Baxter

July 2, 2024

Subject: Field Safety Notice – Correction – PST 500 Precision Surgical Table - Defective Tilt Drive Causing Unwanted Movement During Use

Product Name: PST 500
Product codes and Serial numbers concerned: Product code: 4080100 – Serial number: Refer to Attachment A

Dear Sir, Madam,

Baxter Healthcare Corporation is issuing a Correction for the PST 500 U Precision Surgical Table due to a potential issue with loose spring pins in the spindle drives. This can cause the tabletop to unexpectedly tilt or move at any time, even without active use of the surgical table. This could potentially result in unintentional patient movement during surgical procedures and/or preparation for surgical procedures, including transport.

Baxter will correct this issue by providing a service kit that can be installed either by a hospital technician or by a Baxter technician or authorized representative. If the service kit is self-installed, a Baxter technician or authorized representative will follow up to verify proper installation.

A sudden drop and/or tilt of the surgical tabletop during a surgical procedure may cause unintended patient movement or fall. This could lead to delay or interruption in therapy, ineffective CPR, and could cause critical patient harm such as major musculoskeletal or vital organ injuries. Baxter has received six complaints related to this issue; however, no serious injury was reported.

Our records indicate that 18 customers have received this product in Romania. For your information, please find attached the communication that is being sent to those customers.

Should you have any questions, please contact us at +40748344849

Yours Sincerely,

Name Miruna Stoilescu
Title QA/RA Manager Kral Medical Solutions

Urgent Field Safety Notice

PST 500
FA Number: FA-2024-042
Manufacturer: Baxter Medical Systems GmbH + Co. KG (Single Registration Number: DE-MF-000005071)
Correction

July 1st, 2024

Dear Healthcare Provider or Distributor,

Baxter Healthcare Corporation is issuing a Correction for the PST 500 U Precision Surgical Table due to a potential issue with loose spring pins in the spindle drives. This can cause the tabletop to unexpectedly tilt or move at any time, even without active use of the surgical table. This could potentially result in unintentional patient movement during surgical procedures and/or preparation for surgical procedures, including transport.

Baxter will correct this issue by providing a service kit that can be installed either by a hospital technician or by a Baxter technician or authorized representative. If the service kit is self-installed, a Baxter technician or authorized representative will follow up to verify proper installation.

Affected Product

Product Code	Product Name	Serial Number	UDI Number
4080100	PST 500	Refer to Attachment A	00887761973466

Hazard Involved

A sudden drop and/or tilt of the surgical tabletop during a surgical procedure may cause unintended patient movement or fall. This could lead to delay or interruption in therapy, ineffective CPR, and could cause critical patient harm such as major musculoskeletal or vital organ injuries. Baxter has received six complaints related to this issue; however, no serious injury was reported.

Actions to be Taken by Customers

1. Immediately cease all use of the impacted units until a correction has been completed. If you have alternative tables available, please use them until the service kit is installed by the hospital technician, a Baxter technician, or an authorized representative.
2. Below are two options for correction of the impacted units:

    a. Self-installation of the service kit (part number 2086594) executed by a hospital-defined technician per the technical service bulletin included with the service kit. Once the self-installation is successful, the impacted units are ready for use. For any questions regarding the installation of the service kit, please contact Baxter.

b. A Baxter representative will contact you to schedule inspection of self-corrected units or correct the impacted units at your facility. Do not use the impacted units until the correction has been executed. To request correction of your impacted tables, contact Baxter.

3. Complete the enclosed customer reply form and return it to Baxter by e-mailing it to agi_zag@baxter.com even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices

4. Please provide this information to all users of the PST 500 Precision Surgical Table. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.

5. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this *Correction* in accordance with your customary procedures.

Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact your sales representative or Baxter at below address between working hours.

The local Ministry of Health (MOH) will be notified of this action.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Ági Zag
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Electronically signed by: Agi Zag
Reason: I approve this document
Date: Jul 1, 2024 08:58 GMT+2

Enclosure: Baxter Customer Reply Form
Attachment A: Affected Product Table