URGENT MEDICAL DEVICE NOTICE
Emergency Use Authorization Revocation for Century or AMSCO® 400 Medium Steam Sterilizers

July 30, 2021

ATTN: QUALITY MANAGEMENT OR STERILE PROCESSING DEPARTMENT

Dear Valued STERIS Customer:

In response to the COVID-19 pandemic, STERIS requested, and was granted Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) for the emergency use of the Century and AMSCO 400 Medium Steam Sterilizers and the STERIS STEAM Decontamination Cycle to decontaminate compatible N95 or N95-equivelant respirators for single-user reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of N95 respirators. This EUA was issued on May 21, 2020 and revised and reissued on January 21, 2021.

Effective June 30, 2021, FDA has revoked STERIS's EUA for the STERIS STEAM Decontamination Cycle on Century and AMSCO 400 Medium Steam Sterilizers making them no longer authorized for emergency use.

Based on the increased supply of respirators, the Centers for Disease Control and Prevention's (CDC) updated recommendations, and in alignment with the Occupational Safety and Health Administration's (OSHA) recently published Emergency Temporary Standards, FDA has determined that it is appropriate to revoke this authorization. STERIS has notified FDA that it has ceased operations and associated activities which support the decontamination and re-use of N95 respirators.

It is vital that any activities previously approved under this EUA are ceased immediately. Healthcare facilities should follow updated guidance from FDA and CDC regarding the use of NIOSH approved N95 respirators. STERIS's Century and AMSCO 400 Medium Steam Sterilizers shall only be used according to their 510(k)-cleared indications for use designed for sterilization of heat- and moisture-stable materials used in healthcare facilities and shall no longer be used for decontamination of compatible N95 or N95-equivalent respirators.

All affected Customers will be contacted by a STERIS Service Technician to arrange an onsite visit to deinstall the STERIS STEAM Decontamination Cycle on their unit(s) that had the cycle installed under the EUA.

STERIS would like to take the opportunity to thank our frontline healthcare workers for their sacrifice and commitment and are honored to have supported them during these unprecedented times. If you any have questions regarding this letter, please contact Chris Antonucci, Senior Director of IPT Marketing, STERIS Customer Service at 1-800-548-4873, or your local STERIS Representative.

Regards,

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