STERRAD Reprocessing of N95 Respirator - Procedure

Updated October 18, 2020

KN95 respirators and N95 respirators with exhalation valves may not be reprocessed per updated Emergency Use Authorizations from the FDA; added N95 respirator collection and reprocessing instructions to this document.

The purpose of this document is to provide guidance for the reprocessing and sterilization of the N95 (non-cellulose containing) respirator using STERRAD low temperature sterilizer.

Key considerations

1. Equipment Availability
   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.

2. Follow FDA EUA clearance – see fact sheet and instructions for personnel and facility later in this document.
   a. Due to incompatibility, the STERRAD Sterilization System is not authorized for use with respirators containing cellulose or paper materials.
   b. All compatible N95 respirators used in the STERRAD Sterilizers must be free of visible damage and soil/contamination (e.g. blood, dried sputum, makeup, soil, bodily fluids).
   c. Compatible N95 respirators that are visibly soiled or damaged must be discarded and not reused or decontaminated.
   d. Reprocessing of KN95 respirators and N95 respirators with exhalation valves is not permitted.

3. If unable to process N95s when normal operations are underway, schedule this work after surgical instrument processing is complete.
4. Allow 34 minutes ramp up to cool down STERRAD sterilizer and one hour cooling time.
5. Do not exceed 10 pouches per load.
7. Discourage colleagues being provided N95s from wearing cosmetics below their eyes (cosmetics stain the N95).
8. Allow sufficient number of SPD and other colleagues to permit inspection of N95s before and after processing, e.g. 2-4 colleagues per shift, depending on volume.
9. Urgent Cares and outlying facilities may transport used N95s to centralized location designated by SPD leaders for drop off.
10. Each N95 can be processed 2 times in the STERRAD system and then needs to be discarded
11. Assure N95s include original wearer identification and return processed N95s to this same user.

Used N95 Collection Process

1. Provide a designated collection station/container at the point of use (i.e., hospital floor/unit) with clearly marked signage.
   a. The signage should indicate: Only compatible N95 respirators in compatible sterilization pouches should be placed at this collection station for decontamination. No other items will be decontaminated in the same decontamination cycle.
   b. Provide a STERRAD compatible sterilization pouch, e.g. Tyvek®, with either a STERRAD Chemical Indicator inside or this indicator can be added by SPD personnel prior to running a cycle.
c. Colleagues will place the used N95 inside the sterilization pouch and place in the collection station – **Do not attempt to seal the sterilization pouch.**

2. In order to ensure that the chain of custody is maintained to minimize risk of cross-contamination, colleagues need to label their N95 respirator with their name and other identifier, e.g. unit, and number of decontamination cycles (as shown below) with a permanent marker.

3. 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.

4. Process inside SPD Decontamination area:
   a. Sorting and packaging
      - Remove N95 from pouch
      - Inspect for damage
      - If there are 2 check marks on outer side edge of mask or other area, discard.
      - Place N95 back in pouch
      - Place Pouch with N95 into a STERRAD Sterilizer; each cycle can decontaminate 10 pouches per sterilizer load.
      - Pouches should not overlap or cover other pouches.
      - A Type 1 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.
      - Follow STERRAD Sterilizer User's Guide instructions on how to initiate a cycle and verify successful cycle completion.
      - Following completion of the cycle in the STERRAD Sterilizer, the chemical indicator's color should be compared to the "PASS" reference color. If the colors matched or the color present is lighter, the compatible N95 respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the "PASS" criteria, the compatible N95 respirators should not be considered decontaminated and either re-run through the cycle in the STERRAD Sterilizer or discarded.
      - Upon completion of the cycle, the compatible N95 respirators should be aerated in an opened pouch for 1 hour after which they are ready for use. Add a mark, e.g. with a Sharpie marker to indicate it went through a processing cycle.
      - Utilize routine, existing facility processes to decontaminate case carts or container used.

5. 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.

6. Prior to Use:
   - Colleagues must perform a Fit Seal test.
   - 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.
   - At end of shift, **if 2 check marks are on the N95**, discard.
Image 1. Example of Labeled N95

If number of Cycles is two - discard

Image 2. Additional Example of Labeling of N95 with Identifier of User and number of cycles.