

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.



- 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.

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 pouch, 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 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.