System Highlights

DESCRIPTION AND PATIENT INDICATIONS

The OsteoMed Spine PrimaLOK™ SP Interspinous Fusion System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. PrimaLOK SP is a bilateral locking plate system which attaches to the posterior non-cervical spine at the spinous processes. It is available in various heights and widths to accommodate differing anatomic requirements.

Surgical procedures appropriate for use with PrimaLOK SP include, but are not limited to:

- Supplemental fixation for Anterior Lumbar Interbody Fusion (ALIF), Transforaminal Lumbar Interbody Fusion (TLIF), Lateral Lumbar Interbody Fusion (LLIF), Posterior Lumbar Interbody Fusion (PLIF), Posterior Lateral Fusion (PLF) and lumbar facet screw procedures.

- Supplemental fixation for failed fusion revision and hybrid constructs

INDICATIONS FOR 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 the 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.

For additional information, warnings and contraindications, please refer to the Product Insert.
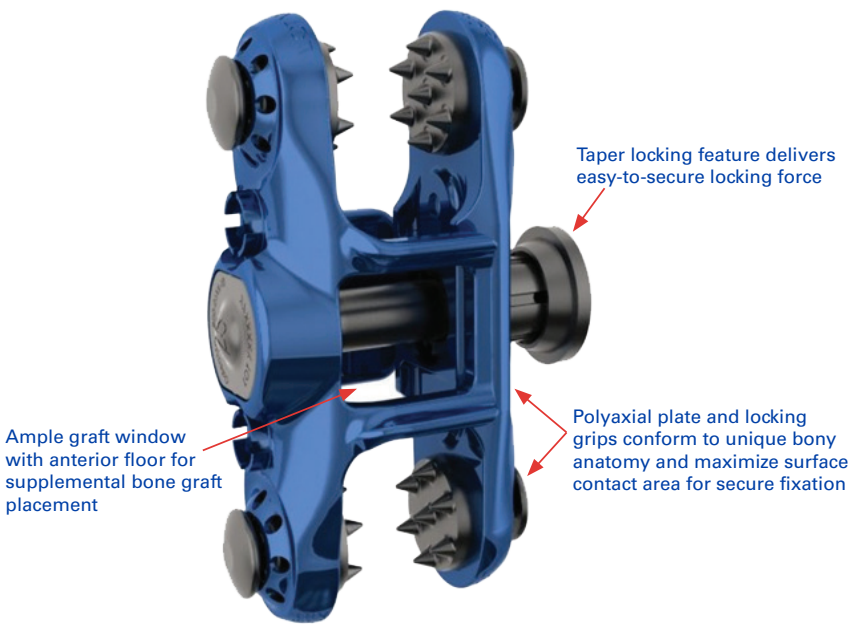
DESIGN RATIONALE

Rethinking lumbar fixation in a fresh new way inspired the design of the OsteoMed Spine PrimaLOK™ SP Interspinous Fusion System. PrimaLOK SP is a next generation posterior lumbar spinous process fixation device. Patent-pending polyaxial technology provides for optimal placement and enhanced fixation to accommodate anatomic variations with minimal disruption to anatomy. These unique features, combined with easy-to-use instrument options for a variety of surgical approaches, result in a streamlined fixation solution tailored to the needs of surgeons and patients.

Taper locking feature delivers easy-to-secure locking force

Polyaxial plate and locking grips conform to unique bony anatomy and maximize surface contact area for secure fixation

Ample graft window with anterior floor for supplemental bone graft placement

DESIGN FEATURES	CLINICAL BENEFITS
Full Polyaxial Design • 4 independent grips/feet • Multi-directional polyaxial plate • 45 degrees of combined grip/plate range of motion	• Accommodates natural variations in anatomy and challenging anatomy • Enables ideal anterior placement where bone quality is best at spinous process/lamina junction • Ideal for placement at L5-S1
Gripping Spikes • 4 grips that independently orient to anatomy • Total of 28 conical spikes (7 per grip) • 1.6mm spike length	• Greater load distribution across each spike provides enhanced fixation while minimizing disruption to spinous process (SP) and reducing fracture risk • Optimal length and number of spikes designed to minimize force concentrations and avoid SP fracture, especially where SP thickness varies
Locking Mechanism • 6 Morse taper locks • Provisional and final locking steps • 300 pounds of compressive force applied to the implant at final lock	• Ability to reposition if necessary before final locking • Locking features designed to minimize risk of implant malfunctions
Graft Window • Integrated window contains approximately .5 2±cc of graft material • Anterior window floor	• Generous graft window can be easily packed with bone graft for supplemental SP fusion • Window floor adds stability and enhances graft containment
Implant Sizes and Sterile Packaging • 7 sizes from 4mm to 18mm • Central post comes in 2 sizes: 25mm standard, 30mm optional • Implants supplied in double peel-pack sterile package that serves as implant loading caddy and allows for placement of the inner tray into the sterile field	• Multiple sizes accommodate variations in patient anatomy and surgical requirements • Sterile packaging maintains implant quality and enhances O.R. speed and ease-of-use