chemical indicator’s color should be compared to the “PASS” reference color. 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 Non-Lumen Cycle in the STERIS 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.
2. Healthcare facilities should utilize existing processes to decontaminate the case carts and sterilize the transport trays or container for reuse and delivery of decontaminated, compatible N95 respirators back to patient areas.

3. Decontaminated, compatible N95 respirators that match the “PASS” criteria should be loaded back in sterilized trays 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.

4. 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.

5. The healthcare facility should make available the “Fact Sheet for Healthcare Personnel: STERIS 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). Respirators that are damaged or contain visible soil should be discarded.
2. N95 respirators or pouches containing cellulose or paper should not be processed in the V-PRO Sterilizer.
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 STERIS:

Healthcare facilities should report any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator to STERIS, 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 STERIS, so that STERIS can provide a weekly report to FDA. Reports of adverse health indications should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.

Advisories on Chemical Indicators:

In the event of Chemical Indicator shortage, the following Parametric Instructions should be followed to determine proper decontamination of the compatible N95 respirators in the Non-Lumen Cycle of the STERIS Sterilization Systems.
Parametric Instructions:

1. Select “Options”

![Figure 6-3. Start CYCLES or Ready Screen](image)

2. Select “Print Options”

![Options Screen Touch Pad](image)
3. Select Printer Format and toggle to “Extended Printout”

Using the extended printout and in accordance with STERIS V-PRO Sterilizer Operator Manual (Appendix A), users can verify the pressure and temperature in each cycle. Specific instructions on how to do so are provided for the Non-Lumen Cycle in Appendix A.
You have been given a **N95 or N95-equivalent respirator** ("compatible N95 respirator") that has been decontaminated for single-user reuse by healthcare personnel in a healthcare setting to help prevent exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of decontaminated, compatible N95 respirators. These compatible N95 respirators have been decontaminated using the **STERIS N95 Respirator Decontamination Cycle (Non-Lumen Cycle)** in **STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 Sterilizers** (hereafter referred to as “decontaminated N95 respirators” and “STERIS Sterilization System” throughout this Fact Sheet).

Decontaminated N95 respirators that have been decontaminated using STERIS Sterilization System are authorized for single-user reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic.

---

**Whether or not you use a respirator, always follow infection control measures: wash hands, cover coughs and sneezes, stay home if you may be sick.**

---

**What are the symptoms of COVID-19?**

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

---

**What do I need to know about the emergency use of decontaminated N95 respirators?**

- The STERIS Sterilization System has been authorized for emergency use to decontaminate compatible N95 respirators for single-user reuse by healthcare personnel during the COVID-19 pandemic to prevent exposure to pathogenic airborne particulates.
  - Compatible N95 or N95-equivalent respirators are those that do not contain cellulose-based materials.
- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through 10 decontamination cycles for viricidal activity, material compatibility, hydrogen peroxide residue, and filtration performance.
- **Preparing compatible N95 respirators for decontamination:**
  - Place compatible N95 respirators at the end of use into Tyvek pouches
  - Write name and/or other identifier using a permanent marker so the respirator may be returned after successful decontamination
  - Place a tick mark on respirator and Tyvek pouch each time a respirator is prepared for decontamination
  - Seal the respirator in the Tyvek pouch, and place it into area for subsequent decontamination per your healthcare facility’s procedures
  - **Discard if decontaminated 10 times** or if visibly soiled or damaged
- **Use of decontaminated N95 respirators:**
  - Decontaminated N95 respirators are not sterile
  - Inspect respirators after each use prior to submission for decontamination
  - If decontaminated N95 respirators are soiled or damaged, they should be discarded
  - Cellulose-based materials are incompatible with the STERIS Sterilization System
FACT SHEET FOR HEALTHCARE PERSONNEL
STERIS Sterilization Systems for Decontaminating Compatible N95 Respirators

April 9, 2020

Coronavirus Disease 2019 (COVID-19)

✓ Report problems with decontaminated N95 respirators to your healthcare facility
✓ N95 respirators may be safely stored in pouches after decontamination
✓ Maintain chain of custody on the N95 respirator to minimize the risk of cross-contamination

• Monitor healthcare personnel for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection for up to and including 14 days after last contact with the SARS-CoV-2 virus and related material, and promptly report such information to STERIS Corporation.

• Report damage or discoloration observed upon receipt of the decontaminated N95 respirators, and potential exposure of healthcare personnel from breaks in or other damage to or degradation of the decontaminated N95 respirators.

Use appropriate personal protective equipment (PPE) when caring for individuals suspected of having COVID-19 as outlined in the CDC webpages, including Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings, Infection Control, and FAQ about PPE.

Current information on COVID-19 for healthcare personnel is available at CDC’s webpage, Information for Healthcare Professionals (see links provided in “Where can I go for updates and more information” section).

What are the known and potential benefits and risks of using decontaminated N95 respirators?

Potential benefits include:
• May help prevent exposure to airborne pathogens, and therefore risk of infection or illness
• Extends the usability of compatible N95 respirators by allowing for decontamination and single-user reuse

Potential risks include:
• Failure of filtration efficiency

• Reduced breathability
• Strap failure and ineffective face-fit
• Reused respirators may not have been effectively decontaminated of SARS-CoV-2 or other pathogens

Overview of the STERIS Sterilization System

The STERIS Sterilization System, including of the V-Pro 1 Plus, V-Pro maX, and V-Pro maX2 models vaporized hydrogen peroxide (VHP) sterilizers, contain a pre-programmed Non-Lumen Cycle, in addition to other cycles, intended for terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in healthcare facilities. For this emergency use of the STERIS Sterilization Systems, specifically the V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 sterilizers, the system must be operated in Non-Lumen Cycle to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms. N95 or N95-equivalent respirators or Tyvek pouches containing paper or cellulose-based materials are not compatible with the STERIS Sterilization Systems. The STERIS 60 Liter chamber units (V-PRO 60 and V-PRO s2) are not included in this emergency use.

When the Non-Lumen Cycle starts, the load is processed by automatic moisture checks in order to ensure the removal of the moisture from the load. VHP is injected four times during each sterilization cycle (pulse). The load is automatically aerated after the last segment and the chamber is exhausted through a catalytic converter that decomposes VHP into water and oxygen. The STERIS Sterilization System enables single-user reuse of compatible N95 respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled must be discarded and not reused or decontaminated.

What is an EUA?

The United States FDA has made the emergency use of the STERIS Sterilization System to decontaminate compatible N95 respirators available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the...
Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of medical devices, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic. The STERIS Sterilization System has been made available under an EUA, and has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe the STERIS Sterilization System may be effective at preventing exposure to pathogenic airborne particulates when there are insufficient supplies of respirators during the COVID-19 pandemic by decontaminating, for a maximum of 10 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The EUA for the STERIS Sterilization System is in effect for the duration of the COVID-19 declaration justifying emergency use of medical devices, unless terminated or revoked (after which the products may no longer be used).

Where can I go for updates and more information?

**CDC webpages:**
- General: [https://www.cdc.gov/COVID19](https://www.cdc.gov/COVID19)

**FDA webpages:**
- General: [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)