

Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination in STERRAD® Sterilization Systems

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Advanced Sterilization Products (ASP) STERRAD Sterilization Systems (hereafter referred to as the “STERRAD Sterilizers”) for use in decontaminating compatible N95 or N95-equivalent respirators (hereafter referred to as “compatible N95 respirators”) for single-user reuse by healthcare personnel. The STERRAD Sterilizer cycles to be used in decontamination of compatible N95 respirators are: **STERRAD 100S Cycle**, **STERRAD NX Standard Cycle**, and **STERRAD 100NX Express Cycle**. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination in a STERRAD Sterilizer.



- **Due to incompatibility, the STERRAD Sterilization System is not authorized for use with respirators containing cellulose or paper materials.**
- **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).**
- **Compatible N95 respirators that are visibly soiled or damaged must be discarded and not reused or decontaminated.**
- **Compatible N95 respirators should be discarded after 2 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.**

Compatible N95 Respirator Marking and Collection:

1. ASP 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 a compatible sterilization pouch, such as a Tyvek pouch, 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 compatible sterilization pouch each time to maintain the decontamination cycle count. **NOTE: Your respirator and sterilization pouch may be decontaminated no more than 2 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 sterilization 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.
6. If at any time the labeling is not legible or there is visible soil or damage, discard the respirator. Discard the respirator and sterilization pouch after 2 decontamination cycles.

NOTE: 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.