

N95 mask reprocessing

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Stryker's mission statement is "together with our customers we are driven to make healthcare better".

To that end, we hope the information below will help healthcare providers better protect themselves and their patient populations in their fight against the global COVID-19 pandemic.

Multiple strategies exist to manage shortage of protective masks and Stryker recommends that healthcare facilities consult existing guidelines from the CDC and Health Canada on optimizing supply of facemasks^{i, ii, iii}. In the event of a shortage one strategy available to healthcare providers when no other alternatives exist is to reprocess and reuse Filtering Facepiece Respirator (FFR)s. Any reprocessing of disposable FFR is not recommended and should only be performed in emergency situations if a risk assessment, performed by qualified professionals from the healthcare facility, shows it offers benefit over the lack of respiratory protection.

About the Sterizone VP4

The Sterizone VP4 is a medical device sterilizer which uses dual sterilants; vaporized hydrogen peroxide (H_2O_2) and ozone (O_3), in a multiphase process, at low temperature. It uses a single pre-set cycle to achieve terminal sterilization of medical devices loads in its 125L chamber. It is intended for use in terminal sterilization of cleaned, rinsed, and dried metal and non-metal reusable medical devices in health care facilities. The single pre-set cycle of the Sterizone VP4 uses hydrogen peroxide and ozone. The injection of vaporized hydrogen peroxide is followed by the injection of ozone, which reacts with residual hydrogen peroxide to form hydroxyl radicals.

The Sterizone VP4 sterilizer is **not** cleared for the processing of single-use medical devices, such as filtering facepiece respirators.

Recommendations for processing FFR in the Sterizone VP4 Sterilizer during the COVID-19 Public Health Emergency

Management of used masks and traceability

Healthcare facilities should establish chain of custody for the used mask and safeguards to prevent inadvertent exposure.

- Hospitals should manage used FFRs following their internal processes for biohazardous material until they are reprocessed
- FFRs packaged to be processed should include a chemical indicator to prevent confusion between processed and unprocessed masks;

FFRs are not designed to be reprocessed and reused.

- Every use and reprocess may reduce the mask functionality.
- It is recommended not to reprocess the FFR more than two times in total.
- Establish a process to identify the number of reprocessing cycles for each FFR;

Report to Stryker any issue related to the reprocessing of FFR with the Sterizone VP4 Sterilizer.

- Customer Service +1 800 668 8323

Compatible mask models

Multiple FFR models are available and have different design and materials.

- All models should be evaluated separately.
- For each model, consult the FFR technical datasheets for information about materials.

Do not process an FFR that contains materials known to be incompatible with H_2O_2 - O_3 sterilizers, including cellulose-based materials, natural rubber or latex.

Some FFR model contains activated carbon.

- Do not reprocess these models as the activated carbon may retain sterilant, causing a respiratory risk to the user.

Processing the masks

Follow the Sterizone VP4 operating instructions:

- Ensure sterilizer is loaded to allow for free flow of vaporized hydrogen peroxide vapor
- Load temperature is between 20-26°C (68-78°F)
- Loading rack has enough weight and surface area to reach 3:30 minute hydrogen peroxide injection time
 - Use of pouch holders will assist with this requirement and enable the sterilization of multiple masks

FFRs can be processed in the Sterizone VP4 Sterilizer along with other medical devices.

If a sterilization cycle aborts, dispose of the FFR.

Do not reprocess an FFR that is:

- Visibly soiled or was soiled by excessive coughing or sneezing
 - The use of cosmetic products on the user face may soil the masks;
- Damaged
- Contains excessive moisture
 - This could lead to residual hydrogen peroxide in the FFR, causing a respiratory risk to the user;

FFR should be packaged for processing following the sterilizer IFU.

Do not stack multiple FFRs together.

Do not process FFR without packaging and chemical indicators.

Be careful not to deform the FFR as it could negatively impact its fit.

Wait for an aeration time of at least 24 hours post-reprocessing before using the FFR.

Inspection and reuse of decontaminated masks

Before donning a sterilized FFR, always observe it for any sign of damage.

- Observe all parts of the masks including the filtration media, the straps, the nose foam, the nose clip, the exhalation valves (parts present will depend on the model design)
- The FFR should not show physical change, including color and texture
- Attention should be paid to the strap to ensure that they can still properly maintain the FFR fit
- If FFR model has an exhalation valve, verify that it properly open and close
- Any FFR showing signs of damage should be discarded

Do not use an FFR that shows:

- visible wetness
- unusual odor

It is recommended to perform an evaluation of the FFR facial fit after being reprocessed following the recommendation of the manufacturer, or the facility policy.

Do not use or continue using an FFR that appears to not be functioning properly.

Note: If an FFR model consistently shows material degradation after processing, discontinue the practice of FFR processing for that model and notify Stryker.

¹CDC - Strategies for Optimizing the Supply of Facemasks; 17 March 2020
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html>

²CDC - Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings; 27 March 2020
<https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>

³Health Canada - Optimizing the use of masks and respirators during the COVID-19 outbreak; 28 April 2020
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/masks-respirators-covid19.html>