

Urgent Field Safety Notice**Adapter for Head Positioning****FA-2026-016****Manufacturer:** Baxter Medical Systems GmbH + Co. KG (Single Registration Number: DE-MF-000005071)**Field Action Type:** Recall4th May, 2026

Dear Healthcare Provider

Baxter Healthcare Corporation is recalling the product listed below due to the potential that the Adapter for Head Positioning accessory (product code 1739994, Adapter) may become loose during patient positioning and unintentionally move when used in conjunction with the side rails of the Upper Back Section H V component (product code 1909812) on Baxter operating tables. The Adapter functions properly when attached directly to the side rails of the **TruSystem 7000** operating table.

To correct this issue, Baxter will replace all affected Adapters listed below.

Affected Product

Product Code	Product Name	Serial Number	UDI Number
1739994	Adapter for Head Positioning	See Attachment A	00887761972780

Hazard Involved

When the Adapter is pushed onto the side rail of the Upper Back Section H V, the reduced contact surface may prevent firm and secure fixation, increasing the risk of unintentional movement or detachment. This could lead to reduced patient oxygenation or significant musculoskeletal or vital organ injury. Detached components may also cause musculoskeletal injury to the user, and both the patient and user may experience muscle strains. No serious injuries or deaths have been reported in relation to this issue.

Actions to be Taken by Customer

1. Please notify all users of the product affected within your facility, especially all operating room staff. The affected Adapters may continue to be used only when mounted directly to the side rails of the operating table back plate. Do not use the Adapter on the Upper Back Section H V side rails (component). Using the Upper Back Section H V (separate component which is attached to the operating table's back plate) in conjunction with the Adapter accessory must be stopped/ceased, until a replacement takes place.
2. Once the newly designed Adapters are available Baxter will contact customers with instructions for return and replacement of the impacted Adapters.
3. Complete the enclosed customer reply form and return it to Baxter by scanning and e-mailing it to device.safety@drugsalesltd.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 Adapter for head positioning. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.

Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact Drugsales Ltd on 21419070/1/2 or email: device.safety@drugsalesltd.com

The Malta Medicines Authority has been notified of this action.

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

Sincerely,

A handwritten signature in blue ink, appearing to read 'A. Busuttil', with a stylized flourish at the end.

Adrian Busuttil RP/Regulatory Affairs Manager
Drugsales Ltd Baxter representative and distributor in Malta

Enclosures: Attachment A
 Baxter Customer Reply Form