

**Appendix A**  
**DePuy Spine, Inc. Technical File 1 Rev. BS**

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	61325	Bone-screw internal spinal fixation system, non-sterile	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	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
520080	ISOLA Spine System	Closed Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	14-Jul-98
520090	ISOLA Spine System	Closed Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	14-Jul-98
520093	ISOLA Spine System	Closed Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	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	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000116	ISOLA Spine System	Throat Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000121	ISOLA Spine System	Trauma Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000131	ISOLA Spine System	Trauma Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000208	ISOLA Spine System	Open Hook Cap	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	28-Sep-99
5003130	ISOLA Spine System	Closed Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	29-Jan-98
5200100	ISOLA Spine System	Closed Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	14-Jul-98
5200101	ISOLA Spine System	Trauma Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	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
20263635	VSP Spine System	Standard Sacral Screw	Non-Sterile	46651	Spinal bone screw, non-bioabsorbable	1	Ib	14-Jul-98
20263640	VSP Spine System	Standard Sacral Screw	Non-Sterile	46651	Spinal bone screw, non-bioabsorbable	1	Ib	14-Jul-98
20263645	VSP Spine System	Standard Sacral Screw	Non-Sterile	46651	Spinal bone screw, non-bioabsorbable	1	Ib	14-Jul-98
20263650	VSP Spine System	Standard Sacral Screw	Non-Sterile	46651	Spinal bone screw, non-bioabsorbable	1	Ib	14-Jul-98
20302710	ISOLA Spine System	TRC	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	25-Sep-98
20302715	ISOLA Spine System	TRC	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	25-Sep-98
20302720	ISOLA Spine System	TRC	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	25-Sep-98
20302725	ISOLA Spine System	TRC	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	25-Sep-98
20302730	ISOLA Spine System	TRC	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	25-Sep-98
22232425	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	22-May-98
22232825	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	22-May-98
22233440	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	22-May-98
22233555	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	12-Aug-98
22233570	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	12-Aug-98
22233630	VSP Spine System	Sacral Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-May-98
22261217	VSP Spine System	Washer	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	10-Sep-98
22262825	VSP Spine System	Pedicle Screw, Standard	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	22-May-98
22263530	VSP Spine System	Bone Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	22-May-98
22263570	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	12-Aug-98
30039635	ISOLA Spine System	Open Hook Cap	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	27-Oct-99
30261920	VSP Spine System	Standard Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	13-Aug-99
30261950	VSP Spine System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	2-Jun-98
30262855	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	23-Mar-00
30262870	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	23-Mar-00
30263270	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	22-May-98
30263570	VSP Spine System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	22-May-98
32042825	University Plate Anterior System	Anterior Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	15-Aug-00
32042830	University Plate Anterior System	Anterior Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	15-Aug-00
32100050	University Plate Anterior System	Plate	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32100060	University Plate Anterior System	Plate	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32100080	University Plate Anterior System	Plate	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32100090	University Plate Anterior System	Plate	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32100095	University Plate Anterior System	Plate	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32100100	University Plate Anterior System	Plate	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32100105	University Plate Anterior System	Plate	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32102820	University Plate Anterior System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32102825	University Plate Anterior System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32102830	University Plate Anterior System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32102835	University Plate Anterior System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32102840	University Plate Anterior System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32102845	University Plate Anterior System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32102855	University Plate Anterior System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32102860	University Plate Anterior System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32102865	University Plate Anterior System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32102870	University Plate Anterior System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32103220	University Plate Anterior System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32103225	University Plate Anterior System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32103235	University Plate Anterior System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32103240	University Plate Anterior System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32103245	University Plate Anterior System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32103250	University Plate Anterior System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32103260	University Plate Anterior System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	1-Jul-95
32103265	University Plate Anterior System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32103270	University Plate Anterior System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	19-Dec-97
32200100	M-2 Anterior Plate System	Plate	Non-Sterile	46653	Spinal fixation plate, non-bioabsorbable	1	Ib	26-Nov-01
32212420	M-2 Anterior Plate System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	21-Oct-97
32212460	M-2 Anterior Plate System	Bolt	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	21-Oct-97
32221920	M-2 Anterior Plate System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	21-Oct-97
32221960	M-2 Anterior Plate System	Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	21-Oct-97
32232425	TiMX Low Back System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	15-Jun-98
32233560	TiMX Low Back System	Pedicle Screw	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	Ib	15-Jun-98
32261004	TiMX Low Back System	ISOLA Slotted Connector Nut	Non-Sterile	32847	Orthopaedic bone nut	1	Ib	15-Jun-98





































































































**Appendix A**  
**DePuy Spine, Inc. Technical File 1 Rev. BS**

Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
179752090	Expedium Spine System	Left Offset Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Jul-04
179752096	Expedium Spine System	Expedium Ti 5.5 Left Angeled Offset Hook with Angled Slot	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	19-Mar-10
179752111	Expedium Spine System	Expedium 5.5 Ti Side Tightening Hook, Left, 11.0mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	31-Oct-07
179752165	Expedium Spine System	Expedium 5.5 Ti Side Tightening Hook, Left, 6.5mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	31-Oct-07
179752180	Expedium Spine System	Expedium 5.5 Ti Side Tightening Hook, Left, 8.0mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	31-Oct-07
179752195	Expedium Spine System	Expedium 5.5 Ti Side Tightening Hook, Left, 9.5mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	31-Oct-07
179752200	Expedium Spine System	Translation Pedicle Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Jul-04
179752210	Expedium Spine System	Translation Reduced Distance Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Jul-04
179752211	Expedium Spine System	Expedium 5.5 Ti Side Tightening Hook, Right, 11.0mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	31-Oct-07
179752220	Expedium Spine System	Translation Angled Blade Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Jul-04
179752230	Expedium Spine System	Translation Narrow Blade Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Jul-04
179752240	Expedium Spine System	Translation Wide Blade Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Jul-04
179752265	Expedium Spine System	Expedium 5.5 Ti Side Tightening Hook, Right, 6.5mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	31-Oct-07
179752280	Expedium Spine System	Expedium 5.5 Ti Side Tightening Hook, Right, 8.0mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	31-Oct-07
179752295	Expedium Spine System	Expedium 5.5 Ti Side Tightening Hook, Right, 9.5mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	31-Oct-07
179754711	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 110mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754712	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 120mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754713	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 130mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754760	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 60mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754765	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 65mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754770	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 70mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754775	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 75mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754780	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 80mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754785	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 85mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754790	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 90mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754795	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 95mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179754799	Viper SAI	Favored Angle Polyaxial Screw, Ti, 5.5mm x 7.5mm x 100mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	10-May-12
179755155	Expedium Spine System	Ti Semi Open Dual Connector 5.5 X 5.5mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	4-Aug-06
179755163	Expedium Spine System	Ti Semi Open Dual Connector 5.5 X 6.35mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	4-Aug-06
179755255	Expedium Spine System	Expedium 5.5 Dual Rod Connector, Closed, Side-By-Side, 5.50mm x 5.50mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	31-Oct-07
179755355	Expedium Spine System	Expedium 5.5 Dual Rod Connector, Closed, End-to-End, 5.50mm x 5.50mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	31-Oct-07
179761000	Expedium Spine System	TI X25 Short Setscrew	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	8-Oct-09
179762030	Moss Miami Spine System	Pre-Cut Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762035	Moss Miami Spine System	Pre-Cut Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762040	Moss Miami Spine System	Pre-Cut Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762045	Expedium Spine System	Pre-Cut Rod 5.5 X 45mm, Ti	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762050	Expedium Spine System	Pre-Cut Rod 5.5 X 50mm, Ti	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762055	Expedium Spine System	Pre-Cut Rod 5.5 X 55mm, Ti	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762060	Expedium Spine System	Pre-Cut Rod 5.5 X 60mm, Ti	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762065	Expedium Spine System	Pre-Cut Rod 5.5 X 65mm, Ti	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762070	Expedium Spine System	Pre-Cut Rod 5.5 X 70mm, Ti	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762075	Expedium Spine System	Pre-Cut Rod 5.5 X 75mm, Ti	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762080	Moss Miami Spine System	Pre-Cut Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762085	Moss Miami Spine System	Pre-Cut Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762090	Moss Miami Spine System	Pre-Cut Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762095	Moss Miami Spine System	Pre-Cut Rod	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	7-Aug-03
179762120	Expedium Spine System	Pre-cut Rod, 120mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	22-Jun-04
179762180	Expedium Spine System	Ti Str. Rod, 180mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	1-Feb-06
179762240	Expedium Spine System	Ti Str. Rod, 240mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	1-Feb-06
179762300	Expedium Spine System	Hex End Rod, 300mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	22-Jun-04
179762480	Expedium Spine System	Hex End Rod, 480mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	22-Jun-04
179766455	Expedium Spine System	Side-by-SideTi Dual Set Screw Connector 5.5x4.75mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	25-Jul-05
179766555	Expedium Spine System	Side-by-Side Ti Dual Set Screw Connector 5.5x5.5mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	25-Jul-05
179766655	Expedium Spine System	Side-by-SideTi Dual Set Screw Connector 5.5x6.35mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	25-Jul-05
179766663	Expedium Spine System	Ti Double Closed/Closed Side-by-Side Connector 6.35/6.35	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	9-Nov-06
179770555	Expedium Spine System	Connector Open/Closed Side Loading 5.5X5.5 TI	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	8-Oct-09
179770655	Expedium Spine System	Connector Open/Closed Side Loading 6.35X5.5 TI	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	8-Oct-09
179771000	Expedium Spine System	TI X25 Variable Connector Setscrew	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	8-Oct-09
179771030	Expedium Spine System	Expedium 5.5 TI Pre-lordosed Rod, 30mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	16-Jun-08
179771035	Expedium Spine System	Expedium 5.5 TI Pre-lordosed Rod, 35mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	16-Jun-08
179771040	Expedium Spine System	Expedium 5.5 TI Pre-lordosed Rod, 40mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	16-Jun-08
179771045	Expedium Spine System	Expedium 5.5 TI Pre-lordosed Rod, 45mm	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IbB	16-Jun-08



























































































































































**Appendix A**  
**DePuy Spine, Inc. Technical File 1 Rev. BS**

Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
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
698233230	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	Iliac Connector, Right	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	13-Nov-00
698500099	ISOLA Spine System	Iliac 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	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Mar-00
698502018	ISOLA Spine System	Single Hole Staple	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Mar-00
698502020	ISOLA Spine System	Single Hole Staple	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Mar-00
698502022	ISOLA Spine System	Single Hole Staple	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	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
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	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Mar-00
698522018	ISOLA Spine System	Single Hole Staple	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Mar-00
698522020	ISOLA Spine System	Single Hole Staple	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Mar-00
698522022	ISOLA Spine System	Single Hole Staple	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	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









**Appendix A**  
**DePuy Spine, Inc. Technical File 1 Rev. BS**

Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
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
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

**Appendix A**  
**DePuy Spine, Inc. Technical File 1 Rev. BS**

Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
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		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000108R	ISOLA Spine System	Offset Hook		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000126M	ISOLA Spine System	Throat Hook	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000180B	ISOLA Spine System	Open Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000190/220	ISOLA Spine System	Open Hook Cap	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	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		61325	Bone-screw internal spinal fixation system, non-sterile	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		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	4-May-00
5000200B	ISOLA Spine System	Open Hook Body, 4.75 X 6.5mm, SS		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	19-May-98
5000203B	ISOLA Spine System	Open Hook Body, 6.35 X 6.5mm		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	19-May-98
5000204LB	ISOLA Spine System	Offset Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000204RB	ISOLA Spine System	Offset Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000205/235	ISOLA Spine System	Open Hook Cap	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	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	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	26-Nov-01
5000205B	ISOLA Spine System	Open Hook Body, 6.35 X 6.5mm		61325	Bone-screw internal spinal fixation system, non-sterile	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		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	19-May-98
5000210B	ISOLA Spine System	Open Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	19-May-98
5000213B	ISOLA Spine System	Open Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	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		61325	Bone-screw internal spinal fixation system, non-sterile	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
5000234RB	ISOLA Spine System	Offset Hook Body		33542	Bone hook	1	IIB	25-Sep-98
5000235B	ISOLA Spine System	Open Hook Body		33542	Bone hook	1	IIB	19-May-98
50002840BTB	Kaneda Anterior Scoliosis System	Closed Screw		46651	Spinal bone screw, non-bioabsorbable	1	IIB	29-May-98
5000293B	ISOLA Spine System	Open Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	19-May-98
5000296B	ISOLA Spine System	Angled Throat Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
50004111L	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Nov-01
50004111R	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Nov-01
50004113L	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Nov-01
50004113R	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Nov-01
50004115L	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Nov-01
50004115R	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Nov-01
5000420B	ISOLA Spine System	Pedicle Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000425B	ISOLA Spine System	Pedicle Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000430B	ISOLA Spine System	Pedicle Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000435B	ISOLA Spine System	Pedicle Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
5000440B	ISOLA Spine System	Pedicle Hook Body		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	25-Sep-98
50005111L	ISOLA Spine System	Offset Plate/Rod Combination	Non-Sterile	61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Nov-01
50005111R	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Nov-01
50005113L	ISOLA Spine System	Offset Plate/Rod Combination		61325	Bone-screw internal spinal fixation system, non-sterile	1	IIB	27-Nov-01





**Appendix A**  
**DePuy Spine, Inc. Technical File 1 Rev. BS**

Part Number	System Name	Part Description	Sterile or Non-Sterile	GMDN Code	GMDN Description	CE Technical File #	CE MDD Class	CE Issued Doc
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