URGENT MEDICAL DEVICE FIELD CORRECTION
MEDISA Automated Endoscope Reprocessor (AER)

March 7, 2025

ATTN: MATERIALS MANAGEMENT OR STERILE PROCESSING DEPARTMENT

Dear Valued STERIS Customer:

STERIS is voluntarily implementing a field correction for all MEDISA Automated Endoscope Reprocessors (AERs) distributed between June 25, 2024 – February 3, 2025 (UDI: 8011517EWD002GL and 8011517EWD001GJ). Our records indicate that your facility purchased one or more of the AERs included in this field correction.

Description of the product – MEDISA AERs are medical devices intended for washing and cold chemical high-level disinfection or sterilization of rigid and flexible endoscopes.

Description of the problem – STERIS identified through Customer complaints that the lid to the MEDISA AER may open unexpectedly during a cycle. There could be risk of exposure to diluted peracetic acid should an employee not be wearing required Personal Protective Equipment (PPE) and be in close proximity to the unit when the lid opens. STERIS determined the issue was caused by communication issues within the unit's panel PC.

STERIS Action – STERIS has developed and tested a fix to address these communication issues. All affected Customers will be notified by a STERIS Service Technician to arrange onsite inspection of the units(s) and perform the correction. A Technician will visit each facility to inspect their MEDISA(s) and complete the correction.

User Action – Users can continue to use their MEDISA AERs prior to completion of the correction. Users are reminded to continue to wear appropriate PPE including gloves, face visor, and face mask when using the MEDISA as instructed in the Operator Manual and in the chemistry's Safety Data Sheet. The Competent Authority of your country has been informed of this notice. STERIS does not require a response to this notice letter.

We apologize for any inconvenience this matter may cause, and as always, STERIS is dedicated to supporting our products and valued Customers. If you have questions regarding this matter, please contact your local STERIS Representative.

Sincerely,

Michelle LaVan

Michelle LaVan
Lead, Quality & Regulatory Compliance Specialist
STERIS