

February 2, 2021

1. Q: Is there a defined protocol to W&D for compatible N95 or N95-equivalent respirators?

A: Currently, STERIS does not have the data to support the use of a STERIS product for washing/disinfecting of respirators. However, the FDA has granted STERIS two Emergency Use Authorizations (EUA). This allows STERIS to temporarily provide two distinct options to effectively decontaminate compatible N95 Respirators* up to 4-times using the [Non-Lumen Cycle of the V-PRO® Low Temperature Sterilization System \(Models: 1 Plus, maX, and maX 2\)](#) or the [STERIS Steam Decon Cycle in ASMCO® 400 or AMSCO® Century Medium Steam Sterilizers](#).

*Specific models of N95 Respirators will vary based on Emergency Use Authorization and Instructions for Use. Please reference the respective Instructions for Healthcare Facilities and Personnel for specific N95 Respirator models.

2. Q: What are the toxicity risks of washing with an enzymatic detergent, alkaline detergent or lubricant on compatible N95 or N95-equivalent respirators?

A: STERIS does not recommend the use of detergents or lubricants on respirators. However, STERIS was granted two Emergency Use Authorizations (EUA) for certain models of [STERIS V-PRO® Low Temperature Sterilizers](#) and the [STERIS Steam Decon Cycle in ASMCO® 400 or AMSCO® Century Medium Steam Sterilizers](#) to decontaminate compatible respirators.

3. Q: Are Prolystica Cleaning Chemistries efficient against the COVID-19 virus?

A: Prolystica cleaning chemistries are formulated primarily for removal of surgical soils on surgical instruments and devices. Though all Prolystica products are preserved formulations, none are registered or marketed as disinfectants.

4. Q: Are Prolystica Cleaning Chemistries preserved effectively against the COVID-19 virus?

A: Thank you for your question. STERIS has conducted preservative studies on those formulas where possibility of contamination exists. The tests are designed to demonstrate that the product is preserved from contamination. Our preservative studies were conducted under United States Pharmacopeia (USP) protocols which include testing for bacteria and fungi, both of which are more resistant to chemical inactivation than viruses. Because the USP protocol does not include viruses in the test, viruses were not included in our preservative testing.

[. Prolystica® 2X Concentrate Alkaline Detergent United States Pharmacopeia \(USP\) Preservative Effectiveness Testing](#)

[Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner United States Pharmacopeia \(USP\) Preservative Effectiveness Testing](#)

- [Prolystica® 2X Concentrate Neutral Detergent United States Pharmacopeia \(USP\) Preservative Effectiveness Testing](#)
- [Prolystica® HP Enzymatic Automated Detergent Preservative Effectiveness Testing](#)
- [Prolystica® HP Enzymatic Manual Cleaner Preservative Effectiveness Testing](#)
- [Prolystica® HP Neutral Detergent/Cleaner Preservative Effectiveness Testing](#)
- [Prolystica® Multi-Enzymatic Cleaner Preservative Effectiveness Testing](#)
- [Prolystica Restore® Descaler and Neutralizing Detergent United States Pharmacopeia \(USP\) Preservative Effectiveness Testing](#)
- [Prolystica® Ultra Concentrate Enzymatic Cleaner United States Pharmacopeia \(USP\) Preservative Effectiveness Testing](#)
- [Prolystica® Ultra Concentrate HP Enzymatic Cleaner United States Pharmacopeia \(USP\) Preservative Effectiveness Testing](#)
- [Prolystica® Ultra Concentrate HP Neutral Detergent United States Pharmacopeia \(USP\) Preservative Effectiveness Testing](#)
- [Prolystica® Ultra Concentrate Neutral Detergent United States Pharmacopeia \(USP\) Preservative Effectiveness Testing](#)

5. Q: Can PPE, respirators and diverse plastic items be decontaminated using Prolystica Cleaning Chemistries?

A: Thank you for your question. STERIS has received similar questions from other healthcare providers around the country. Currently, STERIS does not have the data to support the use of a STERIS product to meet your need. Our scientific teams are currently investigating to determine if an existing STERIS product may be viable for this application. We will continue to update the site with information as it becomes available. In addition, your STERIS Sales Representative will be informed of any updates.

6. Q: If there is an IFU for cleaning rubber respirators, but it does not list Prolystica Cleaning Chemistries, can they still be used?

A: While we cannot speak to what is in IFU for every respirator on the market, we do have extensive substrate compatibility testing for each of our Prolystica brand chemistries. The testing involved a minimum of 16 non-metal materials, including butyl rubber, silicon rubber, and several other elastomeric materials. All four of our Prolystica Neutral detergents are compatible with these materials.

- [Prolystica® 2X Concentrate Neutral Detergent Substrate Compatibility](#)
- [Prolystica® HP Neutral Detergent/Cleaner Substrate Compatibility](#)
- [Prolystica® Ultra Concentrate HP Neutral Detergent Substrate Compatibility](#)
- [Prolystica® Ultra Concentrate Neutral Detergent Substrate Compatibility](#)

7. Q: Is Revital-Ox® Resert® efficient against the COVID-19 virus?

A: The virus is classified as an enveloped virus and is relatively susceptible to inactivation on medical devices following the instructions for use for cleaning and disinfection/sterilization of the device or instrument, but infection prevention recommendations are similar to those already adopted for bloodborne pathogens such as HIV and Hepatitis B. STERIS has demonstrated effectiveness of its medical device reprocessing products (high-level disinfectants, liquid chemical sterilants, terminal sterilization processes) against many enveloped viruses and organisms that are more resistant to inactivation than coronavirus. Normal recommended infection prevention standard precautions for device reprocessing should be followed. These steps include consideration of the Spaulding Classification system and corresponding recommended reprocessing steps for non-critical, semi-critical and critical devices.

8. Q: Can PPE, respirators and diverse plastic items be disinfected using Revital-Ox Resert?

A: Thank you for your question. STERIS has received similar questions from other healthcare providers around the country. Currently, STERIS does not have the data to support the use of a STERIS product to meet your need. Our scientific teams are currently investigating to determine if an existing STERIS product may be viable for this application. We will continue to update the site with information as it becomes available. In addition, your STERIS Sales Representative will be informed of any updates.

9. Q: Can Revital-Ox Resert be used to disinfect the ASPIRE 7900 Ventilator?

A: Thank you for your question. STERIS has received similar questions from other healthcare providers around the country. Currently, STERIS does not have the data to support the use of a STERIS product to meet your need. Our scientific teams are currently investigating to determine if an existing STERIS product may be viable for this application. We will continue to update the site with information as it becomes available. In addition, your STERIS Sales Representative will be informed of any updates.

10. Q: Can single-use tubing be processed via Liquid Chemical Sterilization? A:

Thank you for your question. STERIS has received similar questions from other healthcare providers around the country. Currently, STERIS does not have the data to support the use of a STERIS product to meet your need. Our scientific teams are currently investigating to determine if an existing STERIS product may be viable for this application. We will continue to update the site with information as it becomes available. In addition, your STERIS Sales Representative will be informed of any updates.

11. Q: Can PPE be processed in SYSTEM 1® E or SYSTEM 1® endo Liquid Chemical Sterilant Processing System?

A: Thank you for your question. STERIS has received similar questions from other healthcare providers around the country. Currently, STERIS does not have the data to support the use of a STERIS product to meet your need. Our scientific teams are currently investigating to determine if an existing STERIS product may be viable for this application. We will continue to update the site with information as it becomes available. In addition, your STERIS Sales Representative will be informed of any updates.

12. Q: Can STERIS provide recommendations on hand hygiene and surface disinfection products?

A: Thank you for your inquiry. STERIS divested our healthcare hand hygiene and surface disinfection business in 2016, to [SC Johnson Professional](#). For more information or to place an order, you can contact SC Johnson Professional's Customer Service department at 1-866-783-0422. We appreciate you thinking of STERIS.