



Rethinking Possibilities, Reshaping Lives



next generation polyaxial technology
for optimal placement and enhanced
fixation to accommodate anatomic
variations with minimal tissue disruption


primaLOK SP
INTERSPINOUS FUSION SYSTEM

Indications of Use

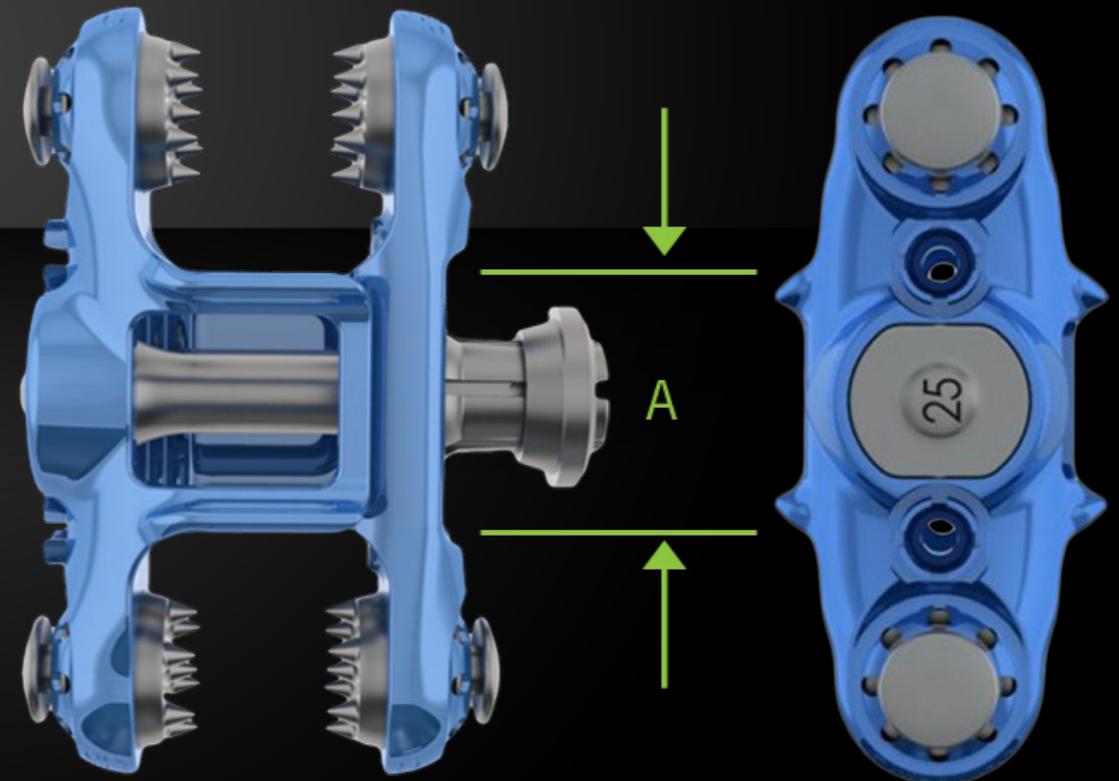
The PrimaLOK™ SP Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The PrimaLOK™ SP Interspinous Fusion System is intended for use at one level, with bone graft material and not intended for stand-alone use.

Surgical Procedures

- Supplemental fixation for ALIF procedures
- Supplemental fixation for TLIF procedures
- Supplemental fixation lateral interbody fusion procedures
- Posterior interlaminar fusion
- Posterolateral fusion
- Revision option in failed fusion / hybrid constructs

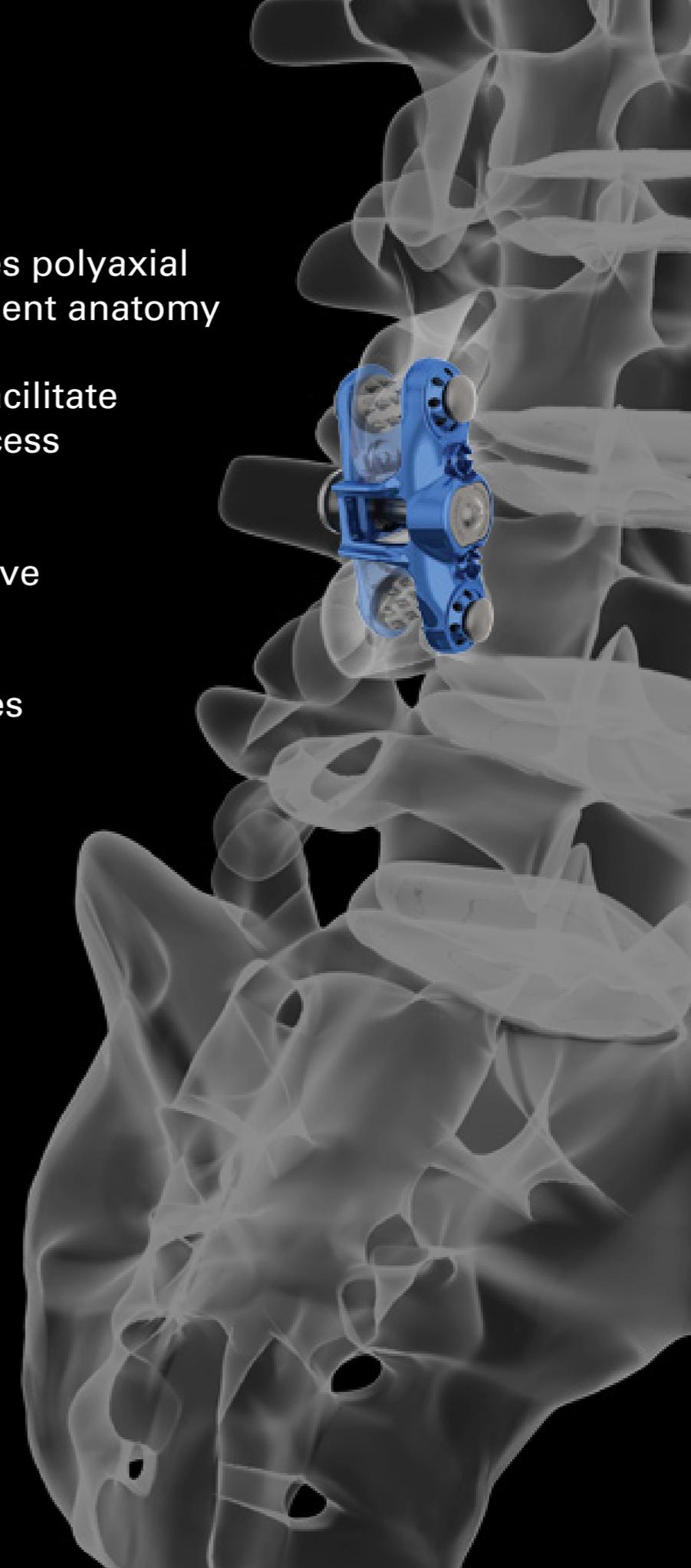
sizing options

| height (A) |
|------------|
| 4mm |
| 6mm |
| 8mm |
| 10mm |
| 12mm |
| 15mm |
| 18mm |



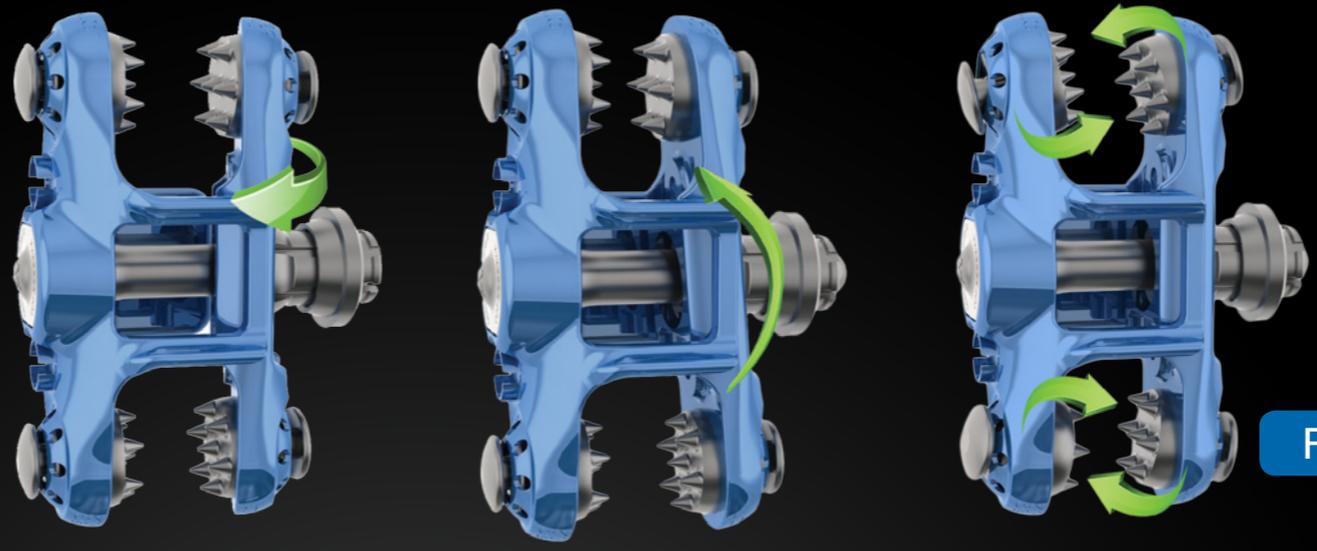
System Features

- **PATENT PENDING POLYAXIALITY:** Innovative implant design incorporates polyaxial implant plate and spiked grips to accommodate natural variations in patient anatomy
- **OPTIMAL IMPLANT PLACEMENT:** Polyaxial plates freely angle open to facilitate both anterior placement of the implant closer to the lamina-spinous process junction where bone quality is greater
- **MINIMALLY DISRUPTIVE:** Implant is placed through a minimally disruptive midline incision
- **ENHANCED GRIP:** Polyaxial spiked grips independently orient themselves for intimate fixation contact with the patient's unique anatomy
- **ANATOMICALLY FRIENDLY:** Smaller spikes provide uncompromising fixation with less-disruption to bony anatomy
- **STRESS FREE FIXATION:** Polyaxial plates freely angle open to accommodate differences in spinous process thicknesses and alignments thus minimizing implant-induced loading; More fixation spikes offer greater fixation load distribution to minimize stress concentrations
- **FUSION READY:** Generous interspinous graft space is easily packed with bone graft or substitute to facilitate interspinous process fusion



Polyaxial Plates

- POLYAXIAL MOVEMENT



Polyaxial Grips

- MULTIPLE SIZES TO MATCH THE PATIENT'S ANATOMY



Implants

| <u>Part Number</u> | <u>Description</u> |
|--------------------|--|
| 800-0104 | PrimaLOK™ SP 4mm Implant Assembly |
| 800-0106 | PrimaLOK™ SP 6mm Implant Assembly |
| 800-0108 | PrimaLOK™ SP 8mm Implant Assembly |
| 800-0110 | PrimaLOK™ SP 10mm Implant Assembly |
| 800-0112 | PrimaLOK™ SP 12mm Implant Assembly |
| 800-0115 | PrimaLOK™ SP 15mm Implant Assembly |
| 800-0118 | PrimaLOK™ SP 18mm Implant Assembly |
| 800-0125-10 | PrimaLOK™ SP 25mm Central Locking Post |
| 800-0130-10 | PrimaLOK™ SP 30mm Central Locking Post |

Instruments

| <u>Part Number</u> | <u>Description</u> |
|--------------------|--------------------------------------|
| 800-0200 | PrimaLOK™ SP Implant Inserter |
| 800-0201 | PrimaLOK™ SP Lock Ring Compressor |
| 800-0202 | PrimaLOK™ SP Retractor Frame |
| 800-0203 | PrimaLOK™ SP Removal Tool |
| 800-0206 | PrimaLOK™ SP 14mm Distractor Screw |
| 800-0207 | PrimaLOK™ SP Distractor Screw Driver |
| 800-0219 | PrimaLOK™ SP Implant Sizer Handle |
| 800-0221 | PrimaLOK™ SP Retractor Extension |
| 800-0308 | PrimaLOK™ SP 8mm Implant Sizer |
| 800-0310 | PrimaLOK™ SP 10mm Implant Sizer |
| 800-0312 | PrimaLOK™ SP 12mm Implant Sizer |
| 800-0315 | PrimaLOK™ SP 15mm Implant Sizer |
| 800-0318 | PrimaLOK™ SP 18mm Implant Sizer |



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