

Appendix A
DePuy Spine, Inc. Technical File 1 Rev. BP

Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
50001.2	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	14-Jul-98
50001.3	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	14-Jul-98
50001.5	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	14-Jul-98
50006.25	ISOLA Spine System	Iliac Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
50007	ISOLA Spine System	Iliac Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
52006.25	ISOLA Spine System	Iliac Screw	Non-Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	23-Jul-96
52007	ISOLA Spine System	Iliac Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	23-Jul-96
202501.2	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
202501.3	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
202501.5	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
202502.2	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
202502.5	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
202503.5	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
202504.5	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
202505.5	VSP Spine System	Bone Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
202506.5	VSP Spine System	Bone Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
202507	VSP Spine System	Bone Plate, Seven Slot	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
202507.5	VSP Spine System	Bone Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
202508	VSP Spine System	Bone Plate, Eight Slot	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
202508.5	VSP Spine System	Bone Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
202509	VSP Spine System	Bone Plate, Nine Slot	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
202509.5	VSP Spine System	Bone Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
203000	ISOLA Spine System	Transverse Rod Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
203001	ISOLA Spine System	Transverse Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
203002	ISOLA Spine System	Transverse Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
203041	ISOLA Spine System	Closed Dual Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Aug-99
203043	ISOLA Spine System	Closed Dual Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Aug-99
203081	ISOLA Spine System	Right Hand Clamp Jaw	Non-Sterile	34949	Bone clamp	1	IIb	12-Aug-98
203082	ISOLA Spine System	Left Hand Clamp Jaw	Non-Sterile	34949	Bone clamp	1	IIb	12-Aug-98
203083	ISOLA Spine System	Unthreaded Clamp Jaw	Non-Sterile	34949	Bone clamp	1	IIb	12-Aug-98
223001	ISOLA Spine System	Transverse Rod Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
223002	ISOLA Spine System	Transverse Rod Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
223009	ISOLA Spine System	Right Thread Clamp Jaw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Sep-98
223010	ISOLA Spine System	Left Thread Clamp Jaw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Sep-98
223042	ISOLA Spine System	Closed Dual Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Aug-99
223044	ISOLA Spine System	Closed Dual Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	26-Nov-01
301013	Kaneda Anterior Scoliosis System	Transverse Rod Coupler	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Aug-99
301014	Kaneda Anterior Scoliosis System	Transverse Rod Coupler	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Aug-99
301015	Kaneda Anterior Scoliosis System	Transverse Rod Coupler	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Aug-99
301016	Kaneda Anterior Scoliosis System	Transverse Rod Coupler	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Aug-99
322615	TiMX Low Back System	Ti Tapered Washer	Non-Sterile	36198	Orthopaedic bone washer	1	IIb	15-Jun-98
500001.2	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
500001.3	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
500001.5	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
500002.5	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	14-Jul-98
500021	ISOLA Spine System	Spinal Wire with Button	Non-Sterile	35685	Orthopaedic bone wire	1	IIb	1-Jul-95
500022	ISOLA Spine System	Double Wire	Non-Sterile	35685	Orthopaedic bone wire	1	IIb	1-Jul-95
500023	ISOLA Spine System	Beaded Wire	Non-Sterile	35685	Orthopaedic bone wire	1	IIb	1-Jul-95
500096	ISOLA Spine System	Throat Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
520080	ISOLA Spine System	Closed Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	14-Jul-98
520090	ISOLA Spine System	Closed Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	14-Jul-98
520093	ISOLA Spine System	Closed Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	1-Jul-95
530057	TiMX Low Back System	Slotted Connector Assembly	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Jun-98
3210410	University Plate Anterior System	Implant Set	Non-Sterile	12143	Instrument Tray	1	IIb	15-Aug-00
5000101	ISOLA Spine System	Trauma Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000116	ISOLA Spine System	Throat Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000121	ISOLA Spine System	Trauma Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000131	ISOLA Spine System	Trauma Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000208	ISOLA Spine System	Open Hook Cap	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	28-Sep-99
5003130	ISOLA Spine System	Closed Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	29-Jan-98
5200100	ISOLA Spine System	Closed Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	14-Jul-98

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Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
174537185	Moss Miami Spine System	5mm Polyaxial Screw 5X85mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Apr-99
174537190	Moss Miami Spine System	5mm Polyaxial Screw 5X90mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Apr-99
174537525	Moss Miami Spine System	Polyaxial Screw 5X25 Tapered	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174537530	Moss Miami Spine System	Polyaxial Screw 5X30 Tapered	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174537535	Moss Miami Spine System	Polyaxial Screw 5X35 Tapered	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174537540	Moss Miami Spine System	Polyaxial Screw 5X40 Tapered	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174537545	Moss Miami Spine System	Polyaxial Screw 5X45 Tapered	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174537550	Moss Miami Spine System	Polyaxial Screw 5X50 Tapered	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174537555	Moss Miami Spine System	Polyaxial Screw 5X55 Tapered	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174537560	Moss Miami Spine System	Polyaxial Screw 5X60 Tapered	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174538000	Moss Miami Spine System	Sacral Screw Polyaxial 5X30	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174539000	Moss Miami Spine System	Sacral Screw Polyaxial 5X35	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174540000	Moss Miami Spine System	Sacral Screw Polyaxial 5X40	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174541000	Moss Miami Spine System	Sacral Screw Polyaxial 5X45	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174542000	Moss Miami Spine System	Sacral Screw Polyaxial 5X50	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174543000	Moss Miami Spine System	Sacral Screw Polyaxial 5X55	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174545505	Moss Miami Spine System	Sacral Extender 5mmX5cm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174545510	Moss Miami Spine System	Sacral Extender 5mmX10cm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174545515	Moss Miami Spine System	Sacral Extender 5mmX15cm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174545520	Moss Miami Spine System	Sacral Extender 5mmX20cm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174550050	Moss Miami Spine System	TRANSLATION Hook Pedicle	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	13-Feb-98
174551051	Moss Miami Spine System	TRANSLATION Hook Reduced Distance	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	13-Feb-98
174551501	Moss Miami Spine System	Laminar Reduced Distance Flare Shoe Hoo	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	13-Feb-98
174554054	Moss Miami Spine System	TRANSLATION Hook Wide	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	13-Feb-98
174554501	Moss Miami Spine System	Laminar Hook 3 Offset Wide Blade	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	13-Feb-98
174554512	Moss Miami Spine System	Wide Blade Hook +12mm	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	13-Feb-98
174557501	Moss Miami Spine System	Extended Body Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	13-Feb-98
174558000	Moss Miami Spine System	Offset Body Hook Right	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	13-Feb-98
174560000	Moss Miami Spine System	5mm Rod	Non-Sterile	33542	Bone hook	1	IIb	13-Feb-98
174560100	Moss Miami Spine System	7mm RodX48cm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174560110	Moss Miami Spine System	1/4in. RodX48cm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174560420	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 20	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560455	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 55	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560460	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 60	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560465	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 65	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560470	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 70	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560475	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 75	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560480	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 80	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560485	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 85	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560490	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 90	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560495	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 95	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560499	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 4.35 X 10	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560500	Moss Miami Spine System	5.0X30cm Hex Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174560501	Moss Miami Spine System	5.0X48cm Hex Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Feb-98
174560520	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 20r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560555	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 55r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560560	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 60r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560565	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 65r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560570	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 70r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560575	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 75r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560580	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 80r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560585	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 85r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560590	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 90r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560595	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 95r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560599	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 5.0 X 100	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560620	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 6.0 X 20r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560625	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 6.0 X 25r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560660	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 6.0 X 60r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560665	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 6.0 X 65r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560670	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 6.0 X 70r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03
174560675	Moss Miami Spine System	Polyaxial Reduction Screw 5.0 X 6.0 X 75r	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	29-Apr-03

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Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
186862014	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x14mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862015	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x15mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862016	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x16mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862017	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x17mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862018	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x18mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862019	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x19mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862020	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x20mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862021	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x21mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862022	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x22mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862023	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x23mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862024	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x24mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862025	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x25mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186862026	SKYLINE Anterior Cervical Plate System	Constrained, Self-Tapping Screw 4.0x26mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186864012	SKYLINE Anterior Cervical Plate System	Constrained, Oversized Screw 4.5x12mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186864014	SKYLINE Anterior Cervical Plate System	Constrained, Oversized Screw 4.5x14mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186864016	SKYLINE Anterior Cervical Plate System	Constrained, Oversized Screw 4.5x16mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
186864018	SKYLINE Anterior Cervical Plate System	Constrained, Oversized Screw 4.5x18mm	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	19-Apr-06
187150015	Aegis Anterior Lumbar Plate	Anterior Lumbar Plate, 15mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-06
187150017	Aegis Anterior Lumbar Plate	Anterior Lumbar Plate, 17mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-06
187150019	Aegis Anterior Lumbar Plate	Anterior Lumbar Plate, 19mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-06
187150021	Aegis Anterior Lumbar Plate	Anterior Lumbar Plate, 21mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-06
187150023	Aegis Anterior Lumbar Plate	Anterior Lumbar Plate, 23mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-06
187150025	Aegis Anterior Lumbar Plate	Anterior Lumbar Plate, 25mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-06
187155021	Aegis Anterior Lumbar Plate	5.2mm Self-Tapping, Variable Bone Screw.	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	14-Mar-07
187155024	Aegis Anterior Lumbar Plate	5.2mm Self-Tapping, Variable Bone Screw.	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-06
187155026	Aegis Anterior Lumbar Plate	5.2mm Self Tapping Screw, 26mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-May-08
187155028	Aegis Anterior Lumbar Plate	5.2mm Self-Tapping, Variable Bone Screw.	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-06
187155032	Aegis Anterior Lumbar Plate	5.2mm Self-Tapping, Variable Bone Screw.	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-06
187155036	Aegis Anterior Lumbar Plate	5.2mm Self-Tapping, Variable Bone Screw.	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-06
187160021	Aegis Anterior Lumbar Plate	Bone Screw, 21mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Feb-10
187160024	Aegis Anterior Lumbar Plate	Bone Screw, 24mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Feb-10
187160026	Aegis Anterior Lumbar Plate	Bone Screw, 26mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Feb-10
187160028	Aegis Anterior Lumbar Plate	Bone Screw, 28mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Feb-10
187160032	Aegis Anterior Lumbar Plate	Bone Screw, 32mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Feb-10
187160036	Aegis Anterior Lumbar Plate	Bone Screw, 36mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Feb-10
187701001	Expedium Anterior Spine System	Dual Hole Staple, Rostral, Small	Non-Sterile	16103	Bone staple	1	IIb	28-Sep-04
187701002	Expedium Anterior Spine System	Dual Hole Staple, Caudal, Small	Non-Sterile	16103	Bone staple	1	IIb	2

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Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
188328312	Mountaineer OCT Spinal System	Minipolyaxial Screw- Favored Angle (C/C)	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188328314	Mountaineer OCT Spinal System	Minipolyaxial Screw- Favored Angle (C/C)	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188328316	Mountaineer OCT Spinal System	Minipolyaxial Screw- Favored Angle (C/C)	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188328318	Mountaineer OCT Spinal System	Minipolyaxial Screw- Favored Angle (C/C)	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188328320	Mountaineer OCT Spinal System	Minipolyaxial Screw- Favored Angle (C/C)	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188341021	Mountaineer OCT Spinal System	Head-to-Head Crossconnector 21mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188341028	Mountaineer OCT Spinal System	Head-to-Head Crossconnector 28mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188341035	Mountaineer OCT Spinal System	Head-to-Head Crossconnector 35mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188341042	Mountaineer OCT Spinal System	Head-to-Head Crossconnector 42mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188341049	Mountaineer OCT Spinal System	Head-to-Head Crossconnector 49mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188341056	Mountaineer OCT Spinal System	Head-to-Head Crossconnector 56mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188341100	Mountaineer OCT Spinal System	Head-to-Head Crossconnector Outer Nut	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188341200	Mountaineer OCT Spinal System	Head-to-Head Crossconnector Inner Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188341300	Mountaineer OCT Spinal System	Cross Connector Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188342200	Mountaineer OCT Spinal System	Inner Set Screw (formerly Summit)	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188343000	Mountaineer OCT Spinal System	3.5mm Small Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188343001	Mountaineer OCT Spinal System	3.5mm Small Hook, M/L	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188343002	Mountaineer OCT Spinal System	3.5mm Large Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188343003	Mountaineer OCT Spinal System	3.5mm Large Hook, M/L	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362006	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 6mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362007	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 7mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362008	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 8mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362009	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 9mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362010	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 10mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362011	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 11mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362012	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 12mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362013	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 13mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362014	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 14mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362015	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 15mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362016	Mountaineer OCT Spinal System	Bone Screw 4.5mm X 16mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362025	Mountaineer OCT Spinal System	Inner Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362027	Mountaineer OCT Spinal System	27mm Occipital Plate	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362031	Mountaineer OCT Spinal System	Occipital Plate 31mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362037	Mountaineer OCT Spinal System	Occipital Plate 37mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362045	Mountaineer OCT Spinal System	Occipital Plate 45mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362106	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 6mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362107	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 7mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362108	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 8mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362109	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 9mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362110	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 10mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362111	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 11mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362112	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 12mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362113	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 13mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362114	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 14mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362115	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 15mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188362116	Mountaineer OCT Spinal System	Bone Screw 5.25mm X 16mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188363100	Mountaineer OCT Spinal System	Pre-bent Spinal Rod 3.5mm X 200-85mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188363200	Mountaineer OCT Spinal System	Pre-bent Spinal Rod 3.5mm X 120-85mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188364003	Mountaineer OCT Spinal System	OC Adjustable Rod Set Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188364100	Mountaineer OCT Spinal System	Articulating Spinal Rod 3.5mm X 220-72m	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188364150	Mountaineer OCT Spinal System	OC Adjustable Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188364200	Mountaineer OCT Spinal System	Articulating Spinal Rod 3.5mm X 120-72m	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188364250	Mountaineer OCT Spinal System	OC Adjustable Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
188365000	Mountaineer OCT Spinal System	Lateral Fixation Washer	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	7-Dec-11
189401101	Expedium SFX Cross Connector System	SFX Connector, Ti, Lateral, 5.5 Rod, F1 (16	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	31-Oct-06
189401102	Expedium SFX Cross Connector System	SFX Connector, Ti, Lateral, 5.5 Rod, F2 (18	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	31-Oct-06
189401103	Expedium SFX Cross Connector System	SFX Connector, Ti, Lateral, 5.5 Rod, F3 (20	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	31-Oct-06
189401104	Expedium SFX Cross Connector System	SFX Connector, Ti, Lateral, 5.5 Rod, F4 (22	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	31-Oct-06
189401105	Expedium SFX Cross Connector System	SFX Connector, Ti, Lateral, 5.5 Rod, F5 (24	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	31-Oct-06
189401106	Expedium SFX Cross Connector System	SFX Connector, Ti, Lateral, 5.5 Rod, F6 (26	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	31-Oct-06
189401107	Expedium SFX Cross Connector System	SFX Connector, Ti, Lateral, 5.5 Rod, F7 (30	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	31-Oct-06

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Appendix A
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Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
698221205	VSP Spine System	Washer	Non-Sterile	36198	Orthopaedic bone washer	1	IIb	15-Nov-00
698222502	VSP Spine System	Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	30-Apr-02
698222503	VSP Spine System	Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	30-Apr-02
698222504	VSP Spine System	Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	30-Apr-02
698222825	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698222830	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698222835	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698222840	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698222845	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698222850	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698222855	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698222860	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698223042	ISOLA Spine System	Dual Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Jan-01
698223044	ISOLA Spine System	Dual Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Jan-01
698223050	ISOLA Spine System	Closed Dual Rod Connector 10mm Spacing	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	17-Jul-03
698223225	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698223230	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698223235	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698223240	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698223245	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698223250	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698223255	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698223260	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	15-Nov-00
698232330	TiMX Low Back System	Pedicle Screw No Cut +5	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	10-May-00
698263225	TiMX Low Back System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	10-May-00
698263230	TiMX Low Back System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	10-May-00
698263260	TiMX Low Back System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	10-May-00
698322599	TiMX Low Back System	Half Slot Plate, Narrow	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	13-Nov-00
698500023	ISOLA Spine System (Custom made device)	Spinal Wire w/Button		35685	Orthopaedic bone wire	1	IIb	22-Mar-01
698500024	Moss Miami Spine System	U-Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	18-Apr-01
698500098	ISOLA Spine System	Illiace Connector, Right	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Nov-00
698500099	ISOLA Spine System	Illiace Connector, Left	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	13-Nov-00
698501030	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698501035	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698501040	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698501045	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698501050	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698501055	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698501060	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698501065	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698501070	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698501075	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698501080	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698502016	ISOLA Spine System	Single Hole Staple	Non-Sterile	16103	Bone staple	1	IIb	27-Mar-00
698502018	ISOLA Spine System	Single Hole Staple	Non-Sterile	16103	Bone staple	1	IIb	27-Mar-00
698502020	ISOLA Spine System	Single Hole Staple	Non-Sterile	16103	Bone staple	1	IIb	27-Mar-00
698502022	ISOLA Spine System	Single Hole Staple	Non-Sterile	16103	Bone staple	1	IIb	27-Mar-00
698503225	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503230	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503235	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503240	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503245	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503250	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503255	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503260	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503265	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503270	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503275	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698503280	ISOLA Spine System	Closed Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Apr-00
698520002	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	17-Oct-02
698520003	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	17-Oct-02

Appendix A
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Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
698520004	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	17-Oct-02
698522016	ISOLA Spine System	Single Hole Staple	Non-Sterile	16103	Bone staple	1	IIb	27-Mar-00
698522018	ISOLA Spine System	Single Hole Staple	Non-Sterile	16103	Bone staple	1	IIb	27-Mar-00
698522020	ISOLA Spine System	Single Hole Staple	Non-Sterile	16103	Bone staple	1	IIb	27-Mar-00
698522022	ISOLA Spine System	Single Hole Staple	Non-Sterile	16103	Bone staple	1	IIb	27-Mar-00
177005SS	Monarch Spine System	MCC Set Screw		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	17-Mar-03
177492020S	Monarch Spine System	Side By Side Dual Connector, 5.5X5.50, TI	Sterile			1	IIb	7-Dec-11
177492060S	Monarch Spine System	End to End Dual Connector, 5.5 X 5.50, TI	Sterile			1	IIb	7-Dec-11
179702000S	Expedium Spine System	EXP SINGLE-INNIE SETSCREW	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702420S	Expedium Spine System	MONOAXIAL SCREW 4.35 X 20MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702425S	Expedium Spine System	MONOAXIAL SCREW 4.35 X 25 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702430S	Expedium Spine System	MONOAXIAL SCREW 4.35 X 30 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702435S	Expedium Spine System	MONOAXIAL SCREW 4.35 X 35 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702440S	Expedium Spine System	MONOAXIAL SCREW 4.35 X 40 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702445S	Expedium Spine System	MONOAXIAL SCREW 4.35 X 45 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702450S	Expedium Spine System	MONOAXIAL SCREW 4.35 X 50 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702525S	Expedium Spine System	MONOAXIAL SCREW 5 X 25 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702530S	Expedium Spine System	MONOAXIAL SCREW 5 X 30 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702535S	Expedium Spine System	MONOAXIAL SCREW 5 X 35 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702540S	Expedium Spine System	MONOAXIAL SCREW 5 X 40 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702545S	Expedium Spine System	MONOAXIAL SCREW 5 X 45 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702550S	Expedium Spine System	MONOAXIAL SCREW 5 X 50 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702630S	Expedium Spine System	MONOAXIAL SCREW 6 X 30 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702635S	Expedium Spine System	MONOAXIAL SCREW 6 X 35 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702640S	Expedium Spine System	MONOAXIAL SCREW 6 X 40 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702645S	Expedium Spine System	MONOAXIAL SCREW 6 X 45 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702650S	Expedium Spine System	MONOAXIAL SCREW 6 X 50 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702655S	Expedium Spine System	MONOAXIAL SCREW 6 X 55 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702730S	Expedium Spine System	MONOAXIAL SCREW 7 X 30 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702735S	Expedium Spine System	MONOAXIAL SCREW 7 X 35 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702740S	Expedium Spine System	MONOAXIAL SCREW 7 X 40 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702745S	Expedium Spine System	MONOAXIAL SCREW 7 X 45 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702750S	Expedium Spine System	MONOAXIAL SCREW 7 X 50 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702755S	Expedium Spine System	MONOAXIAL SCREW 7 X 55 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702765S	Expedium Spine System	MONOAXIAL SCREW 7 X 65 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702780S	Expedium Spine System	MONOAXIAL SCREW 7 X 80 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702835S	Expedium Spine System	MONOAXIAL SCREW 8 X 35 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702840S	Expedium Spine System	MONOAXIAL SCREW 8 X 40 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702845S	Expedium Spine System	MONOAXIAL SCREW 8 X 45 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702850S	Expedium Spine System	MONOAXIAL SCREW 8 X 50 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702855S	Expedium Spine System	MONOAXIAL SCREW 8 X 55 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702865S	Expedium Spine System	MONOAXIAL SCREW 8 X 65 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179702880S	Expedium Spine System	MONOAXIAL SCREW 8 X 80 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179710100S	Moss Miami Spine System	WASHER	Sterile	36198	Orthopaedic bone washer	1	IIb	7-Dec-11
179710200S	Moss Miami Spine System	SPLIT WASHER	Sterile	36198	Orthopaedic bone washer	1	IIb	7-Dec-11
179712420S	Expedium Spine System	POLYAXIAL SCREW 4.35X20MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712425S	Expedium Spine System	POLYAXIAL SCREW 4.35X25MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712430S	Expedium Spine System	POLYAXIAL SCREW 4.35X30MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712435S	Expedium Spine System	POLYAXIAL SCREW 4.35X35MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712440S	Expedium Spine System	POLYAXIAL SCREW 4.35X40MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712445S	Expedium Spine System	POLYAXIAL SCREW 4.35X45MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712450S	Expedium Spine System	POLYAXIAL SCREW 4.35X50MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712525S	Expedium Spine System	POLYAXIAL SCREW 5 X 25 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712530S	Expedium Spine System	POLYAXIAL SCREW 5 X 30 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712535S	Expedium Spine System	POLYAXIAL SCREW 5 X 35 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712540S	Expedium Spine System	POLYAXIAL SCREW 5 X 40 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712545S	Expedium Spine System	POLYAXIAL SCREW 5 X 45 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712550S	Expedium Spine System	POLYAXIAL SCREW 5 X 50 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712630S	Expedium Spine System	POLYAXIAL SCREW 6 X 30 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712635S	Expedium Spine System	POLYAXIAL SCREW 6 X 35 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
179712640S	Expedium Spine System	POLYAXIAL SCREW 6 X 40 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11

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Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
186152540L	Expedium Spine System	Expedium 4.5 Ti Open Hook, Angled Left,	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186152540R	Expedium Spine System	Expedium 4.5 Ti Open Hook, Angled Right	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186152550L	Expedium Spine System	Expedium 4.5 Ti Open Hook, Angled Left,	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186152550R	Expedium Spine System	Expedium 4.5 Ti Open Hook, Angled Right	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186152640L	Expedium Spine System	Expedium 4.5 Ti Open Hook, Offset Left, 4	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186152640R	Expedium Spine System	Expedium 4.5 Ti Open Hook, Offset Right,	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186152650L	Expedium Spine System	Expedium 4.5 Ti Open Hook, Offset Left, 5	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186152650R	Expedium Spine System	Expedium 4.5 Ti Open Hook, Offset Right,	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186154540L	Expedium Spine System	Expedium 4.5 Ti Closed Hook, Angled Left	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186154540R	Expedium Spine System	Expedium 4.5 Ti Closed Hook, Angled Right	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186154550L	Expedium Spine System	Expedium 4.5 Ti Closed Hook, Angled Left	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186154550R	Expedium Spine System	Expedium 4.5 Ti Closed Hook, Angled Right	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186154640L	Expedium Spine System	Expedium 4.5 Ti Closed Hook, Offset Left,	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186154640R	Expedium Spine System	Expedium 4.5 Ti Closed Hook, Offset Right	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186154650L	Expedium Spine System	Expedium 4.5 Ti Closed Hook, Offset Left,	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
186154650R	Expedium Spine System	Expedium 4.5 Ti Closed Hook, Offset Right	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	9-Apr-08
187701001S	Expedium Spine System	DUAL HOLE STAPLE, ROSTRAL, S	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187701002S	Expedium Spine System	DUAL HOLE STAPLE, CAUDAL, S	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187701003S	Expedium Spine System	DUAL HOLE STAPLE, ROSTRAL, M	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187701004S	Expedium Spine System	DUAL HOLE STAPLE, CAUDAL, M	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187701005S	Expedium Spine System	DUAL HOLE STAPLE, ROSTRAL, L	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187701006S	Expedium Spine System	DUAL HOLE STAPLE, CAUDAL, L	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187701009S	Expedium Spine System	WASHER	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187701015S	Expedium Spine System	SI SET SCREW	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
187702630S	Expedium Spine System	MONOAXIAL SCREW 6x30 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
187702635S	Expedium Spine System	MONOAXIAL SCREW 6x35 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
187702640S	Expedium Spine System	MONOAXIAL SCREW 6x40 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
187702645S	Expedium Spine System	MONOAXIAL SCREW 6x45 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
187702650S	Expedium Spine System	MONOAXIAL SCREW 6x50 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
187702655S	Expedium Spine System	MONOAXIAL SCREW 6x55 MM	Sterile	46651	Spinal bone screw, non-bioabsorbable	1	IIb	7-Dec-11
187703045S	Expedium Spine System	PRE-CUT 5.50x45 MM ROD	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187703055S	Expedium Spine System	PRE-CUT 5.50x55 MM ROD	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187703065S	Expedium Spine System	PRE-CUT 5.50x65 MM ROD	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187703070S	Expedium Spine System	PRE-CUT 5.50x70 MM ROD	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187703075S	Expedium Spine System	PRE-CUT 5.50x75 MM ROD	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187703080S	Expedium Spine System	PRE-CUT 5.50x80 MM ROD	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187703085S	Expedium Spine System	PRE-CUT 5.50x85 MM ROD	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187703090S	Expedium Spine System	PRE-CUT 5.50x90 MM ROD	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187703095S	Expedium Spine System	PRE-CUT 5.50x95 MM ROD	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187703450S	Expedium Spine System	5.50x450 MM ROD	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187704013S	Expedium Spine System	CROSS CONNECTOR 13 MM	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187704014S	Expedium Spine System	CROSS CONNECTOR 14 MM	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187704015S	Expedium Spine System	CROSS CONNECTOR 15 MM	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
187704016S	Expedium Spine System	CROSS CONNECTOR 16 MM	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401101S	Expedium Spine System	CONNECTOR 5.5 TI SIZE F1	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401102S	Expedium Spine System	CONNECTOR 5.5 TI SIZE F2	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401103S	Expedium Spine System	CONNECTOR 5.5 TI SIZE F3	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401104S	Expedium Spine System	CONNECTOR 5.5 TI SIZE F4	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401105S	Expedium Spine System	CONNECTOR 5.5 TI SIZE F5	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401206S	Expedium Spine System	CONNECTOR 5.5 TI SIZE F6	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401207S	Expedium Spine System	CONNECTOR 5.5 TI SIZE F7	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401208S	Expedium Spine System	CONNECTOR 5.5 TI SIZE F8	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401209S	Expedium Spine System	CONNECTOR 5.5 TI SIZE F9	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401301S	Expedium Spine System	CONNECTOR 5.5 TI SIZE A1	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401302S	Expedium Spine System	CONNECTOR 5.5 TI SIZE A2	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401303S	Expedium Spine System	CONNECTOR 5.5 TI SIZE A3	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401404S	Expedium Spine System	CONNECTOR 5.5 TI SIZE A4	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401405S	Expedium Spine System	CONNECTOR 5.5 TI SIZE A5	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401406S	Expedium Spine System	CONNECTOR 5.5 TI SIZE A6	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
189401407S	Expedium Spine System	CONNECTOR 5.5 TI SIZE A7	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
196789120S	Viper System	ROD, STRAIGHT 5.5 x 120mm CoCrMo	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11

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Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
196789300S	Viper System	ROD, STRAIGHT 5.5 x 300mm CoCrMo	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
196789480S	Viper System	VIPER2 STRAIGHT ROD480MM, COCR	Sterile	61324	Bone-screw internal spinal fixation system, sterile	1	IIb	7-Dec-11
20251.2A	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
20251.3A	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
20251.5A	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
20252.2A	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
20252.5A	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
2025262A	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	25-Sep-98
20253.5A	VSP Spine System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
20254.5A	VSP Spine System	Bone Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	22-May-98
20254A	VSP Spine System	Bone Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20255.5A	VSP Spine System	Bone Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20255A	VSP Spine System	Bone Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20256.5A	VSP Spine System	Bone Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20256A	VSP Spine System	Bone Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20257.5A	VSP Spine System	Bone Plate		46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20257A	VSP Spine System	Bone Plate		46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20258.5A	VSP Spine System	Bone Plate		46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20258A	VSP Spine System	Bone Plate		46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20259.5A	VSP Spine System	Bone Plate		46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20259A	VSP Spine System	Bone Plate		46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
20262425H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20262430H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20262435H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20262440H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20262445H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20262825H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20262830H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20262835H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20262840H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20262845H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20262850H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20263225H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20263230H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20263235H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20263240H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20263245H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
20263250H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-May-98
22251.2A	VSP Spine System	A-Slot Plate, Double Half Slot	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
22251.3A	VSP Spine System	A-Slot Plate, Triple Half Slot	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
22251.5A	VSP Spine System	A-Slot Plate, One and One Half Slot	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
222510A	VSP Spine System	Bone Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	22-May-98
22252.2A	VSP Spine System	Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
22252.5A	VSP Spine System	Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
22253.5A	VSP Spine System	Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-95
22254.5A	VSP Spine System	Bone Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
22255.5A	VSP Spine System	Bone Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
22256.5A	VSP Spine System	Bone Plate	Non-Sterile	46647	Orthopaedic fixation plate, non-bioabsorbable	1	IIb	1-Jul-98
22263530F	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	12-Aug-98
22263530S	VSP Spine System	Standard Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	4-May-00
22263545S	VSP Spine System	Standard Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	4-May-00
22263550S	VSP Spine System	Standard Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	4-May-00
30261925H	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	12-Aug-98
30261930H	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	12-Aug-98
30261935H	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	12-Aug-98
30261940H	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	12-Aug-98
30261945H	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	12-Aug-98
30261950H	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	12-Aug-98
30262840H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	14-Jul-98
30262845H	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	14-Jul-98
32100070H	University Plate Anterior System	Plate, 70mm		46653	Spinal fixation plate, non-bioabsorbable	1	IIb	28-May-05

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Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
32100080H	University Plate Anterior System	Plate, 80mm		46653	Spinal fixation plate, non-bioabsorbable	1	IIb	28-May-05
32100090H	University Plate Anterior System	Plate, 90mm		46653	Spinal fixation plate, non-bioabsorbable	1	IIb	28-May-05
32100100H	University Plate Anterior System	Plate, 100mm		46653	Spinal fixation plate, non-bioabsorbable	1	IIb	28-May-05
32250.5A	TiMX Low Back System	VSP Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	15-Jun-98
32251.2A	TiMX Low Back System	VSP Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	15-Jun-98
32251.3A	TiMX Low Back System	VSP Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	15-Jun-98
32251.5A	TiMX Low Back System	VSP Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	15-Jun-98
32252.2A	TiMX Low Back System	VSP Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	15-Jun-98
32252.5A	TiMX Low Back System	VSP Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	15-Jun-98
32253.5A	TiMX Low Back System	VSP Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	IIb	15-Jun-98
50000476W	ISOLA Spine System	Open Cap w/o Wedge	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	4-May-00
500005SST	ISOLA Spine System	Hexlobe Set Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	27-Oct-99
50000635W	ISOLA Spine System	Open Cap w/o Wedge	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	4-May-00
50001.2A	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
50001.3A	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
50001.5A	ISOLA Spine System	Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
500010203LP	ISOLA Spine System	Iliac Bolt, extended post 10mm x 30mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Jun-04
500010204LP	ISOLA Spine System	Iliac Bolt, extended post 10mm x 40mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Jun-04
500010205LP	ISOLA Spine System	Iliac Bolt, extended post 10mm x 50mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Jun-04
500010206LP	ISOLA Spine System	Iliac Bolt, extended post 10mm x 60mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Jun-04
500010207LP	ISOLA Spine System	Iliac Bolt, extended post 10mm x 70mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Jun-04
500010208LP	ISOLA Spine System	Iliac Bolt, extended post 10mm x 80mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Jun-04
500010209LP	ISOLA Spine System	Iliac Bolt, extended post 10mm x 90mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Jun-04
500010210LP	ISOLA Spine System	Iliac Bolt, extended post 10mm x 100mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Jun-04
500010211LP	ISOLA Spine System	Iliac Bolt, extended post 10mm x 110mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Jun-04
500010212LP	ISOLA Spine System	Iliac Bolt, extended post 10mm x 120mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	22-Jun-04
5000108L	ISOLA Spine System	Offset Hook		43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000108R	ISOLA Spine System	Offset Hook		43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000126M	ISOLA Spine System	Throat Hook	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000180B	ISOLA Spine System	Open Hook Body		43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000190/220	ISOLA Spine System	Open Hook Cap	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000190/220A	ISOLA Spine System	3/16" Open Hook Cap Only		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	26-Nov-01
5000190/220W	ISOLA Spine System	Open Cap w/o Wedge		43257	Bone-screw internal spinal fixation system	1	IIb	4-May-00
5000190B	ISOLA Spine System	Open Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	19-May-98
50002.5A	ISOLA Spine System	Plate/Rod Combination		43257	Bone-screw internal spinal fixation system	1	IIb	4-May-00
5000200B	ISOLA Spine System	Open Hook Body, 4.75 X 6.5mm, SS		43041	Interlaminar internal spinal fixation system	1	IIb	19-May-98
5000203B	ISOLA Spine System	Open Hook Body, 6.35 X 6.5mm		43041	Interlaminar internal spinal fixation system	1	IIb	19-May-98
5000204LB	ISOLA Spine System	Offset Hook Body		43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000204RB	ISOLA Spine System	Offset Hook Body		43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000205/235	ISOLA Spine System	Open Hook Cap	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	25-Sep-98
5000205/235A	ISOLA Spine System	Hook Accessory		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
5000205/235W	ISOLA Spine System	Open Hook Cap	Non-Sterile	43041	Interlaminar internal spinal fixation system	1	IIb	26-Nov-01
5000205B	ISOLA Spine System	Open Hook Body, 6.35 X 6.5mm		43041	Interlaminar internal spinal fixation system	1	IIb	19-May-98
5000206B	ISOLA Spine System	Throat Hook Body		33542	Bone hook	1	IIb	25-Sep-98
5000207B	ISOLA Spine System	Bifid Hook Body		43257	Bone-screw internal spinal fixation system	1	IIb	19-May-98
5000210B	ISOLA Spine System	Open Hook Body		43257	Bone-screw internal spinal fixation system	1	IIb	19-May-98
5000213B	ISOLA Spine System	Open Hook Body		43257	Bone-screw internal spinal fixation system	1	IIb	19-May-98
5000214LB	ISOLA Spine System	Offset Hook Body		33542	Bone hook	1	IIb	25-Sep-98
5000214RB	ISOLA Spine System	Offset Hook Body		33542	Bone hook	1	IIb	25-Sep-98
5000215B	ISOLA Spine System	Open Hook Body		43257	Bone-screw internal spinal fixation system	1	IIb	19-May-98
5000216B	ISOLA Spine System	Angled Throat Body		33542	Bone hook	1	IIb	25-Sep-98
5000216MB	ISOLA Spine System	Closed Angled Body		33542	Bone hook	1	IIb	25-Sep-98
5000217B	ISOLA Spine System	Bifid Hook Body		33542	Bone hook	1	IIb	19-May-98
5000220B	ISOLA Spine System	Open Hook Body		33542	Bone hook	1	IIb	19-May-98
5000224LB	ISOLA Spine System	Offset Hook Body		33542	Bone hook	1	IIb	25-Sep-98
5000224RB	ISOLA Spine System	Offset Hook Body		33542	Bone hook	1	IIb	25-Sep-98
5000225B	ISOLA Spine System	Open Hook Body		33542	Bone hook	1	IIb	19-May-98
5000226B	ISOLA Spine System	Throat Hook Body		33542	Bone hook	1	IIb	25-Sep-98
5000226MB	ISOLA Spine System	Closed Angled Body		33542	Bone hook	1	IIb	25-Sep-98
5000233B	ISOLA Spine System	Open Hook Body		33542	Bone hook	1	IIb	19-May-98
5000234LB	ISOLA Spine System	Offset Hook Body		33542	Bone hook	1	IIb	25-Sep-98

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Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
5200435B	ISOLA Spine System	Pedicle Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Sep-98
5200440B	ISOLA Spine System	Pedicle Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Sep-98
5200445B	ISOLA Spine System	Pedicle Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	25-Sep-98
52005111L	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	28-Sep-99
52005113R	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	28-Sep-99
52005115R	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	28-Sep-99
5211205/235A	Kaneda SR Anterior System	Open Cap		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Jul-95
52112820B	ISOLA Spine System	Open Screw Body		46651	Spinal bone screw, non-bioabsorbable	1	IIb	19-May-98
52112825B	ISOLA Spine System	Open Screw Body		46651	Spinal bone screw, non-bioabsorbable	1	IIb	19-May-98
52112835B	ISOLA Spine System	Open Screw Body		46651	Spinal bone screw, non-bioabsorbable	1	IIb	19-May-98
52112840B	ISOLA Spine System	Open Screw Body		46651	Spinal bone screw, non-bioabsorbable	1	IIb	19-May-98
52112845B	ISOLA Spine System	Open Screw Body		46651	Spinal bone screw, non-bioabsorbable	1	IIb	19-May-98
52112850B	ISOLA Spine System	Open Screw Body		46651	Spinal bone screw, non-bioabsorbable	1	IIb	19-May-98
52112855B	ISOLA Spine System	Open Screw Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	19-May-98
52112860B	ISOLA Spine System	Open Screw Body		46651	Spinal bone screw, non-bioabsorbable	1	IIb	19-May-98
52112865B	ISOLA Spine System	Open Screw Body		46651	Spinal bone screw, non-bioabsorbable	1	IIb	19-May-98
52112870B	ISOLA Spine System	Open Screw Body		46651	Spinal bone screw, non-bioabsorbable	1	IIb	19-May-98
530055AN	TiMX Low Back System	Angled Slotted Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	21-Jan-01
5300568C	TiMX Low Back System	Curved Twister Connector	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	1-Mar-02
5300568C2	TiMX Low Back System	Twister Connector Washer	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	17-Mar-03
5300568CL	TiMX Low Back System	Curved Offset Twister Connector, Left	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	17-Mar-03
5300568CR	TiMX Low Back System	Curved Offset Twister Connector, Right	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIb	17-Mar-03