

Use the Correct Cycle and Compatible N95 Respirators When Decontaminating Respirators with STERRAD Sterilization Systems - Letter to Health Care Providers

The U.S. Food and Drug Administration (FDA) reminds reprocessing staff in health care facilities to use the correct decontamination cycle associated with certain models of the Advanced Sterilization Products (ASP) STERRAD Sterilization Systems and to only decontaminate compatible N95 or N95-equivalent respirators for reuse during the COVID-19 pandemic.

ASP STERRAD Sterilization Systems use vaporized hydrogen peroxide to decontaminate medical devices. Only the combination of certain models of the ASP STERRAD Sterilization System and their associated STERRAD Decontamination Cycle listed in the FDA's Emergency Use Authorization (</media/136884/download>) (EUA), and shown in the table below, are authorized for the decontamination of compatible N95 respirators.

ASP STERRAD Sterilization System	STERRAD Decontamination Cycle
STERRAD 100S	100S
STERRAD NX	Standard
STERRAD 100NX	Express

There have been no injuries reported to the FDA associated with the use of an incorrect decontamination cycle with the ASP STERRAD Sterilization Systems for decontaminating compatible N95 or N95-equivalent respirators for single-user reuse.

Recommendations

The FDA recommends that reprocessing staff in health care facilities:

- Recognize that new N95 and N95-equivalent respirators, when available, are always the first choice for health care personnel.
- Confirm the N95 or N95-equivalent respirators you are decontaminating do not contain cellulose (i.e., paper-based materials). Respirators that contain cellulose are incompatible with vaporized hydrogen peroxide decontamination.
- Use only the **Express** cycle for the STERRAD 100NX System. Do not use other cycles available on the STERRAD 100NX System to decontaminate compatible N95 respirators.

- If your system currently does not have the **Express** cycle, consider the software upgrade available from the manufacturer to add this cycle to the STERRAD 100NX System at your facility.
- Use only the 100S cycle to decontaminate compatible N95 respirators with the STERRAD 100S System.
- Use only the **Standard** cycle to decontaminate compatible N95 respirators with the STERRAD NX System.
- Review the Fact Sheet and Instructions associated with the Emergency Use Authorization:
 - Fact Sheet for Health care Personnel (/media/136881/download)
 - Instructions for Health care Facilities (/media/136882/download)
 - Instructions for Health care Personnel (/media/136883/download)

Background

ASP STERRAD Sterilization Systems use hydrogen peroxide vapor to decontaminate medical devices at low temperatures through a process that uses a combination of heating and sub-ambient pressures. Several models of ASP STERRAD Sterilization Systems are available, offering decontamination cycles that vary among system models.

During the COVID-19 pandemic, health care facilities are rapidly adopting conservation practices such as decontaminating compatible N95 or N95-equivalent respirators for single-user reuse. Health care facilities alerted the FDA of the potential for reprocessing staff that decontaminate respirators to use an incorrect decontamination cycle and incompatible respirator when using ASP STERRAD Sterilization Systems.

Using the correct decontamination cycle is necessary to avoid potentially compromising the performance, fit, and breathability of decontaminated compatible N95 respirators.^{i,ii} Using the correct cycle also helps preserve the electrostatic properties (such as leakage resistance) of the polypropylene filter in these respirators. These electrostatic properties play a vital role in the respirators' filtration efficiency.ⁱⁱⁱ

FDA Actions

On April 11, 2020, the FDA issued an EUA for decontaminating compatible N95 or N95-equivalent respirators using ASP STERRAD Sterilization Systems, enabling health care facilities to conserve their supply of respirators during the COVID-19 pandemic. The EUA also specifies that these decontaminated respirators are only for single-user reuse, which means the same user uses the same respirator following decontamination.

The FDA updated the Fact Sheet for Healthcare Personnel (</media/136881/download>), Instructions for Healthcare Facilities (</media/136882/download>), and Instructions for Healthcare Personnel (</media/136883/download>) for the ASP STERRAD Sterilization Systems to clarify the importance of using the correct decontamination cycle.

The FDA will continue to keep health care facilities and personnel, manufacturers, and the public informed of new or additional information.

Reporting Problems to the FDA

The FDA encourages health care facilities to report any adverse events or suspected adverse events experienced with decontaminating compatible N95 or N95-equivalent respirators for single-user reuse.


- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>).
- Device manufacturers and user organizations must comply with the applicable Medical Device Reporting (MDR) regulations (</medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>).
- Health care personnel employed by organizations that are subject to the FDA's user facility reporting requirements (</medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>) should follow the reporting procedures established by their organizations.

Prompt reporting of adverse events and product problems can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (DICE) (</medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>).

ⁱ Bergman, MS, et al., 2010 Evaluation of Multiple (3-Cycle) Decontamination Processing for Filtering Facepiece Respirators Filtering Facepiece Respirator, *Journal of Engineered Fibers and Fabrics* 5(4): 33-41.

ii National Institute for Public Health and the Environment, The Netherlands, Reuse of FFP2 Masks. (last accessed 5/16/2020, https://www.rivm.nl/sites/default/files/2020-03/Hergebruik%20mondkapjes%20Informatie%20ENG_def.pdf (https://www.rivm.nl/sites/default/files/2020-03/Hergebruik%20mondkapjes%20Informatie%20ENG_def.pdf)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)).

iii Martin SB and Moyer ES. 2000. Electrostatic Respirator Filter Media: Filter Efficiency and Most Penetrating Particle Size Effects. *Appl Occ Env Hygiene* 15 (8): 609-617.