



URGENT MEDICAL DEVICE CORRECTION
Reliance Vision Single-Chamber Washer/Disinfector

November 30, 2020

ATTN: MATERIALS MANAGEMENT OR STERILE PROCESSING DEPARTMENT

Dear Valued STERIS Customer:

STERIS is voluntarily implementing a field correction for Reliance Vision Single-Chamber Washer/Disinfectors distributed between October 15, 2008 – November 4, 2020. Please reference Attachment A to this letter for the full list of affected serial numbers.

Description of the product – The Reliance Vision Single-Chamber Washer/Disinfector is intended for use in the cleaning and intermediate level disinfection of soiled reusable utensils, trays, glassware, bedpans and urinals, rubber and plastic goods, simple hard-surfaced rigid surgical instruments, such as forceps and clamps, theatre shoes, and other similar and related articles found in healthcare facilities.

Description of the problem – STERIS has identified that in the remote occurrence in which the electrical contactor component present in the drying chamber of the Reliance Vision Single-Chamber Washer/Disinfector malfunctions, the heating elements in the drying chamber could overheat, eventually resulting in smoke and/or fire. This could result in smoke inhalation or a burn which may require medical intervention. It is important to note that the occurrence of smoke/fire has occurred in a very small number of devices.

STERIS has developed an automatic shut off of the power to prevent the heating elements from overheating if this malfunction were to occur. The unit would remain “ON” in an alarm state, informing the user that service is required.

STERIS Action – All affected Customers will be contacted by a STERIS Service Technician to arrange an onsite inspection of their unit(s) and perform the correction.

User Action – Users can continue to use their Reliance Vision Single-Chamber Washer/Disinfectors prior to completion of the correction. Users are reminded to follow the instructions outlined in the Operator Manual should the unit alarm “Drying Temperature Too High” by aborting the cycle, turning off power to the unit, and contacting STERIS.

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 Sarah Brown, Senior Product Manager, at 440-392-7571, STERIS Customer Service at 1-800-548-4873, or your local STERIS Representative.

Sincerely,

A handwritten signature in blue ink that reads "Michelle LaVan".

Michelle LaVan
Lead, Quality & Regulatory Compliance Specialist
STERIS