

Urgent Field Safety Notice

Operating Table Accessories

FA-2023-047

Type of Action: Correction

September, 2023

Dear Sir/Madam,

**Problem
Description**

Baxter Healthcare Corporation is issuing a Correction for various accessories (see Attachment 1 of affected products) used with Operating Room (OR) tables that were distributed without the required Instructions for Use (IFU). The potential impact for the missing IFU is that the users will not have awareness of appropriate use of the accessories, or awareness of the cautions and warnings for each of the operating room table accessories.

Other than the missing IFUs, there are no quality issues with any of the affected devices and there have been no associated complaints or injuries reported due to this issue.

Baxter will contact customers to provide a paper copy of the required Instructions for Use (IFU) once available, in the meantime, an electronic copy of the IFU is available.

**Affected Product
(refer to
attachment 1)**

Product Code	Description	Serial #	UDI
Refer to Attachment 1			

Hazard Involved

Patients undergoing surgery may be at risk for exposure to one or more of the hazards if the user has not read the IFU and continues to use the accessory without knowledge of the indications, contraindications, set up, operating instructions, dangers, warnings, cautions, etc. for the accessory in use. Several hazards have the potential to result in serious health consequences for the patient and/or user.

The most likely hazards to be encountered in this setting is unintentional patient movement or a patient fall during a critical surgical procedure which may occur due to the incorrect positioning of an accessory or patient, or incorrect use of the controller when attempting to manipulate the OR table.

**Action to be
taken by the
user**

Baxter is kindly asking that you take the following actions:

1. Baxter will send you a paper copy of the IFU; however, in the meantime, Baxter will provide you an electronic copy. Please reach out to your local Baxter service organization.
2. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication along with the required IFU once available.
3. If you are a dealer, wholesaler or distributor/reseller that distributed any affected product to other facilities, please notify your customers of this Correction in accordance with your customary procedures, provide them with the required IFU once available and check the associated box on the reply form.
4. Complete the enclosed customer reply form to confirm acknowledgment of this notification and receipt of the IFU. Please return to Baxter by either faxing it or scanning and e-mailing it or sending it by post, 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 purchased this product from a distributor, please note that the Baxter customer reply form is not applicable in this situation. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

Further information and support

For general questions regarding this communication, please contact your Baxter Sales representative.

The local Ministry of Health (MOH) has been notified of this action.

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: Affected Product Table](#)

CUSTOMER REPLY FORM FA-2023-047

Correction

Operating Table Accessories – Distributed without Instruction for Use

August XX, 2023 (to be adapted locally)

FACILITY NAME:

ADDRESS:

(to be adapted locally)

Product Code	Product Description	UDI Number	Serial Numbers
1218646	Side rail extension	00887761971615	
1218804	Clamp radial setting	00887761971608	
1218820	Anaesthesia screen	00887761973176	
1218831	Extension strut	00887761972612	
1218832	Spindle traction mechanism	00887761972551	
1218835	Counter traction post	00887761972605	
1218968	Skull clamp	04250435506196	
1218969	Scull clamp adapter	04250435500569	
1218970	Basic unit neuro	04250435500019	
1265545	Foot support two parts	00887761971882	
1266934	Joint plate Carbon 520	00887761971554	
1272324	Clamp pair for joint plate Carbon	00887761971547	
1294003	Anaesthesia screen with elongation	00887761973145	
1295542	Wrist support 20	00887761973312	
1300079	Retainer for head rests vario	00887761972971	
1300662	Head rest X-RAY	00887761972964	
1317569	Skull clamp X-RAY	04250435502181	
1317577	Holding device for arm and leg	00887761971509	
1341443	Arm support pad 450	00887761973251	
1346755	Universal and hand cuff	00887761971875	
1395188	Knee support right	00887761972681	
1395189	Knee support left	00887761972674	
1424577	Head section X-RAY wide T	00887761972865	
1424588	Head section X-RAY narrow T	00887761972858	
1430023	Adapter X-RAY 3-joint narrow	00887761972841	
1434382	Condylen fixation device	00887761972421	
1446211	Guiding roller for cervical traction	00887761972803	
1483379	Arm support 450 T	00887761973244	
1493532	Arm holder for lateral position 450 T	00887761973206	
1496430	Lateral support height adjustable	00887761971851	
1496431	Lateral support height adjustable concav	00887761971844	
1505900	Widening segment seat section TS/M T	00887761971820	
1505907	Widening segment back sec. TruSystem T	00887761971806	
1505915	Widening segment UBS T	00887761971783	
1537214	Head Rest horseshoe-shaped COMFORT	00887761972797	
1557243	Charging unit mobile AC TS7500	00887761974500	
1574666	Extension adapter	00887761972407	
1574732	MIS-Hip-Aggregat	00887761972377	
1574735	Extension joint strut X-RAY, pair	00887761972346	
1576815	Counter traction post for tibia	00887761972322	
1576816	Adapter counter traction post pivoted	00887761972315	
1582709	Belt for patients X-TRA	00887761971950	
1593158	Adapter extension strut X-RAY	00887761972308	
1616204	OR tabletop Carbon FloatLine V	00887761974449	

1679646	Shoulder support height adjustable	00887761971776
1680904	Shoulder support height adjustable T	00887761971769
1739992	Tabletop segment Carbon 600 H V	00887761970939
1739994	Adapter for head positioning	00887761972780
1753616	Pad tabletop TS 7000 B	00887761969834
1756164	Pad protection for bridge WILSON	00887761973459
1756392	Pad leg section one part H B	00887761969827
1770133	Pad TTS Carbon 600 H B	00887761969797
1783316	Pad spine bridge WILSON set	00887761969780
1789952	Head section basic V	00887761990067
1790098	Leg section two parts V	00887761970526
1790125	Spine bridge WILSON V	00887761973411
1797654	Pad Carbon FloatLine B	00887761969704
1798326	Cable remote control TS7000 (dV)	00887761974289
1814876	FloatLine Catheter Tray	00887761973121
1816914	Cable connection TS7000 (dV)	N/A
1835762	Interface Skull Clamp radiolucent	04250435502136
1850955	Head section double joint H V	00887761970380
1850959	Leg section one part H V	00887761970366
1850989	Tabletop segment Carbon 1200 H V	00887761970328
1850994	Leg section four parts H V	00887761970311
1851579	Pad leg section four parts H B	00887761969674
1851986	Pad leg section X-RAY B	00887761969506
1867128	Docking trolley MIS hip device	00887761972193
1867129	Docking trolley extension unit	00887761972186
1873466	Pad TTS Carbon one part B	00887761969421
1876708	Transfer leg section	00887761972162
1880218	Supporting pad hip B	00887761972148
1880219	Pad Transfer Leg section B	00887761969407
1886332	Angle pad TS7000 B	00887761972124
1891860	Shoulder Chair Dolly TS7000	N/A
1897603	Supporting pad universal MARS B	00887761972117
1905159	SchureLoc Adapter	00810014603698
1905160	SchureLoc Forearm Attachment	00810014603391
1909796	OR tabletop U24 H V	00887761974005
1909814	Pad two-part tabletop H B	00887761969384
1909816	Pad one-part tabletop H B	00887761969377
1909817	Pelvic extension H V	00887761970250
1935665	SchureLoc XPS	00810057372995
2003863	Remote control wireless TS 7500	00887761968660
2009875	Shoulder Chair H	00810014602653
2064469	Cable remote control TS3000	00887761967724
2064471	Remote control wireless TS3000	00887761967717
2064483	Pad head section double joint M B	00887761967915
2065800	Shoulder Chair H with connection holder	00810014602660
2068499	Shoulder Supports	00810057370007
2068500	Shoulder support short	00810057371592
2069528	Cladding Protection TS7000	N/A
2071906	Pad PST 300S B	00887761968035
2072285	Square Adaptor	00810057371653
2072419	Extension adaptor PST 300	00887761968097
2072442	X-Ray Top Set PST 500	00887761973701
2073896	Side Rail OR Table Adaptor Amsco®	04250435501412
2077284	Pad Carbon 600 Narrow H	00887761969247
2077285	Pad Ophthalmology Adaptor H	00887761969230
2077580	Ophthalmology Adaptor H	00887761970090
2077588	Leg Section X-Ray spread joint H	00887761967403
2078586	Pad pelvic extension H G	00887761968844
2080441	Pad leg section four parts H G	00887761969148
2080447	Pad leg section two parts H G	00887761969155
2080466	Pad TTS Carbon one part G	00887761968899
4544166	Side rail	00887761971387
4544436	Crossbar attachment	00887761972773

See attachment A
- Impacted Serial
Numbers

4544448	Counter traction post for femur	00887761972049
4544534	Arthroscopy positioning device basic	00887761971738
4544706	Body strap rotatable	00887761971691
4544710	Anaesthesia screen extendable	00887761973077
4544719	Universal lateral support height adjusta	00887761971332
4544721	Lateral support 215	00887761971684
4544722	Lateral support 170	00887761971677
4544723	Lateral support 85	00887761971660
4544729	Connection holder with joint	00887761972759
4544736	Leg holder GOEPEL	00887761972643
4544773	Pelvis support	00887761971639
4544786	Central holder head rest system	00887761972728
4544787	Cross joint	00887761972711
4544791	Meniscus positioning device	00887761971622
4549730	Head rest basic	00887761973046
4549731	Head rest horseshoe-shaped one part	00887761973039
4549732	Head rest horseshoe-shaped two parts	00887761973022
4549755	Arm holder 450 for lateral position	00887761973374

Please complete this reply form even if there is no remaining inventory at your facility. Completion of the information below indicates that you (1) understand the contents of the attached letter, (2) performed the actions outlined, and (3) disseminated this information, if applicable.

Upon receipt of the IFUs, check this box to indicate that your company has disseminated the IFU within your facility as required. **(to be adapted locally)**

For Dealers, Wholesaler, Distributor/Reseller, or Original Equipment Manufacturer (OEM) Only - Upon receipt of the IFUs, check this box to indicate that your company has disseminated this communication to your direct customers and provided the required the IFU. **(to be adapted locally)**

Completed By: _____ **Title:** _____
Print Name

Email/Phone Number: _____

Signature: _____ **Date:** ____/____/____

Please complete and return one copy of this form per facility either by fax (Fax : _____) or by e-mail (_____) as confirmation that you have received this notification.
 A fax cover sheet is not required.
(To be adapted locally)