

URGENT DEVICE FIELD CORRECTION

June 12th, 2020

ATTN: MATERIALS MANAGEMENT OR STERILE PROCESSING DEPARTMENT

RE: CMAX 3 and CMAX 3-DRIVE Surgical Tables

Dear Valued STERIS Distributor:

STERIS is voluntarily implementing a field correction for all CMAX 3 and CMAX 3-DRIVE Surgical Tables manufactured between October 23, 2017 - July 19, 2019. Our records indicate that your facility purchased one or more of the CMAX 3 and CMAX 3-DRIVE Surgical Tables included in this field correction. The complete list of affected serial numbers is included as attachment to this letter.

Description of the product – The CMAX 3 and CMAX 3-DRIVE surgical tables are intended to support and position patients during surgical procedures carried out in an operating room, and during transfer to and from the patient's bed. CMAX surgical tables shall be operated in a controlled environment by a healthcare professional familiar with appropriate techniques with such equipment.

Description of the problem – STERIS has identified that the circuit board within the auxiliary (override) control may not prevent damage caused by fluid intrusion. The auxiliary control has an incomplete seal around the cursor side of the control which may allow fluid to enter, and over time, cause the circuit board to short, potentially resulting in undesired table movement or the table becoming unresponsive to user inputs.

STERIS Action – STERIS will provide you with the replacement auxiliary control and service instructions required to replace each CMAX 3 and CMAX 3-DRIVE Surgical Table's auxiliary control.

User Action – If you have further distributed these products, please identify your Customers, notify them of this field correction and perform the replacement of the auxiliary control. In the interim, the table should be both visually inspected and functionally tested prior to each use. Additionally, users should follow proper cleaning practices as outlined in the operator manual which will ensure excess fluid does not remain on the auxiliary control.

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,

A handwritten signature in blue ink, appearing to read "Veronique Mordelles", written over a light blue horizontal line.

Veronique Mordelles
Senior Quality Manager
STERIS