

Prohlášení o shodě

(v souladu ISO/IEC 17050-1)

| IDENTIFIKACE VÝROBKU | |
|--|----------------------|
| JMÉNO SYSTÉMU NAME: PEDIKULÁRNÍ ŠROUBOVÁ SYSTÉMY | |
| Název značky | Klasifikace výrobku* |
| ARI™ Anterior Staple Systém | I |
| | IIb |
| CANYON™ Retractor Systémy | I |
| | I(m) |
| DENALI® MI Pátevní Systém | I |
| | I(m) |
| DENALI® Pátevní Systém | IIb |
| | I |
| DENALI® Pátevní Systém | I(m) |
| | IIb |
| EVEREST® Pátevní Systém | I |
| | I(m) |
| EVEREST® Pátevní Systém | IIb |
| | I |
| KEYS™ MI Anterior Deformity Pátevní Systém | I |
| | IIb |
| LURAY™ Corpectomy Cage Systém | I |
| MESA® Small Stature Pátevní Systém | I |
| | I(m) |
| MESA® Pátevní Systém | IIb |
| | I |
| MESA® Pátevní Systém | I(m) |
| | IIb |
| NILE™ Alternative Fixation Systém | I |
| | IIb |
| NILE™ Proximal Fixation Systém | I |
| | IIb |
| TASMAN Pátevní Systém | I |
| | IIb |

*Zařízení třídy I: Zplnomocněný zástupce

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

FORM-CE-000 Rev 78 v Master Control obsahuje seznam částí označených CE, které se řídí tímto prohlášením o shodě

| VÝROBCE | | |
|-------------------|---|------------------------------------|
| Jméno společnosti | Adresa | Zástupce firmy |
| K2M, Inc. | 600 Hope Parkway, SE Leesburg, VA 20175 USA. | Meriam Gabera Sr. Manager, RAQA |

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

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 | 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 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 |
|-----------|--|--------------------------|-----------------------|-------------------------|------------|------------|--------|--------------|-----------------|-------------------|------------|----------------|----------|
| 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 |
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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 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90026 | Temporary Fixation Pin | | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 4 804504/R | CE0086 | | 8 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90029 | Plate Holder, Cervical Driver | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90030 | Driver | Size 10 | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90031 | Fixed Drill Guide | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90032 | Variable Drill Guide | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90033 | Temporary Pin Insertor | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90035 | Caliper | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 32262 I(m) | CE0086 | | 7 513674/R | | | 2 MD 0106 | Rule 6 |
| 201-90061 | Reduction Screw | Size 12 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 4 804504/R | CE0086 | | 8 513670/R | | | 12 MD 0106 | Rule 6 |
| 201-90062 | Reduction Screw | Size 14 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 4 804504/R | CE0086 | | 8 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90066 | Plate Bender, Cervical Universal | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513674/R | | | 2 MD 0106 | Rule 6 |
| 201-90071 | Driver, Torque Limiting | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90072 | Drill | Size Ø2.3x10 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90073 | Drill | Size Ø2.3x12 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90074 | Drill | Size Ø2.3x14 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90075 | Drill | Size Ø2.3x16 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90078 | Driver | Size 10 | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90080 | Driver, Torque Limiting | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90089 | Variable Drill Guide | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90100 | Fixed Drill Guide | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90102 | Thread Former | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90103 | Drill | Size Ø2.3x10 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90104 | Drill | Size Ø2.3x12 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90105 | Drill | Size Ø2.3x14 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90106 | Drill | Size Ø2.3x16 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90111 | Temporary Pin Insertor | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90115 | Awl | Size 10 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90116 | Tap | Size Ø2.3x10 mm | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90118 | Tapered Driver | Size 10 | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90120 | Screw Extractor | | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90121 | Plate Holder | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90127 | Non-Tapered Torque Driver | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90131 | Ratcheting Handle | AO | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513670/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 513674/R | | | 2 MD 0106 | Rule 6 |
| 201-90141 | Tapered Driver | Size 13 | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90144 | Awl | Size 12 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90145 | Semi-Constrained Screw, Shank Extractor | | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90146 | Capture Driver, Sleeve | Size 10 | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90147 | Plate Holder | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90148 | Plate Bender, Cervical | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90149 | Capture Driver | Size 10 | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90151 | Spin Top Handle, AO | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90152 | Spin Top Handle, Internal AO, (Short) | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90171 | Plate Holder, Inner Shaft | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513670/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 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90175 | Drill Guide, Inner Shaft | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90177 | Fast Awl | Size 10 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90178 | Fast Awl | Size 12 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90179 | Fast Awl | Size 14 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90180 | Fast Awl | Size 16 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90181 | FAST Drill Guide | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90185 | Drill Guide, Fixed, Translational | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90248 | Clip | Size 1 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90249 | Clip | Size 2 mm | PYRENEES® Cervical Plate System | Single Use, Non-Sterile | Instrument | 61300 I(a) | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| 201-90250 | Anti-Torque Guide, Translational | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90251 | Translational FAST, Guide | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90253 | Translational Plate, Distractor | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90254 | Translational Plate, Compressor | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| 201-90259 | Anti-Torque Guide, Constrained | | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/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 513613/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 513613/R | CE0086 | | 1 513613/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 513613/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 513613/R | CE0086 | | 1 513613/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 513613/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 513613/R | CE0086 | | 1 513613/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 513613/R | | | 2 MD 0202 | Rule 8 |
| 208-41F24-G1 | Constrained Plate, 1 Level | Size 24 mm | PYRENEES® Cervical Plate System | Cervical Plate System | Implant | | | | | | | | |

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 |

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| Catalog# | Item Description1 | Item Description 2 | System | Technical File | Type | GMDN | Class | CE or CE0086 | Class Rationale | Reportorio Number | TF/ER/ DOC | Device Subcat. | MDD Rule |
|----------------|--|-------------------------------------|-----------------------------------|----------------------|------------|------------|-------|--------------|-----------------|-------------------|------------|----------------|----------|
| 3001-90071 | Straight Thoracic Probe | | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| 3001-90072 | Curved Lumbar Probe | | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| 3001-90073 | Straight Lumbar Probe | | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| 3001-90074 | Depth Gauge | Size 80 mm | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 32845 (I)m | | CE0086 | | 7 513674/R | | 1 MD 0106 | Rule 6 |
| 3001-90075 | Awl | Size 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 Inserter, Threaded | | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| 3001-90114 | Threaded Hook Inserter, Inner Assembly | | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| 3001-90115 | Hook Pusher | | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| 3001-90116 | Pedicle Hook Trial | Size 4 mm | MESA® Small Stature Spinal System | Interbody Placement | Instrument | 44759 Ila | | CE0086 | | 3 1332244/R | | 13 MD 0106 | Rule 6 |
| 3001-90117 | Pedicle Hook Trial | Size 8 mm | MESA® Small Stature Spinal System | Interbody Placement | Instrument | 44759 Ila | | CE0086 | | 3 1332244/R | | 13 MD 0106 | Rule 6 |
| 3001-90118 | Hook Elevator | | MESA® Small Stature Spinal System | Interbody Placement | Instrument | 44759 Ila | | CE0086 | | 3 1332244/R | | 13 MD 0106 | Rule 6 |
| 3001-90119 | Torque Limiting Shaft | Size 20 | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| 3001-90120 | Anti Torque Alignment Tube | | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| 3001-90121 | Single Action Rod Reducer | Firefly™ | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 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 Locker | 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 |
| 3001-845150 | 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 | | 2 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 |

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-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 | | 2 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-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, Narrow | 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-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, Narrow | Size 10 mm | MESA® Spinal System | Pedicle Screw System | Implant | 61324 IIB | | CE0086 | | 2 803328/R | | 1 MD 0202 | Rule 8 |
| 801-81003H | Pedicle Hook | Size 10 mm | MESA® Spinal System | Pedicle Screw System | Implant | 61325 IIB | | CE0086 | | 1 803328/R | | 1 MD 0202 | Rule 8 |
| 801-81003H-SG | Pedicle Hook | Size 10 mm | MESA® Spinal System | Pedicle Screw System | Implant | 61324 IIB | | CE0086 | | 2 803328/R | | 1 MD 0202 | Rule 8 |
| 801-81101H | Transverse Process Hook | Size 11 mm | MESA® Spinal System | Pedicle Screw System | Implant | 61325 IIB | | CE0086 | | 1 803328/R | | 1 MD 0202 | Rule 8 |
| 801-81101H-SG | Transverse Process Hook | Size 11 mm | MESA® Spinal System | Pedicle Screw System | Implant | 61324 IIB | | CE0086 | | 2 803328/R | | 1 MD 0202 | Rule 8 |
| 801-81103H | Pedicle Hook | Size 11 mm | MESA® Spinal System | Pedicle Screw System | Implant | 61325 IIB | | CE0086 | | 1 803328/R | | 1 MD 0202 | Rule 8 |
| 801-81103H-SG | Pedicle Hook | Size 11 mm | MESA® Spinal System | Pedicle Screw System | Implant | 61324 IIB | | CE0086 | | 2 803328/R | | 1 MD 0202 | Rule 8 |
| 801-8555HD | Axial Connector | MESA Rail™ | MESA® Spinal System | Pedicle Screw System | Implant | 61325 IIB | | CE0086 | | 1 803331/R | | 1 MD 0202 | Rule 8 |
| 801-8555HE | Parallel Connector, Closed | MESA Rail™ | MESA® Spinal System | Pedicle Screw System | Implant | 61325 IIB | | CE0086 | | 1 803331/R | | 1 MD 0202 | Rule 8 |
| 801-8555HF | Parallel Connector, Open/Closed | MESA Rail™ | MESA® Spinal System | Pedicle Screw System | Implant | 61325 IIB | | CE0086 | | 1 803331/R | | 1 MD 0202 | Rule 8 |
| 801-8555HWE | Parallel Connector, Open | 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 | | 1 MD 0106 | Rule 6 |
| 801-90094 | Screw Insertor, Round | | MESA® Spinal System | Interbody Placement | Instrument | 44759 IIA | | CE0086 | | 6 1332244/R | | 13 MD 0106 | |

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| Catalog# | Item Description1 | Item Description 2 | System | Technical File | Type | GMDN | Class | CE or CE0086 | Class Rationale | Reportorio Number | TF/ER/ DOC | Device Subcat. | MDD Rule |
|---------------|--|-------------------------------------|--------------------------------|---------------------------|------------|-------------|--------|--------------|-----------------|-------------------|------------|----------------|----------|
| K2-08-2368-01 | 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 1513387/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 | Distraction | | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 6 MD 0106 | Rule 6 |
| K2-11-2031-01 | Compressor | | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 6 MD 0106 | Rule 6 |
| K2-11-2032-01 | Small Pedicle Probe | | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 6 MD 0106 | Rule 6 |
| K2-11-2035-01 | Mini Axial AO Handle, Ratchet | | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 6 MD 0106 | Rule 6 |
| K2-11-2037-01 | Mini Axial AO Handle, Fixed | | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 6 MD 0106 | Rule 6 |
| K2-11-2038-01 | 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 | Size Ø3.5 mm | 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 | Rule 6 |
| K2-11-2134-01 | Dual Action Rod Reducer | | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | | | | |

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| Catalog# | Item Description1 | Item Description 2 | System | Technical File | Type | GMDN | Class | CE or CE0086 | Class Rationale | Reportorio Number | TF/ER/ DOC | Device Subcat. | MDD Rule |
|---------------|--|--------------------------|-----------------------------------|----------------------|------------|------------|--------|--------------|-----------------|-------------------|------------|----------------|----------|
| 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 Inserters (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 Inserters, 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 Inserters, 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 Inserters | | 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 | 32085 (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 Inserters, 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 Inserters, 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 Thoracic Probe | | MESA* Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| K2-30-2040-01 | Visc Grips | Size Ø4.5 mm | MESA* Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| K2-30-2041-01 | Coronal Bender (Left) | Size Ø4.5 mm, MESA Rail™ | MESA* Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| K2-30-2042-01 | Coronal Bender (Right) | Size Ø4.5 mm, MESA Rail™ | MESA* Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| K2-30-2043-01 | Partial Locker | MESA Rail™ | MESA* Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| K2-30-2044-01 | Reduction Jack | | MESA* Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | |

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 | MESAS® Mini 90° Screw Inserter | | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | | CE | | 8 513670/R | | 6 MD 0106 | Rule 6 |
| SP-1120-01 | Curved Probe | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1120-02 | Straight Probe | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1120-03 | Thoracic Probe | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1120-04 | Thoracic Probe | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1120-05 | Awl | Long | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1120-06 | Head Adjuster | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1120-07 | Rod Pusher | | MESAS® 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 | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1142 | Distractor | | MESAS® 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 | | MESAS® 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 | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1181 | Flat Cobb Elevator | No slip | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1182 | Elevator | Shovel nose | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1183 | Collar Retrieval Tool | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1189 | Collar Retrieval Tool | | LURAY™ Corpectomy Cage System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1190 | Collar Retrieval Tool | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1198 | Collar Retrieval Tool | | MESAS® 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 | | MESAS® 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 | | MESAS® Spinal System | Pedicle Screw System | Instrument | 15275 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1259 | Thoracic Probe | Short | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1260 | Straight Lumbar Probe | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1261-02 | Insertor Shaft | Size Uniplanar | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1261-03 | Insertor, Sleeve Assembly | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1261-04 | Insertor Nut | | MESAS® Spinal System | Pedicle Screw System | Instrument | 13180 I | | CE | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1262-02 | Insertor Shaft | | MESAS® 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 |

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| Catalog# | Item Description1 | Item Description 2 | System | Technical File | Type | GMDN | Class | CE or CE0086 | Class Rationale | Reportorio Number | TF/ER/ DOC | Device Subcat. | MDD Rule |
|------------|---|------------------------------|-----------------------------------|-------------------------|------------|------------|--------|--------------|-----------------|-------------------|------------|----------------|----------|
| SP-1472 | Curved Probe | | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1474 | Rotation Tube, Spring Loaded | | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1483-01 | Angled Blade | Size 25', 50 mm | TERRA NOVA® MI Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1483-02 | Angled Blade | Size 30', 50 mm | TERRA NOVA® MI Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1483-03 | Angled Blade | Size 40', 50 mm | TERRA NOVA® MI Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1483-04 | Angled Blade | Size 25', 60 mm | TERRA NOVA® MI Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1483-05 | Angled Blade | Size 30', 60 mm | TERRA NOVA® MI Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1483-06 | Angled Blade | Size 40', 60 mm | TERRA NOVA® MI Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1483-07 | Angled Blade | Size 25', 70 mm | TERRA NOVA® MI Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1483-08 | Angled Blade | Size 30', 70 mm | TERRA NOVA® MI Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1483-09 | Angled Blade | Size 40', 70 mm | TERRA NOVA® MI Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1486 | Bone Packing Mold | | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1487 | Screw Alignment Guide | | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1496-01 | Serrated Curette | Size Up 30" #2 | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13135 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1496-02 | Serrated Curette | Size Up 30" #4 | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13135 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1498-01 | Osteotome | Flat, Long | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1498-02 | Osteotome | Curved, Long | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1503-01 | Wood Dilator Pin | Size 19 mm | DENALI® MI Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1503-02 | Wood Dilator Pin | Size 25 mm | DENALI® MI Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1507 | MI Rod Reducer | | DENALI® MI Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1513 | Driver | | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1521 | Hook Pusher | | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1552-01 | Tapered Tap | Size Ø5.5 mm | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1552-02 | Tapered Tap | Size Ø6.5 mm | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1552-03 | Tapered Tap | Size Ø7.5 mm | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1552-04 | Tapered Tap | | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1555 | Blade Handle | | RAVINE™ Lateral Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1555-01 | Blade Handle | | RAVINE™ Lateral Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1555-02 | Blade Handle | | RAVINE™ Lateral Access System | Interbody Access System | Instrument | 13180 I | CE | | | 8 513670/R | | 8 MD 0106 | Rule 6 |
| SP-1568 | Locker | Threaded | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1569 | Anti Torque Handle | | MESA® Spinal System | Pedicle Screw System | Instrument | 47830 (I)m | CE0086 | | | 7 513674/R | | 1 MD 0106 | Rule 6 |
| SP-1585-01 | Tap, Special Connector | Size Ø4.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1585-02 | Tap, Special Connector | Size Ø5.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1585-03 | Tap, Special Connector | Size Ø6.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1585-04 | Tap, Special Connector | Size Ø7.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1585-05 | Tap, Special Connector | Size Ø8.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1610 | Torque Wrench | Size 120 in-lbs | MESA® Spinal System | Pedicle Screw System | 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, Left | | 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, Left | | 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-1731 | Tap Sleeve | | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1749 | X-Ray Marker (Left) | | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1755 | Reduction Jack | Modular | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1761 | MESA® Mini Screw Insertor | Special Adapter | CASPIAN® Spinal System | Interbody Placement | Instrument | 44759 Ila | CE0086 | | | 6 1332244/R | | 13 MD 0106 | Rule 5 |
| SP-1802-01 | Disc Scraper | Size 7 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1802-02 | Disc Scraper | Size 8 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1802-03 | Disc Scraper | Size 9 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1802-04 | Disc Scraper | Size 10 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1802-05 | Disc Scraper | Size 11 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1802-06 | Disc Scraper | Size 12 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1802-07 | Disc Scraper | Size 13 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1802-08 | Disc Scraper | Size 14 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1802-09 | Disc Scraper | Size 15 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1802-10 | Disc Scraper | Size 16 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 3 MD 0106 | Rule 6 |
| SP-1804 | Reduction Jack | Size 5.5 mm Rail Easy Clean | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1805 | Reduction Jack, Driver | Size 20 | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1821 | Tapered Driver | Size 25 | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1824-01 | Awl | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 15275 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1828-01 | MI Single Action Anti-Torque, Rod Reducer | Size Anti Torque Rod Reducer | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1833 | Tensioning Instrument | | NILE™ Alternative Fixation System | Interbody Systems | Instrument | 13180 I | CE | | | 8 513670/R | | 1 MD 0106 | Rule 6 |
| SP-1838 | Torque Limiting Shaft | W/ Wings | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 59009 (I)m | CE0086 | | | 7 513674/R | | 3 MD 0106 | Rule 6 |
| SP-1839-01 | Flex Shaft Non-tapered Driver | Size 20, 90" | CAYMAN® Plate System-MI | Cayman Plate System | Instrument | 13180 I | CE | | | 8 513670/R | | 5 MD 0106 | Rule 6 |
| SP-1839-02 | Flex Shaft Tapered Driver | Size 20, 90" | CAYMAN® Plate System-MI | Cayman Plate System | Instrument | 13180 I | CE | | | | | | |

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| Catalog# | Item Description1 | Item Description 2 | System | Technical File | Type | GMDN | Class | CE or CE0086 | Class Rationale | Reportorio Number | TF/ER/ DOC | Device Subcat. | MDD Rule |
|------------|-----------------------------|--------------------------------|---------------------------------|-----------------------|------------|-----------|--------|--------------|-----------------|-------------------|------------|----------------|----------|
| SP-1984-08 | MESA 2 Tap | Size 7.0 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-1984-09 | MESA 2 Tap | Size 7.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-1984-10 | MESA 2 Tap | Size 8.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-1984-11 | MESA 2 Tap | Size 9.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-1984-12 | MESA 2 Tap | Size 10.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-1984-13 | MESA 2 Tap | Size 11.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-1984-14 | MESA 2 Tap | Size 12.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-1997 | Modular Screw Inserter | | DENALI® Spinal System | Interbody Placement | Instrument | 44759 Ila | CE0086 | | 8 513670/R | 6 1332244/R | | 13 MD 0106 | Rule 5 |
| SP-1998 | Straight Curette | | DENALI® Spinal System | Pedicle Screw System | Instrument | 31335 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-1999-01 | Straight Probe | Large T-Handle | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-1999-02 | Curved Probe | Large T-Handle | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2001 | Special Ball Tip Probe | | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2002-01 | Pedicle Marker | Left | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2002-02 | Pedicle Marker | Right | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2003 | Anti-Splay Tube | | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2004 | Handle Extension | MESA Locker | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2008 | Scraper | | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2009-01 | Double Sided Rasp | Size 8 mm, Short | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2009-02 | Double Sided Rasp | Size 5 mm, Short | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2013-01 | Retractor | PENFIELD L-Shaped 10 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 35315 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2013-02 | Retractor | PENFIELD L-Shaped 5 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 35315 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2014-01 | Retractor | PENFIELD Bayonetted 10 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 35315 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2014-02 | Retractor | PENFIELD Bayonetted 5 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 35315 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2015 | Retractor | Penfield (Wide) | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 35315 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2018 | Anti-Splay Tube | | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2025 | Tap Sleeve | With Window | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2027 | Ball Tip Feeler | Size Small | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2028 | Small Pedicle Probe | | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 6 MD 0106 | Rule 6 |
| SP-2030-01 | Tapered Tap | Size Ø3.5 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2030-02 | Tapered Tap | Size Ø4.5 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2030-03 | Tapered Tap | Size Ø5.5 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2030-04 | Tapered Tap | Size Ø6.5 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2030-05 | Tapered Tap | Size Ø7.5 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2030-06 | Tapered Tap | Size Ø8.5 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2031-01 | Packing Tamp | Size 3 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2031-02 | Packing Tamp | Size 4 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2031-03 | Packing Tamp | Size 3 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2037 | Straight Lumbar Probe | Long | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2039 | Non-Ratcheting Axial Handle | | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2041 | Straight Pusher | | CASCADIA™ Interbody System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2063-01 | Head Adjuster | Dia 5.5 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2063-02 | Head Adjuster | Dia 4.5 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2065 | Head Adjuster | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2080 | Rod Bender | Dual Action | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2086-01 | Pyramid Awl (long) | No Stop | MESA® Spinal System | Pedicle Screw System | Instrument | 15275 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2086-02 | Pyramid Awl (Short) | No Stop | MESA® Spinal System | Pedicle Screw System | Instrument | 15275 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2087 | Rod Holder | | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-2092-01 | Curette | #1 Straight | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13135 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2092-02 | Curette | #0 Straight | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13135 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2092-03 | Curette | #1 Angled | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13135 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2092-04 | Curette | #0 Angled | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13135 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2093-01 | Rod Bender | Right | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 6 MD 0106 | Rule 6 |
| SP-2093-02 | Rod Bender | Left | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 6 MD 0106 | Rule 6 |
| SP-2126 | Insertor | | CASCADIA™ Interbody System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-2359 | Wool Dilator Pin | Pin | DENALI® MI Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-321 | Deformity Screw Inserter | Size Short | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-381 | Handle | Teardrop 1/4 in. Quick Connect | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-489 | Thoracic Probe | Extended | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-493 | Pusher | | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-494 | Cortical Tap Quick Connect | Size 5.0 mm | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-496 | Cortical Tap Quick Connect | Size Ø6.0 mm | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-51 | Awl | | DENALI® Spinal System | Pedicle Screw System | Instrument | 15275 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-512 | Rongeur | Size 6 mm Straight Kerrison | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 2 MD 0106 | Rule 6 |
| SP-513 | Rongeur | Size 4 mm Straight Kerrison | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 2 MD 0106 | Rule 6 |
| SP-514 | Rongeur | Size 6 mm Angled Kerrison | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 2 MD 0106 | Rule 6 |
| SP-515 | Rongeur | Size 4 mm Angled Kerrison | PYRENEES® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 2 MD 0106 | Rule 6 |
| SP-516 | Angled Curette | Right | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13135 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-517 | Angled Curette | Left | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13135 I | CE | | 8 513670/R | 6 1332244/R | | 3 MD 0106 | Rule 6 |
| SP-520 | Rod Template | | NITINOL | | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-536 | Nerve Root Retractor | | DENALI® MI Spinal System | Pedicle Screw System | Instrument | 35315 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-537 | Stylet | | DENALI® MI Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-538 | Outer Dilator | | DENALI® MI Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-539 | K-Wire Driver | For .044 Dia. Guide Wire | DENALI® MI Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-543 | Anti Torque Handle | | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-580 | Tap | 6.5 Screw | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-584 | Straight Probe | Diamond Probe | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-621 | Distractor | | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 6 MD 0106 | Rule 6 |
| SP-622 | Compressor | | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 6 MD 0106 | Rule 6 |
| SP-625 | MI Rod Inserter | | DENALI® MI Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-653-01 | Tissue Retractor | | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-653-02 | Fixation Pin | | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 6 1332244/R | | 1 MD 0106 | Rule 6 |
| SP-653-10 | Nerve Root Retractor | Camulated Nerve Retractor | MESA® Spinal System | Pedicle Screw 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-2426 | Straight Hook Holder | Long | DENALI* Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-2405 | Rasp | Tapered | SAHARA* Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-2448 | T-Handle Wrench | | CHESAPEAKE* Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-2380 | Plate Holder, Buttress | | CAYMAN* Plate System | Cayman Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 5 MD 0106 | Rule 6 |
| SP-2424 | Awl | 20mm | CAYMAN* Plate System | Cayman Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 5 MD 0106 | Rule 6 |
| SP-2425 | Tapered Driver | Size 25 | CAYMAN* Plate System | Cayman Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 5 MD 0106 | Rule 6 |
| 5101-90065 | Add On Kit, Retractors/Wires | Size Ø1.3 mm (Qty 2 ea) SS | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90066 | Add On Kit, Retractors/Wires | Size Ø1.3 mm (Qty 2 ea) NITI | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90068 | Add On Kit, Retractors/Wires | Size Ø1.4 mm (Qty 2 ea) NITI | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90069 | Add On Kit, Retractors/Wires, Beveled | Size Ø1.3 mm (Qty 2 ea) SS | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90070 | Add On Kit, Retractors/Wires, Beveled | Size Ø1.3 mm (Qty 2 ea) NITI | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90071 | Add On Kit, Retractors/Wires, Beveled | Size Ø1.4 mm (Qty 2 ea) SS | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90072 | Add On Kit, Retractors/Wires, Beveled | Size Ø1.4 mm (Qty 2 ea) NITI | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90073 | Add On Kit, Retractors/Wires, Beveled | Size Ø1.5 mm (Qty 2 ea) SS | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90074 | Add On Kit, Retractors/Wires, Beveled | Size Ø1.5 mm (Qty 2 ea) NITI | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90075 | 1 Level Kit, Retractors/Wires | Size Ø1.3 mm (Qty 4 ea) SS | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90076 | 1 Level Kit, Retractors/Wires | Size Ø1.3 mm (Qty 4 ea) NITI | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90078 | 1 Level Kit, Retractors/Wires | Size Ø1.4 mm (Qty 4 ea) NITI | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90079 | 1 Level Kit, Retractors/Wires, Beveled | Size Ø1.3 mm (Qty 4 ea) SS | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90080 | 1 Level Kit, Retractors/Wires, Beveled | Size Ø1.3 mm (Qty 4 ea) NITI | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90081 | 1 Level Kit, Retractors/Wires, Beveled | Size Ø1.4 mm (Qty 4 ea) SS | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90082 | 1 Level Kit, Retractors/Wires, Beveled | Size Ø1.4 mm (Qty 4 ea) NITI | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90083 | 1 Level Kit, Retractors/Wires, Beveled | Size Ø1.5 mm (Qty 4 ea) SS | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| 5101-90084 | 1 Level Kit, Retractors/Wires, Beveled | Size Ø1.5 mm (Qty 4 ea) NITI | EVEREST* Spinal System | Sterile Instrument System | Instrument | 44052 Ila | CE0086 | | 5 804514/R | | | 4 MD 0106 | Rule 6 |
| SP-1434 | Anterior Pituitary Rounger | Size 13* 2 mm | ALEUTIAN* Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| 4508-90147 | Self Retaining Screw Inserter | | CAYMAN* Plate System-MI | Cayman Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 5 MD 0106 | Rule 6 |
| SP-1489 | Screw Inserter | Short w/AO Connect | MESA* Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-1436 | Quick Connect Adapter | | EVEREST* Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| 5101-90104 | Cannulated, Modular Screw Inserter- Tabbed Screw | | EVEREST* Spinal System | Interbody Placement | Instrument | 44759 Ila | CE0086 | | 3 1332244/R | | | 13 MD 0106 | Rule 6 |
| SP-1534 | Lateral Access Retractor | | RAVINE** Lateral Access System | Interbody Access System | Instrument | 8 513670/R | CE | | 8 513670/R | | | 8 MD 0106 | Rule 6 |
| 801-90208 | Compressor, Multi-Span | | MESA* Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-1561 | Fixation Pin Driver | | TERRA NOVA* MI Access System | Interbody Access System | Instrument | 13180 I | CE | | 8 513670/R | | | 8 MD 0106 | Rule 6 |
| SP-1566-01 | Distractor | Size 7 mm | CHESAPEAKE* Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-1566-02 | Distractor | Size 9 mm | CHESAPEAKE* Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-1566-03 | Distractor | Size 11 mm | CHESAPEAKE* Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-1566-04 | Distractor | Size 13 mm | CHESAPEAKE* Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-1566-05 | Distractor | Size 15 mm | CHESAPEAKE* Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-1566-06 | Distractor | Size 17 mm | CHESAPEAKE* Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-1566-07 | Distractor | Size 19 mm | CHESAPEAKE* Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-1566-08 | Distractor | Size 21 mm | CHESAPEAKE* Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-1598 | Pedicle Probe | | EVEREST* Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| 5908-42F30 | Plate, 2 Level | Size 30 mm | PYRENEES* Cervical Plate System | Cervical Plate System | Implant | 61325 Iib | CE0086 | | 1 804494/R | | | 2 MD 0202 | Rule 8 |
| 5908-42F31 | Plate, 2 Level | Size 31 mm | PYRENEES* Cervical Plate System | Cervical Plate System | Implant | 61325 Iib | CE0086 | | 1 804494/R | | | 2 MD 0202 | Rule 8 |
| SP-1654 | Modular Partial Locker | | CASPIAN* Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 6 MD 0106 | Rule 6 |
| SP-1715 | Rod Puller | | 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 | 13180 I | 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-H645300 | 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 | Disc Spreader | 10 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | 8 | 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2183-02 | Elevator, Bayoneted | 10 mm - Reverse | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | 8 | 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2213 | Parallel Distractor | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | 8 | 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2208 | MI Rod Inserter, Bearing Drive | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | 8 | 513670/R | 1 MD 0106 | | Rule 6 | |
| 4601-90041 | Reduction Jack Short | | KEYS™ MI Anterior Deformity Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | 8 | 513670/R | 1 MD 0106 | | Rule 6 | |
| 6401-90101 | MI Posterior Retractor Arm Left | | CANYON™ Retractor Systems | Pedicle Screw System | Instrument | 35315 I | CE | 8 | 513670/R | 1 MD 0106 | | Rule 6 | |
| 6401-90102 | MI Posterior Retractor Arm Right | | CANYON™ Retractor Systems | Pedicle Screw System | Instrument | 35315 I | CE | 8 | 513670/R | 1 MD 0106 | | Rule 6 | |
| 6401-90103 | MI Posterior Retractor Rack | Size 120 mm | CANYON™ Retractor Systems | Pedicle Screw System | Instrument | 35315 I | CE | 8 | 513670/R | 1 MD 0106 | | Rule 6 | |
| 6401-90111 | Straight Blade | Size 23x30 mm | CANYON™ Retractor Systems | Pedicle Screw System | Instrument | 13180 I | CE | 8 | 513670/R | 1 MD 0106 | | Rule 6 | |
| 6401-90112 | Straight Blade | Size 23x40 mm | CANYON™ Retractor Systems | Pedicle Screw System | Instrument | 13180 I | CE | 8 | 513670/R | 1 MD 0106 | | Rule 6 | |

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| Catalog# | Item Description1 | Item Description 2 | System | Technical File | Type | GMDN | Class | CE or CE0086 | Class Rationale | Reportorio Number | TF/ER/ DOC | Device Subcat. | MDD Rule |
|--------------------|---|------------------------|---|-------------------------|------------|------------|--------|--------------|-----------------|-------------------|------------|----------------|----------|
| SP-2309-06 | Lordotic Rasp | 10° 24x30x19 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2309-07 | Lordotic Rasp | 10° 24x30x21 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2306 | Anti-Torque Fixed Handle | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2310 | Overhead Reamer | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| 5101-90252 | Modular Compressor C-Shaped (R) Fulcrum | KAMPRESSOR | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| 5101-90253 | Modular Compressor C-Shaped (L) | KAMPRESSOR | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| 5101-90251 | XT Sleeve | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2331-01 | Retractor | XT Tower | EVEREST® Spinal System | Pedicle Screw System | Instrument | 35315 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2331-02 | Retractor | XT Tower | EVEREST® Spinal System | Pedicle Screw System | Instrument | 35315 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2322 | Insertor Handle Sleeve | Extended | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2311 | Non-Ratcheting Axial Handle | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2312 | T-Handle | Non-Ratcheting | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2176 | Endoscope Holder | | RAVINE™ Lateral Access System | Interbody Access System | Instrument | 13180 I | CE | | 8 513670/R | 8 MD 0106 | | Rule 6 | |
| 3201-91290 | Slap Hammer Hudson Connection | | RAVINE™ Lateral Access System | Interbody Access System | Instrument | 13180 I | CE | | 8 513670/R | 8 MD 0106 | | Rule 6 | |
| SP-2229 | Counter-Torque Arm | | CAYMAN® Plate System-MI | Cayman Plate System | Instrument | 13180 I | CE | | 8 513670/R | 5 MD 0106 | | Rule 6 | |
| SP-2230 | Drill | 3.0 x 10 mm | CAYMAN® Plate System-MI | Cayman Plate System | Instrument | 36235 I | CE | | 8 513670/R | 5 MD 0106 | | Rule 6 | |
| SP-2256 | Insertor Outer Shaft | | CAYMAN® Plate System-MI | Cayman Plate System | Instrument | 13180 I | CE | | 8 513670/R | 5 MD 0106 | | Rule 6 | |
| SP-2353 | Rake Curette | 15 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2343 | Rake Curette | 15 mm 30° Forward | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2344-01 | Rake Curette | 15 mm Bayonetted Right | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2344-02 | Rake Curette | 15 mm Bayonetted Left | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2304 | Reamer | With T-Handle | MESA® Small Stature Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2354 | Slap Hammer | Long | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2132-01 | Lateral Access Blade Extender | 20 mm | RAVINE™ Lateral Access System | Interbody Access System | Instrument | 13180 I | CE | | 8 513670/R | 8 MD 0106 | | Rule 6 | |
| SP-2132-02 | Lateral Access Blade Extender | 30 mm | RAVINE™ Lateral Access System | Interbody Access System | Instrument | 13180 I | CE | | 8 513670/R | 8 MD 0106 | | Rule 6 | |
| SP-2220 | Canulated Curved Probe | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| 5101-90250 | XTower Caliper Offset | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 32262 I(m) | CE0086 | | 7 513674/R | 1 MD 0106 | | Rule 6 | |
| SP-2231 | French Rail Bender | | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2266 | Insertor | Large Handle | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2334-01 | Canulated Tap | Ø4.0 mm Front Cutting | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2334-02 | Canulated Tap | Ø4.5 mm Front Cutting | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2334-03 | Canulated Tap | Ø5.5 mm Front Cutting | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2334-04 | Canulated Tap | Ø6.5 mm Front Cutting | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2334-05 | Canulated Tap | Ø7.5 mm Front Cutting | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2334-06 | Canulated Tap | Ø8.5 mm Front Cutting | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2287-02 | Bone Funnel Pusher | Short | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2287-01 | Bone Funnel | 45° Tip | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2358 | Special Ball Tip Probe | | DENALI® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| 8101-90009 | Rod Clamp | Size Ø5.5 mm | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90010 | Rail Clamp | | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90011 | Rod Clamp | Size Ø6.0 mm | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90012 | Clamp Distractor | | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90005 | Clamp Driver | | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90006 | Clamp Driver Inner Shaft | | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90007 | Saw Guide, Right | | CAPRI™ Corpectomy Cage System | Single Use, Non-Sterile | Instrument | 61300 Ila | CE0086 | | 4 804504/R | 12 MD 0106 | | Rule 6 | |
| 8101-90008 | Saw Guide, Left | | CAPRI™ Corpectomy Cage System | Single Use, Non-Sterile | Instrument | 61300 Ila | CE0086 | | 4 804504/R | 12 MD 0106 | | Rule 6 | |
| 8101-90004 | Saw Forceps | | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90001 | PLL Cutter | | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90003 | Saw Handle | | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90000 | In-situ Rod Flexer | | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90013 | Clamp Distractor Driver | | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 13180 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90014 | Malleable Retractor | Size 32 mm | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 53515 I | CE | | 8 513670/R | 10 MD 0106 | | Rule 6 | |
| 8101-90015 | Malleable Retractor | Size 50 mm | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 61300 Ila | CE0086 | | 4 804504/R | 12 MD 0106 | | Rule 6 | |
| 8101-90016 | Malleable Retractor | Size 76 mm | CAPRI™ Corpectomy Cage System | Corpectomy Cage System | Instrument | 61300 Ila | CE0086 | | 4 804504/R | 12 MD 0106 | | Rule 6 | |
| SP-2360 | Anti Torque Handle | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2361 | Anti Torque Alignment Tube | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2359 | Sleeve | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2345 | Head Adjuster | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-1271-07 | Lordotic Rasp | 12x17x11 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-1271-08 | Lordotic Rasp | 12x17x12 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-1271-09 | Lordotic Rasp | 12x17x13 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-1271-10 | Lordotic Rasp | 12x17x14 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-1271-11 | Lordotic Rasp | 12x17x15 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-1272-07 | Parallel Rasp | 12x17x11 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-1272-08 | Parallel Rasp | 12x17x12 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-1272-09 | Parallel Rasp | 12x17x13 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-1272-10 | Parallel Rasp | 12x17x14 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-1272-11 | Parallel Rasp | 12 x17x15 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| 6201-90097 | Partial Locker, Reduction Jack | Size 90° | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2364-01 | Tap | 3.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2364-02 | Tap | 4.0 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2364-03 | Tap | 4.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2364-04 | Tap | 5.0 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2364-05 | Tap | 5.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2364-06 | Tap | 6.0 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2364-07 | Tap | 6.5 mm | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2352 | Torque Limiting Shaft | Size 30 | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2288 | Bone Funnel | 45° tip | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| 4601-90042 | Offset Compressor | | KEYS™ MI Anterior Deformity Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2340 | Parallel Distractor | Valve Paddle | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2341 | Parallel Distractor | Starter Tip | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2366 | Slap Hammer | Hudson Adapter | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | 3 MD 0106 | | Rule 6 | |
| SP-2365 | Distractor | | TERRA NOVA® MI Access System | Interbody Access System | Instrument | 13180 I | CE | | 8 513670/R | 8 MD 0106 | | Rule 6 | |
| SP-2316-01 | Provisional Screwdriver (Short) | Size 30 | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2316-02 | Provisional Screwdriver (Long) | Size 30 | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2317-01 | Driver, Height Adjustment | Size 25 (Short) | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| SP-2317-02 | Driver, Height Adjustment | Size 25 (Long) | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | 1 MD 0106 | | Rule 6 | |
| 6101-2852404N16-G2 | AN Interbody | Size 8.5x24x4 mm, 6° | CASCADIA™ Interbody System | Interbody Systems | Implant | 34170 Iib | CE0086 | | 2 1332686/R | 3 MD 0202 | | Rule 8 | |
| 6101-2852405N16-G2 | AN Interbody | Size 8.5x24x4 mm, 6° | CASCADIA™ Interbody System | Interbody Systems | Implant | 34170 Iib | CE0086 | | 2 1332686/R | 3 MD 02 | | | |

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 |
|-----------------|--|--------------------|----------------------------------|-------------------------|------------|-----------|--------|--------------|-----------------|-------------------|------------|----------------|----------|
| M5111-07590-G1 | Polyaxial Screw, Cannulated | Size Ø7.5x90 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-085100-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x100 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-085110-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x110 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08535-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x35 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08540-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x40 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08545-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x45 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08550-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x50 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08555-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x55 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08560-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x60 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08565-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x65 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08570-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x70 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08575-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x75 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08580-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x80 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08585-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x85 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-08590-G1 | Polyaxial Screw, Cannulated | Size Ø8.5x90 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-04530-G1 | Fenestrated, Polyaxial Screw | Size Ø4.5x30 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-04535-G1 | Fenestrated, Polyaxial Screw | Size Ø4.5x35 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-04540-G1 | Fenestrated, Polyaxial Screw | Size Ø4.5x40 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-04545-G1 | Fenestrated, Polyaxial Screw | Size Ø4.5x45 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-05540-G1 | Fenestrated, Polyaxial Screw | Size Ø5.5x40 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-05545-G1 | Fenestrated, Polyaxial Screw | Size Ø5.5x45 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-07530-G1 | Fenestrated, Polyaxial Screw | Size Ø7.5x30 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-08540-G1 | Fenestrated, Polyaxial Screw | Size Ø8.5x40 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-08560-G1 | Fenestrated, Polyaxial Screw | Size Ø8.5x60 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-010100-G1 | Sacroiliac Screw, Cannulated | Size Ø10.5x100 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-010110-G1 | Sacroiliac Screw, Cannulated | Size Ø10.5x110 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-010120-G1 | Sacroiliac Screw, Cannulated | Size Ø10.5x120 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-010405-G1 | Sacroiliac Screw, Cannulated | Size Ø10.5x45 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-01050-G1 | Sacroiliac Screw, Cannulated | Size Ø10.5x50 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-01055-G1 | Sacroiliac Screw, Cannulated | Size Ø10.5x55 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-01070-G1 | Sacroiliac Screw, Cannulated | Size Ø10.5x70 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-01080-G1 | Sacroiliac Screw, Cannulated | Size Ø10.5x80 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-01090-G1 | Sacroiliac Screw, Cannulated | Size Ø10.5x90 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-095100-G1 | Sacroiliac Screw, Cannulated | Size Ø9.5x100 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-095110-G1 | Sacroiliac Screw, Cannulated | Size Ø9.5x110 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-095120-G1 | Sacroiliac Screw, Cannulated | Size Ø9.5x120 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-09540-G1 | Sacroiliac Screw, Cannulated | Size Ø9.5x40 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-09545-G1 | Sacroiliac Screw, Cannulated | Size Ø9.5x45 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-09550-G1 | Sacroiliac Screw, Cannulated | Size Ø9.5x50 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-09555-G1 | Sacroiliac Screw, Cannulated | Size Ø9.5x55 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-09570-G1 | Sacroiliac Screw, Cannulated | Size Ø9.5x70 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-09580-G1 | Sacroiliac Screw, Cannulated | Size Ø9.5x80 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| M5111-09590-G1 | Sacroiliac Screw, Cannulated | Size Ø9.5x90 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-3530T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø5.5x30 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-3535T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø5.5x35 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-3540T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø5.5x40 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-3545T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø5.5x45 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-3635T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø6.5x35 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-3640T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø6.5x40 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-3645T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø6.5x45 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-3650T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø6.5x50 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-3655T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø6.5x55 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-37535T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø7.5x35 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-37540T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø7.5x40 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-37545T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø7.5x45 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-37550T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø7.5x50 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| F2911-37555T-G1 | Uniplanar Screw, Fenestrated Transverse | Size Ø7.5x55 mm | EVEREST® Spinal System | Pedicle Screw System | Implant | 61324 IIB | CE0086 | | 2 803267/R | | | 1 MD 0202 | Rule 8 |
| SP-2376 | Cervical Inserter | | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-2381 | MI Rod Insertor | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-2373 | Adjustable Insertor | | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-2384-01 | Footprint Trial | 24x30 mm, Tapered | SAHARA® Stabilization System | Interbody Placement | Instrument | 44759 IIA | CE0086 | | 3 1332244/R | | | 13 MD 0106 | Rule 6 |
| SP-2384-02 | Footprint Trial | 28x36 mm, Tapered | SAHARA® Stabilization System | Interbody Placement | Instrument | 44759 IIA | CE0086 | | 3 1332244/R | | | 13 MD 0106 | Rule 6 |
| SP-2384-03 | Footprint Trial | 30x40 mm, Tapered | SAHARA® Stabilization System | Interbody Placement | Instrument | 44759 IIA | CE0086 | | 3 1332244/R | | | 13 MD 0106 | Rule 6 |
| SP-2342 | Plate Holder | | PYRENESS® Cervical Plate System | Cervical Plate System | Instrument | 13180 I | CE | | 8 513670/R | | | 2 MD 0106 | Rule 6 |
| SP-2385 | Cannulated Probe | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-2374 | Axial Handle, 1/4" Standard Female Hex Chuck | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-2399-01 | Tap | Ø3.5 mm | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 6 MD 0106 | Rule 6 |
| SP-2399-02 | Tap | Ø4.0 mm | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 6 MD 0106 | Rule 6 |
| SP-2399-03 | Tap | Ø4.5 mm | CASPIAN® Spinal System | OCT Spinal Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 6 MD 0106 | Rule 6 |
| SP-2407-01 | Implant Pusher | 1MM | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-2407-02 | Implant Pusher | 2MM | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-2412 | Cervical Insertor | Size 16 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-2315-01 | Rotation Wrench | Straight | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-2315-02 | Rotation Wrench | Angled | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-2390 | Single Barrel Drill/Screw | 16 mm Screw | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 36235 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-2417 | Universal Drill | 25 mm | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 36235 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-2411 | Blade Handle | | RAVINE™ Lateral Access System | Interbody Access System | Instrument | 13180 I | CE | | 8 513670/R | | | 8 MD 0106 | Rule 6 |
| SP-2422 | Retractor | XT | EVEREST® Spinal System | Pedicle Screw System | Instrument | 35315 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-2423 | Tower Support Rod | | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 | | | | | | | |

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 | |
| 5101-90045 | 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 | |
| 5101-90047 | 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 | |
| 5101-90051 | 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-1342 | 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 Insert | Size 14 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | 8 513670/R | | 3 MD 0106 | | Rule 6 | |
| SP-3182-02 | Cervical Insert | 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 | Insert, Outer Shaft/Handle | | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | 8 513670/R | | 3 MD 0106 | | Rule 6 | |
| SP-3226 | Polyaxial Screw Insert | 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 Insert | | 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 | | | | | | | | | | | | | |

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 |
| 801-80805HN | 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 |
| 801-80605SH | 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 |
| 801-80604SH | 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 |
| 801-81005SH | 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 |
| 801-81004SH | 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 | Interbody Systems | Instrument | 61300 Ila | CE0086 | | 4 804504/R | | | 12 MD 0106 | Rule 6 |
| SP-3018 | Anti Torque Handle | | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| 6201-90095 | Driver | Cricket 2 | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-3065-01 | Canulated Tap | Size 4.0 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-3065-02 | Canulated Tap | Size 4.5 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-3065-03 | Canulated Tap | Size 5.0 mm | EVEREST® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-3065-04 | Canulated Tap | Size 6.5 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 7.5 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 8.5 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 | Size 5x8 mm, Bayoneted | 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 Interlock | | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-3043 | Inner Shaft | | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-3044 | T-Handle Tightener | | CHESAPEAKE® Stabilization System | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-3062 | Locking Screw Insertor | | YUKON OCT Spinal System | Interbody Placement | Instrument | 44759 Ila | CE0086 | | 3 N/A | | | 13 MD 0106 | Rule 6 |
| SP-3068 | Curved Thoracic Probe | | MESA® Spinal System | Pedicle Screw System | Instrument | 13180 I | CE | | 8 513670/R | | | 1 MD 0106 | Rule 6 |
| SP-1651 | Modular Unlocker | | 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 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-3060-05 | Parallel Disc Scraper | Size 10 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-3060-06 | Parallel Disc Scraper | Size 11 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 513670/R | | | 3 MD 0106 | Rule 6 |
| SP-3060-07 | Parallel Disc Scraper | Size 12 mm | ALEUTIAN® Interbody Systems | Interbody Systems | Instrument | 13180 I | CE | | 8 51 | | | | |

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

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