

Prohlášení o shodě

(v souladu ISO/IEC 17050-1)

IDENTIFIKACE VÝROBKU	
JMÉNO SYSTÉMU: K2M MEZITĚLOVÁ SYSTÉMY	
SYSTÉMY Název značky	Klasifikace výrobku*
ALEUTIAN® mezitělový systém	I
	I(m)
	IIb
CASCADIA™ mezitělový systém	I
	IIb
CHESAPEAKE® stabilizační systém	I
	I(m)
	IIb
PANAREA™ mezitělový systém	I
	IIb
SAHARA™ stabilizační systém	I
	I(m)
	IIb

*Zařízení třídy I: Zplnomocněný zástupce

*Zařízení třídy I(m), IIa, IIb: Notifikovaná osoba

FORM-CE-000 Rev 76 v Master Control obsahuje seznam částí označených CE, které se řídí tímto prohlášením o shodě

VÝROBCE		
Jméno společnosti	Adresa	Zástupce firmy
K2M, Inc.	600 Hope Parkway, SE Leesburg, VA 20175 USA	Ed Crown Sr. ředitel, kvality

AUTHORIZED REPRESENTATIVE		
Jméno společnosti	Adresa	Telefon/email
Emergo Europe	Prinsessegracht 20 2514 AP Hague, Nizozemí	+31.70.345.8570 - telefon +31.70.346.7299 - fax service@emergogroup.com

POSOUZENÍ SHODY			
Klasifikace výrobku	Klasifikační pravidlo podle přílohy IX	Cesta ke shodě	Aplikovaný standard
Třída I	Příloha IX pravidlo 6 odrážka 2	Příloha VII	Viz technický soubor

REGISTRAČNÍ INFORMACE	
Notifikační subjekt a ID	Číslo certifikátu CE
BSI, 0086 & 2797	Obecné (522965) a třída I (m) (533085)

CONFORMITY ASSESSMENT			
Klasifikace výrobku	Klasifikační pravidlo podle přílohy IX	Cesta ke shodě	Aplikovaný standard
Třída IIb Třída IIb (sterilní)	Příloha IX pravidlo 8 Příloha IX pravidlo 8 ve spojení s přílohou VII.5	Annex II, excluding Section 4	Viz technický soubor
Třída I(m)	Příloha IX pravidlo 6 odrážka 2 ve spojení s přílohou VII oddíl 5 odrážka 2	Annex V	Viz technický soubor

Společnost K2M, Inc. prohlašuje, že výše uvedené výrobky splňují ustanovení směrnice Rady 93/42 / EHS ve znění směrnice 2007/47 / ES pro zdravotnické prostředky, jak je transponováno v členských státech.



28/6/2019

DATUM PODPISU

ZÁSTUPCE SPOLEČNOSTI / REGULACE: Ed Crown

TITUL: Ředitel, kvality

Master CE Mark List

Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
K2-10-2093-01	Cannulated Screw Inserter		DENALI® MI Spinal System	Interbody Placement	Instrument	44759 Ila		CE0086		6 1332244/R		13 MD 0106	Rule 5
K2-10-2104-01	Screw Alignment Guide	MI	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
K2-10-2203-01	MI Offset Rod Reducer	Yellow Jacket™	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
K2-10-2246-01	Modular Screw Inserter		DENALI® MI Spinal System	Interbody Placement	Instrument	44759 Ila		CE0086		6 1332244/R		13 MD 0106	Rule 5
1001-90001	Cannulated Screw Inserter		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90003	Cannulated Tap, Quick Connect	Size Ø4.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90004	Cannulated Tap, Quick Connect	Size Ø5.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90005	Cannulated Tap, Quick Connect	Size Ø6.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90006	Cannulated Tap, Quick Connect	Size Ø7.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90007	Cannulated Tap, Quick Connect	Size Ø8.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90015	Pedicle Access Needle	Size 9G	DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086		4 804504/R		12 MD 0106	Rule 6
1001-90016	Hinged Rod Holder		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90017	Gelpi Retractor	Size 3.5"	DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90018	Gelpi Retractor	Size 4.5"	DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90019	Gelpi Retractor	Size 5"	DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90020	Gelpi Retractor	Size 5.5"	DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90021	Gelpi Retractor	Size 6"	DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90022	Gelpi Retractor	Size 6.75"	DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90023	Gelpi Retractor	Size 7.5"	DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90024	Cannulated Screw Inserter, Anti-Rotate Sleeve		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90025	Gelpi Retractor	Size 6.25"	DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90030	Retractor/Extractor		DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90031	SS Guidewire	Size Ø1.1x520 mm SS	DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086		4 804504/R		12 MD 0106	Rule 6
1001-90051	Cannulated Power Driver, Attachment		DENALI® MI Spinal System	Interbody Placement	Instrument	44759 Ila		CE0086		6 1332244/R		13 MD 0106	Rule 5
1001-90053	Cannulated Drill Bit		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90062	Perfect Scalpel™		DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086		4 804504/R		12 MD 0106	Rule 6
1001-90065	Cannulated Power Driver, Jacobs Chuck Attachment		DENALI® MI Spinal System	Interbody Placement	Instrument	44759 Ila		CE0086		6 1332244/R		13 MD 0106	Rule 5
1001-90068	MI Short Pear Handle		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90069	MI, Tap Sleeve		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90070	Awl Tap	Size Ø5.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	15275 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90071	Awl Tap	Size Ø6.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	15275 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90072	Awl Tap	Size Ø7.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	15275 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90074	Rod Caliper		DENALI® MI Spinal System	Pedicle Screw System	Instrument	32262 I(m)		CE0086		7 513674/R		1 MD 0106	Rule 6
1001-90076	Compressor		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90077	SS Guidewire, Threaded & Blunt	Size Ø1.1	DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086		4 804504/R		12 MD 0106	Rule 6
1001-90079	Gelpi Retractor, Blunt		DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90080	MI, Tap Sleeve	Phase 1	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90096	Retractor/Extractor, Hexalobe		DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90097	Contoured Rod Inserter, Hex Tip		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90100	Screw Alignment Guide, Short Sylet	MI	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90101	Pedicle Access Needle, Short Sylet	Size 9G	DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086		4 804504/R		12 MD 0106	Rule 6
1001-90102	Cannulated Straight Probe		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90103	Cannulated Curved Probe		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90105	MI Rod Inserter		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90106	Perfect Scalpel™ (Narrow)		DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086		4 804504/R		12 MD 0106	Rule 6
1001-90109	Tap Sleeve Guide		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90110	Guide Wire	Size Ø1.1x575mm CoCr	DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086		4 804504/R		12 MD 0106	Rule 6
1001-90111	MI Hexalobe, Hudson Fitting	Size 25	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90112	Perfect Scalpel™, Molded Handle	Ø1.3 mm Cannula	DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086		4 804504/R		12 MD 0106	Rule 6
1001-90112-SG	Perfect Scalpel™	Ø1.3 mm Cannula	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila		CE0086		5 804504/R		4 MD 0106	Rule 6
1001-90113	Perfect Scalpel™, Molded Handle (Narrow)	Ø1.3 mm Cannula	DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086		4 804504/R		12 MD 0106	Rule 6
1001-90113-SG	Perfect Scalpel™ (Narrow)	Ø1.3 mm Cannula	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila		CE0086		5 804504/R		4 MD 0106	Rule 6
1001-90114	Retractor/Extractor, Spring Loaded		DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90115	Recovery Tool		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90116	Screw Head, Adjuster Assembly	MI	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90117	MI Rod Reducer	Praying Mantis™	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90118	Awl Tap	Size Ø5.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	15275 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90119	Awl Tap	Size Ø6.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	15275 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90120	Awl Tap	Size Ø7.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	15275 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90122	Guidewire Pack	Size Ø1.1 mm SS (Qty 3)	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila		CE0086		5 804514/R		4 MD 0106	Rule 6
1001-90123	Add On Kit, Retractors (2), SS Wires (3)	(Qty 2)/(Qty 3) SS	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila		CE0086		5 804514/R		4 MD 0106	Rule 6
1001-90128	Pedicle Access Needle, Modular Handle	Size 11G	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila		CE0086		5 804504/R		4 MD 0106	Rule 6
1001-90129	Pedicle Access Needle, Fixed Handle	Size 11G	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila		CE0086		5 804504/R		4 MD 0106	Rule 6
1001-90130	SS Guidewire	Size Ø0.044x26.5" (1.1x673 mm) SS	DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086		4 804504/R		12 MD 0106	Rule 6
1001-90131	Cannulated Screw Inserter		DENALI® MI Spinal System	Interbody Placement	Instrument	44759 Ila		CE0086		6 1332244/R		13 MD 0106	Rule 5
1001-90132	MI Hex Tapered Driver	Size 25	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90133	Torque Indicating Wrench	Size 25, MI	DENALI® MI Spinal System	Pedicle Screw System	Instrument	59009 I(m)		CE0086		7 513674/R		1 MD 0106	Rule 6
1001-90135	MI Rod Caliper		DENALI® MI Spinal System	Pedicle Screw System	Instrument	32262 I(m)		CE0086		7 513674/R		1 MD 0106	Rule 6
1001-90137	MI Inner Dilator		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90138	Outer Dilator	MI	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90155	Awl Tap	Size Ø8.5 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	15275 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90157	Pedicle Access Needle, Beveled	Size 11G	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila		CE0086		5 804504/R		4 MD 0106	Rule 6
1001-90160	Retractor Pack	(Qty 2)	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila		CE0086		5 804504/R		4 MD 0106	Rule 6
1001-90161	Needle Double Diamond Tip	Size 11G	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila		CE0086		5 804514/R		4 MD 0106	Rule 6
1001-90162	Needle Double Diamond Tip	Size 8G	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila		CE0086		5 804504/R		4 MD 0106	Rule 6
1001-90166	MI Offset Rod Reducer	Yellow Jacket™	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90172	MI Rod Reducer		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90173	Anti Torque Handle, MIS Rod Reducer		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90174	Quick Connect, Hex Wrench		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90175	MIS Rod Reducer, Removal Device		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90176	Fulcrum, MI Rod Reducer		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90177	Compressor, MI Rod Reducer		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
1001-90178	Distractor, MIS Rod Reducer		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 01	

Master CE Mark List

Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
101-90005	Quick Connect Tap	Size Ø5.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90006	Quick Connect Tap	Size Ø6.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90007	Quick Connect Tap	Size Ø7.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90008	Quick Connect Tap	Size Ø8.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90009	Curved Probe		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90010	Straight Probe		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90011	Depth Gauge		DENALI® Spinal System	Pedicle Screw System	Instrument	32845 I(m)	CE0086		7 513674/R			1 MD 0106	Rule 6
101-90012	X-Ray Marker (Left)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90013	X-Ray Marker (Right)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90014	X-Ray Marker Insert		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90015	Fixed T-Handle, Quick Connect		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90016	Ratchet T-Handle, Quick Connect		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90017	Fixed Pear Handle, Quick Connect		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90018	Ratchet Pear Handle, Quick Connect		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90019	Polyaxial Screw Insert		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90020	Provisional Screwdriver		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90021	Reamer		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90022	Screw Head Adjuster		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90023	Rod Reducer	Praying Mantis™	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90024	Torsional Rod Reducer (Right)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90025	Anti Torque Alignment Tube		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90026	Threaded Rod Reducer		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90027	Medial/Lateral Rod Bender (Right)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90028	Medial/Lateral Rod Bender (Left)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90029	In Situ Bender (Left)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90030	In Situ Bender (Right)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90031	French Rod Bender		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90033	Ratcheting Rod Cutter		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90034	Compressor		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90035	Distractor		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90036	Wedge Distractor		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90038	Rod Holder		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90039	Rod Introducing Forceps		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90040	Vise Grips		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90041	Caliper, Transverse Connector		DENALI® Spinal System	Pedicle Screw System	Instrument	32262 I(m)	CE0086		7 513674/R			1 MD 0106	Rule 6
101-90043	Rod Template	Size 80 mm	DENALI® Spinal System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
101-90044	Rod Template	Size 150 mm	DENALI® Spinal System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
101-90045	Rod Cutter		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90047	Awl Ball Handle (Long)		DENALI® Spinal System	Pedicle Screw System	Instrument	15275 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90049	Torque Limiting Handle, Hudson Fitting (Beere)		DENALI® Spinal System	Pedicle Screw System	Instrument	47830 I(m)	CE0086		7 513674/R			1 MD 0106	Rule 6
101-90050	Rod Fork		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90051	Anti Torque Handle		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90054	Thoracic Probe		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90055	Monaxial Screw/Hook Insert		DENALI® Spinal System	Interbody Placement	Instrument	44759 I(a)	CE0086		6 1332244/R			13 MD 0106	Rule 5
101-90063	Screw Gauge		DENALI® Spinal System	Pedicle Screw System	Instrument	32845 I(m)	CE0086		7 513674/R			1 MD 0106	Rule 6
101-90079	In Situ Bender (Left)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90080	In Situ Bender (Right)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90081	Torsional Rod Reducer (Left)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90088	Sleeve		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90089	Fixed Transverse Connector, Bender (Left)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90090	Fixed Transverse Connector, Bender (Right)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90093	Polyaxial Screw Insert (Short)		DENALI® Spinal System	Interbody Placement	Instrument	44759 I(a)	CE0086		6 1332244/R			13 MD 0106	Rule 5
101-90095	Torque Limiting Guide, Transverse Connector		DENALI® Spinal System	Pedicle Screw System	Instrument	47830 I(m)	CE0086		7 513674/R			1 MD 0106	Rule 6
101-90099	Screw Alignment Guide (Long)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90100	Driver Shaft, Transverse Connector		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90101	Torque Limiting Shaft	Size 25	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90114	Adjustable Awl		DENALI® Spinal System	Pedicle Screw System	Instrument	15275 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90115	Lumbar Hook Trial	Size (S)	DENALI® Spinal System	Interbody Placement	Instrument	44759 I(a)	CE0086		3 1332244/R			13 MD 0106	Rule 6
101-90116	Lumbar Hook Trial	Size (L)	DENALI® Spinal System	Interbody Placement	Instrument	44759 I(a)	CE0086		3 1332244/R			13 MD 0106	Rule 6
101-90117	Pedicle Hook Trial	Size (S)	DENALI® Spinal System	Interbody Placement	Instrument	44759 I(a)	CE0086		3 1332244/R			13 MD 0106	Rule 6
101-90118	Pedicle Hook Trial	Size (L)	DENALI® Spinal System	Interbody Placement	Instrument	44759 I(a)	CE0086		3 1332244/R			13 MD 0106	Rule 6
101-90119	Lumbar Hook Elevator		DENALI® Spinal System	Interbody Placement	Instrument	44759 I(a)	CE0086		3 1332244/R			13 MD 0106	Rule 6
101-90120	Thoracic Hook Elevator		DENALI® Spinal System	Interbody Placement	Instrument	44759 I(a)	CE0086		3 1332244/R			13 MD 0106	Rule 6
101-90122	Screw Alignment Guide (Short)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90123	Hook Insert, Cam Lever		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90125	Rotating Rod Holder		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90126	Hook Pusher		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90127	Hook Seater		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90128	Set Screw Insert, 2 Sided	ATR™	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90136	Straight Hook Holder		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90137	Offset Hook Holder		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90138	Saddle Hook Holder		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90140	Rotation Wrench		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90142	Rod Template	Size 300 mm	DENALI® Spinal System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
101-90143	Rod Template	Size 400 mm	DENALI® Spinal System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
101-90147	DC Ring		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90148	Anti Torque Alignment Tube (Short)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90154	Sacral Tap	Size Ø6.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90155	Sacral Tap	Size Ø7.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90156	Sacral Tap	Size Ø8.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90157	Vise Grips		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90158	Compressor, Multi-Span		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90159	Torque Wrench Tip EDM		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90186	Provisional Screwdriver, Handle		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90187	Set Screw Removal Wrench		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90190	Torque Indicating Wrench		DENALI® Spinal System	Pedicle Screw System	Instrument	59009 I(m)	CE0086		7 513674/R			1 MD 0106	Rule 6
101-90194	Ratcheting Rod Cutter	Size Ø5.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90197	Special, Straight Thoracic Probe		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90208	Torque Limiting Shaft (Short)	Size 25	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90213	NB LP Handle		DENALI® Spinal System	Pedicle Screw System	Instrument	47830 I(m)	CE0086		7 513674/R			1 MD 0106	Rule 6
101-90214	Ball Tip Feeler		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90216	Wrench For DC Ring		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90217	In Situ Bender, Narrow (Left)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90218	In Situ Bender, Narrow (Right)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90219	Torque Limiting Handle	Size 90 in-lb (10.2 N-m)	DENALI® Spinal System	Pedicle Screw System	Instrument	47830 I(m)	CE0086		7 513674/R			1 MD 0106	Rule 6
101-90220	Connector Holder		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90222	Rod Connector Holder, Parallel 2 Piece		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
101-90224	Cortical Tap Quick Connect	Size Ø4.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6

Master CE Mark List

Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
201-90024	Tap	Size Ø4.0x10 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90025	Spring Loaded Awl	Size 10 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	15275 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90026	Temporary Fixation Pin		PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	4 804504/R	CE0086		8 53670/R			12 MD 0106	Rule 6
201-90027	Freehand Tap	Size Ø4.0x10 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90029	Plate Holder, Cervical Driver		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90030	Driver	Size 10	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90031	Fixed Drill Guide		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90032	Variable Drill Guide		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90033	Temporary Pin Insertor		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90034	Spin Top Handle, Quick Connect		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90035	Calliper		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	32262 I(m)	CE0086		7 53674/R			2 MD 0106	Rule 6
201-90061	Reduction Screw	Size 12 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	4 804504/R	CE0086		8 53670/R			12 MD 0106	Rule 6
201-90062	Reduction Screw	Size 14 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	4 804504/R	CE0086		8 53670/R			12 MD 0106	Rule 6
201-90065	Fixed Drill Guide, Double Barrel Screw Thru		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90066	Plate Bender, Cervical Universal		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90070	Torque Limiting Handle (1/4" Square Quick Connect)		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	47830 I(m)	CE0086		7 53674/R			2 MD 0106	Rule 6
201-90071	Driver, Torque Limiting		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90072	Drill	Size Ø2.3x10 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90073	Drill	Size Ø2.3x12 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90074	Drill	Size Ø2.3x14 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90075	Drill	Size Ø2.3x16 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90078	Driver	Size 10	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90080	Driver, Torque Limiting		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90089	Variable Drill Guide		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90100	Fixed Drill Guide		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90101	Variable Drill Guide, Single Barrel Screw Thru		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90102	Thread Former		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90103	Drill	Size Ø2.3x10 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90104	Drill	Size Ø2.3x12 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90105	Drill	Size Ø2.3x14 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90106	Drill	Size Ø2.3x16 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90111	Temporary Pin Insertor		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90115	Awl	Size 10 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90116	Tap	Size Ø2.3x10 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90117	Freehand Tap	Size Ø2.3x10 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90118	Tapered Driver	Size 10	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90120	Screw Extractor		PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90121	Plate Holder		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90122	Spring Loaded Awl	Size 10 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	15275 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90127	Non-Tapered Torque Driver		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90131	Ratcheting Handle	AO	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90133	Non-Tapered Torque Driver	Size 10	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90140	Torque Limiting Handle	Size 20 in-lbs (2.3 N-m)	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	47830 I(m)	CE0086		7 53674/R			2 MD 0106	Rule 6
201-90141	Tapered Driver	Size 13	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90142	Non-Tapered Driver	Size 13	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90143	Drill Guide, Fixed, Snap-On		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90144	Awl	Size 12 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90145	Semi-Constrained Screw, Shank Extractor		PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90146	Capture Driver, Sleeve	Size 10	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90147	Plate Holder		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90148	Plate Bender, Cervical		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90149	Capture Driver	Size 10	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90150	Semi-Constrained, Capture Driver	Size 13	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90151	Spin Top Handle, AO		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90152	Spin Top Handle, Internal AO, (Short)		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90171	Plate Holder, Inner Shaft		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90172	Drill Guide, Fixed, Screw Thru		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90173	Spin Top Handle, Internal AO (Long)		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90174	Drill Guide, Fixed, Screw Thru		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90175	Drill Guide, Inner Shaft		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90176	Drill Guide, Fixed, Screw Thru		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90177	Fast Awl	Size 10 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90178	Fast Awl	Size 12 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90179	Fast Awl	Size 14 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90180	Fast Awl	Size 16 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90181	FAST Drill Guide		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90185	Drill Guide, Fixed, Translational		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90248	Clip	Size 1 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90249	Clip	Size 2 mm	PYRENEES® Cervical Plate System	Single Use, Non-Sterile	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90250	Anti-Torque Guide, Translational		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90251	Translational FAST, Guide		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90252	Translational Fixed, Screw Thru Guide		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90253	Translational Plate, Distractor		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90254	Translational Plate, Compressor		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
201-90259	Anti-Torque Guide, Constrained		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 53670/R			2 MD 0106	Rule 6
208-41F18	Constrained Plate, 1 Level	Size 18 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 I(b)	CE0086		1 53613/R			2 MD 0202	Rule 8
208-41F18-G1	Constrained Plate, 1 Level	Size 18 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	2 53613/R	CE0086		1 53613/R			2 MD 0202	Rule 8
208-41F20	Constrained Plate, 1 Level	Size 20 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 I(b)	CE0086		1 53613/R			2 MD 0202	Rule 8
208-41F20-G1	Constrained Plate, 1 Level	Size 20 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	2 53613/R	CE0086		1 53613/R			2 MD 0202	Rule 8
208-41F22	Constrained Plate, 1 Level	Size 22 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 I(b)	CE0086		1 53613/R			2 MD 0202	Rule 8
208-41F22-G1	Constrained Plate, 1 Level	Size 22 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	2 53613/R	CE0086		1 53613/R			2 MD 0202	Rule 8
208-41F24	Constrained Plate, 1 Level	Size 24 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 I(b)	CE0086		1 53613/R			2 MD 0202	Rule 8
208-41F24-G1	Constrained Plate, 1 Level	Size 24 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	2 53613/R	CE0086		1 53613/R			2 MD 0202	

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
2112-90042	Bone Funnel Pusher		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
2112-90043	Caliper	Size 150 mm	CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	32262 (I)m	CE0086		7 513674/R			10 MD 0106	Rule 6
2112-90046	Insertor		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
2601-90004	Mini Axial AO Handle, Fixed		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2601-90005	Mini Axial AO Handle, Ratchet		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2601-90006	T Handle AO Fixed		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2601-90007	T Handle AO Ratchet		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2601-90008	Streamline Spin Cap		OZARK Cervical Plate System	OZARK Cervical Plate System	Instrument	13180 I	CE		8 513670/R			16 MD 0106	Rule 6
2601-90009	T-Handle, Fixed Square Drive		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2601-90015	Medium A/O Ratchet Handle		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2601-90016	Driver (Short) AO Connection	Size 25	MESA® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		6 1332244/R			13 MD 0106	Rule 5
2601-90017	Driver (Short) AO Connection	Size 20	MESA® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		6 1332244/R			13 MD 0106	Rule 5
2601-90018	Driver (Short) AO Connection	Size 15	MESA® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		6 1332244/R			13 MD 0106	Rule 5
2601-90019	Driver (Short) AO Connection	Size 10	MESA® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		6 1332244/R			13 MD 0106	Rule 5
2601-90023	Mini T Handle AO Ratchet		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2601-90024	Mini Axial AO Handle, Ratchet		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2601-90025	Standard Ratcheting T-Handle, External AO Connect		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2601-90027	Ratcheting T Handle, Square Drive		NILE™ Alternative Fixation System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2601-90028	Short Screwdriver Shaft	Size 20	NILE™ Alternative Fixation System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
2701-90000	Scalpel Blade Holder		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90001	Rongeur	Size 3 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90002	Rongeur	Size 5 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90003	Straight Curette	Size #2	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13133 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90004	Straight Curette	Size #4	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13133 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90005	Angled Curette	Size #2	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13133 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90006	Angled Curette	Size #4	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13133 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90007	Curette	Size 11 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13133 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90010	Hess, Nerve Retractor	Size 90° 5 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	35315 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90011	12 FR Suction (Long)		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90012	Reverse Angled Curette	Size #2	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13133 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90013	Reverse Angled Curette	Size #4	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13133 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90014	Cone Ring Curette	Size #3	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13133 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90015	End Plate Rasp	Size 12.7 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90016	Angled Cobb Elevator	Size 12.7 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90017	Flat Cobb Elevator	Size 19 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90028	Fixation Pin	Size 70 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90029	Fixation Pin	Size 80 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90030	Fixation Pin	Size 90 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90031	Fixation Pin	Size 100 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90032	Fixation Pin	Size 110 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90033	Fixation Pin	Size 120 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90034	Fixation Pin	Size 130 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90035	Fixation Pin	Size 140 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90036	Fixation Pin	Size 150 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90037	Fixation Pin	Size 160 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90038	Fixation Pin Driver	Size 15	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90039	Lateral Access Blade	Size 24x70 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90040	Lateral Access Blade	Size 24x80 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90041	Lateral Access Blade	Size 24x90 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90042	Lateral Access Blade	Size 24x100 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90043	Lateral Access Blade	Size 24x110 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90044	Lateral Access Blade	Size 24x120 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90045	Lateral Access Blade	Size 24x130 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90046	Lateral Access Blade	Size 24x140 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90047	Lateral Access Blade	Size 24x150 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90048	Lateral Access Blade	Size 24x160 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90049	A/P Lateral Access Blade	Size 13x70 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90050	A/P Lateral Access Blade	Size 13x80 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90051	A/P Lateral Access Blade	Size 13x90 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90052	A/P Lateral Access Blade	Size 13x100 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90053	A/P Lateral Access Blade	Size 13x110 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90054	A/P Lateral Access Blade	Size 13x120 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90055	A/P Lateral Access Blade	Size 13x130 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90056	A/P Lateral Access Blade	Size 13x140 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90057	A/P Lateral Access Blade	Size 13x150 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90058	A/P Lateral Access Blade	Size 13x160 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90059	Fluoro Modulator		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90060	Lateral Access Blade Shim		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90061	Lateral Access Shim Insertor		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90062	Lateral Access Shim Extractor		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90063	Lateral Access Guide Wire	Size Ø3.0x330 mm	RAVINE™ Lateral Access System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
2701-90064	Dissector	Size 6 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90065	Dissector	Size 14 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90066	Dissector	Size 24 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90067	Stabilization Arm Attachment		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90068	Fluoro Saver Forceps		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90069	Lateral Access Retractor		RAVINE™ Lateral Access System	Interbody Access System	Instrument	35315 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90072	Light Probe, Dual	Size 50 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90073	Light Source Adapter		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90074	Light Source Adapter		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90075	Light Source Adapter		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90076	Light Source Adapter		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
2701-90077	Forward Angled Curette	Size #2	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13133 I	CE		8 513670/R			8 MD 0106	Rule 6

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
3001-90071	Straight Thoracic Probe		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90072	Curved Lumbar Probe		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90073	Straight Lumbar Probe		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90074	Depth Gauge	Size 80 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	32845 (I/m)	CE0086		7 513674/R			1 MD 0106	Rule 6
3001-90075	Awl	Size 02.75 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90076	Ratcheting Rod Cutter	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90077	French Rod Bender	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90078	In Situ Bender (Left)		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90079	In Situ Bender (Right)		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90080	Tube Rod Bender		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90081	Rod Locking Set Screw		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90082	Wedge Distractor		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90083	Rod Template	Size 500 mm	MESA® Small Stature Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R		13 MD 0106	Rule 6	
3001-90084	Rod Rotation Wrench	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90085	Torsional Rod Reducer (Left)		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90086	Torsional Rod Reducer (Right)		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90087	Rod Holding Forceps	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90088	Coronal Bender (Left)	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90089	Coronal Bender (Right)	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90090	Vise Grips	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90092	Parallel Distractor (Wide)	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90094	Screw Insertor		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90095	MESA Rail / Rod Puller, Sleeve	MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90096	MESA Rail / Rod Puller, Shaft Assembly	MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90097	MESA Rail / Rod Puller, Tip	MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90098	Screw Head Adjuster		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90099	Locker		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90100	Unlocker		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90101	A/O Quick Knob		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90102	Over Cricket Locker		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90103	Manipulator		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90104	T-Bar Screw Remover		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90105	Reduction Jack Rotation Tube, w/Driver		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90106	Reduction Jack Rotation Tube		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90107	Reduction Jack	Size 04.5 mm, Cricket®	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90108	Offset Hook Holder		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90109	Saddle Hook Holder		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90110	Lateral Hook Holder		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90111	Straight Hook Holder		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90112	Rod Fork		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90113	Hook Inserter, Threaded		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90114	Threaded Hook Inserter, Inner Assembly		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90115	Hook Pusher		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90116	Pedicle Hook Trial	Size 4 mm	MESA® Small Stature Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R		13 MD 0106	Rule 6	
3001-90117	Pedicle Hook Trial	Size 8 mm	MESA® Small Stature Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R		13 MD 0106	Rule 6	
3001-90118	Hook Elevator		MESA® Small Stature Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R		13 MD 0106	Rule 6	
3001-90119	Torque Limiting Shaft	Size 20	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90120	Anti Torque Alignment Tube		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90121	Single Action Rod Reducer	Firefly™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	31860 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90122	Transverse Connector Calipers		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	32262 (I/m)	CE0086		7 513674/R			1 MD 0106	Rule 6
3001-90123	MESA Rail™ Rotation Wrench	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90124	In Situ Bender (Right)	MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90125	In Situ Bender (Left)	MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90126	Flat Benders	Size 04.5 mm, MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90127	Vise Grips	Size 04.5 mm, MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90128	Coronal Bender (Left)	Size 04.5 mm, MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90129	Coronal Bender (Right)	Size 04.5 mm, MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90130	MESA Rail™ Cutter	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90131	MESA Rail™ Bender	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90132	Unlocker	Size 04.5 mm, MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90133	Quick Locker	Size MESA Rail™ 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90134	Reduction Jack	Size 04.5 mm, MESA Rail™ Cricket®	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90135	Partial Lock	Size 04.5 mm, Superfly™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90136	Dual Action Rod Reducer	Size 04.5 mm, MESA Rail™ Dragonfly™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90138	MESA Rail/Rod Distractor		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90139	Compressor		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90141	Tap, Long	Size 03.0 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90142	Tap, Long	Size 03.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90143	Tap, Long	Size 04.0 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90144	Tap, Long	Size 04.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90145	Tap, Long	Size 05.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90146	Tap, Long	Size 06.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90147	Tap, Long	Size 07.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90148	Dual Action Rod Reducer	Size 04.5 mm, Dragonfly™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90157	Over Cricket Unlocker		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-90158	MESA Rail / Rod Puller		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
3001-845100	Straight Deformity Rod, Dual Hex	Size 04.5x100 mm, TI	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	1 803292/R	CE0086		1 803292/R			1 MD 0202	Rule 8
3001-845100	Straight Deformity Rod, Dual Hex	Size 04.5x150 mm, TI	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	1 803292/R	CE0086		1 803292/R			1 MD 0202	Rule 8
3001-845200	Straight Deformity Rod, Dual Hex	Size 04.5x200 mm, TI	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	1 803292/R	CE0086		1 803292/R			1 MD 0202	Rule 8
3001-845300	Straight Deformity Rod, Dual Hex	Size 04.5x300 mm, TI	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	1 803292/R	CE0086		1 803292/R			1 MD 0202	Rule 8
3001-845300-G2	Straight Deformity Rod, Dual Hex	Size 04.5x300 mm, TI	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	1 803292/R	CE0086		2 803292/R			1 MD 0202	Rule 8
3001-845400	Straight Deformity Rod, Dual Hex	Size 04.5x400 mm, TI	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	1 803292/R	CE0086		1 803292/R			1 MD 0202	Rule 8
3001-845400-G2	Straight Deformity Rod, Dual Hex	Size 04.5x400 mm, TI	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	1 803292/R	CE0086		2 803292/R				

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
4508-90027	Plate Template, Half	Size 13	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90028	Plate Template, Half	Size 14	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90029	Plate Template, Half	Size 15	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90030	Plate Template, Half	Size 16	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90031	Plate Template, Half	Size 17	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90032	Plate Template, Half	Size 18	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90033	Plate Template, Half	Size 19	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90034	Plate Template, Half	Size 20	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90044	Drill	Size Ø3.0x20 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90045	Drill	Size Ø3.0x25 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90046	Drill	Size Ø3.0x30 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90047	Drill	Size Ø3.0x65 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90057	Drill Guide, Fixed, Screw Thru		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90058	Drill Guide, Variable		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90059	Drill Guide, Fixed		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90060	Non-Tapered Driver	Size 20	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90061	Spin Top Handle, Quick Connect	Size 1/8"	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90062	Ratcheting Flat Handle	Hudson	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90063	Tapered Driver	Size 20	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90068	Tap	Size Ø5.5x20 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90069	Tap	Size Ø5.5x25 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90070	Tap	Size Ø5.5x30 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90071	Tap	Size Ø5.0x20 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90072	Tap	Size Ø5.0x25 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90073	Tap	Size Ø5.0x30 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90074	Inner Shaft Assembly		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90075	Spring Loaded Awl	Size 20 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	15275 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90076	Awl	Size 20 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	15275 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90077	Awl	Size 25 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	15275 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90078	Awl	Size 30 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	15275 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90105	Offset Guide		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90107	Flex Shaft Awl	Size Ø3.0x20 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	15275 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90108	Flex Shaft Awl	Size Ø3.0x25 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	15275 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90109	Flex Shaft Awl	Size Ø3.0x30 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	15275 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90110	Flex Shaft Drill	Size Ø2.5x20 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90111	Flex Shaft Drill	Size Ø2.5x25 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90112	Flex Shaft Drill	Size Ø2.5x30 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90113	Flex Shaft Drill	Size Ø2.5x65 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90114	Plate Template Flex Shaft		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90115	Plate Template	Size 7	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90116	Plate Template	Size 8	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90117	Plate Template	Size 9	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90118	Plate Template	Size 10	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90119	Plate Template	Size 11	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90120	Plate Template	Size 12	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90121	Plate Template	Size 13	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90122	Plate Template	Size 14	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90123	Plate Template	Size 15	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90124	Plate Template	Size 16	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90125	Plate Template	Size 17	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90126	Plate Template	Size 18	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90127	Plate Template	Size 19	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90128	Plate Template	Size 20	CAYMAN® Plate System-MI	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R			13 MD 0106	Rule 6
4508-90129	Flex Shaft Non-tapered Driver	Size 20	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90130	Flex Shaft Tapered Driver	Size 20	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90131	Flex Shaft Drill	Size Ø3.0x20 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90132	Flex Shaft Drill	Size Ø3.0x25 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90133	Flex Shaft Drill	Size Ø3.0x30 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90134	Flex Shaft Drill	Size Ø3.0x65 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90135	Flex Shaft Tap	Size Ø5.0x20 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90136	Flex Shaft Tap	Size Ø5.0x25 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90137	Flex Shaft Tap	Size Ø5.0x30 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90138	Flex Shaft Screw Extractor	Size 20	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90139	Angled Drill Guide, Fixed, Screw Thru		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90140	Angled Drill Guide, Variable		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90141	Angled Drill Guide, Fixed		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90142	Center Hole Plate Holder		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90143	Inner Threaded Flex Shaft		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90146	Center Hole Plate Holder, w/Alignment foot		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4508-90148	Temporary Fixation Pin, Smooth		CAYMAN® Plate System-MI	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086	4 804504/R			12 MD 0106	Rule 6
4508-90151	Temporary Fixation Pin, Smooth	Size Ø1.8x19 mm	CAYMAN® Plate System-MI	Single Use, Non-Sterile	Instrument	61300 Ila		CE0086	4 804504/R			12 MD 0106	Rule 6
4508-90152	Osteophyte Rongeur, Flat Nose	Size 5 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I		CE	8 513670/R			5 MD 0106	Rule 6
4601-15520A	Supplemental Screw	Size Ø5.5x20 mm	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Implant	61325 Ila		CE0086	1 1471173/R			1 MD 0202	Rule 8
4601-15525A	Supplemental Screw	Size Ø5.5x25 mm	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Implant	61325 Ila		CE0086	1 1471173/R			1 MD 0202	Rule 8
4601-15530A	Supplemental Screw	Size Ø5.5x30 mm	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Implant	61325 Ila		CE0086	1 1471173/R			1 MD 0202	Rule 8
4601-15535A	Supplemental Screw	Size Ø5.5x35 mm	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Implant	61325 Ila		CE0086	1 1471173/R			1 MD 0202	Rule 8
4601-15540A	Supplemental Screw	Size Ø5.5x40 mm	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Implant	61325 Ila		CE0086	1 1471173/R			1 MD 0202	Rule 8
4601-16020A	Supplemental Screw	Size Ø6.0x20 mm	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Implant	61325 Ila		CE0086	1 1471173/R			1 MD 0202	Rule 8
4601-16025	Screw Assembly	Size Ø6.0x25 mm	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Implant	61325 Ila		CE0086	1 1471173/R			1 MD 0202	Rule 8
4601-16025A	Supplemental Screw	Size Ø6.0x25 mm	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Implant	61325 Ila		CE0086	1 1471173/R			1 MD 0202	Rule 8
4601-16025DL	Dual Screw Assembly, Left	Size Ø6.0x25 mm	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Implant	61325 Ila		CE0086	1 1471173/R			1 MD 0202	Rule 8
4601-16025DR	Dual Screw Assembly, Right	Size Ø6.0x25 mm	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Implant	61325 Ila		CE0086	1 1471173/R			1 MD 0202	Rule 8
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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
801-80600H-SG	Laminar Hook, Extended Body	Size 6 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80600H-SG	Laminar Hook, Extended Body	Size 6 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 795844/R			1 MD 0202	Rule 8
801-80601H	Transverse Process Hook	Size 6 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80601H-SG	Transverse Process Hook	Size 6 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80602H	Laminar Hook	Size 6 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80602HN	Laminar Hook, Narrow	Size 6 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80602HN-SG	Laminar Hook, Narrow	Size 6 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80602H-SG	Laminar Hook	Size 6 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80603H	Pedicle Hook	Size 6 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80603H-SG	Pedicle Hook	Size 6 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 795844/R			1 MD 0202	Rule 8
801-80800H	Laminar Hook, Extended Body	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80800H-SG	Laminar Hook, Extended Body	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80800H-SG	Laminar Hook, Extended Body	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 795844/R			1 MD 0202	Rule 8
801-80801H	Transverse Process Hook	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80801H-SG	Transverse Process Hook	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80802H	Laminar Hook	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80802HN	Laminar Hook, Narrow	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80802HN-SG	Laminar Hook, Narrow	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80802H-SG	Laminar Hook	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80803H	Pedicle Hook	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80803H-SG	Pedicle Hook	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80803H-SG	Pedicle Hook	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 795844/R			1 MD 0202	Rule 8
801-80804H	Angled Transverse Process Hook, Left	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80804H-SG	Angled Transverse Process Hook, Left	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80805H	Angled Transverse Process Hook, Right	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80805H-SG	Angled Transverse Process Hook, Right	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-80806H	Offset Laminar Hook, Left	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80806HN	Offset Laminar Hook, Narrow, Left	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80807H	Offset Laminar Hook, Right	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-80807HN	Offset Laminar Hook, Narrow, Right	Size 8 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-81000H	Laminar Hook, Extended Body	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-81000H-SG	Laminar Hook, Extended Body	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-81000H-SG	Laminar Hook, Extended Body	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 795844/R			1 MD 0202	Rule 8
801-81001H	Transverse Process Hook	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-81001H-SG	Transverse Process Hook	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-81002H	Laminar Hook	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-81002HN	Laminar Hook, Narrow	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-81002HN-SG	Laminar Hook, Narrow	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-81002H-SG	Laminar Hook	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-81003H	Pedicle Hook	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-81003H-SG	Pedicle Hook	Size 10 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-81101H	Transverse Process Hook	Size 11 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-81101H-SG	Transverse Process Hook	Size 11 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-81103H	Pedicle Hook	Size 11 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R			1 MD 0202	Rule 8
801-81103H-SG	Pedicle Hook	Size 11 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086		2 803328/R			1 MD 0202	Rule 8
801-8555HD	Axial Connector	MESA Rail™	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803331/R			1 MD 0202	Rule 8
801-8555HE	Parallel Connector, Closed	MESA Rail™	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803331/R			1 MD 0202	Rule 8
801-8555HF	Parallel Connector, Open/Closed	MESA Rail™	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803331/R			1 MD 0202	Rule 8
801-8555HWE	Parallel Connector, Open/Closed	Rigid Rail	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803331/R			1 MD 0202	Rule 8
801-8555HWF	Parallel Connector, Open/Closed	Rigid Rail	MESA® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803331/R			1 MD 0202	Rule 8
801-90001	Screw Removal Tool	Size 25	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90003	Rod Pusher		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90004	T-Bar Screw Remover		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90008	Quick Locker		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90024	Guiding Reamer		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90025	Quick Unlocker		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90026	Wedge Distractor		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90027	Compressor		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90028	Distractor		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90029	Screw Insertor		MESA® Spinal System	Interbody Placement	Instrument	44759 IIA	CE0086		6 1332244/R			13 MD 0106	Rule 5
801-90031	Head Adjuster		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90032	Threaded Rod Reducer		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90038	Dual Action Rod Reducer	Dragonfly™	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90046	Rod Puller		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90048	Special Guiding Reamer	Size Ø2.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90050	Parallel Compressor (Lightweight)		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90051	Parallel Distractor (Lightweight)		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90052	Special Screw Remover, w/Handle		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90053	Deformity Screw Insertor		MESA® Spinal System	Interbody Placement	Instrument	44759 IIA	CE0086		6 1332244/R			13 MD 0106	Rule 5
801-90054	Manipulator		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90058	Reduction Jack	Crick™	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90059	Manipulator Wrench		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90060	Partial Locker	Superfly™	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90061	Ratcheting T-Handle, Fine Ratchet (Short)		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90066	Deformity Reduction Jack	Crick™	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90067	Torque Limiting Handle	Size 30 in-lbs (3.4 N-m)	MESA® Spinal System	Pedicle Screw System	Instrument	47830 I(m)	CE0086		7 513674/R			1 MD 0106	Rule 6
801-90068	Reduction Jack, Driver	Size 25	MESA® Spinal System	Interbody Placement	Instrument	44759 IIA	CE0086		6 1332244/R			13 MD 0106	Rule 5
801-90069	Manipulator Wrench		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90070	Rod Puller Plus		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90072	Tap	Size Ø4.0 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90073	Reduction Jack Rotation Tube		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90074	Cobb		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90090	Transverse Coupler	Size (S)	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
801-90091	Transverse Coupler	Size (M)	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R				

Master CE Mark List

Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
K2-08-2368-01	MESA Rail™ Cutter		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2369-01	MESA Rail / Rod Puller	MESA Rail™	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2369-02	MESA Rail / Rod Puller, Sleeve	MESA Rail™	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2369-03	MESA Rail / Rod Puller, Shaft Assembly	MESA Rail™	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2369-09	MESA Rail / Rod Puller, Tip	MESA Rail™	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2370-01	MESA Rail™ Rotation Wrench		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2379-01	Vise Grips	MESA Rai™	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2390-01	MESA Rail™ Connector Holder		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2417-01	Compressor, Angle	MESA Rail™	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2421-01	Compressor, Multi-Span		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2425-01	Torque Limiting Shaft, Square Driver		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2443-02	Insertor Shaft		MESA® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		6 1332244/R			13 MD 0106	Rule 5
K2-08-2443-03	Insertor, Sleeve Assembly		MESA® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		6 1332244/R			13 MD 0106	Rule 5
K2-08-2443-04	Nut-Replacement Part		MESA® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		6 1332244/R			13 MD 0106	Rule 5
K2-08-2453-02	Inner Shaft Assembly		MESA® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		6 1332244/R			13 MD 0106	Rule 5
K2-08-2458-01	Fixed Handle		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2467-01	MESA Hook Forceps		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-08-2480-01	Hook Pusher		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2098-01	Screw Head, Adjuster Assembly	MI	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2099-01	Recovery Tool		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2100-01	Tap Sleeve Guide		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2110-01	Contoured Rod Insertor, Hex Tip		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2111-01	MI Rod Reducer	Praying Mantis™	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2115-01	MI Reamer Coarse		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2115-02	MI Reamer Fine		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2116-01	MI Reamer Sleeve		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2119-01	Rod Pusher		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2196-01	Retractor Pack		SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804504/R			4 MD 0106	Rule 6
K2-10-2198-01	Perfect Scalpel™, Molded Handle		SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804504/R			4 MD 0106	Rule 6
K2-10-2209-01	8G ANGIOTECH Needle Pouch		SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804504/R			4 MD 0106	Rule 6
K2-10-2211-01	Guidewire Pouch	Size Ø1.1 mm SS (Qty 3)	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 151387/R			4 MD 0106	Rule 6
K2-10-2215-01	Pedicle Access Needle, Beveled	Size 11G	SERENGETI® MI Retractor System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804504/R			4 MD 0106	Rule 6
K2-10-2216-01	MI Rod Reducer		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2230-01	Fulcrum, MI Rod Reducer		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-10-2239-01	NITI Guidewire	Size .044 x 20.5 N	DENALI® MI Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
K2-10-2242-01	Quick Connect, Hex Wrench		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
K2-11-2007-01	Unlocker		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2019-01	Screw Head Adjuster	Size 10	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2021-01	Head Adjuster	Mini MESA®	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2022-01	Rod Holding Forceps		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2023-01	DENALI® Mini Screw Insertor	Mini MESA®	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2024-01	Rod Bender	Size Ø3.5 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2026-01	Ball Tip Feeler		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2027-01	Awl		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	15275 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2028-01	Tap	Size Ø3.5 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2029-01	Reamer	Size Ø4.0 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2030-01	Reamer		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2031-01	Distractor		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2032-01	Compressor		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2035-01	Small Pedicle Probe		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2037-01	Mini Axial AO Handle, Ratchet		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2038-01	Mini Axial AO Handle, Fixed		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2040-01	In Situ Bender (Left)		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2041-01	DENALI® Mini Screw Insertor	Mini DENALI®	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2042-01	Torque Limiting Driver	Size 15	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2044-01	Torque Driver, Tapered	Size 15	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2047-01	Tapered Double Ended Driver	Size 15	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2048-01	Torsional Rod Reducer (Right)		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2049-01	Torsional Rod Reducer (Left)		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2051-01	Rod Reducer		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2052-01	Head Adjuster	Standard	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2053-01	Adjustable Drill	Size Ø3.5 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	36235 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2053-02	Adjustable Drill	Size Ø4.0 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	36235 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2054-01	Adjustable Drill Guide	Size 6-50 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2056-01	Fixed Drill Guide		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2057-01	Anti Torque Alignment Tube		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2058-01	Rod Puller Plus		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2059-01	Hook Holder	Cervical	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2078-01	Universal Driver		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2079-01	Universal Joint Tap	Size Ø4.5 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2082-01	Torque Limiting Handle	Size 30 in-lbs (3.4 N-m) AO Connect	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	47830 I(lm)	CE0086		7 513674/R			6 MD 0106	Rule 6
K2-11-2083-01	In Situ Bender (Right)		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2084-01	Tap		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2091-01	Universal Joint Drill	Size Ø3.0 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	36235 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2097-01	Occipital Plate Bender (Long)		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2097-02	Occipital Plate Bender (Short)		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2098-01	Tap	Size Ø4.5 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2109-01	Forceps Rod Fork		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2111-01	Mini Reduction Jack	Mini Cricket™	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2112-01	Rod Holder		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2118-01	DENALI® Mini Screw Alignment Guide	Mini DENALI™	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
K2-11-2119-01	Ø 2.3 Fixed Drill Bit	Size 12 mm-118° Tip	CASPIAN® Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
K2-11-2129-02	Ø 2.3 Fixed Drill Bit	Size 14 mm-118° Tip	CASPIAN® Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
K2-11-2129-04	Ø 2.3 Fixed Drill Bit	Size 16 mm-118° Tip	CASPIAN® Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
K2-29-2001-02	Provisional Screwdriver (Long)	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2002-01	Rod Reducer	Cicada™	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2003-01	Threaded Rod Reducer		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2005-01	Rod Fork		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2006-01	Head Adjuster		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2007-01	Lateral Hook Holder		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2008-01	Offset Hook Holder		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2009-01	Rod Pusher		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2010-01	Torque Indicating Wrench	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	50600 (I)M	CE0086		8 513674/R	1 MD 0106		Rule 6	
K2-29-2012-01	Anti-Torque Alignment Tube (Short)		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2013-01	Torque Limiting Shaft (Long)	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2014-01	Torque Wrench	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2014-02	Torque Wrench Tip	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2015-01	Screw Removal Tool	Size 25	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2016-01	Quick Connect Adapter, Rod Reducer		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2025-01	Polyaxial Screw Insertor (Short)		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2029-01	French Rod Bender	Size Ø5.5-6.0 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2030-01	Visc Grips, Rod	Size Ø6.0 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2031-01	Hook Pusher		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2032-01	Hook Seater		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2033-01	Lumbar Hook Elevator, Straight		EVEREST® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R	13 MD 0106		Rule 6	
K2-29-2034-01	Lumbar Hook Elevator, Angled		EVEREST® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R	13 MD 0106		Rule 6	
K2-29-2035-01	Threaded Rod Reducer		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2044-01	Rod Fork		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2060-01	Provisional Screwdriver (Short)	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2060-02	Provisional Screwdriver (Long)	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2065-01	Tapered Tap	Size Ø9.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2065-02	Tapered Tap	Size Ø10.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2067-01	Anti-Torque Alignment Tube, Closed screw (Short)		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2075-01	Polyaxial Screw Insertor, Closed screw (Short)		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-29-2075-02	Polyaxial Screw Insertor, Closed screw (Long)		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2001-01	Unlocker		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2002-01	Screw Insertor		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2003-01	Tap	Size Ø3.0 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2003-02	Tap	Size Ø3.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2003-03	Tap	Size Ø4.0 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2003-04	Tap	Size Ø4.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2003-05	Tap	Size Ø5.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2003-06	Tap	Size Ø6.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2004-01	Locker		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2005-01	MESA Rail™ Cutter	Size Ø4.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2006-01	A/O Quick Knob		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2007-01	Awl	Size Ø2.75 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2008-01	Screw Head Adjuster		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2009-01	Depth Gauge	Size 80 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	32045 (I)M	CE0086		7 513674/R	1 MD 0106		Rule 6	
K2-30-2010-01	Guiding Reamer		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2011-01	Wedge Distractor		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2012-01	Reduction Jack Rotation Tube, w/Driver		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2013-01	Distractor		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2014-01	Compressor		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2015-01	Rod Rotation Wrench	Size Ø4.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2016-01	In Situ Bender (Right)		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2017-01	In Situ Bender (Left)		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2018-01	Torsional Rod Reducer (Right)		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2019-01	Torsional Rod Reducer (Left)		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2020-01	Tapered Driver	Size 20	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2021-01	Manipulator		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2022-02	MESA Rail / Rod Puller, Sleeve	MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2022-03	MESA Rail / Rod Puller, Shaft Assembly	MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2022-09	MESA Rail / Rod Puller, Tip	MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2023-01	Deformity Reduction Jack		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2024-01	Partial Locker		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2025-01	Dual Action Rod Reducer	Size Ø4.5 mm, Dragonfly™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2026-01	Pedicle Hook Trial	Size 4 mm	MESA® Small Stature Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R	13 MD 0106		Rule 6	
K2-30-2026-02	Pedicle Hook Trial	Size 8 mm	MESA® Small Stature Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R	13 MD 0106		Rule 6	
K2-30-2027-01	Hook Elevator		MESA® Small Stature Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R	13 MD 0106		Rule 6	
K2-30-2028-02	Threaded Hook Insertor, Outer Assembly		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2028-05	Threaded Hook Insertor, Inner Assembly		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2029-01	Single Action Rod Reducer	Firefly™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2030-01	Hook Pusher		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2031-01	Straight Hook Holder		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2032-01	Offset Hook Holder		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2033-01	Saddle Hook Holder		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2034-01	Lateral Hook Holder		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2035-01	Anti-Torque Alignment Tube		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2036-01	Torque Limiting Handle	Size 6 N-m	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	47830 (I)M	CE0086		7 513674/R	1 MD 0106		Rule 6	
K2-30-2037-01	Rod Holding Forceps	Size Ø4.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2038-01	Double Ended Ball Tip Feeler		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2039-01	Straight Throacic Probe		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2040-01	Visc Grips	Size Ø4.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2041-01	Coronal Bender (Left)	Size Ø4.5 mm, MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2042-01	Coronal Bender (Right)	Size Ø4.5 mm, MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2043-01	Partial Locker	MESA Rail™	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2044-01	Reduction Jack		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2045-01	Transverse Connector Calipers		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	32262 (I)M	CE0086		7 513674/R	1 MD 0106		Rule 6	
K2-30-2046-01	Parallel Distractor (Wide)	Size Ø4.5 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
K2-30-2049-01	Rod Fork		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 010			

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
SP-1107	Polyaxial Screw Inserter		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1107-01	Driver Shaft		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1108	Polyaxial Screw Inserter		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1108-01	Driver Shaft		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1112-01	Angled Blade	Size 23x60 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1112-02	Angled Blade	Size 23x70 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1112-03	Angled Blade	Size 23x80 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1112-04	Retractor/Distractor	Size 70 mm, Medium	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1112-05	Retractor/Distractor	Size 90 mm, Small	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1112-06	Retractor/Distractor	Size 90 mm, Medium	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1112-07	Retractor/Distractor	Size 90 mm, Large	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1118	MESAS® Mini 90° Screw Inserter		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
SP-1120-01	Curved Probe		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1120-02	Straight Probe		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1120-03	Thoracic Probe		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1120-04	Thoracic Probe		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1120-05	Awl	Long	MESA® Spinal System	Pedicle Screw System	Instrument	15275 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1120-06	Head Adjuster		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1120-07	Rod Pusher		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1128	Tap	Size Ø4.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1129	PLL Cutter		LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1130-01	Saw Blade	Size 50 mm	LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1130-02	Saw Blade	Size 70 mm	LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1130-03	Saw Blade	Size 100 mm	LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1131	Wire Saw	Handle	LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1132	Rod Flexer		LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1134-01	Retractor Blade	Size 13" x 1-1/4"	LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	35315 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1134-02	Retractor Blade	Size 13" x 2"	LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	35315 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1134-03	Retractor Blade	Size 13" x 3"	LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	35315 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1135	Unlocker		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1142	Distractor		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1145-01	Retractor/Distractor	Size 20-27.5 mm 2-Level	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1145-02	Retractor/Distractor	Size 30-47.5 mm 2-Level	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1145-03	Retractor/Distractor	Size 40-67.5 mm 2-Level	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1158-01	Dual Action Rod Reducer		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1166	Scraper, Bayoneted		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1170-01	Thoracic Probe		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1170-02	Straight Lumbar Probe		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1177	Torque Indicating Wrench	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	50009 I(m)	CE0086		7 513674/R			1 MD 0106	Rule 6
SP-1178	Rod Reducer		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1179	Collar Retrieval Tool		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1181	Flat Cobb Elevator	No slip	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1182	Elevator	Shovel nose	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1183	Collar Retrieval Tool		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1189	Insertor		LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1190	Collar Retrieval Tool		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1198	Collar Retrieval Tool		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1216	Canulated Reamer		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1217	Quick Locker		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1223-01	Curette	Size #3 Straight Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13133 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1223-02	Curette	Size #3 Straight Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13133 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1223-03	Curette	Size #4 Straight Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13133 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1223-04	Curette	Size #4 Straight Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13133 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1223-05	Curette	Size #3 Angle Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13133 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1223-06	Curette	Size #3 Angle Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13133 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1223-07	Curette	Size #4 Angle Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13133 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1223-08	Curette	Size #4 Angle Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13133 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1224-01	TULF II Trial	Size 10x28x6 mm 7"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1224-02	TULF II Trial	Size 10x28x7 mm 7"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1224-03	TULF II Trial	Size 10x28x8 mm 7"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1224-04	TULF II Trial	Size 10x28x9 mm 7"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1224-05	TULF II Trial	Size 10x28x10 mm 7"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1224-06	TULF II Trial	Size 10x28x11 mm 7"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1224-07	TULF II Trial	Size 10x28x12 mm 7"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1224-08	TULF II Trial	Size 10x28x13 mm 7"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1224-09	TULF II Trial	Size 10x28x14 mm 7"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1224-10	TULF II Trial	Size 10x28x15 mm 7"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1226	Probe		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1235	Spring Loaded Awl		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	15275 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1236	Osteotome		LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1237	Osteotome		LURAY™ Corpectomy Cage System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1238	Rasp	Size 8 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1239	Rasp	Size 8 mm, Angled Up	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1244	Rasp	Size 8 mm, Angled Down	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1258	Awl		MESA® Spinal System	Pedicle Screw System	Instrument	15275 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1259	Thoracic Probe	Short	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1260	Straight Lumbar Probe		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1261-02	Insertor Shaft	Size Uniplanar	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1261-03	Insertor, Sleeve Assembly		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1261-04	Insertor Nut		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1262-02	Insertor Shaft		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1264-01	Trial	Barracuda Tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1264-02	Trial	Size 9 mm Connector	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1264-03	Trial	Size 11 mm Connector	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1264-04	Trial	Size 13 mm Connector	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1264-05	Trial	Size 15 mm Connector	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1264-06	Trial	Size											

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
SP-1472	Curved Probe		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1474	Rotation Tube, Spring Loaded		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1483-01	Angled Blade	Size 25', 50 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1483-02	Angled Blade	Size 30', 50 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1483-03	Angled Blade	Size 40', 50 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1483-04	Angled Blade	Size 25', 60 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1483-05	Angled Blade	Size 30', 60 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1483-06	Angled Blade	Size 40', 60 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1483-07	Angled Blade	Size 25', 70 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1483-08	Angled Blade	Size 30', 70 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1483-09	Angled Blade	Size 40', 70 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1486	Bone Packing Mold		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1487	Screw Alignment Guide		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1496-01	Serrated Curette	Size Up 30" #2	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1496-02	Serrated Curette	Size Up 30" #4	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1498-01	Osteotome	Flat, Long	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1498-02	Osteotome	Curved, Long	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1503-01	Wood Dilator Pin	Size 19 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1503-02	Wood Dilator Pin	Size 25 mm	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1507	MI Rod Reducer		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1513	Driver		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1521	Hook Pusher		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1552-01	Tapered Tap	Size Ø5.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1552-02	Tapered Tap	Size Ø6.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1552-03	Tapered Tap	Size Ø7.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1552-04	Tapered Tap		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1555	Blade Handle		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1555-01	Blade Handle		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1555-02	Blade Handle		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE			8 513670/R		8 MD 0106	Rule 6
SP-1568	Locker	Threaded	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1569	Anti Torque Handle		MESA® Spinal System	Pedicle Screw System	Instrument	47830 (I)m	CE0086			7 513674/R		1 MD 0106	Rule 6
SP-1585-01	Tap, Special Connector	Size Ø4.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1585-02	Tap, Special Connector	Size Ø5.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1585-03	Tap, Special Connector	Size Ø6.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1585-04	Tap, Special Connector	Size Ø7.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1585-05	Tap, Special Connector	Size Ø8.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1610	Hook Holder	Size 120 in-lbs	MESA® Spinal System	Torque Wrench	Instrument	59099 (I)m	CE0086			7 513674/R		1 MD 0106	Rule 6
SP-1611-01	Rod Template	Base	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1611-02	Rod Template	Top 70 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1611-03	Rod Template	Top 120 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1611-04	Rod Template	Top 240 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1620	Awl	With impactor cap	MESA® Spinal System	Pedicle Screw System	Instrument	15275 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1621-01	X-Ray Marker (Left)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1621-02	X-Ray Marker (Right)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1632	Hook Holder		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1634-01	Hook Holder		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1639	Rod Bender		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1640	Insertor	Size 12 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1658	Driver	Size 20 Non Tapered	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1666-01	Tapered Tap	Size Ø4.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1666-02	Tapered Tap	Size Ø5.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1666-03	Tapered Tap	Size Ø6.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1666-04	Tapered Tap	Size Ø7.5 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1691-01	Straight Probe	Straight	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1691-02	Curved Probe		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1693	Curved Probe		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1700-01	Drill Guide	Size 6 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1700-02	Drill Guide	Size 7 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1711-01	Distraction, Right		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	35315 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1711-02	Distraction, Left		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1711-03	Distraction, Right		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1711-04	Distraction, Left		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	35315 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1711-05	Distraction, Right		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	61300 Ila	CE0086			4 804504/R		12 MD 0106	Rule 6
SP-1722	Slap Hammer Assembly (Long)	Size 14 mm Caspar	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	35315 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-173-01	Tap Sleeve		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1749	X-Ray Marker (Left)		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1755	Reduction Jack	Modular	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1761	MESA® Mini Screw Insertor	Special Adapter	CASPIAN® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086			6 1332244/R		13 MD 0106	Rule 5
SP-1802-01	Disc Scraper	Size 7 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1802-02	Disc Scraper	Size 8 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1802-03	Disc Scraper	Size 9 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1802-04	Disc Scraper	Size 10 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1802-05	Disc Scraper	Size 11 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1802-06	Disc Scraper	Size 12 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1802-07	Disc Scraper	Size 13 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1802-08	Disc Scraper	Size 14 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1802-09	Disc Scraper	Size 15 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1802-10	Disc Scraper	Size 16 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE			8 513670/R		3 MD 0106	Rule 6
SP-1804	Reduction Jack	Size 5.5 mm Rail Easy Clean	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1805	Reduction Jack, Driver	Size 20	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1821	Tapered Driver	Size 25	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1824-01	Awl		EVEREST® Spinal System	Pedicle Screw System	Instrument	15275 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1828-01	MI Single Action Anti-Torque, Rod Reducer	Size Anti Torque Rod Reducer	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1833	Tensioning Instrument		NILE™ Alternative Fixation System	Interbody Systems	Instrument	13180 I	CE			8 513670/R		1 MD 0106	Rule 6
SP-1838	Torque Limiting Shaft	W/ Wings	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	59009 (I)m	CE0086			7 513674/R		3 MD 0106	Rule 6
SP-1839-01	Flex Shaft Non-tapered Driver	Size 20, 90"	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I	CE			8 513670/R		5 MD 0106	Rule 6
SP-1839-02	Flex Shaft Tapered Driver	Size 20, 90"	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I	CE						

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
SP-1984-08	MESA 2 Tap	Size 7.0 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-1984-09	MESA 2 Tap	Size 7.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-1984-10	MESA 2 Tap	Size 8.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-1984-11	MESA 2 Tap	Size 9.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-1984-12	MESA 2 Tap	Size 10.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-1984-13	MESA 2 Tap	Size 11.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-1984-14	MESA 2 Tap	Size 12.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-1997	Modular Screw Inserter		DENALI® Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		6 1332244/R		13 MD 0106	Rule 5	
SP-1998	Straight Curette		DENALI® Spinal System	Pedicle Screw System	Instrument	31335 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-1999-01	Straight Probe	Large T-Handle	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-1999-02	Curved Probe	Large T-Handle	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2001	Special Ball Tip Probe		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2002-01	Pedicle Marker	Left	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2002-02	Pedicle Marker	Right	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2003	Anti-Splay Tube		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2004	Handle Extension	MESA Locker	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2008	Scraper		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2009-01	Double Sided Rasp	Size 8 mm, Short	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2009-02	Double Sided Rasp	Size 5 mm, Short	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2013-01	Retractor	PENFIELD L-Shaped 10 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	35315 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2013-02	Retractor	PENFIELD L-Shaped 5 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	35315 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2014-01	Retractor	PENFIELD Bayonetted 10 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	35315 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2014-02	Retractor	PENFIELD Bayonetted 5 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	35315 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2015	Retractor	Penfield (Wide)	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	35315 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2018	Anti-Splay Tube		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2025	Tap Sleeve	With Window	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2027	Ball Tip Feeler	Size Small	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2028	Small Pedicle Probe		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		6 MD 0106	Rule 6
SP-2030-01	Tapered Tap	Size Ø3.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2030-02	Tapered Tap	Size Ø4.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2030-03	Tapered Tap	Size Ø5.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2030-04	Tapered Tap	Size Ø6.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2030-05	Tapered Tap	Size Ø7.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2030-06	Tapered Tap	Size Ø8.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2031-01	Packing Tamp	Size 3 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2031-02	Packing Tamp	Size 4 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2031-03	Packing Tamp	Size 3 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2037	Straight Lumbar Probe	Long	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2039	Non-Ratcheting Axial Handle		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2041	Straight Pusher		CASCADIA™ Interbody System	Interbody Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2063-01	Head Adjuster	Dia 5.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2063-02	Head Adjuster	Dia 4.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2065	Head Adjuster		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2080	Rod Bender	Dual Action	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2086-01	Pyramid Awl (long)	No Stop	MESA® Spinal System	Pedicle Screw System	Instrument	15275 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2086-02	Pyramid Awl (short)	No Stop	MESA® Spinal System	Pedicle Screw System	Instrument	15275 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2087	Rod Holder		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-2092-01	Curette	#1 Straight	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2092-02	Curette	#0 Straight	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2092-03	Curette	#1 Angled	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2092-04	Curette	#0 Angled	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2093-01	Rod Bender	Right	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		6 MD 0106	Rule 6
SP-2093-02	Rod Bender	Left	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		6 MD 0106	Rule 6
SP-2126	Insertor		CASCADIA™ Interbody System	Interbody Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-2359	Wool Dilator Pin	Pin	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-321	Deformity Screw Inserter	Size Short	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-381	Handle	Teardrop 1/4 in. Quick Connect	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-489	Thoracic Probe	Extended	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-493	Pusher		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-494	Cortical Tap Quick Connect	Size 5.0 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-496	Cortical Tap Quick Connect	Size Ø6.0 mm	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-51	Awl		DENALI® Spinal System	Pedicle Screw System	Instrument	15275 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-512	Rongeur	Size 6 mm Straight Kerrison	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		2 MD 0106	Rule 6
SP-513	Rongeur	Size 4 mm Straight Kerrison	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		2 MD 0106	Rule 6
SP-514	Rongeur	Size 6 mm Angled Kerrison	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		2 MD 0106	Rule 6
SP-515	Rongeur	Size 4 mm Angled Kerrison	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		2 MD 0106	Rule 6
SP-516	Angled Curette	Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-517	Angled Curette	Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R	6 1332244/R		3 MD 0106	Rule 6
SP-520	Rod Template		NITINOL		Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-536	Nerve Root Retractor		DENALI® MI Spinal System	Pedicle Screw System	Instrument	35315 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-537	Stylet		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-538	Outer Dilator		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-539	K-Wire Driver	For .044 Dia. Guide Wire	DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-543	Anti Torque Handle		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-580	Tap	6.5 Screw	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-584	Straight Probe	Diamond Probe	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-621	Distractor		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		6 MD 0106	Rule 6
SP-622	Compressor		CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R	6 1332244/R		6 MD 0106	Rule 6
SP-625	MI Rod Inserter		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-653-01	Tissue Retractor		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-653-02	Fixation Pin		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-653-10	Nerve Root Retractor	Size (10 mm) Blade Assembly	MESA® Spinal System	Pedicle Screw System	Instrument	35315 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-653-15	Nerve Root Retractor	Size (20 mm) Blade Assembly	MESA® Spinal System	Pedicle Screw System	Instrument	35315 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-653-20	Nerve Root Retractor	Size (25 mm) Blade Assembly	MESA® Spinal System	Pedicle Screw System	Instrument	35315 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-653-35	Nerve Root Retractor	Size (30 mm) Blade Assembly	MESA® Spinal System	Pedicle Screw System	Instrument	35315 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-654	Straight Probe		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-655	Curved Probe		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-656	Depth Gauge		MESA® Spinal System	Pedicle Screw System	Instrument	32845 I(jm)	CE0086		7 1332244/R		1 MD 0106	Rule 6	
SP-661	Tap	6.5 Screw	DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-671	Stylet		DENALI® MI Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	6 1332244/R		1 MD 0106	Rule 6
SP-704	Retractor/Distractor		TERRA NOVA® MI Access System	Interbody Access System	Instrument	35315 I	CE		8 513670/R	6 1332244/R		8 MD 0106	Rule 6
SP-705	Angled Blade	Size 50x50 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE	</					

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
SP-2426	Straight Hook Holder	Long	DENALI* Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2405	Rasp	Tapered	SAHARA* Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2448	T-Handle Wrench		CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2380	Plate Holder, Buttress		CAYMAN* Plate System	Cayman Plate System	Instrument	13180 I	CE		8 513670/R			5 MD 0106	Rule 6
SP-2424	Awl	20mm	CAYMAN* Plate System	Cayman Plate System	Instrument	13180 I	CE		8 513670/R			5 MD 0106	Rule 6
SP-2425	Tapered Driver	Size 25	CAYMAN* Plate System	Cayman Plate System	Instrument	13180 I	CE		8 513670/R			5 MD 0106	Rule 6
5101-90065	Add On Kit, Retractors/Wires	Size Ø1.3 mm (Qty 2 ea) SS	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90066	Add On Kit, Retractors/Wires	Size Ø1.3 mm (Qty 2 ea) NITI	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90068	Add On Kit, Retractors/Wires	Size Ø1.4 mm (Qty 2 ea) NITI	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90069	Add On Kit, Retractors/Wires, Beveled	Size Ø1.3 mm (Qty 2 ea) SS	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90070	Add On Kit, Retractors/Wires, Beveled	Size Ø1.3 mm (Qty 2 ea) NITI	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90071	Add On Kit, Retractors/Wires, Beveled	Size Ø1.4 mm (Qty 2 ea) SS	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90072	Add On Kit, Retractors/Wires, Beveled	Size Ø1.4 mm (Qty 2 ea) NITI	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90073	Add On Kit, Retractors/Wires, Beveled	Size Ø1.5 mm (Qty 2 ea) SS	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90074	Add On Kit, Retractors/Wires, Beveled	Size Ø1.5 mm (Qty 2 ea) NITI	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90075	1 Level Kit, Retractors/Wires	Size Ø1.3 mm (Qty 4 ea) SS	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90076	1 Level Kit, Retractors/Wires	Size Ø1.3 mm (Qty 4 ea) NITI	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90078	1 Level Kit, Retractors/Wires	Size Ø1.4 mm (Qty 4 ea) NITI	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90079	1 Level Kit, Retractors/Wires, Beveled	Size Ø1.3 mm (Qty 4 ea) SS	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90080	1 Level Kit, Retractors/Wires, Beveled	Size Ø1.3 mm (Qty 4 ea) NITI	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90081	1 Level Kit, Retractors/Wires, Beveled	Size Ø1.4 mm (Qty 4 ea) SS	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90082	1 Level Kit, Retractors/Wires, Beveled	Size Ø1.4 mm (Qty 4 ea) NITI	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90083	1 Level Kit, Retractors/Wires, Beveled	Size Ø1.5 mm (Qty 4 ea) SS	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
5101-90084	1 Level Kit, Retractors/Wires, Beveled	Size Ø1.5 mm (Qty 4 ea) NITI	EVEREST* Spinal System	Sterile Instrument System	Instrument	44052 Ila	CE0086		5 804514/R			4 MD 0106	Rule 6
SP-1434	Anterior Pituitary Rounger	Size 13* 2 mm	ALEUTIAN* Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
4508-90147	Self Retaining Screw Inserter		CAYMAN* Plate System-MI	Cayman Plate System	Instrument	13180 I	CE		8 513670/R			5 MD 0106	Rule 6
SP-1489	Screw Inserter	Short w/AO Connect	MESA* Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1436	Quick Connect Adapter		EVEREST* Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
5101-90104	Cannulated, Modular Screw Inserter- Tabbed Screw		EVEREST* Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-1534	Lateral Access Retractor		RAVINE** Lateral Access System	Interbody Access System	Instrument	8 513670/R	CE		8 513670/R			8 MD 0106	Rule 6
801-90208	Compressor, Multi-Span		MESA* Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1561	Fixation Pin Driver		TERRA NOVA* MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-1566-01	Distractor	Size 7 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1566-02	Distractor	Size 9 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1566-03	Distractor	Size 11 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1566-04	Distractor	Size 13 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1566-05	Distractor	Size 15 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1566-06	Distractor	Size 17 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1566-07	Distractor	Size 19 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1566-08	Distractor	Size 21 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1598	Pedicle Probe		EVEREST* Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
5908-42F30	Plate, 2 Level	Size 30 mm	PYRENEES* Cervical Plate System	Cervical Plate System	Implant	61325 Iib	CE0086		1 804494/R			2 MD 0202	Rule 8
5908-42F31	Plate, 2 Level	Size 31 mm	PYRENEES* Cervical Plate System	Cervical Plate System	Implant	61325 Iib	CE0086		1 804494/R			2 MD 0202	Rule 8
SP-1654	Modular Partial Locker		CASPIAN* Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
SP-1715	Rod Puller 1/8		CASPIAN* Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
SP-1668-01	Universal Drill	Size 20 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	36235 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1668-02	Universal Drill	Size 25 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	36235 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1668-03	Universal Drill	Size 30 mm	CHESAPEAKE* Stabilization System	Interbody Systems	Instrument	36235 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1648	Modular Locker		CASPIAN* Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
SP-1650	Modular Unlocker		CASPIAN* Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
6301-90002	Multi-Level Clip		CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90004	Cortical Blade	Size 40 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90005	Cortical Blade	Size 50 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90006	Cortical Blade	Size 60 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90007	Cortical Blade	Size 70 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90008	Cortical Blade	Size 80 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90009	Cortical Blade	Size 90 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90010	Cortical Blade	Size 100 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90011	Cortical Blade	Size 110 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90012	Narrow Cortical Blade	Size 40 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90013	Narrow Cortical Blade	Size 50 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90014	Narrow Cortical Blade	Size 60 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90015	Narrow Cortical Blade	Size 70 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90016	Narrow Cortical Blade	Size 80 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90017	Narrow Cortical Blade	Size 90 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90018	Narrow Cortical Blade	Size 100 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90019	Narrow Cortical Blade	Size 110 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90020	Angled Cortical Blade, Left	Size 40 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90021	Angled Cortical Blade, Left	Size 50 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90022	Angled Cortical Blade, Left	Size 60 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90023	Angled Cortical Blade, Left	Size 70 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90024	Angled Cortical Blade, Left	Size 80 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90025	Angled Cortical Blade, Left	Size 90 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90026	Angled Cortical Blade, Left	Size 100 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90027	Angled Cortical Blade, Left	Size 110 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90028	Angled Cortical Blade, Right	Size 40 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90029	Angled Cortical Blade, Right	Size 50 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90030	Angled Cortical Blade, Right	Size 60 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90031	Angled Cortical Blade, Right	Size 70 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90032	Angled Cortical Blade, Right	Size 80 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90033	Angled Cortical Blade, Right	Size 90 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90034	Angled Cortical Blade, Right	Size 100 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
6301-90035	Angled Cortical Blade, Right	Size 110 mm	CANYON** Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R				

Master CE Mark List

Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
811-H556007-250	Dual Transition Rail	Size 05.5x600, 250 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 lib	CE0086		1 803307/R			1 MD 0202	Rule 8
811-H556007-275	Dual Transition Rail	Size 05.5x600, 275 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 lib	CE0086		1 803307/R			1 MD 0202	Rule 8
811-H556007-300	Dual Transition Rail	Size 05.5x600, 300 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 lib	CE0086		1 803307/R			1 MD 0202	Rule 8
811-H556007-325	Dual Transition Rail	Size 05.5x600, 325 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 lib	CE0086		1 803307/R			1 MD 0202	Rule 8
811-H556007-350	Dual Transition Rail	Size 05.5x600, 350 mm	MESA® Spinal System	Pedicle Screw System	Implant	61325 lib	CE0086		1 803307/R			1 MD 0202	Rule 8
SP-2100-01	Parallel Distractor	size 18 mm x 50 mm x 4 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2100-02	Parallel Distractor	size 18 mm x 50 mm x 4 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2100-03	Parallel Distractor	size 18 mm x 60 mm x 4 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2100-04	Parallel Distractor	size 18 mm x 50 mm x 4 mm Angled	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2101-02	Parallel Distractor	size 18 mm x 50 mm x 6 mm Angled	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2101-03	Parallel Distractor	size 18 mm x 60 mm x 4 mm Angled	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2101-04	Parallel Distractor	size 18 mm x 60 mm x 6 mm Angled	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
4601-90036	Manipulator	Plug	KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2102	Deformity Rod Reducer		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2103-01	Transverse Coupler	Size Small	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2103-02	Transverse Coupler	Size Medium	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2103-03	Transverse Coupler	Size Large	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2006-01	Removable Distractor, Left Tip	Knurled Angled Tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2006-02	Removable Distractor, Right Tip	Knurled Angled Tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2006-03	Removable Distractor, Right Tip	Long Angled Tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2006-04	Removable Distractor, Left Tip	Long Angled Tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2006-05	Removable Distractor, Right Tip	Forward Angled Tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2006-06	Removable Distractor, Left Tip	Forward Angled Tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2040	Straight Lumbar Probe		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2062	Nerve Root Retractor		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	35315 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2088	Tip	Size 05.0 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2089	Tip	Size: 6.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
5901-14524C	Screw, Self-Tapping	Size 04.5x24 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-14526C	Screw, Self-Tapping	Size 04.5x26 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-14724C	Screw, Self-Tapping	Size 04.75x24 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-14726C	Screw, Self-Tapping	Size 04.75x26 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-15024C	Screw, Self-Tapping	Size 05.0x24 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-15026C	Screw, Self-Tapping	Size 05.0x26 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-14524D	Screw, Self-Tapping	Size 04.5x24 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-14526D	Screw, Self-Tapping	Size 04.5x26 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-14724D	Screw, Self-Tapping	Size 04.75x24 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-14726D	Screw, Self-Tapping	Size 04.75x26 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-15024D	Screw, Self-Tapping	Size 05.0x24 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
5901-15026D	Screw, Self-Tapping	Size 05.0x26 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Implant	61325 lib	CE0086		1 804494/R			2 MD 0202	Rule 8
SP-2119-01	Straight Blade	Size: 23x40 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2119-02	Straight Blade	Size: 23x50 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2119-03	Straight Blade	Size: 23x60 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2119-04	Straight Blade	Size: 23x70 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2119-05	Straight Blade	Size: 23x80 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2119-06	Straight Blade	Size: 23x90 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2119-07	Straight Blade	Size: 23x100 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2119-08	Straight Blade	Size: 23x110 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2119-09	Straight Blade	Size: 23x120 mm	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2115-01	Parallel Rasp	Size: 18x45x6 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-02	Parallel Rasp	Size: 18x45x7 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-03	Parallel Rasp	Size: 18x45x8 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-04	Parallel Rasp	Size: 18x45x9 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-05	Parallel Rasp	Size: 18x45x10 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-06	Parallel Rasp	Size: 18x45x11 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-07	Parallel Rasp	Size: 18x45x12 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-08	Parallel Rasp	Size: 18x45x13 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-09	Parallel Rasp	Size: 18x45x14 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-10	Parallel Rasp	Size: 18x45x15 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-11	Parallel Rasp	Size: 18x45x16 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-12	Parallel Rasp	Size: 18x45x17 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-13	Parallel Rasp	Size: 18x45x18 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2115-14	Parallel Rasp	Size: 18x45x19 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2117-01	Box Cutter	Size: 6 mm Shaft	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2117-02	Box Cutter	Size: 8 mm Shaft	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2117-03	Box Cutter	Size: 10 mm Shaft	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2116-04	Box Cutter	Size: 12 mm Shaft	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 lib	CE0086		3 1332244/R			13 MD 0106	Rule 6
SP-2139	Anti Torque Alignment Tube		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2140	Awl, Stop		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2104	Blade Holder, Retractor	W/ Fixed Axial Handle	TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2055	Screw Based Distractor		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2148	Probe	With Inner Stylet	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2141	Parallel Compressor	05.5/06.0 mm, 0-40 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2026	Locking Screw Insert	Closed Tip	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2131	Ball Tip Feeler	Size: 1.5mm Ball	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2138-01	Tapered Thread Tap, Cannulated	Size: 04.0 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2138-02	Tapered Thread Tap, Cannulated	Size: 04.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2138-03	Tapered Thread Tap, Cannulated	Size: 05.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2138-04	Tapered Thread Tap, Cannulated	Size: 06.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2138-05	Tapered Thread Tap, Cannulated	Size: 07.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2138-06	Tapered Thread Tap, Cannulated	Size: 08.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2129-01	Straight Curette	Size: #2	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
E5112-38590T	Uniplanar Screw, Extended Tab, Transverse, Fenestrated	Size Ø8.5x90 mm	EVEREST® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803267/R		1 MD 0202		Rule 8	
E5112-38595T	Uniplanar Screw, Extended Tab, Transverse, Fenestrated	Size Ø8.5x95 mm	EVEREST® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803267/R		1 MD 0202		Rule 8	
E5112-385100T	Uniplanar Screw, Extended Tab, Transverse, Fenestrated	Size Ø8.5x100 mm	EVEREST® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803267/R		1 MD 0202		Rule 8	
E5112-385105T	Uniplanar Screw, Extended Tab, Transverse, Fenestrated	Size Ø8.5x105 mm	EVEREST® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803267/R		1 MD 0202		Rule 8	
E5112-385110T	Uniplanar Screw, Extended Tab, Transverse, Fenestrated	Size Ø8.5x110 mm	EVEREST® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803267/R		1 MD 0202		Rule 8	
7501-90002	Footprint Trial	Size 12x14/13x16 mm	CAPRI™ Corpectomy Cage System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
7501-90003	Footprint Trial	Size 14x18/16x20 mm	CAPRI™ Corpectomy Cage System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90607	Horseshoe Trial, Parallel	Size 11.5x16x5 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90608	Horseshoe Trial, Parallel	Size 11.5x16x6 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90609	Horseshoe Trial, Parallel	Size 11.5x16x7 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90610	Horseshoe Trial, Parallel	Size 11.5x16x8 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90611	Horseshoe Trial, Parallel	Size 11.5x16x9 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90612	Horseshoe Trial, Parallel	Size 11.5x16x10 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90613	Horseshoe Trial, Parallel	Size 11.5x16x11 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90614	Horseshoe Trial, Parallel	Size 11.5x16x12 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90615	Horseshoe Trial, Parallel	Size 11.5x16x13 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90616	Horseshoe Trial, Parallel	Size 11.5x16x14 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90617	Horseshoe Trial, Parallel	Size 11.5x16x15 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90618	Horseshoe Trial, Parallel	Size 12.5x18x5 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90619	Horseshoe Trial, Parallel	Size 12.5x18x6 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90620	Horseshoe Trial, Parallel	Size 12.5x18x7 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90621	Horseshoe Trial, Parallel	Size 12.5x18x8 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90622	Horseshoe Trial, Parallel	Size 12.5x18x9 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90623	Horseshoe Trial, Parallel	Size 12.5x18x10 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90624	Horseshoe Trial, Parallel	Size 12.5x18x11 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90625	Horseshoe Trial, Parallel	Size 12.5x18x12 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90626	Horseshoe Trial, Parallel	Size 12.5x18x13 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90627	Horseshoe Trial, Parallel	Size 12.5x18x14 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90628	Horseshoe Trial, Parallel	Size 12.5x18x15 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90629	Horseshoe Trial, Parallel	Size 12.5x20x5 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90630	Horseshoe Trial, Parallel	Size 12.5x20x6 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90631	Horseshoe Trial, Parallel	Size 12.5x20x7 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90632	Horseshoe Trial, Parallel	Size 12.5x20x8 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90633	Horseshoe Trial, Parallel	Size 12.5x20x9 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90634	Horseshoe Trial, Parallel	Size 12.5x20x10 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90635	Horseshoe Trial, Parallel	Size 12.5x20x11 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90636	Horseshoe Trial, Parallel	Size 12.5x20x12 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90637	Horseshoe Trial, Parallel	Size 12.5x20x13 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90638	Horseshoe Trial, Parallel	Size 12.5x20x14 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
402-90639	Horseshoe Trial, Parallel	Size 12.5x20x15 mm	CASCADIA™ Interbody System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
SP-2186	Distraction, MIS Rod Reducer	w/ Soft Tissue Retraction	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
5101-90218	XT Support Tower		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
5101-90219	XT Support Tower Reducer		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
5101-90221	Anti Torque Handle XT Support Tower	Size XT Support Tower	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
5101-90222	Quick Connect Hex Wrench XT Support Tower Reducer	Size XT Support Tower	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
5101-90223	Locking Screw Inserter XTower, Cannulated	Size XTower, Cannulated	EVEREST® Spinal System	Interbody Placement	Instrument	44759 IIA	CE0086	3 1332244/R		13 MD 0106		Rule 6	
SP-2205-01	Curette	Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2205-02	Curette	Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2206-01	Curette	Right Curved	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2206-02	Curette	Left Curved	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2171	Removable retractor Paddle	Distraction Tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	35315 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2199	A/O Adapter		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-2198	Modular Anterior Insertion Ramp	Insertion Ramp	CHESSAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2202	Tamp		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2197	Anti Torque Alignment Tube, Fixed Handle		ALEUTIAN® Interbody Systems	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
101-8655325	Contoured Deformity Rod, Dual Hex	Size Ø5.5x325 mm Ti	DENALI® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803292/R		1 MD 0202		Rule 8	
111-8655325	Contoured Deformity Rod, Dual Hex	Size Ø5.5x325 mm CoCr	DENALI® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803275/R		1 MD 0202		Rule 8	
3001-H645300	MESA Rail™ Deformity Contoured	Size 600 mm Ti	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803307/R		1 MD 0202		Rule 8	
3001-H645325	MESA Rail™ Deformity Contoured	Size 325 mm Ti	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803307/R		1 MD 0202		Rule 8	
3001-H645300	MESA Rail™ Deformity Contoured	Size 300 mm Ti	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803307/R		1 MD 0202		Rule 8	
3011-H645600	MESA Rail™ Deformity Contoured	Size 600 mm CoCr	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803307/R		1 MD 0202		Rule 8	
3011-H645325	MESA Rail™ Deformity Contoured	Size 325 mm CoCr	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803307/R		1 MD 0202		Rule 8	
3011-H645300	MESA Rail™ Deformity Contoured	Size 300 mm CoCr	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803307/R		1 MD 0202		Rule 8	
3001-H645325	Contoured Deformity Rod, Dual Hex	Size Ø4.5x325 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 1513341/R		1 MD 0202		Rule 8	
3011-H645325	Contoured Deformity Rod, Dual Hex	Size Ø4.5x325 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 1513341/R		1 MD 0202		Rule 8	
3001-H645350	MESA Rail™ Deformity Contoured	Size 350 mm Ti	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803307/R		1 MD 0202		Rule 8	
3011-H645350	MESA Rail™ Deformity Contoured	Size 350 mm CoCr	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1 803307/R		1 MD 0202		Rule 8	
SP-750-03	Serrated Curette	Hockey Stick - Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-750-04	Serrated Curette	Hockey Stick - Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2193-01	Disc Spreader	8 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2193-02	Disc Spreader	10 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2193-03	Disc Spreader	12 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2193-04	Disc Spreader	10 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2183-02	Elevator, Bayoneted	10 mm - Reverse	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-2213	Parallel Distractor		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-2208	MI Rod Inserter, Bearing Drive		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
4601-90041	Reduction Jack Short		KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
6401-90101	MI Posterior Retractor Arm Left		CANYON™ Retractor Systems	Pedicle Screw System	Instrument	35315 I	CE	8 513670/R		1 MD 0106		Rule 6	
6401-90102	MI Posterior Retractor Arm Right		CANYON™ Retractor Systems	Pedicle Screw System	Instrument	35315 I	CE	8 513670/R		1 MD 0106		Rule 6	
6401-90103	MI Posterior Retractor Rack	Size 120 mm	CANYON™ Retractor Systems	Pedicle Screw System	Instrument	35315 I	CE	8 513670/R		1 MD 0106		Rule 6	
6401-90111	Straight Blade	Size 23x30 mm	CANYON™ Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
6401-90112	Straight Blade	Size 23x40 mm	CANYON™ Retractor Systems	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
SP-2309-06	Lordotic Rasp	10° 24x30x19 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2309-07	Lordotic Rasp	10° 24x30x21 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2306	Anti-Torque Fixed Handle		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2310	Overhead Reamer		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
5101-90252	Modular Compressor C-Shaped (R) Fulcrum	KAMPRESSOR	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
5101-90253	Modular Compressor C-Shaped (L)	KAMPRESSOR	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
5101-90251	XT Sleeve		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2331-01	Retractor	XT Tower	EVEREST® Spinal System	Pedicle Screw System	Instrument	35315 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2331-02	Retractor	XT Tower	EVEREST® Spinal System	Pedicle Screw System	Instrument	35315 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2322	Insertor Handle Sleeve	Extended	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2311	Non-Ratcheting Axial Handle		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2312	T-Handle	Non-Ratcheting	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2176	Endoscope Holder		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
3201-91290	Slap Hammer Hudson Connection		RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2229	Counter-Torque Arm		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I	CE		8 513670/R			5 MD 0106	Rule 6
SP-2230	Drill	3.0 x 10 mm	CAYMAN® Plate System-MI	Cayman Plate System	Instrument	36235 I	CE		8 513670/R			5 MD 0106	Rule 6
SP-2256	Insertor Outer Shaft		CAYMAN® Plate System-MI	Cayman Plate System	Instrument	13180 I	CE		8 513670/R			5 MD 0106	Rule 6
SP-2353	Rake Curette	15 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2343	Rake Curette	15 mm 30° Forward	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2344-01	Rake Curette	15 mm Bayonetted Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2344-02	Rake Curette	15 mm Bayonetted Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2304	Reamer	With T-Handle	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2354	Slap Hammer	Long	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2132-01	Lateral Access Blade Extender	20 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2132-02	Lateral Access Blade Extender	30 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2220	Canulated Curved Probe		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
5101-90250	XTower Caliper Offset		EVEREST® Spinal System	Pedicle Screw System	Instrument	32262 I (M)	CE0086		7 513674/R			1 MD 0106	Rule 6
SP-2231	French Rail Bender		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2266	Insertor	Large Handle	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2334-01	Canulated Tap	Ø4.0 mm Front Cutting	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2334-02	Canulated Tap	Ø4.5 mm Front Cutting	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2334-03	Canulated Tap	Ø5.5 mm Front Cutting	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2334-04	Canulated Tap	Ø6.5 mm Front Cutting	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2334-05	Canulated Tap	Ø7.5 mm Front Cutting	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2334-06	Canulated Tap	Ø8.5 mm Front Cutting	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2287-02	Bone Funnel Pusher	Short	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2287-01	Bone Funnel	45° Tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2358	Special Ball Tip Probe		DENALI® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
8101-90009	Rod Clamp	Size Ø5.5 mm	CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90010	Rail Clamp		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90011	Rod Clamp	Size Ø6.0 mm	CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90012	Clamp Distractor		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90005	Clamp Driver		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90006	Clamp Driver Inner Shaft		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90007	Saw Guide, Right		CAPRI™ Corpectomy Cage System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
8101-90008	Saw Guide, Left		CAPRI™ Corpectomy Cage System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
8101-90004	Saw Forceps		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90001	PLL Cutter		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90003	Saw Handle		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90000	In-situ Rod Flexer		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90013	Clamp Distractor Driver		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	13180 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90014	Malleable Retractor	Size 32 mm	CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	53515 I	CE		8 513670/R			10 MD 0106	Rule 6
8101-90015	Malleable Retractor	Size 50 mm	CAPRI™ Corpectomy Cage System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
8101-90016	Malleable Retractor	Size 76 mm	CAPRI™ Corpectomy Cage System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
SP-2360	Anti Torque Handle		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2361	Anti Torque Alignment Tube		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2359	Sleeve		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2345	Head Adjuster		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1271-07	Lordotic Rasp	12x17x11 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1271-08	Lordotic Rasp	12x17x12 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1271-09	Lordotic Rasp	12x17x13 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1271-10	Lordotic Rasp	12x17x14 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1271-11	Lordotic Rasp	12x17x15 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1272-07	Parallel Rasp	12x17x11 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1272-08	Parallel Rasp	12x17x12 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1272-09	Parallel Rasp	12x17x13 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1272-10	Parallel Rasp	12x17x14 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1272-11	Parallel Rasp	12 x17x15 mm	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
6201-90097	Partial Locker, Reduction Jack	Size 90°	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2364-01	Tap	3.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2364-02	Tap	4.0 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2364-03	Tap	4.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2364-04	Tap	5.0 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2364-05	Tap	5.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2364-06	Tap	6.0 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2364-07	Tap	6.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2352	Torque Limiting Shaft	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2288	Bone Funnel	45° tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
4601-90042	Offset Compressor		KEYS™ MI Anterior Deformity Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2340	Parallel Distractor	Valve Paddle	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2341	Parallel Distractor	Starter Tip	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2366	Slap Hammer	Hudson Adapter	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-2365	Distractor		TERRA NOVA® MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R			8 MD 0106	Rule 6
SP-2316-01	Provisional Screwdriver (Short)	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2316-02	Provisional Screwdriver (Long)	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-2317-01	Driver, Height Adjustment	Size 25 (Short)	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6

Master CE Mark List

Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
4501-155278	Screw	Size 05.5x27 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155288	Screw	Size 05.5x28 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155298	Screw	Size 05.5x29 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155308	Screw	Size 05.5x30 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155318	Screw	Size 05.5x31 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155328	Screw	Size 05.5x32 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155338	Screw	Size 05.5x33 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155348	Screw	Size 05.5x34 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155358	Screw	Size 05.5x35 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155368	Screw	Size 05.5x36 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155378	Screw	Size 05.5x37 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155388	Screw	Size 05.5x38 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155398	Screw	Size 05.5x39 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155408	Screw	Size 05.5x40 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155418	Screw	Size 05.5x41 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155428	Screw	Size 05.5x42 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155438	Screw	Size 05.5x43 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155448	Screw	Size 05.5x44 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155458	Screw	Size 05.5x45 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155468	Screw	Size 05.5x46 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155478	Screw	Size 05.5x47 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155488	Screw	Size 05.5x48 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155498	Screw	Size 05.5x49 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155508	Screw	Size 05.5x50 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155518	Screw	Size 05.5x51 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155528	Screw	Size 05.5x52 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155538	Screw	Size 05.5x53 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155548	Screw	Size 05.5x54 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155558	Screw	Size 05.5x55 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155568	Screw	Size 05.5x56 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155578	Screw	Size 05.5x57 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155588	Screw	Size 05.5x58 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155598	Screw	Size 05.5x59 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
4501-155608	Screw	Size 05.5x60 mm	CAYMAN® Plate System-MI	Cayman Plate System	Implant	61325 IIB	CE0086	1 804268/R		5 MD 0202		Rule 8	
SP-1339	Counter-Torque Arm		CHEAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-1340	SS Guidewire	Size 01.4 mm SS	EVEREST® Spinal System	Single Use, Non-Sterile	Instrument	61300 IIB	CE0086	4 804504/R		12 MD 0106		Rule 6	
SP-1341	SS Guidewire	Size 01.3 mm SS	EVEREST® Spinal System	Single Use, Non-Sterile	Instrument	61300 IIB	CE0086	4 804504/R		12 MD 0106		Rule 6	
SP-1342	SS Guidewire, Trocar Tip	Size 01.4 mm SS	EVEREST® Spinal System	Single Use, Non-Sterile	Instrument	61300 IIB	CE0086	4 804504/R		12 MD 0106		Rule 6	
SP-1346	Axial Handle, 1/4" Standard Female Hex Chuck		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-1347	Temporary Fixation Pin Smooth Long		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE	8 513670/R		2 MD 0106		Rule 6	
SP-1372	Variable Drill Guide		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE	8 513670/R		2 MD 0106		Rule 6	
SP-1373-01	Drill	Size 02.3x12 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	36235 I	CE	8 513670/R		2 MD 0106		Rule 6	
SP-1373-02	Drill	Size 02.3x14 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	36235 I	CE	8 513670/R		2 MD 0106		Rule 6	
SP-1373-03	Drill	Size 02.3x16 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	36235 I	CE	8 513670/R		2 MD 0106		Rule 6	
SP-3239-01	Provisional Screwdriver	Size 30, Short	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3239-02	Provisional Screwdriver	Size 30, Long	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3120-01	Retractor	ATP	RAVINE® Lateral Access System	Interbody Access System	Instrument	35315 I	CE	8 513670/R		8 MD 0106		Rule 6	
SP-3182-01	Cervical Inserter	Size 14 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-3182-02	Cervical Inserter	Size 16 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-3215	Torque Indicating Wrench	Size 30	EVEREST® Spinal System	Pedicle Screw System	Instrument	59009 I(m)	CE0086	7 513674/R		1 MD 0106		Rule 6	
SP-3119-01	Spring Loaded Awl		CHEAPEAKE® Stabilization System	Interbody Systems	Instrument	15275 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-3119-02	Spring Loaded Awl	Angled, 30°	CHEAPEAKE® Stabilization System	Interbody Systems	Instrument	15275 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-3119-03	Spring Loaded Awl	Angled, 50°	CHEAPEAKE® Stabilization System	Interbody Systems	Instrument	15275 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-3180	Temporary Fixation Pin		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE	8 513670/R		2 MD 0106		Rule 6	
SP-3241-01	Thoracic Probe	Straight, Long, TIN Coated	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3241-02	Thoracic Probe	Curved, Long, TIN Coated	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3129	Insertor, Outer Shaft/Handle		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-3226	Polyaxial Screw Insertor	Closed screw (Extra Short)	EVEREST® Spinal System	Interbody Placement	Instrument	44759 I(a)	CE0086	6 1332244/R		13 MD 0106		Rule 6	
SP-3222	Plate Holder		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	13180 I	CE	8 513670/R		2 MD 0106		Rule 6	
SP-3079	MI Rod Insertor		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3076-01	Provisional Screwdriver	Size Short	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3076-02	Provisional Screwdriver	Size Long	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3076-03	Provisional Screwdriver	Size Short	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3076-04	Provisional Screwdriver	Size Long	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3201	Canulated Probe	with Inner Stylet	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3201-01	Canulated Probe		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3201-02	Canulated Probe		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3228	Anti Torque Alignment Tube		YUKON OCT Spinal System	OCT Spinal Systems	Instrument	13180 I	CE	8 N/A		6 MD 0106		Rule 6	
2901-90207	Cortical Tap Quick Connect	Size 03.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
2901-90208	Cortical Tap Quick Connect	Size 04.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
2901-90209	Cortical Tap Quick Connect	Size 05.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
2901-90210	Cortical Tap Quick Connect	Size 06.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
2901-90211	Cortical Tap Quick Connect	Size 07.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
2901-90212	Cortical Tap Quick Connect	Size 08.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3163-01	Lateral Access Blade Extender	Right, 15 x 15	RAVINE® Lateral Access System	Interbody Access System	Instrument	13180 I	CE	8 513670/R		8 MD 0106		Rule 6	
SP-3163-02	Lateral Access Blade Extender	Right, 20 x 15	RAVINE® Lateral Access System	Interbody Access System	Instrument	13180 I	CE	8 513670/R		8 MD 0106		Rule 6	
SP-3163-03	Lateral Access Blade Extender	Left, 15 x 15	RAVINE® Lateral Access System	Interbody Access System	Instrument	13180 I	CE	8 513670/R		8 MD 0106		Rule 6	
SP-3163-04	Lateral Access Blade Extender	Left, 20 x 15	RAVINE® Lateral Access System	Interbody Access System	Instrument	13180 I	CE	8 513670/R		8 MD 0106		Rule 6	
SP-3165	Lateral Access Shim Extractor		RAVINE® Lateral Access System	Interbody Access System	Instrument	13180 I	CE	8 513670/R		8 MD 0106		Rule 6	
SP-3198-01	Tapered Tap	Size 03.5 mm, Non-Fluted	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3198-02	Tapered Tap	Size 04.5 mm, Non-Fluted	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3198-03	Tapered Tap	Size 05.5 mm, Non-Fluted	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3198-04	Tapered Tap	Size 06.5 mm, Non-Fluted	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3198-05	Tapered Tap	Size 07.5 mm, Non-Fluted	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3198-06	Tapered Tap	Size 08.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
SP-3198-07	Taper												

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
SP-3137-13	A/P Lateral Access Blade	Adjustable, 13 x 200 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
SP-3187	Angled Lateral Inserter	40°	ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R	3 MD 0106		Rule 6	
SP-3173	Screw Head Assembly		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3193	Universal Tapered Driver	Size 20	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R	3 MD 0106		Rule 6	
SP-3174-01	Cobb	Size 1-4 mm	ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R	3 MD 0106		Rule 6	
SP-3174-02	Cobb	Size 2-6 mm	ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R	3 MD 0106		Rule 6	
6301-90111	Depth Gauge	Aluminum	CANYON™ Retractor Systems	Pedicle Screw System	Instrument	3285 (I)M	CE0086		7 513674/R	1 MD 0106		Rule 6	
6301-N90060-M	Tap	Size Ø3.5 mm MESA 2 Cortical	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 Ila	CE0086		6 1332244/R	14 MD 0106		Rule 5	
6301-N90061-M	Tap	Size Ø4.0 mm MESA 2 Cortical	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 Ila	CE0086		6 1332244/R	14 MD 0106		Rule 5	
6301-N90062-M	Tap	Size Ø4.5 mm MESA 2 Cortical	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 Ila	CE0086		6 1332244/R	14 MD 0106		Rule 5	
6301-N90063-M	Tap	Size Ø5.0 mm MESA 2 Cortical	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 Ila	CE0086		6 1332244/R	14 MD 0106		Rule 5	
6301-N90064-M	Tap	Size Ø5.5 mm MESA 2 Cortical	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 Ila	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-3134-01	Straight Blade	Size 23x30 mm	TERRA NOVA™ MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
SP-3134-02	Straight Blade	Size 23x40 mm	TERRA NOVA™ MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
SP-3134-03	Straight Blade	Size 23x50 mm	TERRA NOVA™ MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
SP-3134-04	Straight Blade	Size 23x60 mm	TERRA NOVA™ MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
SP-3134-05	Straight Blade	Size 23x70 mm	TERRA NOVA™ MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
SP-3134-06	Straight Blade	Size 23x80 mm	TERRA NOVA™ MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
SP-3134-07	Straight Blade	Size 23x90 mm	TERRA NOVA™ MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
SP-3134-08	Straight Blade	Size 23x100 mm	TERRA NOVA™ MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
SP-3134-09	Straight Blade	Size 23x110 mm	TERRA NOVA™ MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
SP-3134-10	Straight Blade	Size 23x120 mm	TERRA NOVA™ MI Access System	Interbody Access System	Instrument	13180 I	CE		8 513670/R	8 MD 0106		Rule 6	
1101-03516FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x16 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03518FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x18 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03520FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x20 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03522FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x22 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03524FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x24 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03526FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x26 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03528FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x28 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03530FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x30 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03532FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x32 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03534FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x34 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03536FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x36 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03538FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x38 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-03540FN	MESA™ Mini Long Shank Screw, Modified	Size Ø3.5x40 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04016FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x16 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04018FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x18 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04020FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x20 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04022FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x22 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04024FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x24 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04026FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x26 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04028FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x28 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04030FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x30 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04032FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x32 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04034FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x34 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04036FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x36 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04038FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x38 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-04040FN	MESA™ Mini Long Shank Screw, Modified	Size Ø4.0x40 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 513628/R	6 MD 0202		Rule 8	
1101-10006	Occipital Anchor Short, Left Hand	Size 7 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 N/A	6 MD 0202		Rule 8	
1101-10007	Occipital Anchor Short, Left Hand	Size 11 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 N/A	6 MD 0202		Rule 8	
1101-10008	Occipital Anchor Long, Left Hand	Size 7 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 N/A	6 MD 0202		Rule 8	
1101-10009	Occipital Anchor Long, Left Hand	Size 11 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 N/A	6 MD 0202		Rule 8	
1101-90322	Anchor Inserter Short, Left Hand		CASPIAN™ Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R	6 MD 0106		Rule 6	
1101-90323	Anchor Inserter Medium, Left Hand		CASPIAN™ Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R	6 MD 0106		Rule 6	
1101-90324	Anchor Inserter Long, Left Hand		CASPIAN™ Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R	6 MD 0106		Rule 6	
1101-10012	Occipital Anchor (Long)	Size 5mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 N/A	6 MD 0202		Rule 8	
1101-10013	Occipital Anchor (Short)	Size 5mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 N/A	6 MD 0202		Rule 8	
1101-10010	Occipital Anchor Short, Left Hand	Size 5mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 N/A	6 MD 0202		Rule 8	
1101-10011	Occipital Anchor Long, Left Hand	Size 5mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61325 Iib	CE0086		1 N/A	6 MD 0202		Rule 8	
1101-14508-G1	Occipital tfix®Screw	Size Ø4.5x8 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806488/R	6 MD 0202		Rule 8	
1101-14510-G1	Occipital tfix®Screw	Size Ø4.5x10 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806488/R	6 MD 0202		Rule 8	
1101-14512-G1	Occipital tfix®Screw	Size Ø4.5x12 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806488/R	6 MD 0202		Rule 8	
1101-14514-G1	Occipital tfix®Screw	Size Ø4.5x14 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806488/R	6 MD 0202		Rule 8	
1101-15206-G1	Occipital tfix®Screw	Size Ø5.25x6 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806488/R	6 MD 0202		Rule 8	
1101-15208-G1	Occipital tfix®Screw	Size Ø5.25x8 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806488/R	6 MD 0202		Rule 8	
1101-15210-G1	Occipital tfix®Screw	Size Ø5.25x10 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806488/R	6 MD 0202		Rule 8	
1101-15212-G1	Occipital tfix®Screw	Size Ø5.25x12 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806488/R	6 MD 0202		Rule 8	
1101-15214-G1	Occipital tfix®Screw	Size Ø5.25x14 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806488/R	6 MD 0202		Rule 8	
1101-42530-G1	Occipital Plate	Size 30 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806492/R	6 MD 0202		Rule 8	
1101-42540-G1	Occipital Plate	Size 40 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806492/R	6 MD 0202		Rule 8	
1101-42550-G1	Occipital Plate	Size 50 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806492/R	6 MD 0202		Rule 8	
1101-72631M-G1	Transverse Connector, Adjustable, Modified	Size (S)	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806475/R	6 MD 0202		Rule 8	
1101-73747M-G1	Transverse Connector, Adjustable, Modified	Size (L)	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806475/R	6 MD 0202		Rule 8	
1101-83535-G1	Parallel Rod Connector	Size Ø3.5 / Ø3.5 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806475/R	6 MD 0202		Rule 8	
1101-83555D-G1	Axial Rod Connector	Size Ø3.5 mm/Ø5.5 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806475/R	6 MD 0202		Rule 8	
1101-14506-G1	Occipital tfix®Screw	Size Ø4.5x6 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806471/R	6 MD 0202		Rule 8	
1101-535240-G1	Straight Rod	Size Ø3.5x240 mm	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806471/R	6 MD 0202		Rule 8	
1101-535300-55-G1	Transition Rod	Size Ø3.5-5.5 mm x 300 mm Ti	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806471/R	6 MD 0202		Rule 8	
1111-835200-G1	Straight Rod, Dual Hex	Size Ø3.5x200 mm, CoCr	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806470/R	6 MD 0202		Rule 8	
1111-835300-G1	Straight Rod, Dual Hex	Size Ø3.5x300 mm, CoCr	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806470/R	6 MD 0202		Rule 8	
1111-535300-55-G1	Transition Rod	Size Ø3.5-5.5x300 mm, CoCr	CASPIAN™ Spinal System	OCT Spinal Systems	Implant	61324 Iib	CE0086		2 806470/R	6 MD 0202		Rule 8	
1101-535500-55-G1	Transition Rod	Size Ø3.5-5.5 mm x500 mm Ti	CASPIAN™										

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
5808-21940L15	Expandable ALIF	Size 30x40x19 mm, 15"	SAHARA™ Stabilization System	Interbody Systems	Implant	57806 IIB	CE0086		1 1412249/R	3 MD 0202		Rule 8	
5808-22040L15	Expandable ALIF	Size 30x40x20 mm, 15"	SAHARA™ Stabilization System	Interbody Systems	Implant	57806 IIB	CE0086		1 1412249/R	3 MD 0202		Rule 8	
SP-3189	Angled Tear drop Curette		ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	51335 I	CE		8 513670/R	3 MD 0106		Rule 6	
3901-04320D	Self-Starting, Variable Screw	Size Ø4.3x20 mm	BLUE RIDGE™ Hybrid Cervical Plate System	Cervical Plate System	Implant	61325 IIB	CE0086		1 804279/R	2 MD 0202		Rule 8	
801-80605H	Angled Transverse Process Hook, Right	Size 6 mm	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R	1 MD 0202		Rule 8	
801-80604H	Angled Transverse Process Hook, Left	Size 6 mm	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R	1 MD 0202		Rule 8	
801-81005H	Angled Transverse Process Hook, Right	Size 10 mm	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R	1 MD 0202		Rule 8	
801-81004H	Angled Transverse Process Hook, Left	Size 10 mm	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R	1 MD 0202		Rule 8	
801-80805H	Angled Transverse Process Hook, Right	Size 8 mm	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R	1 MD 0202		Rule 8	
801-80804H	Angled Transverse Process Hook, Left	Size 8 mm	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R	1 MD 0202		Rule 8	
801-80605H	Angled Transverse Process Hook, Right	Size 6 mm	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R	1 MD 0202		Rule 8	
801-80604H	Angled Transverse Process Hook, Left	Size 6 mm	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R	1 MD 0202		Rule 8	
801-81005H	Angled Transverse Process Hook, Right	Size 10 mm	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R	1 MD 0202		Rule 8	
801-81004H	Angled Transverse Process Hook, Left	Size 10 mm	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803328/R	1 MD 0202		Rule 8	
801-H55500TW	Transition Rail, Rigid	Size Ø5.5x500 mm, TI, MESA Rail™	MESA™ Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086		1 803307/R	1 MD 0202		Rule 8	
402-90528	Convex Trial	Size 12x14x13 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90529	Convex Trial	Size 12x14x14 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90530	Convex Trial	Size 12x14x15 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90531	Convex Trial	Size 13x16x6 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90532	Convex Trial	Size 13x16x7 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90533	Convex Trial	Size 13x16x8 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90534	Convex Trial	Size 13x16x9 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90535	Convex Trial	Size 13x16x10 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90536	Convex Trial	Size 13x16x11 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90537	Convex Trial	Size 13x16x12 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90538	Convex Trial	Size 13x16x13 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90539	Convex Trial	Size 13x16x14 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90540	Convex Trial	Size 13x16x15 mm	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90199	Lordotic Trial	Size 14x16x5 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90200	Lordotic Trial	Size 14x16x6 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90201	Lordotic Trial	Size 14x16x7 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90202	Lordotic Trial	Size 14x16x8 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90203	Lordotic Trial	Size 14x16x9 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90204	Lordotic Trial	Size 14x16x10 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90205	Lordotic Trial	Size 14x16x11 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90206	Lordotic Trial	Size 14x16x12 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90207	Lordotic Trial	Size 14x16x13 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90208	Lordotic Trial	Size 14x16x14 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90209	Lordotic Trial	Size 14x16x15 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90210	Lordotic Trial	Size 15x18x5 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
402-90211	Lordotic Trial	Size 15x18x6 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
2901-90214	Provisional Screwdriver (Short)	Size 30	EVEREST™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
2901-90215	Provisional Screwdriver (Long)	Size 30	EVEREST™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3144	Curved Thoracic Probe		EVEREST™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3056	Retractor	Hinged	ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	35315 I	CE		8 513670/R	3 MD 0106		Rule 6	
SP-3113	Compressor	Screw Based	EVEREST™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3166	Head Adjuster		CASPIAN™ Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R	6 MD 0106		Rule 6	
SP-3126-01	Curette	Size 10 mm Box Curette, Up	ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	31335 I	CE		8 513670/R	3 MD 0106		Rule 6	
SP-3126-02	Curette	Size 10 mm Box Curette, Down	ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	31335 I	CE		8 513670/R	3 MD 0106		Rule 6	
SP-3125-01	Straight Curette	Size #4	ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	31335 I	CE		8 513670/R	3 MD 0106		Rule 6	
SP-3125-02	Angled Curette	Size #4, Right	ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	31335 I	CE		8 513670/R	3 MD 0106		Rule 6	
SP-3125-03	Angled Curette	Size #4, Left	ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	31335 I	CE		8 513670/R	3 MD 0106		Rule 6	
4601-90053	Straight Probe		KEYS™ Ml Anterior Deformity Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
4601-90058	Modular Locker		KEYS™ Ml Anterior Deformity Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
4601-90059	Distractor		KEYS™ Ml Anterior Deformity Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3122	Ratcheting T-Handle	AO	YUKON OCT Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 N/A	6 MD 0106		Rule 6	
SP-3123	Ratcheting Palm Handle	AO	YUKON OCT Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 N/A	6 MD 0106		Rule 6	
SP-3117	Guiding Reamer	Size Aggressive	MESA™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3118	Guiding Reamer	Size Fine	MESA™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3080	Provisional Screwdriver	T-Handle	EVEREST™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3124	Trial	Size 11x14x4 mm, 7"	ALEUTIAN™ Interbody Systems	Interbody Placement	Instrument	44759 IIA	CE0086		3 1332244/R	13 MD 0106		Rule 6	
SP-3049	Parallel Compressor	Modular	EVEREST™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3052	Parallel Distractor	Modular	EVEREST™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3059-01	Replaceable Tip	Straight	EVEREST™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3069-02	Replaceable Tip	Offset	EVEREST™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3131-01	Tap	Size 4.5 mm	MESA™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3131-02	Tap	Size 5.5 mm	MESA™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-3102	Retractor		ALEUTIAN™ Interbody Systems	Interbody Systems	Instrument	35315 I	CE		8 513670/R	3 MD 0106		Rule 6	
SP-3061	Outer Dilator		EVEREST™ Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R	1 MD 0106		Rule 6	
SP-981-M	Screw Insertor	MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-982-M	Polyaxial Screw Insertor	MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1162-M	Deformity Screw Insertor	MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1163-M	Polyaxial Screw Insertor	MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1164-01-M	Cortical Tap	Size Ø3.5 mm MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1164-02-M	Cortical Tap	Size Ø4.5 mm MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1164-03-M	Cortical Tap	Size Ø5.5 mm MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1164-04-M	Cortical Tap	Size Ø6.5 mm MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1164-05-M	Cortical Tap	Size Ø7.5 mm MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1164-06-M	Cortical Tap	Size Ø8.5 mm MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1172-01-M	Quick Start Tap	Size Ø3.5 mm Quick Start MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1172-02-M	Quick Start Tap	Size Ø4.5 mm Quick Start MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1172-03-M	Quick Start Tap	Size Ø5.5 mm Quick Start MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1172-04-M	Quick Start Tap	Size Ø6.5 mm Quick Start MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1172-05-M	Quick Start Tap	Size Ø7.5 mm Quick Start MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244/R	14 MD 0106		Rule 5	
SP-1172-06-M	Quick Start Tap	Size Ø8.5 mm Quick Start MESA	Navigation Instruments	K2M Navigation Instruments	Instrument	44759 IIA	CE0086		6 1332244				

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
7601-90026	Fixed Drill Bit	Size Ø2.3x18 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90027	Fixed Drill Bit	Size Ø2.3x20 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90028	Fixed Drill Bit	Size Ø2.3x22 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90029	Fixed Drill Bit	Size Ø2.3x24 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90030	Fixed Drill Bit	Size Ø2.3x26 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90031	Fixed Drill Bit	Size Ø2.8x10 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90032	Fixed Drill Bit	Size Ø2.8x12 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90033	Fixed Drill Bit	Size Ø2.8x14 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90034	Fixed Drill Bit	Size Ø2.8x16 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90035	Fixed Drill Bit	Size Ø2.8x18 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90036	Fixed Drill Bit	Size Ø2.8x20 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90037	Fixed Drill Bit	Size Ø2.8x22 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90038	Fixed Drill Bit	Size Ø2.8x24 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90039	Fixed Drill Bit	Size Ø2.8x26 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90040	Fixed Drill Bit	Size Ø3.0x10 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90041	Fixed Drill Bit	Size Ø3.0x12 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90042	Fixed Drill Bit	Size Ø3.0x14 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90043	Fixed Drill Bit	Size Ø3.0x16 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90044	Fixed Drill Bit	Size Ø3.0x18 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90045	Fixed Drill Bit	Size Ø3.0x20 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90046	Fixed Drill Bit	Size Ø3.0x22 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90047	Fixed Drill Bit	Size Ø3.0x24 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
7601-90048	Fixed Drill Bit	Size Ø3.0x26 mm	YUKON OCT Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 N/A			12 MD 0106	Rule 6
SP-3105	Drill	Guidewire	YUKON OCT Spinal System	OCT Spinal Systems	Instrument	36235 I	CE		8 N/A			6 MD 0106	Rule 6
SP-3110	Rod Fork		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3108	Fixed Handle		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3072-01	Bone Funnel	Size 8mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3072-02	Bone Funnel	Size 10mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3073-01	Bone Funnel Pusher	Size 8mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3073-02	Bone Funnel Pusher	Size 10mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3063	Handle Extension	3:1 Ratio	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3005	Adjustable Drill Bit	Size Ø 2.8 mm	CASPIAN® Spinal System	Single Use, Non-Sterile	Instrument	61300 Ila	CE0086		4 804504/R			12 MD 0106	Rule 6
SP-3018	Anti Torque Handle		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
6201-90095	Driver	Cricket 2	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3065-01	Canulated Tap	Size 4.0 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3065-02	Canulated Tap	Size 4.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3065-03	Canulated Tap	Size 5.0 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3065-04	Canulated Tap	Size 5.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3065-05	Canulated Tap	Size 6.0 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3065-06	Canulated Tap	Size 6.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3065-07	Canulated Tap	Size 7.0 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3065-08	Canulated Tap	Size 7.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3065-09	Canulated Tap	Size 8.0 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3041	Fixed Drill Guide		PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	36235 I	CE		8 513670/R			2 MD 0106	Rule 6
SP-3004-01	Tap	Size Ø 3.0 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
SP-3004-02	Tap	Size Ø 3.5 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
SP-3004-03	Tap	Size Ø 4.0 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
SP-3004-04	Tap	Size Ø 4.5 mm	CASPIAN® Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 513670/R			6 MD 0106	Rule 6
SP-3046	Angled Lateral Insertor Driver		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3078	Mini Thoracic Probe		YUKON OCT Spinal System	OCT Spinal Systems	Instrument	13180 I	CE		8 N/A			6 MD 0106	Rule 6
SP-3082	Scraper, Bayoneted	Size 7 mm, Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3083	Scraper, Bayoneted	Size 7 mm, Double Sided	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3084	Double Sided Rasp,Bayoneted	Size 6x9 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3085-01	Serrated Curette, Bayoneted	Size #3, Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3085-02	Serrated Curette, Bayoneted	Size #3, Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3086-01	Serrated Curette, Bayoneted	Size #3, Bent Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3086-02	Serrated Curette, Bayoneted	Size #3, Bent Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3087	Double Sided Rasp,Bayoneted	Size 5x8 mm, Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3088	Convex Rasp	Size 5x8 mm, Bayoneted	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3089	Bayoneted	Teardrop Curette	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3090	Teardrop Curette	Bayoneted, Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3091-01	Serrated Curette, Bayoneted	Size #2, Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3091-02	Serrated Curette, Bayoneted	Size #2, Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3092-01	Serrated Curette, Bayoneted	Size #2, Bent Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3092-02	Serrated Curette, Bayoneted	Size #2, Bent Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3093-01	Osteotome	Size 8 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3093-02	Osteotome	Size 10 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3093-03	Osteotome	Size 12 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3094	Ring Curette, Bayoneted	Size 7 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3095	Ring Curette, Bayoneted	Size 7 mm, Bent	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3096	Angled Ring Curette	Size 7 mm, Bayoneted	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3097	Pusher	Bayoneted	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3098	Angled Pusher	Bayoneted	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-1655	Modular Partial Locker		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3033	Implant Interfer		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3043	Inner Shaft		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3044	T-Handle Tightener		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3062	Locking Screw Insertor		YUKON OCT Spinal System	Interbody Placement	Instrument	44759 Ila	CE0086		3 N/A			13 MD 0106	Rule 6
SP-3068	Curved Thoracic Probe		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1651	Modular Locker		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1649	Modular Locker		MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-3060-01	Parallel Disc Scraper	Size 6 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3060-02	Parallel Disc Scraper	Size 7 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3060-03	Parallel Disc Scraper	Size 8 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 513670/R			3 MD 0106	Rule 6
SP-3060-04	Parallel Disc Scraper	Size 9 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I	CE		8 5136				

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Reportorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
SP-2477-02	Lordotic Trial	Size 6x20x60 mm 8"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2477-03	Lordotic Trial	Size 7x20x60 mm 8"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2477-04	Lordotic Angled Trial	Size 20x60x5 mm, 8"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2477-05	Lordotic Angled Trial	Size 20x60x6 mm, 8"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2477-06	Lordotic Angled Trial	Size 20x60x7 mm, 8"	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2454-01	Cortical Tap	4.0 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2454-02	Cortical Tap	5.0 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2454-03	Cortical Tap	6.0 mm	MESA® Small Stature Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-3022	Anti Torque Alignment Tube		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2463-01	Parallel Trial	Size 5x20x60 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2463-02	Parallel Trial	Size 6x20x60 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2463-03	Parallel Trial	Size 7x20x60 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2482	Insertor	Short	MESA® Small Stature Spinal System	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2463-04	Parallel Angled Trial	Size 5x20x60 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2463-05	Parallel Angled Trial	Size 6x20x60 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2463-06	Parallel Angled Trial	Size 7x20x60 mm	ALEUTIAN® Interbody Systems	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2478	Retractor		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	35315 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2391	Drill	14 mm Screw	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	36235 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-3017-01	Disc Scraper	Size 4 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-3017-02	Disc Scraper	Size 5 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-3017-03	Disc Scraper	Size 6 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-3017-04	Disc Scraper	Size 7 mm	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-3011	Anti Torque Handle		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-3009	Spring Loaded Awl		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	15275 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2418	Lamina Spreader		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2273-01	Disc Spreader	Left	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2273-02	Disc Spreader	Right	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2432-01	Tapered Tap	Size 3.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2432-02	Tapered Tap	Size 4.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2432-03	Tapered Tap	Size 5.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2432-04	Tapered Tap	Size 6.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2432-05	Tapered Tap	Size 7.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2432-06	Tapered Tap	Size 8.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-3008	Pusher	90°, Short	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2457	Horseshoe, Threaded Insertor		ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2474	Table Top Shearing Rod Cutter		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2429	Distactor	Rail/5/5/6.0 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2430	Distactor		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-3014	Ball Tip Feeler		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-1193-02	Curette	Size #2 (L) - Serrated	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-1193-01	Curette	Size #2 (R) - Serrated	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2349	Screw Insertor Special Connection		EVEREST® Spinal System	Interbody Placement	Instrument	44759 Ila		CE0086	3 1332244/R	13 MD 0106		Rule 6	
SP-2314	French Rod Bender	Ø5.5-6.0 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-3001	Single Barrel Drill Guide		CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	36235 I		CE	8 513670/R	3 MD 0106		Rule 6	
7501-10001-G1	Locking Screw - Height		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	34170 Iib		CE0086	2 1560868/R	10 MD 0202		Rule 8	
7501-10002-G1	Locking Screw - Angle		CAPRI™ Corpectomy Cage System	Corpectomy Cage System	Instrument	34170 Iib		CE0086	2 1560868/R	10 MD 0202		Rule 8	
SP-2382-01	Curette	#3 Straight Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2382-02	Curette	#3 Straight Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2382-03	Curette	#4 Straight Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2382-04	Curette	#4 Straight Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2382-05	Curette	#3 Angle Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2382-06	Curette	#3 Angle Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2382-07	Curette	#4 Angle Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2382-08	Curette	#4 Angle Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13135 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2460	Universal Driver	Size 20	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2466	Tensioner		NILE™ Proximal Fixation System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2469-01	Longitudinal Coupler, (Short)		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2469-02	Longitudinal Coupler, (Long)		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2464-01	Double Sided Rasp	Straight	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2464-02	Double Sided Rasp	Angled	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2367	Distactor	Hinged	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2420	Anti Torque Handle	X Tower	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2433	Anti Torque Alignment Tube		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2006-07	Removable Distractor, Left Tip	Extended Angled Tip - Left	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2006-08	Removable Distractor, Right Tip	Extended Angled Tip - Right	ALEUTIAN® Interbody Systems	Interbody Systems	Instrument	13180 I		CE	8 513670/R	3 MD 0106		Rule 6	
SP-2400	Canulated Probe w/Inner Stylet	W/ Inner Stylet	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2400-01	Canulated Probe		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2400-02	Stylet		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2434	Probe		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2446-01	Tap Sleeve	Small	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2446-02	Tap Sleeve	Large	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2435	Anti Torque Alignment Tube		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2254	Hook Holder		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2453	Rod Fork		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-3006	Ratcheting Torque Handle	Size 20 in-lbs (2.3 N-m) T-Handle	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	47830 I(m)		CE0086	7 513674/R	3 MD 0106		Rule 6	
SP-3007	Ratcheting Torque Handle	Size 20 in-lbs (2.3 N-m)	CHESAPEAKE® Stabilization System	Interbody Systems	Instrument	47830 I(m)		CE0086	7 513674/R	3 MD 0106		Rule 6	
SP-2415	Canulated Probe w/Inner Stylet	With Inner Stylet	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2415-01	Canulated Probe		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2415-02	Stylet		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2348-01	Tap	3.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2348-02	Tap	4.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2348-03	Tap	5.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2348-04	Tap	6.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2348-05	Tap	7.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2348-06	Tap	8.5 mm	EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2414	Screw Head Adjuster		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-3000	Outer Dilator		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
2701-90230	RAVINE™ Lateral Retractor		RAVINE™ Lateral Access System	Interbody Access System	Instrument	35315 I		CE	8 513670/R	8 MD 0106		Rule 6	
SP-2362-01	Tap	Size 3.5 mm	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I		CE	8 513670/R	1 MD 0106		Rule 6	
SP-2362-02	Tap	Size											

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Catalog#	Item Description1	Item Description 2	System	Technical File	Type	GMDN	Class	CE or CE0086	Class Rationale	Repertorio Number	TF/ER/ DOC	Device Subcat.	MDD Rule
SP-3145-05	Retractor Blade	C-C, Adjustable 24 x 110 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3145-06	Retractor Blade	C-C, Adjustable 24 x 120 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3145-07	Retractor Blade	C-C, Adjustable 24 x 130 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3145-08	Retractor Blade	C-C, Adjustable 24 x 140 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3145-09	Retractor Blade	C-C, Adjustable 24 x 150 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3145-10	Retractor Blade	C-C, Adjustable 24 x 160 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3145-11	Retractor Blade	C-C, Adjustable 24 x 170 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3145-12	Retractor Blade	C-C, Adjustable 24 x 180 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3145-13	Retractor Blade	C-C, Adjustable 24 x 190 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3145-14	Retractor Blade	C-C, Adjustable 24 x 200 mm	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3136-01	Adjustment Fork	Side Pins	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3136-02	Adjustment Fork	Middle Pins	RAVINE™ Lateral Access System	Interbody Access System	Instrument	13180 I		CE		8 513670/R		8 MD 0106	Rule 6
SP-3025	Needle Holder		EVEREST® Spinal System	Pedicle Screw System	Instrument	13180 I		CE		1 513670/R		1 MD 0106	Rule 6