



URGENT FIELD CORRECTION NOTICE

March 9, 2015

ATTN: QUALITY MANAGER, RISK AND PATIENT SAFETY DEPARTMENT

RE: AMSCO C and AMSCO 400 Steam Sterilizers

Dear Valued Customer:

STERIS Corporation is voluntarily implementing a field correction of AMSCO C and AMSCO 400 Steam Sterilizers distributed between April 14, 2014, and February 18, 2015. Our records indicate that your facility purchased one or more of the sterilizers included in this field correction.

Description of the Product – The AMSCO Steam Sterilizers are designed for sterilization of heat and moisture-stable materials used in healthcare facilities.

Description of the Problem – AMSCO C and AMSCO 400 steam sterilizers provide the operator with several utility service options including the selection of daily sterilizer shutdown and start up times.

STERIS has identified the control board software in select AMSCO C and AMSCO 400 units will interrupt and cancel a processing cycle should the selected sterilizer shutdown time coincide with a processing cycle. This may result in a procedure delay should the facility immediately require instruments from the cancelled processing cycle. If the processing cycle is interrupted the cycle should not be considered complete and the instruments should be reprocessed.

STERIS has received no reports of procedure delays associated with the occurrence of these events.

STERIS Action – The control board software is being revised to ensure the utility shutdown feature will not interrupt an ongoing processing cycle. STERIS Field Representatives will contact Customers to schedule installation of the new control board software on affected AMSCO steam sterilizers.

We apologize for any inconvenience this matter may cause you and as always STERIS Corporation is dedicated to supporting our products and valued Customers. If you have questions regarding this matter, please contact STERIS Customer Service at 1-800-548-4873, Marie LaFrance, Product Manager, at 440-392-7648, or your local sales representative.

Sincerely,

A handwritten signature in black ink that reads "Kate Cadorette".

Kate Cadorette
Senior Manager, Quality & Regulatory Compliance