



Attention, See Instructions For Use located in the Surgical Technique Guide, P/N 030-0806, available at no charge

Description

The **OSTEOMED SPINE PrimaLOK™ FF** Facet Fixation System is designed to stabilize the posterior elements of a spinal level as an adjunct to fusion in the lumbar spine. These facet screws are cannulated to assist in placement and have a cancellous thread form for fixation into the pedicle. The 4.5mm diameter **PrimaLOK™ FF** screw implant assembly is available in 25mm, 30mm, 35mm, 40mm and 45mm lengths to accommodate variations in anatomy. The **PrimaLOK™ FF** Facet Fixation System provides instruments to facilitate proper placement of the screws. These include an access needle, guide wire, wire stiffener, cannula inserter assembly, standard cannula, EMG cannula, cannulated tap, cannulated drill, ratcheting driver handle, implant driver, threaded implant driver shaft-cannulated, threaded implant driver shaft-solid and implant removal driver.

Material

The facet fixation implant assembly device is made from Titanium Alloy (ASTM F-136) and Titanium (ASTM F-67). The instrumentation is made from various grades of stainless steel, TiN coated stainless steel, titanium alloy (ASTM F-136), anodized aluminum, nitinol (ASTM F-2063) and/or medical grade plastic.

Clinical Indications

The **OSTEOMED SPINE PrimaLOK™ FF** Facet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. It is intended for use with or without bone graft, at a single or multiple levels from L1 to S1 inclusive,

The **OSTEOMED SPINE PrimaLOK™ FF** Facet Fixation System is indicated for the posterior surgical treatment of any or all of the following: degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, degenerative disease of the facets with instability, trauma (i.e., fracture or dislocation), spondylolisthesis, spondylolysis, and pseudarthrosis and failed fusions which are symptomatic or which may cause secondary instability or deformity.

For transfacet fixation, the screws are inserted through the inferior articular process across the facet joint and into the pedicle.

Contraindications

Contraindications may be relative or absolute. The choice to implant the **PrimaLOK™ FF** Facet Fixation 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 not limited to:

1. Allergy or sensitivity to Titanium or Titanium Alloy
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™ FF** Facet Fixation System is also contraindicated where an anatomical deficit exists leaving an absence or destruction of any portion of the facet joint, pars defect, or in conjunction with procedures which require removal of any portion of the facet joint.
8. Spondylolisthesis > grade 1
9. Alcoholism or heavy smoking
10. Pregnancy
11. Any case requiring the mixing of metals from two different systems.
12. Any patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation screw 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™ FF** Facet Fixation System has not been evaluated for safety and compatibility in the MR environment. The **PrimaLOK™ FF** Facet Fixation System has not been tested for heating or migration in the MR environment.
4. This device is not intended for fixation to the posterior elements of the cervical or thoracic 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. OsteoMed single use devices cannot be reused and/or reprocessed. The device has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. Because this device has not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.
7. It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient.
8. Pre-Plan to avoid damage to vital soft tissue and ensure guide wires are not implanted too deep per the preplanned location.
9. Ensure during procedure that the guide wire does not advance further than the planned location.
10. If guide wire is inadvertently removed during procedure, reinsert by repeating surgical steps in surgical technique guide (030-0806).

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™ FF** Facet Fixation 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 operation 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 access needle, guide wires, and threaded implant driver shaft – cannulated.**
7. **OSTEOMED SPINE** recommends the use of **OSTEOMED SPINE** products in a sterile environment.

1. With the patient prone on a radiolucent table, use AP and Lateral fluoroscopy to target the appropriate spinal level, the start point on the facet, the trajectory of the implant, and the entry point on the skin. The AP view should be adjusted to the lordosis of the level being treated. Place the C-arm into a Ferguson angle so the inferior end plate of the superior level being treated appears as a single line.
2. To determine the entry point on the facets identify and mark the following. Using a guide wire or similar tool locate the midline of the spine, the inferior endplate of the superior vertebral body being treated, and a line connecting the medial borders of the pedicles of the levels above and below the level being treated. The intersection of these two lines represents the docking point for the access needle.
3. Switching to a lateral view, determine the trajectory of the access needle. This will help determine the entry point thru the skin. The entry point is usually a level or two above the level being treated. The trajectory needs to go thru the superior and inferior facet, and continue through the center of the pedicle into the vertebral body.
4. Once you have determined your docking point on the facet and your lateral trajectory, a mid line entry point can be established. In the AP view, mark the point on the mid line where a line from the medial half of the pedicle through your docking point on the facet intersects midline with the same line from the opposite side.
5. Once the entry point is determined, make a small midline stab incision to introduce the access needle. The trajectory of the implant will be medial to lateral. The medial to lateral trajectory will be roughly 10°.
6. Insert the single bevel access needle with the bevel facing up. This will help prevent the needle from skiving off the facet. Advancing of the needle through the skin incision is accompanied by repeated AP and lateral fluoroscopy to confirm precise placement of the access needle.
7. Tap the access needle into the cortex of the superior facet.
8. The access needle can be carefully advanced thru the superior facet and into the inferior facet, or the inner obturator of the access needle can be removed and guide wire inserted. This will be dependent upon quality of bone and surgeon preference. The guide wire can be driven manually or under the assistance of a power wire driver. Drive the guide wire across the facet joint and thru the center of the pedicle into the posterior third of the inferior vertebral body. The wire stiffener placed over the wire at the proximal end of the access needle will help prevent wire bending. Note: under fluoroscopy confirm advancement of guide wire as driven manually or under power.
9. Once the guide wire is placed remove the access needle.
10. With the guide wire placed, extend the skin and facial incisions to 15 mm for placement of the Cannula inserter assembly. The facial incision needs to be incised inferiorly to the skin incision to allow proper placement of the cannula introducer.
11. Prepare the cannula introducer by sliding the standard or EMG cannula over the dilator shaft while the knob is in position #2. Lock the cannula into place by turning the knob to position #1
12. The cannula introducer is placed over the guide wire and advanced until the dilator is docked on the facet.
13. With the dilator docked on the facet turn the knob to position #2. This unlocks the cannula.
14. Press the handle down, sliding the cannula into place.
15. With downward pressure, hold the standard/EMG cannula in place and carefully pull up on the handle, removing the dilator. Make sure that as the Cannula Introducer is removed that the guide wire stays in place.
16. Advance the drill roughly 30mm, to the junction of the pedicle and the vertebral body. **Be careful not to advance the guide wire as the drill is advanced.**
17. Tapping is optional. The **PrimaLOK™ FF** Screw is self tapping. Make sure the tap doesn't advance the guide wire as the tap is advanced. As a visual reference, the threaded portion of the tap is 20 mm.
18. The threaded implant driver shaft is designed with a threaded distal tip to retain the screw to the implant driver. This insures the screw will not disengage the driver while being passed over the guide wire. Seat the tip of the driver into the head of the screw and rotate the knob on the proximal end of the driver clockwise to capture the threads in the head of the screw.
19. **NOTE FOR PLACEMENT UNDER DIRECT VISUALIZATION:** If the screw is being placed under direct visualization and a guide wire is not utilized, the optional solid non-cannulated threaded implant driver shaft should be used to retain the screw to the driver. Since this shaft is solid and not cannulated, it may not be used over a guide wire.
20. Confirm with fluoroscopy the trajectory and depth as the screw is advanced over the guide wire. **Be careful not to advance the guide wire as the screw is advanced.**
21. Once screw placement has been confirmed, the screw driver can be disengaged from the implant. Turn the knob on the proximal end of the screw driver counter clockwise to unthread the inner retention shaft from the screw.

Removal of PrimaLOK™ FF Implant Assembly

1. To remove the **PrimaLOK™ FF** Screw, use the Removal Driver seated into the Ratcheting Driver Handle. Gain Access to the head of the screw through a small incision.
2. Using the solid Removal Driver, engage the Driver tip with the screw head and rotate counterclockwise. Due to the initial lagging of the screw into the bone, and the anti rotation mechanism in the washer, a fair amount of resistance may be encountered to break the screw, washer, and bone interfaces.
Note: The Removal Driver is a non-cannulated instrument. Do not use the **PrimaLOK™ FF** Implant Driver and Threaded shaft to remove the screw. Do not try to re-engage the threads of the Threaded Implant Driver Shaft with the threads in the head of the screw, as cross threading may occur, damaging the Threaded Implant Driver Shaft.
Note: If the tip of the internal implant driver shaft breaks in the screw, the screw can be removed by using the Implant driver without the Threaded Implant Driver Shaft.

Cleaning

- Instruments 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 Instrumentation:
 1. Prepare an enzymatic detergent such as Enzo® according to the manufacturer's recommendations at 1oz/gal of lukewarm tap water.
 2. Using a clean soft cloth that has been soaked in the detergent, wipe the entire article.
 3. Immerse the article in the detergent. Flush with 50mL all hard to reach areas using a syringe with the prepared detergent. Allow the article to soak for 15 minutes.
 4. Using a soft bristled brush, brush the entire surface of the article paying close attention to all hard to clean areas such as cracks, crevices and matted surfaces. Actuate the article while brushing to ensure the reach of all areas. Use a syringe to flush any lumen or matted surface with at least 50mL of prepared detergent.
 5. Brush any lumen a minimum of 5 times from both ends using a lumen brush or similar.
 6. Rinse the articles in RO/DI (reverse-osmosis/deionized) water until all visible evidence of detergent is removed. Flush any lumens or matted surfaces with the RO/DI water. Once all evidence of detergent is removed continue to rinse for an additional 30 seconds.

7. Drain excess water from the article and dry using a clean soft cloth or filtered pressurized air.
8. Prepare a non-enzymatic detergent such as Renu-Klenz™ per manufacturer's recommendations at ¼ oz/gal of lukewarm tap water.
9. Fully immerse the articles in the detergent and flush all lumens with at least 50mL of the detergent.
10. Allow the articles to soak for a minimum of 15 minutes.
11. Thoroughly brush the exterior of the articles using a soft bristled brush. Flush all lumens and matted surfaces a minimum of 5 times.
12. Prepare a fresh cleaning detergent such as Renu-Klenz™ in an ultra sonic cleaner. Fully immerse the articles in the solution and allow the articles to sonicate for a minimum of 10 minutes.
13. Rinse the articles in RO/DI water until all visible evidence of detergent is removed. Flush any lumens or matted surfaces with the RO/DI water. Once all evidence of detergent is removed continue to rinse for an additional 30 seconds.
14. Drain excess water from the article and dry using a clean soft cloth or filtered pressurized air.
15. Visually examine each instrument for cleanliness. If visible soil is noted on the instruments, repeat cleaning procedure.
16. Steam Autoclave per the following Sterilization Instructions.

Sterilization Instructions

Sterility

1. Facet Fixation Screw Devices are supplied **STERILE and NON-STERILE**.
2. Instrumentation is supplied **NON-STERILE**.
3. Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
4. The user facility must clean and disinfect devices prior to sterilization per manual or mechanical cleaning options listed above or per standard hospital procedures.
5. Non-sterile devices should be sterilized by steam sterilization (autoclaving). For sterilization of the **OSTEOMED PrimaLOK™ FF** implant system, the following parameters should be used.

TRAY SYSTEM:

Pre-Vacuum Steam Sterilization

Temperature: 270°F (132°C)
 Cycle Time: 4 minutes
 Minimum Dry Time: 30 minutes

Configuration: Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential envelope folding techniques.

Note: Biological Indicator of *G. stearothermophilus* was used in sterilization validation.

Configuration: 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.

Note: Biological Indicator of *G. stearothermophilus* was used in sterilization validation.

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		Catalogue Number
	Use By (Date)		Do not use if sterile package is damaged
	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture		Manufacturer
	Attention, See Instructions for Use, Caution, Consult Accompanying Documents		Authorized Representative in the European Community
	Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.		Sterile, Method of Sterilization Using Irradiation
	Non-sterile		