Instructions for Use for Reprocessing N95 Masks in STERRAD® Sterilization Systems during the COVID-19 Public Health Emergency

Advanced Sterilization Products (ASP) STERRAD Sterilization Systems hold 510(k) clearance for the following indications:

STERRAD®100S Sterilizer

The STERRAD 100S Sterilizer can sterilize medical devices with titanium surfaces and medical devices with only a single stainless-steel lumen with:

- An inside diameter of 1 mm or larger and a length of 125 mm or shorter
- An inside diameter of 2 mm or larger and a length of 250 mm or shorter

STERRAD NX® Sterilizer Standard Cycle

Medical devices with the following materials and dimensions can be processed in the STERRAD NX Sterilizer Standard Cycle:

Single channel stainless steel lumens with

- An inside diameter of 1 mm or larger and a length of 150 mm or shorter
- An inside diameter of 2 mm or larger and a length of 400 mm or shorter

Note: The validation testing for this lumen size was conducted using a maximum of 10 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing.

STERRAD® 100NX Sterilizer Express Cycle

The STERRAD 100NX Sterilizer Express Cycle is designed for surface sterilization of both metal and nonmetal medical devices at low temperatures.

- It can sterilize instrument surfaces and instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors
- It can sterilize rigid and semi-rigid endoscopes without lumens

Note: The validation studies for Express Cycle were performed using a validation load consisting of a single instrument tray weighing 10.7 lbs placed on the bottom shelf.

While sterilization of N95 and similar respirators is outside the scope of the currently cleared indications, information on how to use the STERRAD Sterilization System is being provided based on the FDA guidance document, “Enforcement Policy for Sterilizers, Disinfectant Devices and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency” published March 2020.

WARNINGS:

All warnings and precautions identified in the STERRAD Sterilization System User's Guides apply for this use of the system. In addition:

Due to incompatibility with the STERRAD Sterilization Systems, do not reprocess respirator masks (N95 masks) containing cellulose or cellulose-based materials.

Compatible respirator masks that are visibly damaged or soiled should not be reprocessed and should be discarded.

Collection and preparation of N95 Masks

N95 Masks should be collected and labeled per healthcare facility policy. Masks should only be reprocessed a maximum of two (2) times. The healthcare facility policy should include methods to document reprocessing cycles.

Packaging

Prior to placing in the STERRAD System, N95 masks should be individually packaged in an appropriately sized Tyvek® Self Seal pouch or equivalent product. The following pouches have been used in testing and qualified to work for reprocessing N95 masks in the STERRAD Sterilization Systems.

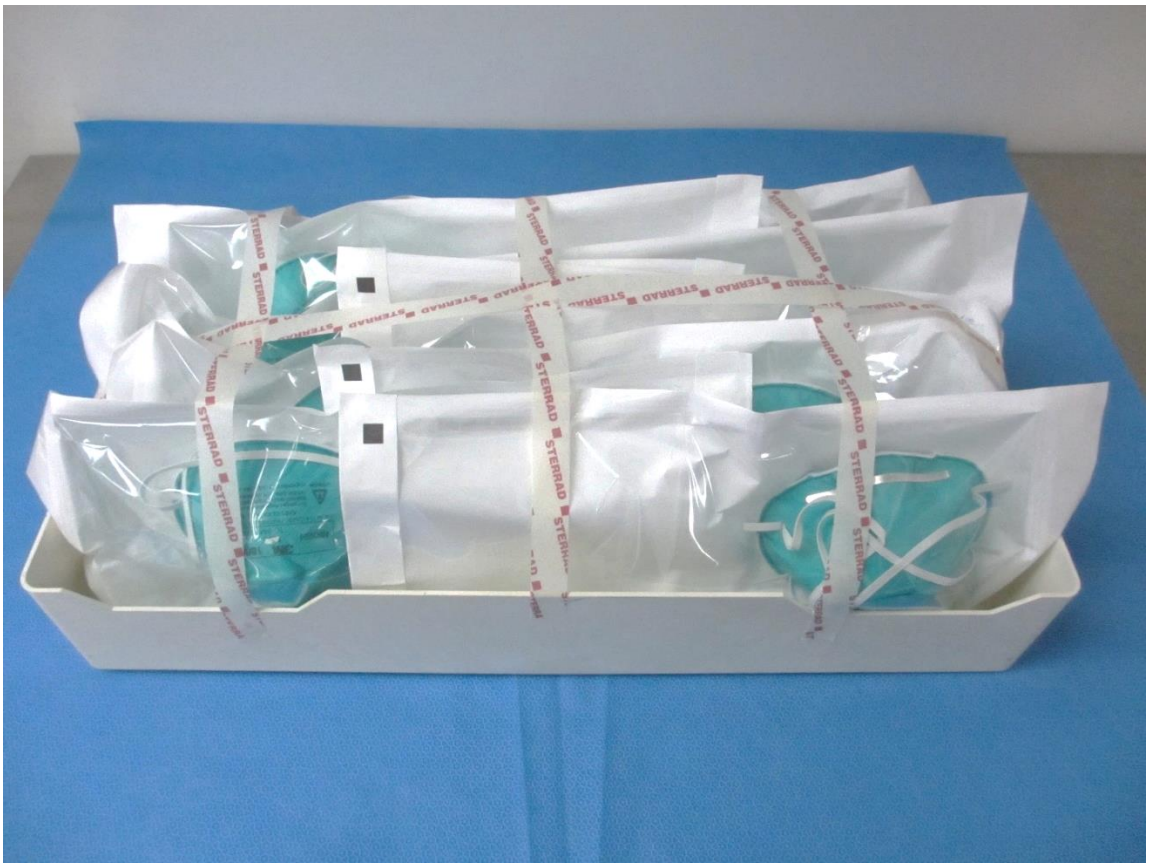
Table 1: Packaging Pouch sizes

PRODUCT DESCRIPTION	PACKAGING	ASP Item CODE
Tyvek Pouch with STERRAD Chemical Indicator, Self Seal, 6" x 12.5"	2x250 shelf packs; 500/case	12332
Tyvek Pouch with STERRAD Chemical Indicator, Self Seal, 8" x 16"	2x250 shelf packs; 500/case	12340

ASP Sterilization Systems, Cycles and Loads

After packaging, the individually packaged masks should be loaded into the STERRAD Sterilizer. Users should follow the appropriate STERRAD Sterilizer User's Guides for loading of the chamber, including load weight limits and placement. Note that pouches should be placed on edge so that they are not layered on top of each other. Additionally, it is recommended to use a STERRAD Systems compatible tape to secure pouches so that they do not move during the sterilization process and block sensors within the system. Ensure that masks are not crushed or damaged when packaged or placed in the sterilization chamber. See **Figure 1**.

Figure 1: Example of Packaging N95 masks for Loading



See **Table 2** for summary cycle information and where to load within each STERRAD System.

Table 2: STERRAD Sterilizer Cycle and Loading Parameters

ASP System	Cycle	Cycle Time	Placement
STERRAD 100S System	Short	55 Minutes	Both shelves
STERRAD NX System	Standard	28 Minutes	Both shelves
STERRAD 100NX System	Express	24 Minutes	Bottom shelf only

Follow existing Instructions for Use for your STERRAD System to operate your STERRAD Sterilization System.

It is recommended to place a STERRAD VELOCITY® Biological Indicator in the chamber per standard instructions for use for monitoring of each load processed.

Post Processing Instructions:

Once the cycle is complete pouches and masks should be visually inspected for physical damage. If any mask appears physically damaged it should be discarded. All masks that do not appear damaged should be allowed to aerate for one (1) hour prior to returning the masks for use.

If a STERRAD VELOCITY Biological Indicator was used in the load, process per standard Instructions for Use prior to release of the masks for use.

Additional Materials

The following materials may be used in the STERRAD Sterilization System for reprocessing N95 masks.

PRODUCT DESCRIPTION	PACKAGING	ASP Item CODE
STERRAD Chemical Indicator Strip	250/pack; 4 packs/case	14100
STERRAD SEALSURE® Chemical Indicator Tape	60 yd/roll; 6 rolls/case	14202
STERRAD VELOCITY Biological Indicator	30/box; 2 boxes/case	43210
Tyvek Pouch with STERRAD Chemical Indicator, Self Seal, 6” x 12.5”	2x250 shelf packs; 500/case	12332
Tyvek Pouch with STERRAD Chemical Indicator, Self Seal, 8” x 16”	2x250 shelf packs; 500/case	12340
Tyvek Roll with STERRAD Chemical Indicator, 6” x 228’	4/case	12415
Tyvek Roll with STERRAD Chemical Indicator, 8” x 228’	4/case	12420
Tyvek Pouch with STERRAD Chemical Indicator, Heat Seal, 6” x 12.5”	2x250 shelf packs; 500/case	12532

Device Performance:

STERRAD Systems sterilization efficacy has been demonstrated against enveloped and non-enveloped viruses, mycobacteria, and bacterial spores, which represent the most difficult to sterilize micro-organisms. This testing has been previously reviewed and included in the premarket notifications cleared by the U.S. FDA. Although COVID-19 has not been specifically tested, as an enveloped virus, coronavirus is not more resistant than the virus strains (Poliovirus Type 1 or Herpes simplex virus Type 1) used in verification and validation of the various STERRAD System cycles and is much less resistant than the bacterial spores used to demonstrate sterilization.

In addition to all previous verification and validation testing completed for the STERRAD Sterilization Systems, ASP has completed testing to demonstrate compatibility and performance of the STERRAD Sterilization Systems for the reprocessing of N95 and similar masks that do not contain cellulose. N95 masks were prepared and loaded into the STERRAD systems as described in this IFU. Results of that testing identified that N95 masks can be reprocessed a minimum of two (2) times and potentially up to five (5) times depending on unit and STERRAD Sterilizer cycle used. Testing conducted with ALLClear® Technology disabled.

Important information: Prior to use, refer to the instructions for use supplied with this device for the standard indications, contraindications, warnings and precautions.

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