

URGENT MEDICAL DEVICE FIELD CORRECTION

February 10, 2022

ATTN: MATERIALS MANAGEMENT OR QUALITY DEPARTMENT

RE: CMAX 3, CMAX 3-DRIVE, CMAX 3E, and CMAX 3E-DRIVE Surgical Tables

Dear Valued STERIS Customer:

STERIS is voluntarily implementing a field correction for all CMAX 3, CMAX 3-DRIVE, CMAX 3E, and CMAX 3E-DRIVE Surgical Tables manufactured between April 27, 2021 – July 27, 2021. Our records indicate that your facility purchased one or more of the tables included in this field correction. The complete list of affected serial numbers is included as an attachment to this letter.

Description of the product – The CMAX 3, CMAX 3-DRIVE, CMAX 3E, and CMAX 3E-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.

Description of the problem – STERIS has identified that the surgical table's slide motor pin may break potentially resulting in undesired tabletop movement or loss of powered table control.

STERIS Action – STERIS has updated the motor pin to make it more resistant to unintentional breakage caused by an excess external force or impact. A STERIS Service Technician will arrange an onsite inspection of your table(s) for replacement of the motor slide assembly.

User Action – Users can continue to use the CMAX 3, CMAX 3-DRIVE, CMAX 3E, and CMAX 3E-DRIVE Surgical Tables prior to this replacement. Users are advised to avoid applying excess force to the tabletop or having the table impact walls or other pieces of equipment.

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 STERIS Customer Service at +33 (0) 5 56 93 94 94 or your local STERIS Representative.

Sincerely,

Veronique Mordelles
Senior Quality Manager
STERIS

List of Affected CMAX 3 and CMAX 3-DRIVE CMAX 3E, and
CMAX 3E-DRIVE Surgical Tables by Serial Number

185276	185808	186650	188658
185293	185809	186681	188659
185294	185810	186682	188660
185295	186350	186683	188661
185296	186351	186684	188662
185572	186352	186686	188664
185573	186353	186687	189462
185574	186354	186688	189463
185575	186355	186689	189464
185576	186356	186690	189465
185644	186357	186691	189466
185645	186364	186692	189467
185646	186365	186704	189468
185647	186366	186705	189469
185805	186367	188456	189470
185806	186368	188656	
185807	186649	188657	