URGENT MEDICAL DEVICE CORRECTION
Reliance® Synergy Washer/Disinfector

April 14, 2022

ATTN: PURCHASING DEPARTMENT

Dear Valued STERIS Distributor:

STERIS is voluntarily implementing a field correction for Reliance Synergy Washer/Disinfectors distributed between January 22, 2003 – October 12, 2016.

**Description of the product** – The Reliance Synergy Washer/Disinfector is intended for use in the cleaning and low-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) 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 Synergy 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** – STERIS will provide you with the service kit and installation instructions required to upgrade each affected Reliance Synergy Washer/Disinfector.

**User Action** – If you have further distributed this product, please identify your Customer(s), notify them of this field correction and perform the correction. Users can continue to use their Reliance Synergy 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, positioning building electrical disconnect switch to OFF, 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,

[Signature]

Michelle LaVan
Lead, Quality & Regulatory Compliance Specialist
STERIS