Part No.**030-1663**
Rev**. K**

OSTEOMED SPINE
Interspinous Fusion System
PrimaLOK™ SP

Product Information and Instructions for Use

Description

The **OSTEOMED SPINE PrimaLOK™ SP** Interspinous Fusion System is a bilateral locking plate system which attaches to the posterior non-cervical spine at the spinous processes. It is available in various interspinous heights and widths to accommodate differing anatomic requirements. The Generation I instruments include retractors, sizers, inserter, lock ring compressor, an optional laminar spreader and removal tool to facilitate the placement of the device. The Generation II instruments include a Laminar Spreader, sizers, rasps, inserter compressor, plate inserters, plate compressor, provisional locker, final locker, and removal tool to facilitate the placement and removal of the device. The **PrimaLOK™ SP** is intended to be used to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine.

Material

The device is made from Titanium Alloy (ASTM F-136). The instrumentation is made from various grades of chrome coated stainless steel, anodized aluminum, and/or medical grade plastic.

Clinical Indications

The **OSTEOMED SPINE 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.

Contraindications

Contraindications may be relative or absolute. The choice to implant the **PrimaLOK™ SP** Interspinous Fusion Device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome. Contraindications include, but are not limited to:

1. Allergy or sensitivity to Titanium
2. Active or suspected infection
3. Patients who are immune-compromised
4. Any condition that may affect the process of normal bone remodeling, including, but not limited to osteoporosis, bone absorption, osteopenia, or certain metabolic disorders affecting osteogenesis
5. Morbid obesity
6. Signs of local infection or inflammation
7. The **PrimaLOK™ SP** Interspinous Fusion System is also contraindicated where an anatomical deficit exists in the lamina or posterior arch (i.e. laminectomy, pars defect, or incompetent spinous processes)
8. Fracture of spinous process
9. Spondylolisthesis > grade 1
10. Alcoholism or heavy smoking
11. Pregnancy
12. Any case requiring the mixing of metals from two different systems
13. Any patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation implants

Possible Complications

Possible complications specific to the device may include:

1. Implant breakage, failure, loosening, or migration
2. Bone fracture or fracture to the spinous process
3. Allergic reaction to the implant material

Other general complications associated with any spinal surgery may include:

1. Pseudoarthrosis
2. Pain
3. Revision surgery
4. Bleeding
5. Infection, early or late
6. Tissue or nerve damage
7. Spinal fluid leakage
8. Scar formation
9. Complications due to the use of bone grafting, including donor site complications.

Warnings

1. Use of an undersized device in an area of high functional stresses may lead to implant fracture and failure.
2. Plates, rods and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
3. The **PrimaLOK™ SP** Interspinous Fusion System has not been evaluated for safety and compatibility in the MR environment. The **PrimaLOK™ SP** Interspinous Fusion System has not been tested for heating or migration in the MR environment. The safety and compatibility in the MR environment concerns magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts.
4. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
5. Based on fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
6. Over distraction with the laminar spreader or distractor screws may cause damage to the spinous process or lamina.
7. If the user wants to adjust the PrimaLOK™ implant after the first provisional lock, the implant must be removed and unlocked, then re-inserted with insertion/compression tools before re-applying a provisional lock.
8. Using instruments that have not been properly maintained may lead to inadequate performance and damage to the spinous process or lamina.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation products and techniques.
2. The surgeon must exercise reasonable judgment when deciding which implant sizes to use for specific indications.
3. The **OSTEOMED SPINE PrimaLOK™ SP** Interspinous Fusion System is not intended to endure excessive abnormal functional stresses.
4. Failure to use dedicated, unique **OSTEOMED SPINE** Instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
5. Carefully inspect the **OSTEOMED SPINE** instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to **OSTEOMED SPINE** for disposition and repair.
6. **All the instruments are reusable with the exception of the distraction pins.**
7. **OSTEOMED SPINE** recommends the use of **OSTEOMED SPINE** products in a sterile environment.

Instructions for Use, PrimaLOK™ SP Interspinous Fusion System

Attention, See Instructions For Use located in the Surgical Technique guide, P/N 030-0802, available upon request at no charge

1. With the patient prone, identify the operative level through palpation and intraoperative fluoroscopy.
2. Make a 4-5cm midline incision and elevate the paraspinous musculature exposing the spinous processes and lamina.
3. Remove the supraspinous and interspinous ligaments to allow for proper sizing, distraction and placement of the PrimaLOK™ SP implant.
   Note: Removal of excess soft tissue and osteophytes may be necessary to allow for an optimal placement and fixation of the implant grips to the spinous process

Using Generation I instruments:

4. Place distractor screws in the spinous processes and distract the space using the Lumbar retractor and extension arms. An optional Laminar Spreader may be used in place of the distractor pins.

NOTE: Maintain distraction during implant placement and final locking

NOTE: Distraction of the interspinous space with the Laminar Spreader or Distractor Screws is only intended to provide just enough space to slip the PrimaLOK™ SP implant into position.

5. Size the interspinous space starting with the 4mm sizer and increasing sequentially until proper size is determined. If necessary, utilize a 4mm rasp to facilitate preparation of the interspinous space

NOTE: Bone graft can be packed into the interspinous space of the implant prior to or after insertion of the implant.

6. Holding the implant inserter, make sure the slider tab on the inserter is in the CLAMP position. Open the distal jaws of the inserter by releasing the ratchet arm. (Additional opening of the distal jaws can be achieved by depressing the tab on the ratchet arm.)
7. Locate the corresponding implant in the implant caddy (or load directly from packaging). Place the inserter over the desired implant and align the spherical tabs on the inserter with the mating holes on the implant. Gently squeeze the inserter engaging the inserter to the implant.
8. With the implant secured to the inserter, lift from the caddy and place into the interspinous space, as far anterior and close to the lamina as possible.
9. Gently squeeze the inserter to compress the implant plates together, seating the teeth on the grips into the bone. Confirm that each poly axial grip has seated into the spinous process, and locked out having no motion.
10. Place the slider tab into the LOCK position.
11. With the implant seated, provisionally lock the **PrimaLOK™ SP** into position by squeezing the inserter until an audible click is heard.
12. Place the slider tab back into the CLAMP position and release the ratchet arm. Gently rock the inserter to disengage the spherical tabs from the implant.
13. Confirm placement with fluoroscopy and visual inspection prior to final locking of the implant.
14. Align the Lock Ring Compressor so the circular cut out fits over the tip of the central post, lateral to the locking ring, and the dimple seats onto the base of the post on the opposite side of the implant.
15. Squeeze the locking tool until an audible click is heard. This indicates that the final locking compressive force on the lock ring has been achieved.
16. Pack graft material into the graft space.
17. Release distraction and remove the distractor pins. If distraction was provided by the Laminar Spreaders, to return the tips to their minimum distance apart, release the ratchet. Remove the Laminar Spreader tips by pulling them back and rotating them out from underneath the implant.

Using Generation II Instruments:

Option A

4. Place the Laminar Spreader in the interspinous space and and distract the tips using the ratchet. Optional distractor screws inserted into the spinous processes may be used to distract the space using the Lumbar retractor and extension arms in place of the Laminar Spreader.

NOTE: Maintain distraction during implant placement and final locking

NOTE: Distraction of the interspinous space with the Laminar Spreader or Distractor Screws is only intended to provide just enough space to slip the PrimaLOK™ SP implant into place.

5. Size the interspinous space starting with the 4mm spacer and increasing sequentially until proper size is determined. If necessary, utilize a 4mm Rasp to facilitate preparation of the interspinous space.
6. Once the implant size is determined, select the indicated size from the implant caddy or the Backup Plate Caddy (or load directly from packaging). Prior to loading the implant, ensure the ratchet arm of the Inserter Compressor is up.
7. Align tabs of pivoting tip to polyaxial plate.
8. Snap tabs of pivoting tip into polyaxial plate.
9. Align tabs of rigid tip to post plate.
10. Snap tabs of rigid tip into post plate and lift from caddy.
11. Place the implant into the operative site as far anterior and close to the lamina as possible.
12. Visually confirm that all four polyaxial grips engage the spinous processes.

NOTE:

- In cases requiring extreme angulation of the polyaxial plate and pivoting leg of Inserter Compressor, there is a risk of the pivoting leg blocking the lock ring and preventing sufficient provisional lock. In such cases, the user is advised to insert, compress, and provisionally lock the implant using Generation 2, Option B Instrumentation (see Using Generation II Instruments Option B below).
- The implant can be placed with the lock ring and tip of the central post placed on either side of the spinous process.
- If the implant post tip is close to a facet, confirm there is clearance for the placement of the provisional and final locking instruments.
- Bone graft can be packed into the interspinous space of the implant prior to or after insertion of the implant.

13. Firmly squeeze the Inserter Compressor to compress the implant plates together, fully seating the teeth of the polyaxial grips into the bone.
14. Confirm that each polyaxial grip of the implant has locked out and has no polyaxial motion by gently attempting to translate the implant with the inserter or a probe.
15. Drop and engage the ratchet arm of the inserter compressor to maintain desired implant compression.

NOTE:

- Avoid instrument interference when placing and removing instruments.
- Exercise caution when compressing the implant onto the spinous processes to avoid damage to the spinous processes.

16. With the Inserter Compressor maintaining compression, place the Provisional Locker over the implant.
17. Locate the solid tip of the Provisional Locker over the nub of the Inserter Compressor and the Horseshoe tip over the protruding end of the central post, lateral to the lock ring.
18. Visually confirm correct placement of the distal tips of the Provisional Locker upon the implant.
19. Firmly squeeze the Provisional Locker until it clicks and/or the visual indicator markings align, indicating that the force required to achieve a provisional lock of the implant plates to the spinous processes has been achieved.

NOTE:

- Ensure the ratchet of the Plate Compressor is applied to maintain compression during provisional locking.

20. Remove compressors and provisional locker.
21. Insert the Lock Ring Compressor over the implant assembly.
22. Align the compressor so the circular cut-out fits over the central post tip, lateral to the locking ring.
23. Align the dimpled end of the compressor over the nub of the central post head.
24. Grip and squeeze the Lock Ring Compressor until an audible click is heard. This click indicates that the final locking compressive force on the lock ring has been achieved and the implant is securely placed.

Using Generation II instruments:

Option B

4. Place the Laminar Spreader in the interspinous space and and distract the tips using the ratchet. Optional distractor screws inserted into the spinous processes may be used to distract the space using the Lumbar retractor and extension arms in place of the Laminar Spreader.

NOTE: Maintain distraction during implant placement and final locking

NOTE: Distraction of the interspinous space with the Laminar Spreader or Distractor Screws is only intended to provide just enough space to slip the PrimaLOK™ SP implant into place.

5. Size the interspinous space starting with the 4mm spacer and increasing sequentially until proper size is determined. If necessary, utilize a 4mm Rasp to facilitate preparation of the interspinous space.

NOTE: Bone graft can be packed into the interspinous space of the implant prior to or after insertion of the implant.

6. Holding the implant inserter, open the distal jaws of the Post Plate Inserter by releasing the ratchet arm and allowing the tips to spread apart at their maximum tip to tip distance.
7. Locate the corresponding implant in the implant caddy. Place the Polyaxial Plate Inserter over the desired implant until it "snaps." Once the implant is secured onto both Plate Inserters, lift the implant from the caddy and place into the interspinous space as far anterio and close to the lamina as possible by gently impacting by hand or with the mallet. Loosely place the Plate Compressor over the implant and engage the spherical tabs of the compressor into the mating pockets of the implant. Place another Plate Compressor loosely over the implant on the opposite side.

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8. Remove the Polyaxial Plate Inserter before fully compressing the plates with the plate compressors.
9. Firmly squeeze the handles of both Plate Compressors to fully compress the implant plates together. Confirm that each poly axial grip has seated into the spinous process, and that each polyaxial grip of the implant has no polyaxial motion.
10. Remove the Post Plate Inserter by depressing the side button, and releasing it from the implant.
11. With both of the Plate Compressors maintaining implant plate compression, place the Offset Provisional Locker over the implant. Locate the solid post tip of the Offset Provisional Locker over the nub of the central post, and the horseshoe tip over the protruding end of the central post, lateral to the lock ring. Visually confirm correct placement of the distal tips of the Offset Provisional Locker upon the implant.
12. Firmly squeeze the Offset Provisional Locker until an audible click is heard to indicate that sufficient force has been applied to provisionally lock the PrimaLOK™ SP implant to the spinous processes.
13. Confirm placement with fluoroscopy and visual inspection prior to applying final locking of the implant. Remove the Offset Provisional Locker and plate compressors from the implant.
14. Align the Lock Ring Compressor so the circular cut out fits over the tip of the central post, lateral to the locking ring, and the dimple seats onto the base of the post on the opposite side of the implant.
15. Squeeze the locking tool until an audible click is heard. This indicates that the final locking compressive force on the lock ring has been achieved and the implant is securely placed.

16. Release distraction and remove the distractor pins. If distraction was provided by the Laminar Spreaders, to return the tips to their minimum distance apart, release the ratchet. Remove the Laminar Spreader tips by pulling them back and rotating them out from underneath the implant.

Removal of PrimaLOK™ SP

NOTE: Do not reuse an implant that has been previously locked and unlocked.

1. To unlock the lock ring using the removal tool, confirm that the removal is set in the Number 1 position.
2. Place the forked end of the removal tool between the lock ring and the lateral side of the implant, with the paddle end engaging the tip of the central post.
3. Squeeze the removal tool to disengage the lock ring.
4. With the locking ring disengaged, the implant plates can be grasped, disassembled and separated, and subsequently removed from the spinous processes.
5. If necessary, put removal tool in the Number 2 position to loosen the polyaxial collet.
6. Place the forked end of the removal tool between the lock ring and the lateral side of the implant, with the paddle end engaging the base of the post.
7. Squeeze the removal tool to disengage the polyaxial collet.

Cleaning

- Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
- **OSTEOMED** recommends the following cleaning and sterilization instructions for re-usable Instrumentation:

1. Rinse the articles to be cleaned under running cool tap water (<40°C) to remove visible soil until visibly clean.
2. Prepare an enzymatic cleaner, Klenzyme®, per manufacturer's recommendations. Fully immerse the articles in the solution and soak for a minimum of 10 minutes. Actuate the articles while immersed in the solution to ensure complete penetration of cleaning solution.
3. Using a soft bristled brush, clean the entire article paying close attention to hard to reach areas until all evidence of soil is removed. A syringe may be used to clean the lumens and other hard to reach areas. Actuate the articles while brushing in order to clean matted surfaces and movable parts.
4. Prepare a mild detergent such as Renu-Klenz™, per manufacture's recommendations. Fully immerse the articles in the prepared solutions and sonicate the articles for a minimum of 10 minutes. Following sonication, remove the articles and proceed to the rinse step.
5. Rinse the articles under running reverse osmosis/deionized (RO/DI) water until all evidence of detergent is removed.
6. Steam Autoclave per the following Sterilization Instructions.

Sterility

1. System instruments are supplied NON-STERILE and implants are supplied NON-STERILE and STERILE.
2. Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
3. The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
4. Non-sterile devices should be sterilized by steam sterilization (autoclaving). For sterilization of ***OSTEOMED*** **PrimaLOK™ SP** implant systems, the following parameters should be used.

TRAY SYSTEM:

Pre-Vacuum Steam Sterilization
Temperature: 270°F (132°C)
Time: 4 minutes
Dry Time: 30 minutes

Configuration: Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600-510(k) K082554) using sequential wrapping techniques.
Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

Caution

- **Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.**
- **Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.**

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Symbols and Definitions

Single Use Only		**REF**	Catalogue Number
Use By (Date)		STERILE R	Sterile, Method of Sterilization Using Irradiation
Batch Code (Lot Number)			Consult Instructions for Use
Date of Manufacture			Manufacturer
Attention, See Instructions for Use Caution, Consult Accompanying Documents		EC REP	Authorized Representative in the European Community
Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.			

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