Part No. 030-1669
Rev. F

OSTEOMED SPINE
Facet Fixation System
PrimaLOK™ FF
Product Information and Instructions for Use

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, 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 patients 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).
11. The OSTEOMED SPINE PrimaLOK™ FF Facet Fixation System has not been tested for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.
12. Evaluation of the safety and compatibility of the device in the MR environment, the following concerns were determined based on the implant material, MDD 93/42/EEC and ISO14630: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.

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.

Instructions for Use, PrimaLOK™ FF Facet Fixation System

Attention, See Instructions For Use located in the Surgical Technique guide, P/N 030-0806, available at no charge or Full IFU 030-1668

Removal of PrimaLOK™FF Implant Assembly
1. To remove the PrimaLOK™ FF Screw use the Removal Driver seated into the Ratcheting Driver Handel. 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 as Enzol® according to the manufacturer's recommendations at 1oz/gal of lukewarm tap water.
2. Using a clean soft cloth that has been soak 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.
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 *OSTEOMED* PrimaLOK™ FF implant systems, the following parameters should be used.

TRAY SYSTEM:
Pre-Vacuum Steam Sterilization
Temperature: 270ºF (132ºC)
Cycle Time: 10 minutes
Dry Time: 30 minutes

Configuration: Wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600-510(k) K082554) using sequential wrapping techniques.

Do not exceed 275ºF (135ºC), 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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CE 0086

Symbols and Definitions

	Single Use Only	REF	Catalogue Number
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture (MFG Date)	EC REP	Authorized Representative in the European Community
	Manufacturer (MFR)		Attention, See Instructions for Use Caution, Consult Accompanying Documents
	Keep dry	Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.
	Do not use if sterile package is damaged	STERILE R	Sterile, Method of Sterilization Using Irradiation

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