

COVID–19 N95 Mask reprocessing: ASP & Steris

FAQs

*This data is current as of April 13, 2020

Effective April 13, 2020, Steris and ASP have both received EUA for the reprocessing of N95 respirator masks. The equipment listed below has been cleared at their current system programs to reprocess use in decontaminating compatible N95 or N95 equivalent respirators. The equipment and disposables can be accessed through these mention Vizient agreements CE3101 Fortive ASP Low temperature Sterilizers and CE3102 Steris Low Temperature Sterilizers.

Manufacturer	Equipment EUA approved	Price (each)
Steris	V-PRO 1 Plus, V-PRO maX and V-PRO maX 2	Negotiated based on member preference
Fortive ASP	STERRAD 100S, NX, and 100NX S	Negotiated based on member preference

1. How can I place an order for the disposables needed?

Orders can be placed through your distribution channel or direct from the either Steris or ASP.

2. What disposables are needed?

A cycle must be run with the following products. The products will vary in price according to the manufacturer and tier placement of the member. Below you will find a list of supplies needed to perform a cycle for the mentioned equipment. 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.

- Type 1 chemical indicator for vaporized hydrogen peroxide, such as Chemical Indicator Strips, or Chemical Indicator Tape
- Biological Indicator/Process Challenge Device
- Compatible sterilization pouch identified for use in vaporized hydrogen peroxide. Tyvek pouch Minimum of 8"x12" recommended so as to provide necessary space to package/reprocess compatible N95 respirator.

3. Can you only obtain the consumables from the OEM?

No. The following agreements also encompass compatible products mentioned above

- Cardinal MS5061 - Sterilization Packs and Pouches MS5061
- Medical Action SMS5062- Sterilization Packs and Pouches MS5062
- Medline MS5063 - Sterilization Packs and Pouches MS5063
- Vital Care MS5064- Sterilization Packs and Pouches MS5064
- 3M MS4170 - Sterility Assurance Products

The FDA however has cleared the reprocessing of the N95 respirator masks utilizing OEM disposables with OEM sterilizers. Members may consult the FDA EUA clearance documents here for both Steris and Fortive ASP.

[Steris FDA Emergency Use Authorization Letter](#)

[Fortive ASP FDA Emergency Use Authorization Letter](#)

4. Are orders subject to allocation?

Orders will be prioritized by receipt of PO. Suppliers are not currently experiencing any backlogs in requests for these products and have ramped up production forecasting the potential need for product.

5. How many times can a mask be reprocessed?

Currently due to the technology difference between ASP and Steris this varies please see below for identification. The ASP STERRAD units using plasma technology to sterilize products in the equipment's chamber while Steris VPRO units utilize pure hydrogen peroxide.

Steris – N95 respirator masks can be reprocessed up to 10 times

Fortive ASP - N95 respirator masks can be reprocessed up to 2 times

6. How does my facility reprocess N95 masks?

Suppliers have provided a comprehensive guide into how their respective systems should be utilized when cycles are run to sterilize the N95 masks. Below are the cycle processes that healthcare facilities should use by supplier.

[Steris: Health care personnel protocol](#)

[Fortive ASP: Health care personnel protocol](#)

7. What if my answer isn't listed here?

Fortive ASP and Steris have been tremendous partners by working with both the FDA and mask manufactures to provide a solution so quickly with pre-existing equipment. I have included the links from both organizations with comprehensive answers to Healthcare professionals concerns. Steris and Fortive ASP also have "Ask a healthcare professional" links on their sites where members can ask technical questions or voice concerns. These queries will receive responses in 24 hours.

Steris – [Comprehensive COVID-19 N95 reprocessing guide](#)

Fortive ASP - [Comprehensive COVID-19 N95 reprocessing guide](#)

Questions?

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