STERIS
Infection Prevention Technologies

May 23, 2020

To Our Valued Customers:

The SARS-CoV-2 Coronavirus pandemic has created unprecedented challenges for patient care and staff safety. As your partner for infection prevention, we have been working with regulators to find solutions to your most pressing needs.

The FDA has granted STERIS an additional Emergency Use Authorization ("EUA"). This allows STERIS to temporarily provide a distinct option to effectively decontaminate 3M® Models 1860, 1860S, and 1804 NIOSH-approved N95 respirators, **up to 10 times** using an **AMSCO® 400 or AMSCO® Century Medium Steam Sterilizer**.

Testing demonstrated effective decontamination of 3M Models 1860, 1860S, and 1804 NIOSH-approved N95 respirators inoculated with a surrogate virus more resistant than SARS-CoV-2 Coronavirus. Studies also demonstrated reprocessing as permitted by the EUA does not impact the function of the respirators or alter the materials of construction.

STERIS service personnel will need to install special software and two new temporary cycles to the sterilizers to support this application. **Contact STERIS Service at 1-800-333-8828** with the serial number of your AMSCO® 400 and AMSCO® Century Medium Steam Sterilizer(s).

To help navigate Healthcare Customers through this process, STERIS has updated our COVID-19 landing page, which includes all required information on how to prepare the respirators for decontamination in an AMSCO 400 or AMSCO Century Medium Steam Sterilizer.

Prior to using the STEAM Decon Cycle, you are required to review and implement the Healthcare Facility Requirements (L-Q) located in the Emergency Use Authorization Letter of Authorization (pages 7&8) received by STERIS and utilize the labeling and fact sheet authorized by FDA for use of this application. These documents are located on the COVID-19 landing page.

General information is also included on other STERIS modalities related to SARS-CoV-2 Coronavirus, including the **previously granted EUA**, V-PRO® Low Temperature Sterilization System (models: 1 Plus, maX, maX 2). Customers with more than one sterilization modality must ensure that an individual mask is reprocessed in only one type of sterilizer.

If you have specific questions, please contact your STERIS Account Manager, Clinical Specialist and/or submit your questions to STERIS directly.

STERIS remains committed to your success in delivering patient care through this pandemic. Thank you for all that you are doing to serve patients.

Best Regards,

STERIS

Infection Prevention Technologies