

FIELD SAFETY CORRECTIVE ACTION - RECALL

REC 2021-02

IMMEDIATE ACTION REQUIRED

To: Customers, Distributors and Sales Department

Affected Product: Streamline MIS fenestrated Polyaxial Pedicle screw
Streamline TL fenestrated Polyaxial Pedicle screw
Streamline TL reduction fenestrated Polyaxial Pedicle screw

Manufacturer, **Manufacturer**
Paradigm Spine GmbH

Date of Recall 06.08.2021

Type of Recall Field Safety Corrective Action (FSCA)

Artikelnummer	Losnummer	UDI
PAC46555	1320000089	(01)04260636671104(17)250531(10)1320000089
PAC46550	1320000088	(01)04260636671098(17)250531(10)1320000088
PAC46545	1320000092	(01)04260636671081(17)250531(10)1320000092
PAC46540	1320000084	(01)04260636671074(17)250531(10)1320000084
PAC45540	1320000081	(01)04260636671005(17)250531(10)1320000081
PAC45535	1320000079	(01)04260636670992(17)250531(10)1320000079
PAC86550	1320000071	(01)04260636671814(17)250331(10)1320000071
PAC86545	1320000070	(01)04260636671807(17)250331(10)1320000070
PAC86540	1320000085	(01)04260636671791(17)250531(10)1320000085
PAC86550	1320000086	(01)04260636671814(17)250331(10)1320000086
PAC85535	1320000087	(01)04260636671715(17)250531(10)1320000087
PAC85540	1320000063	(01)04260636671722(17)250331(10)1320000063
PAC85535	1320000062	(01)04260636671715(17)250331(10)1320000062
PAC86555	1320000072	(01)04260636671821(17)250331(10)1320000072
PAC86540	1320000069	(01)04260636671791(17)250331(10)1320000069
PAC85545	1320000091	(01)04260636671739(17)250531(10)1320000091
PAC85545	1320000064	(01)04260636671739(17)250331(10)1320000064
PAC85540	1320000090	(01)04260636671722(17)250331(10)1320000090
PAC46545	1320000144	(01)04260636671081(17)250630(10)1320000144
PAC46555	1320000143	(01)04260636671104(17)250630(10)1320000143
PAC66540	1320000142	(01)04260636671432(17)250630(10)1320000142
PAC66545	1320000140	(01)04260636671449(17)250630(10)1320000140
PAC66555	1320000141	(01)04260636671463(17)250630(10)1320000141
PAC65540	1320000131	(01)04260636671364(17)250630(10)1320000131
PAC65545	1320000125	(01)04260636671371(17)250630(10)1320000125
PAC85535	1320000127	(01)04260636671715(17)250630(10)1320000127
PAC85540	1320000130	(01)04260636671722(17)250630(10)1320000130
PAC85545	1320000124	(01)04260636671739(17)250630(10)1320000124
PAC45535	1320000129	(01)04260636670992(17)250630(10)1320000129
PAC45540	1320000132	(01)04260636671005(17)250630(10)1320000132
PAC45545	1320000138	(01)04260636671012(17)250630(10)1320000138
PAC45545	1320000137	(01)04260636671012(17)250630(10)1320000137

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Artikelnummer	Losnummer	UDI
PAC45545	1320000126	(01)04260636671012(17)250630(10)1320000126
PAC46545	1320000139	(01)04260636671081(17)250630(10)1320000139
PAC65535	1320000128	(01)04260636671357(17)250630(10)1320000128
PAC86540	1320000136	(01)04260636671791(17)250630(10)1320000136
PAC86545	1320000135	(01)04260636671807(17)250630(10)1320000135
PAC86555	1320000134	(01)04260636671821(17)250630(10)1320000134
PAC86555	1320000133	(01)04260636671821(17)250630(10)1320000133
PAC46540	1320000163	(01)04260636671074(17)250731(10)1320000163
PAC46545	1320000164	(01)04260636671081(17)250630(10)1320000164
PAC46545	1320000165	(01)04260636671081(17)250731(10)1320000165
PAC46550	1320000150	(01)04260636671098(17)250731(10)1320000150
PAC47540	1320000159	(01)04260636671142(17)250731(10)1320000159
PAC47545	1320000160	(01)04260636671159(17)250731(10)1320000160
PAC47550	1320000161	(01)04260636671166(17)250731(10)1320000161
PAC47555	1320000162	(01)04260636671173(17)250731(10)1320000162
PAC66550	1320000148	(01)04260636671456(17)250731(10)1320000148
PAC67540	1320000152	(01)04260636671500(17)250731(10)1320000152
PAC67545	1320000153	(01)04260636671517(17)250731(10)1320000153
PAC67550	1320000151	(01)04260636671524(17)250731(10)1320000151
PAC67555	1320000154	(01)04260636671531(17)250731(10)1320000154
PAC86550	1320000149	(01)04260636671814(17)250731(10)1320000149
PAC87555	1320000157	(01)04260636671890(17)250731(10)1320000157
PAC87540	1320000158	(01)04260636671869(17)250731(10)1320000158
PAC87545	1320000155	(01)04260636671876(17)250731(10)1320000155
PAC87550	1320000156	(01)04260636671883(17)250731(10)1320000156

Reason for FSCA: Damage to a screw component has been detected, which can be attributed to an assembly failure. As a result, the screw head may clamp, which in turn may make it difficult to align the screw head during surgery.

Clinical effect: There may be a short-term delay in OR time (<30 minutes) due to increased difficulty in aligning the screw head.

Action required: We would like you to identify all affected products in your warehouse as well as in your field inventory in the hospitals and return them immediately for inspection and quarantine. These items must not be sold or used. Please fill in the attached form to confirm that you have checked your inventory and that the affected parts will be returned or have been already used.

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Further
information:

For further questions related to this Field Safety Corrective Action (FSCA) do not hesitate to contact our customer sales department or Quality Assurance at:

Paradigm Spine GmbH
Eisenbahnstraße 84
78573 Wurmlingen / Germany
psg-service@surgalign.com
psg-quality@surgalign.com
Tel.: +49(0)7461 963599-0

We deeply regret the inconvenience, and will take all possible corrective and preventive action to avoid this in the future. We appreciate your quick response, your cooperation and your understanding.

CONFIRMATION OF RECEIPT

Please sign and return to Paradigm Spine GmbH

I hereby confirm that I have received this Notice.	
Date:	
Signature:	

