

# Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

PRODUCT IDENTIFICATION	
SYSTEM NAME: PEDICLE SCREW SYSTEM	
Branding name	Device Classification*
ARI™ Anterior Staple System	I
	IIb
CANYON™ Retractor Systems	I
	I(m)
DENALI® MI Spinal System	I
	I(m)
	IIb
DENALI® Spinal System	I
	I(m)
	IIb
EVEREST® Spinal System	I
	I(m)
	IIb
KEYS™ MI Anterior Deformity Spinal System	I
	IIb
LURAY™ Corpectomy Cage System	I
MESA® Small Stature Spinal System	I
	I(m)
	IIb
MESA® Spinal System	I
	I(m)
	IIb
NILE™ Alternative Fixation System	I
	IIb
NILE™ Proximal Fixation System	I
	IIb
TASMAN Spinal System	I
	IIb

\*Class I Devices: Authorized Representative

\*Class I(m), IIa, IIb Devices: Notified Body

FORM-CE-000 Rev 78 in Master Control contains the list of CE Marked parts governed by this Declaration of Conformity

MANUFACTURER		
Name of company	Address	Company Representative
K2M, Inc.	600 Hope Parkway, SE Leesburg, VA 20175 U.S.A.	

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	



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 Insertor		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 Insertor		DENALI® MI Spinal System	Interbody Placement	Instrument	44759 Ila		CE0086		6 1332244/R		13 MD 0106	Rule 5
1001-90001	Cannulated Screw Insertor		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 Insertor, 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 Insertor, 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 Insertor		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 Insertor		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 Handle, 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	Cervical Plate System	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	Caliper		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	Cervical Plate System	Instrument	4 804504/R	CE0086		8 53670/R			12 MD 0106	Rule 6
201-90062	Reduction Screw	Size 14 mm	PYRENEES® Cervical Plate System	Cervical Plate System	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	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90073	Drill	Size Ø2.3x12 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90074	Drill	Size Ø2.3x14 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90075	Drill	Size Ø2.3x16 mm	PYRENEES® Cervical Plate System	Cervical Plate System	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	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90104	Drill	Size Ø2.3x12 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90105	Drill	Size Ø2.3x14 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90106	Drill	Size Ø2.3x16 mm	PYRENEES® Cervical Plate System	Cervical Plate System	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	Cervical Plate System	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	Cervical Plate System	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	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90145	Semi-Constrained Screw, Shank Extractor		PYRENEES® Cervical Plate System	Cervical Plate System	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
201-90170	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	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90178	Fast Awl	Size 12 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90179	Fast Awl	Size 14 mm	PYRENEES® Cervical Plate System	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90180	Fast Awl	Size 16 mm	PYRENEES® Cervical Plate System	Cervical Plate System	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	Cervical Plate System	Instrument	61300 I(a)	CE0086		4 804504/R			12 MD 0106	Rule 6
201-90249	Clip	Size 2 mm	PYRENEES® Cervical Plate System	Cervical Plate System	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	Rule 8
208-41F26	Constrained Plate, 1 Level	Size 26 mm	PYRENEES® Cerv										











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
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







































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
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 Ø2.75 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 Ø4.5 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 Ø4.5 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 Ø4.5 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 Ø4.5 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 Ø4.5 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 Ø4.5 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 Ø4.5 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 Ø4.5 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 Ø4.5 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 Insertor, 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 Insertor, 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 Ø4.5 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 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
3001-90127	Vise Grips	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
3001-90128	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
3001-90129	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
3001-90130	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
3001-90131	MESA Rail™ Bender	Size Ø4.5 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 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
3001-90133	Quick Locker	Size MESA Rail™ Ø4.5 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 Ø4.5 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 Ø4.5 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 Ø4.5 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 Ø3.0 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 Ø3.5 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 Ø4.0 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 Ø4.5 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 Ø5.5 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 Ø6.5 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 Ø7.5 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 Ø4.5 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 Ø4.5x100 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 Ø4.5x150 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 Ø4.5x200 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 Ø4.5x300 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 Ø4.5x300 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 Ø4.5x400 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 Ø4.5x400 mm, TI	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	1 803292/R	CE0086		2 803292/R			1 MD 0202	Rule 8
3001-845													































































































































































































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
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	
801-81103H-SG	Pedicle Hook	Size 11 mm	MESA® Spinal System	Pedicle Screw System	Implant	61324 IIB	CE0086	2 795844/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	
801-8555SHWF	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		1 MD 0106		Rule 6	
801-90092	Transverse Coupler	Size (L)	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE	8 513670/R		1 MD 0106		Rule 6	
801-90093	Universal Joint Driver, Hex	Size 25	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 IN	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	Distraction		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	







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
K2-29-2001-02	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 010	



























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
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	MESA® 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	Insertion		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 I(a)		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 I(a)		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 I(a)		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 I(a)		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 I(a)		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 I(a)		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 I(a)		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 I(a)		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 I(a)		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 I(a)		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	Insertion Shaft	Size Uniplanar	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
SP-1261-03	Insertion, Sleeve Assembly		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
SP-1261-04	Insertion Nut		MESA® Spinal System	Pedicle Screw System	Instrument	13180 I		CE		8 513670/R		1 MD 0106	Rule 6
SP-1262-02	Insertion 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											



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
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		3 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			4 804504/R		12 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		MESA® 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						



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
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 Insertor		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 Insertor	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 Insertor		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	Camulated Nerve Retractor	MESA® Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8				



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
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		MESA* Spinal System	Pedicle Screw System	Instrument	13180 I	CE		8 513670/R			1 MD 0106	Rule 6
SP-1436	Quick Connect Adapter	Short w/AO Connect	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
E5112-38590T	Uniplanar Screw, Extended Tab, Transverse, Fenestrated	Size Ø8.5x90 mm	EVEREST® Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	3	1803267/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	3	1803267/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	3	1803267/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	3	1803267/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	3	1803267/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	1803292/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	1803275/R	1 MD 0202		Rule 8	
3001-H645600	MESA Rail™ Deformity Contoured	Size 600 mm Ti	MESA® Small Stature Spinal System	Pedicle Screw System	Implant	61325 IIB	CE0086	1	1803307/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	1803307/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	1803307/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	1803307/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	1803307/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	1803307/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	1803307/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	1803307/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	Elevator, Bayoneted	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	







































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
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 NOVAM® 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		CHESSAPEAKE® 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		CHESSAPEAKE® Stabilization System	Interbody Systems	Instrument	15275 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-3119-02	Spring Loaded Awl	Angled, 30°	CHESSAPEAKE® Stabilization System	Interbody Systems	Instrument	15275 I	CE	8 513670/R		3 MD 0106		Rule 6	
SP-3119-03	Spring Loaded Awl	Angled, 50°	CHESSAPEAKE® 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	Stylet		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													



















































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
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	32845 (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										







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
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
801-80804HN	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
801-80804HN	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
801-80605HN	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
801-80604HN	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
801-81005HN	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
801-81004HN	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	Deforming 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



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
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	Crick 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 Inserter		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 Inserter		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 51367				































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
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	EVEREST® Spinal System	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



Master CE Mark List

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











































































































































































































































































































































































































































































































































































































Master CE Mark List

Annex

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ix



























## Classification / Rationale / CE Mark

### 1.0 **Class IIb:** Non-sterile Implants: Annex IX Rule 8. Route to Conformity: Annex II.3

- Not intended to be placed in teeth
- Not intended to be used in direct contact with the heart, central circulatory system or central nervous system
- Not intended to have a biological effect or to be wholly or mainly absorbed
- Not intended to undergo chemical change in the body

### 2.0 **Class IIb:** Sterile Implants: Annex IX Rule 8 in association with Annex VII.5. Route to Conformity: Annex II.3

- Not intended to be placed in teeth
- Not intended to be used in direct contact with the heart, central circulatory system or central nervous system
- Not intended to have a biological effect or to be wholly or mainly absorbed
- Not intended to undergo chemical change in the body
- Association with Annex VII.5 regarding securing and maintaining sterile conditions

### 3.0 **Class IIa:** Reusable Trials, Elevators, Templates: Annex IX Rule 6. Route to Conformity: Annex II.3

- Intended for transient use
- Not intended to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system
- Not intended for use in direct contact with the central nervous system
- Not intended to supply energy in the form of ionizing radiation
- Not intended to have a biological effect or to be wholly or mainly absorbed
- Not intended to administer medicines
- Up-classified by BSI to Class IIa

### 4.0 **Class IIa:** Single Use (Non-Sterile) Instruments: Annex IX Rule 6. Route to Conformity: Annex II.3

- Intended for transient use
- Not intended to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system
- Not reusable surgical instruments
- Not intended for use in direct contact with the central nervous system
- Not intended to supply energy in the form of ionizing radiation
- Not intended to have a biological effect or to be wholly or mainly absorbed
- Not intended to administer medicines

### 5.0 **Class IIa:** Single Use (Sterile) Instruments: Annex IX Rule 6 in association with Annex VII.5. Route to Conformity: Annex II.3

- Intended for transient use
- Not intended to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system
- Not reusable surgical instruments
- Not intended for use in direct contact with the central nervous system
- Not intended to supply energy in the form of ionizing radiation
- Not intended to have a biological effect or to be wholly or mainly absorbed
- Not intended to administer medicines
- Association with Annex VII.5 regarding securing and maintaining sterile conditions

### 6.0 **Class IIa:** Instruments connected to an active device: Annex IX Rule 5. Route to Conformity: Annex II.3

- Intended to connect to an active medical device in Class IIa
- Intended for transient use

### 7.0 **Class I(m):** Measuring Devices: Annex IX Rule 6 Indent 2 in association with Annex VII, Section 5, Indent 2. Route to Conformity: Annex V

- Intended for transient use
- Not intended to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system
- Are reusable surgical instruments, in which case they are Class I
- Not intended for use in direct contact with the central nervous system
- Not intended to supply energy in the form of ionizing radiation
- Not intended to have a biological effect or to be wholly or mainly absorbed
- Not intended to administer medicines
- Association with Annex VII.5 indent 2 regarding conformity of the products with the metrological requirements.

### 8.0 **Class I:** Non-Sterile, Reusable Instruments: Annex IX Rule 6 Indent 2. Route to Conformity: Annex VII.

- Intended for transient use
- Not intended to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system



## Classification / Rationale / CE Mark

- Are reusable surgical instruments, in which case they are Class I
  - Not intended for use in direct contact with the central nervous system
  - Not intended to supply energy in the form of ionizing radiation
  - Not intended to have a biological effect or to be wholly or mainly absorbed
  - Not intended to administer medicines
-