Urgent Field Safety Notice

TruSystem 7000 and **TruSystem 7500** Surgical Tables

Field Action Reference: FA-2026-027

Manufacturer: Baxter Medical Systems GmbH + Co. KG (Single Registration Number: DE-MF-000005071)

Type of Action: Correction

October XX, 2026 (to be adapted locally)

Dear Sir/Madam, (to be adapted locally)

Baxter Healthcare Corporation is issuing a voluntary correction for certain **TruSystem 7000** and **TruSystem 7500** Surgical Tables due to a reported issue with the main lift mechanism. Customers have reported instances in which the main lift on a TruSystem 7500 unexpectedly dropped from its set position to its lowest position during use. In these cases, the tabletop could not be raised again after the drop occurred. The issue has been associated with unexpected wear of the main lift assembly, also known as the telescopic spindle.

Based on Baxter's risk assessment to date, Baxter is not removing **TruSystem 7000** or **TruSystem 7500** Surgical Tables from the field at this time. Customers should use their clinical judgment about continued use of these products in light of the information contained in this Urgent Medical Device Correction letter.

Please note that affected **TruSystem 7000** Surgical tables and **TruSystem 7500** Surgical Tables that were distributed between May 2026 and June 2026 and **TruSystem 7500** Surgical Tables that were distributed between April 2021 and February 2026 are subject to this voluntary correction. (to be adapted locally)

Affected Product (to be adapted locally)

Product Code	Product Description	Serial Number	UDI-DI Number
4091000	TruSystem 7500	See Attachment A	00887761968639
1704695	Operating table column TS7500 MOBIUS	See Attachment A	00887761974425
1717020	Operating table stationary column TS7500	See Attachment A	00887761974418
1717021	Operating table floor mounting column TS7500	See Attachment A	00887761974401
1717023	Operating table mobile column TS7500	See Attachment A	00887761974395
1454298	Operating table mobile column TS7500	See Attachment A	N/A
1854087	TruSystem 7500 Hybrid Plus (FC)	See Attachment A	00887761974067
1841048	TruSystem 7000 (MBW)	See Attachment A	00887761968707

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1841049	TruSystem 7000 (dV)	See Attachment A	00887761968691
2065385	TruSystem 7000 U14 (MBW)	See Attachment A	00887761968653

Hazard Involved

An uncontrolled drop of the surgical table may result in an abrupt patient displacement during surgery. Serious or critical adverse health consequences may occur, including traumatic injury, airway compromise, and surgical procedure complications, among others. Baxter has received three complaints related to this issue, with no reported patient injury

Actions to be Taken by Customers

1. ~~A Baxter representative will contact your facility when the correction for this issue becomes available. Baxter expects to begin contacting customers with more information about the correction by the end of 2026.~~
2. Although Baxter's risk assessment to date has not identified a clear cause for this issue, customers should continue to monitor the table as instructed in the applicable IFU during use for unusual noises or changes in performance. If an unusual noise is observed, discontinue use of the affected product. ~~and contact Baxter Technical Service for assistance.~~
3. Please post this communication by the impacted devices until the correction is completed to maintain user awareness.
4. Complete the enclosed customer reply form and return it to Baxter by either scanning and e-mailing it to (insert local contact information) or sending it by post to (insert local contact information), 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.
5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
6. 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.
7. 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 (to be adapted locally)

For general questions regarding this communication or any product issue you are experiencing, contact Baxter at (insert local contact information), between the hours of (insert local information).

The local Ministry of Health (MOH) has been notified of this action. (to be adapted locally)

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

Sincerely,

Name (to be adapted locally)
Title (to be adapted locally)
Baxter Healthcare Corporation (to be adapted locally)

Attachment 1: ATTACHMENT A: Affected Product – TruSystem 7000 & 7500 Surgical Table (to be adapted locally)

Attachment 2: Customer Reply Form (to be adapted locally)

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