

Princeton Medical Center Processing of N95 Respirators using Sterrad Sterilization (3M styles 8210, 1860, 1860s)

Why is there a decision to reprocess N95 Respirators?

As the supply of Personal Protective Equipment across the U.S. and Globally declines, Penn Medicine Princeton Health wants to ensure that you have the PPE needed to protect you when caring for PUI & Covid + patients during aerosolizing procedures.

The Science behind the Decision:

We have monitored the advice of the CDC, FDA, ASP Sterrad and the emerging science regarding the feasibility of reprocessing N95 Respirators (masks) using a vaporous hydrogen peroxide.

Sterrad is a low temperature sterilizer that uses hydrogen peroxide gas plasma technology. It uses multiphases of exposure to hydrogen peroxide; a vapor phase hydrogen peroxide (VPHP) and plasma phase. These exposure phases produce an environment that not only kills the corona virus but also any bacterial matter that is present on the mask.

There is a Sterrad indicator located inside the individually personalized sterilization pouch. This indicator will turn from a **RED** color to a **Yellow-Orange** color to indicate that respirator has successfully completed the Sterrad cycle and is safe to use.

It is important to check the mask components such as straps, nose bridge, quality of fit and seal prior to reusing. If the integrity of any part of the N95 is compromised, or if successful user seal check cannot be performed, discard the mask and obtain a new mask.

CDC Reference: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>

FDA Reference: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease>

ASC Sterrad Reference:

[https://www.asp.com/sites/default/files/covid-19/AP-2000011-Instructions for Use for Reprocessing N95 Masks in STERRAD Sterilization Systems.pdf](https://www.asp.com/sites/default/files/covid-19/AP-2000011-Instructions%20for%20Use%20for%20Reprocessing%20N95%20Masks%20in%20STERRAD%20Sterilization%20Systems.pdf)

The below process outlines the procedure for safely reprocessing and the return of your individually personalized mask.

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Healthcare Care Providers (HCP) Responsibilities

- Healthcare Professional (HCP) will obtain a new N95 respirator per the department's distribution process. Upon completion of shift, HCP will perform the following for reprocessing N95 Respirators
 1. Don clean gloves prior to removing N95 mask
 2. Inspect mask after use for any breakdowns
 3. Discard visibly soiled or damaged masks
 4. Obtain a Sterrad reprocessing envelope/pouch w/sterilization indicator (**RED**) inside using clean gloves



5. Mark the front of the Sterrad envelope/pouch with:
 - Your Name (Last name, First name)
 - The Unit/Department in which you work
 - The number of the reprocessing cycle (The Maximum Sterrad sterilization is two cycles)
**It will be the HCP's responsibility to track their usage and recognize when they have reached the two (2) cycle limit.
6. Remove the N95 mask and place in envelope/pouch minimizing contact as much as possible and making sure there is a sterilization indicator inside bag.
7. Remove gloves and seal envelope with clean hands/gloves.
8. Put masks in contaminated mask holding **YELLOW** bin for pick up.



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Returning Used N95 Respirator for Sterrad sterilization

- Respirators will be returned to the location identified by the department for the collection of used respirators.

Criteria for the Sterrad Team Accepting N95 Respirators for Sterrad Sterilization

- Respirators placed and labeled correctly in Sterrad envelope/pouch with
 - HCP name (Last name, First name)
 - Reprocessing cycle number
 - Department
 - Sterilization Indicator
- If the respirator fails to meet the above criteria, the Sterrad team will discard the respirator upon receipt and will not be returned to the owner. (You will need to obtain a new mask)
- Respirators that have been accepted and completed the Sterrad process will be returned to the location as indicated on the respirator in a **GREEN** bin.
 - Sterilized respirators will be returned in a sealed Sterrad pouch. The pouch will already be labeled with the owner's name (last name, first name, Unit/Department location, and reprocessing cycle).
 - A Sterrad indicator located inside the pouch will turn **Yellow-Orange** color to confirm that respirator has successfully completed the Sterrad cycle



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