

## **STEAM Decon Cycle External Q&A**

**The FDA has granted STERIS a second Emergency Use Authorization (EUA).** This allows STERIS to temporarily provide a distinct option to effectively decontaminate **3M® Models 8210, 3M 1860, 3M 1860S, and 3M 1804 NIOSH approved N95 respirators up to 4 times using the STERIS STEAM Decon Cycle in AMSCO® 400 or AMSCO® Century Medium Steam Sterilizers.** Below is a list of questions and answers designed to assist healthcare providers in implementing this process. This Q&A is effective as of February 7, 2021 and supersedes any previous versions. Please reference the protocol for specific instructions.

### **General Questions:**

**Q: Where can I find more information about STERIS Infection Prevention solutions? A:**

Visit [steris.com](https://steris.com) and the [COVID-19 landing page](#) for additional information.

**Q: What is an Emergency Use Authorization?**

A: The [Emergency Use Authorization \(EUA\)](#) is a process available to the U.S. Food and Drug Administration to allow the unapproved use of a 510(k) cleared product for certain emergency circumstances.

**Q: Did STERIS complete microbiocidal testing to support the use of the cycle to decontaminate compatible 3M® Models 8210, 3M 1860, 3M 1860S, and 3M 1804 NIOSH approved N95 respirators?**

A: Yes. STERIS followed guidelines published by [FDA: Enforcement Guideline for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency](#). STERIS completed validation testing with a surrogate virus that is more resistant to inactivation than SARS-CoV-2 virus. Use of the STERIS STEAM Decon Cycle in AMSCO® 400 and AMSCO® Century Medium Steam Sterilizers achieved  $\geq 3$  log reduction of virus in the presence of soil.

**Q: Was functional testing completed to support the use of the cycle to decontaminate compatible 3M® Models 8210, 3M 1860, 3M 1860S, and 3M 1804 NIOSH approved N95 respirators?**

A: Yes. The respirator manufacturer completed testing on respirator performance and confirmed up to 4 STERIS STEAM Decon Cycles are not expected to have a detrimental impact on respirator filtration performance.

**Q: Did the OEM approve use of the STERIS STEAM Decon Cycle in STERIS AMSCO® 400 or AMSCO® Century Medium Steam Sterilizers for reprocessing compatible 3M® Models 8210, 3M 1860, 3M 1860S, and 3M 1804 NIOSH approved N95 respirators?**

A: The U.S. Food and Drug Administration provided STERIS with an Emergency Use Authorization based upon evidence of successful decontamination in the STERIS STEAM Decon Cycle.

**Q: What is 3M's stance on the use of the STERIS STEAM Decon Cycle to decontaminate compatible N95 respirators?**

A: STERIS worked with 3M as we developed the protocol to provide respirator decontamination solutions to healthcare professionals and 3M has evaluated the performance of respirators after processing.

**Q: Do I need additional/different PPE?**

A: No. PPE that is normally used in the decontamination area of sterile processing should be used when preparing the respirators for reprocessing. To prevent contamination of the sterile processing area, hospitals should implement practices to pouch the compatible N95 respirators outside the sterile processing departments, for example, at a collection point in each employee work area.

**Q: Do I need to write separate policies and procedures for the STERIS STEAM Decon Cycle?**

A: Healthcare facilities should determine if separate policies and procedures are required. Recommended procedures are included in the STERIS STEAM Decon Cycle protocol.

**Q: Are there In-Service materials available for the STERIS STEAM Decon Cycle?**

A: Yes. STERIS has in-service materials available at STERIS University for operation of the steam sterilizers. [The Instructions for Healthcare Facilities](#) are available and identify how to load the chamber in order to successfully reprocess the compatible N95 respirators.

**Q: Why are only certain respirators and steam sterilizer models included in the protocol?**

A: At this time, testing was only completed on 3M 8210, 3M 1860, 3M 1860S, and 3M 1804 NIOSH approved N95 respirators only in the AMSCO® 400 and AMSCO® Century Medium Steam Sterilizers.

**Q: Which STERIS high-temperature steam sterilizers can be used to decontaminate compatible N95 respirators?**

A: AMSCO® 400 or AMSCO® Century Medium Steam Sterilizers can be used to decontaminate 3M® Models 1860, 1860S, and 1804 NIOSH-approved N95 respirators. Only the Decon cycle is to be used. Standard cycles on the steam sterilizers will damage the respirator.

**Q: Can AMSCO® Evolution, AMSCO® 600, AMSCO® C, and/or AMSCO® Eagle Sterilizers be used to reprocess compatible N95 respirators?**

A: No. The AMSCO® Evolution, AMSCO® 600, AMSCO® C, and/or AMSCO® Eagle sterilizers cannot be used to reprocess 3M 8210, 3M 1860, 3M 1860S, and 3M 1804 NIOSH approved N95 respirators.

**Q: Will STERIS be conducting further use/real world evident (RWE) testing for fit, filtration and marking of respirators?**

A: STERIS is currently working with FDA to appropriately update the EUA based on their condition for maintaining authorization.

## **STERIS STEAM Decon Cycle Questions:**

### **Q: Do I need to modify or change anything to an existing STERIS AMSCO® 400 Medium Steam Sterilizer or AMSCO® Century Medium Steam Sterilizer?**

A: Yes. STERIS service personnel are required to download special software to decontaminate 3M 8210, 3M 1860, 3M 1860S, and 3M 1804 NIOSH approved N95 respirators. Following the software download, the sterilizer will have two new cycles available, 'Decon' and 'WARM/COOL'.

Contact STERIS Service at 1-800-333-8828 with the serial number of the AMSCO® 400 and AMSCO® Century Medium Steam Sterilizer.

### **Q: Is there a cost to have the software added to existing STERIS AMSCO® 400 Medium Steam Sterilizer or AMSCO® Century Medium Steam Sterilizers?**

A: Contact your local STERIS Field Service Representative or STERIS Service at 1-800-333- 8828 for information.

### **Q: When do I use the WARM/COOL Cycle?**

A: The new low temperature STEAM Decon Cycle has a temperature parameter well below the normal operating temperature of your steam sterilizer. When the sterilizer is powered up or turned on from Standby, in order to run the Decon Cycle, the sterilizer will prompt you to run the WARM/COOL Cycle to condition the chamber.

Additionally, if you wish to use the Decon Cycle after the completion of a standard high temperature cycle, the sterilizer will prompt you to run the WARM/COOL Cycle.

The [Instructions for Healthcare Facilities](#) include information about the use of this cycle.

### **Q: Can I include instruments and other steam items when running the STEAM Decon Cycle?**

A: No.

### **Q: How are the compatible N95 respirators cleaned before I place them in the steam sterilizer?**

A: The respirators do not need to be cleaned prior to putting them into steam. If there is a visibly damaged or heavily soiled respirator, the respirator should be discarded.

### **Q: How is the compatible N95 respirator prepared prior to putting into the steam sterilizer?**

A: The respirator is packaged in a high temperature pouch and sealed prior to initiating the cycle. STERIS provides a 7.5" x 13" STERIS Vis-U-All pouch 884713 or 883713. Alternatively, any 7.5"x13" High Temperature pouch FDA cleared for steam sterilization would be effective. If desired, pouches may be marked with a sharpie or ink marker for traceability, tracking decontamination cycles, or other purposes.

### **Q: Are there other pouch sizes I can use to package the compatible N95 respirator? A:**

Yes. The minimum size pouch is 7.5"x13", but larger pouches can be used. Respirators should only be packaged one per pouch regardless of pouch size. Using a larger pouch may reduce the number of respirators that can be processed in each cycle.

**Q: Does the steam sterilizer require daily qualification testing?**

A: Yes. Continue to do normal daily qualification testing on your steam sterilizers.

**Q: Does a biological indicator need to be used within the STERIS STEAM Decon Cycle for release of the compatible N95 respirators?**

A: The use of a biological indicator is not required for the release of reprocessed respirators in the STERIS STEAM Decon Cycle. The healthcare facility should maintain their documented processes for biological monitoring of the steam sterilizer.

**Q: Do I need to use a Chemical Indicator (CI) when decontaminating the compatible N95 respirators in the STERIS STEAM Decon Cycle?**

A: No. Based on the cycle parameters in the EUA, chemical indicators are not required.

**Q: What are the required parameters in the steam sterilizer using the STERIS STEAM Decon Cycle process?**

A: Once a STERIS service person downloads the new software on the sterilizer, the Decon Cycle will use the following parameters:

During the exposure phase, if result of temperature (EXPOSE TEMP) is between 145.4 - 163.4°F, pressure is between 10 – 24inHg, and time (EXPOSE TIME) is 30 minutes, all respirators processed within that load may be considered decontaminated and the cycle will completed normally.

**Q: Are there limitations on how many compatible N95 respirators can go in each cycle?** A: Yes. The chart below outlines the maximum number of masks per cycle given the model and size of the steam sterilizer. Respirators should not be stacked for decontamination.

<b>Sterilizer Size/Models</b>	<b>Number of Trays</b>	<b>Number of Pouched Respirators</b>
26"x37.5"x36" AMSCO Century 36" AMSCO 400 36H, 36SL, 36CH, 36CSL	9	108
26"x37.5"x48" AMSCO Century 48" AMSCO 400 48H, 48SL, 48CH, 48CSL	12	144
26"x37.5"x60" AMSCO Century 60" AMSCO 400 60H, 60SL, 60CH, 60CSL	15	180

**Q: Can the compatible N95 respirators be stacked in their pouches when placed in the steam sterilizer?**

A: No. In order to achieve appropriate penetration of steam in the cycle, the respirators cannot be stacked on top of each other.

**Q: Can the compatible N95 respirators be stored in the pouch after processing?** A:

Yes. The respirators can be stored in the pouch after processing.

**Q: Should the compatible N95 respirators be decontaminated in the STERIS STEAM Decon Cycle after each use?**

A: Yes. Each respirator should be processed after each use up to a maximum of 4 times. The facility needs to implement a method to identify the number of reprocessing cycles of the respirator.

**Q: What is the “Hierarchy of Decontamination and Bioburden Reduction System for Surgical Masks and/or Respirators”?**

A: In May of 2020, The U.S. Food and Drug Administration released [Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators during the Coronavirus Diseases 2019 Public Health Emergency](#). These recommendations included guidance to sponsors (e.g STERIS) to provide evidence in their submissions that the critical parameters are controlled and follow the hierarchy levels, or tiers, of resistance of microorganisms to germicidal chemicals.

**Q: What tier of decontamination is the use of the STEAM Decon Cycle to reprocess compatible N95 or N95-equivalent respirators in AMSCO Century and 400 Medium Steam Sterilizers?**

A: Based on evidence submitted by STERIS to The U.S. Food and Drug Administration, the use of the STEAM Decon Cycle to reprocess compatible N95 or N95-equivalent respirators in AMSCO Century and 400 Medium Steam Sterilizers is considered **Tier 1: Decontamination of Surgical Masks and/or Respirators for Single- or Multiple-Users**.

**Q: Do I need to reuse my same (per individual) respirator?**

A: Though the use of the STEAM Decon Cycle to reprocess compatible N95 or N95-equivalent respirators in AMSCO Century and 400 Medium Steam Sterilizers is considered **Tier 1**, it is strongly recommended to maintain a single-user approach and chain of custody on the respirator to minimize the risk of cross-contamination. STERIS labeling will continue to recommend a single-user reuse process.

**Q: Can I use this cycle forever?**

A: No. Reprocessing of compatible N95 respirators in the STERIS STEAM Decon Cycle is only permissible during the pandemic and only if there is insufficient supply of new respirators available to protect healthcare workers. Once the EUA is no longer applicable the cycle will be removed from the sterilizers by STERIS service personnel.

**Q: Can the same compatible N95 respirator be reprocessed in both a STERIS STEAM Decon Cycle and other equipment (e.g., two different steam sterilizer models or the Non Lumen Cycle of a V-PRO®)?**

A: No. None of the EUA, protocol, or compatibility testing contemplate a respirator being reprocessed in more than one type of equipment.

For example, do not reprocess a respirator two times using the STERIS STEAM Decon Cycle and then two times in V-PRO. Similarly, do not process a respirator three times in an AMSCO 400 Medium Steam Sterilizer then one time in an AMSCO Century Medium Steam Sterilizer.

Like the chain of custody for respirator wearers, the healthcare facility should ensure each mask reprocessed in a steam sterilizer is done exclusively in the STERIS STEAM Decon Cycle of the same steam sterilizer model.

**Q: Can I use the STERIS protocol for decontaminating compatible N95 respirators in non-STERIS Steam Sterilizers (e.g. Getinge® or Belimed®)?**

A: No. The protocol developed by STERIS and submitted to the FDA as part of the EUA is applicable only to AMSCO 400 and AMSCO Century Medium Steam Sterilizers. Customers should refer to other manufacturers' EUAs and protocols for processing N95 respirators in other equipment.