### **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:			

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	



2064483 Pad head section double joint M B 00887761967915 -			
1739992			
1739994   Adapter for head positioning   00887761972780     1753616   Pad tabletop TS 7000 B   00887761968834     1756164   Pad protection for bridge WILSON   00887761968827     1756392   Pad leg section one part H B   0088776196827     1756392   Pad TS Zarbon 600 H B   00887761969827     1770133   Pad TTS Carbon 600 H B   00887761969780     1783951   Pad spine bridge WILSON set   00887761969780     1789952   Head section basic V   00887761969780     1799098   Leg section two parts V   00887761970526     1790125   Spine bridge WILSON V   00887761970526     1790125   Spine bridge WILSON V   00887761970526     1790125   Spine bridge WILSON V   00887761970526     1790126   Spine bridge WILSON V   00887761973411     1798266   Cable remote control TS7000 (dV)   00887761973429     1814876   Pad Carbon FloatLine B   00887761973121     1816914   Cable connection TS7000 (dV)   NIA     18135762   Interface Skull Clamp radiolucent   04250435502136     1850995   Head section double joint H V   00887761970380     1850996   Leg section one part H V   00887761970380     1850996   Leg section four parts H D   00887761970328     1851986   Pad leg section four parts H B   0088776190311     1851986   Pad leg section NaPAR B   0088776190897031     1851986   Pad leg section Four parts H B   008877619089674     1851986   Pad leg section Four parts H B   008877619089670     1867128   Docking trolley MIS hip device   00887761909506     1867129   Docking trolley MIS hip device   00887761909506     1867129   Docking trolley extension unit   00887761909506     1867129   Docking trolley attension unit   00887761909506     1867129   Docking trolley extension unit   00887761909506     1869094   Pad Transfer Leg section   00887761909506     1869094   Pad Transfer Leg section   00887761909304     18909976   Ook of tabletop day of the visual pad hip B   0088776190642     1876708   Transfer Leg section   00887761906407     1880309   SchureLoc Adapter   00887761968407     18909976   Ook of table day of the visual pad of the visual pad of the			
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1770133 Pad TTS Carbon 600 H B 00887761969797 1783916 Pad spine bridge WILSON set 00887761990760 1789952 Head section basic V 00887761990067 1790125 Spine bridge WILSON V 00887761970326 1790125 Spine bridge WILSON V 00887761973411 1797654 Pad Carbon FloatLine B 00887761993704 1798326 Cable remote control TS7000 (dV) 00887761973411 1816914 Cable connection TS7000 (dV) 00887761973212 1816914 Cable connection TS7000 (dV) N/A 1835762 Interface Skull Clamp radiolucent 04250435502136 1850955 Head section double joint H V 00887761970380 1850955 Leg section one part H V 00887761970380 1850959 Leg section four parts H V 00887761970380 1850989 Tabletop segment Carbon 1200 H V 00887761970381 1851579 Pad leg section four parts H B 00887761970311 1851579 Pad leg section four parts H B 0088776196674 1851386 Pad leg section Float Parts H B 0088776196674 1851386 Pad leg section Float Parts H B 00887761969356 1867128 Docking trolley MIS hip device 00887761972186 1873466 Pad TTS Carbon one part B B 00887761969421 1873466 Pad TTS Carbon one part B B 00887761969421 1876708 Transfer leg section B 00887761969421 1876708 Transfer leg section B 0088776196941 1876708 Transfer leg section B 00887761972142 1880218 Supporting pad hip B 00887761972142 1880218 Supporting pad hip B 00887761972144 1890603 Supporting pad universal MARS B 00887761972144 1891600 SchureLoc Forearm Attachment 0081014603698 1905160 SchureLoc Forearm Attachment 0081014603698 1909976 OR tabletop U4 H V 00887761972159 1909976 OR tabletop U5 H B 00887761990377 19099775 SchureLoc Forearm Attachment 00810014603698 1909976 OR tabletop U4 H V 00887761972050 1909977 SchureLoc Forearm Attachment 00810014603698 1909978 SchureLoc Forearm Attachment 00810014603698 1909979 SchureLoc Forearm Attachment 00810014603698 1909979 SchureLoc Forearm Attachment 00810014603698 1909979 SchureLoc Forearm Attachment 00810073774005 1909979 SchureLoc Forearm Attachment 00810073774005 1909979 SchureLoc Mary SchureLoc Forearm Attachment 00810073774005 1909979 SchureLoc Mary SchureLoc Mary Schur			
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1790125   Spine bridge WILSON V			
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1798326			
1814876			
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R850994   Leg section four parts H V			
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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           1905161         OR tabletop U24 H V         00887761969334           1909814         Pad two-part tabletop H B         00887761969377           1909816         Pad one-part tabletop H B         00887761969377           1909817         Pelvic extension H V         00887761969377           1909817         Pelvic extension H V         00887761969660           2003863         Remote control Wireless TS 7500         008877619679724           20044469         Cable remote control TS3000         00887761967717           20644411         Remote control wireless TS3000         00887761967915           2064429         Shoulder Supports         008100573769715           2064430         Should	1867129		00887761972186
1880218         Supporting pad hip B         00887761972148           1880219         Pad Transfer Leg section B         00887761969407           1886332         Angle pad TS7000 B         00887761972124           1891860         Shoulder Chair Dolly TS7000         NIA           1897603         Supporting pad universal MARS B         00887761972117           1905159         SchureLoc Forearm Attachment         00810014603698           1905160         SchureLoc Forearm Attachment         00810014603391           1909796         OR tabletop U24 H V         00887761974005           1909814         Pad two-part tabletop H B         00887761969337           1909817         Pelvic extension H V         00887761969377           1909817         Pelvic extension H V         008877619670250           1935665         SchureLoc XPS         00810057372995           2003863         Remote control wireless TS 7500         008877619670250           209875         Shoulder Chair H         00880761967714           2064449         Cable remote control TS3000         00887761967717           2064483         Pad head section double joint M B         00887761967915           2065800         Shoulder Supports         00810057370007           2068499         Shoulder Su	1873466	Pad TTS Carbon one part B	00887761969421
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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           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           2064880         Shoulder Chair H with connection holder         00810014602660           2068499         Shoulder Supports         00810057371652           2068500         Shoulder Support short         00810057371652           2069528         Cladding Protection TS7000         N/A           2071906         Pad PST 300S B         00887761968035           2072419         Extension adapter PS	1880219		00887761969407
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   2064483   Pad head section double joint M B   00887761967915   2065800   Shoulder Chair H with connection holder   00810014602660   NA			
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   1935665   SchureLoc XPS   00810057372995   1935665   SchureLoc XPS   00810057372995   1935665   SchureLoc XPS   00810014602663   19064469   Cable remote control wireless TS 7500   0088776196660   19064469   Cable remote control TS3000   00887761967724   19064483   Pad head section double joint M B   00887761967915   19064483   Pad head section double joint M B   00887761967915   19068800   Shoulder Supports   00810057370007   19068500   Shoulder Supports   00810057371592   19069528   Cladding Protection TS7000   N/A   19071906   Pad PST 300S B   00887761968035   19072442   N-Ray Top Set PST 500   00887761968097   19072442   N-Ray Top Set PST 500   00887761968097   1907284   Pad Carbon 600 Narrow H   00887761968097   1907285   Pad Ophthalmology Adaptor H   00887761969247   1907588   Leg Section X-Ray spread joint H   00887761968844   190887761968844   190887761968844   190887761968844   190887761968844   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761968899   190887761971387   190887761971387   190887761968899   190887761971387   19088776197138			
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           20644471         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           2069528         Cladding Protection TS7000         N/A           2071906         Pad PST 300S B         00887761968035           2072245         Square Adaptor         00810057371653           2072442         X-Ray Top Set PST 500         00887761968037           2077284         Pad Carbon 6			
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         00887761967717           2064481         Remote control wireless TS3000         00887761967717           2064483         Pad head section double joint M B         00887761967915           2065800         Shoulder Chair H with connection holder         00810057370007           2068499         Shoulder Supports         00810057371592           2069528         Cladding Protection TS7000         N/A           2071906         Pad PST 300S B         00887761968035           2072285         Square Adaptor         0081057371653           2072442         X-Ray Top Set PST 500         00887761968097           2077284         Pad Carbon 600 Narrow H         00887761969247           2077285         Pad Ophthalmology A	<b></b>		
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           2069528         Cladding Protection TS7000         N/A           2071906         Pad PST 300S B         00887761968035           2072285         Square Adaptor         00810057371653           20724419         Extension adapter PST 300         00887761968097           2073896         Side Rail OR Table Adaptor Amsco®         04250435501412           2077284         Pad Carbon 600 Narrow H         00887761969230           2077580 <td< td=""><td></td><td></td><td></td></td<>			
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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 adapter PST 300         00887761968097           2072442         X-Ray Top Set PST 500         00887761968097           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         00887761967403           2077588         Leg Section X-Ray spread joint H         00887761968844           2080441         Pad leg section four parts H G         00887761969148			
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 adapter 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         00887761967403           2078586         Pad pelvic extension H G         00887761968844           2080441         Pad leg section four parts H G         00887761969148           2080466         Pad TTS Carbon one part G         00887761971387			
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 adapter 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         00887761967403           2077588         Leg Section X-Ray spread joint H         00887761967403           2078586         Pad pelvic extension H G         00887761968844           2080447         Pad leg section two parts H G         00887761969155           2080466         Pad TTS Carbon one part G         00887761968899           4544166 </td <td></td> <td></td> <td></td>			
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 adapter 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         0088776197090           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           2080446         Pad TTS Carbon one part G         00887761968899           4544166         Side rail         00887761971387			
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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	2077284	Pad Carbon 600 Narrow H	00887761969247
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	2077285		00887761969230
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			00887761970090
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2080447         Pad leg section two parts H G         00887761969155           2080466         Pad TTS Carbon one part G         00887761968899           4544166         Side rail         00887761971387			
2080466         Pad TTS Carbon one part G         00887761968899           4544166         Side rail         00887761971387			
4544166 Side rail 00887761971387		·	
4544436   Crossbar attachment   00887761972773			
	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

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