The following surgical technique is for illustrative purposes only. As with all orthopedic surgical procedures, the technique used in each case will depend on the surgeon’s medical judgment as to the best treatment for each patient. Detailed pre-operative planning is essential. Preoperative diagnostic evaluation followed by a carefully executed surgical technique is required. Only those individuals with specialized training and experience in spinal surgery should attempt use of the Osteomed PrimaLok™ FF Facet Fixation System. Refer to the instructions for use for the complete list of indications, contraindications, warnings, cautions and other information about the system.
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.

Indications for Use

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.

Warnings

Use of an undersized device in an area of high functional stresses may lead to implant fracture and failure. Plates, rods and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site. 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. This device is not intended for fixation to the posterior elements of the cervical or thoracic spine. 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. 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. It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient. Pre-Plan to avoid damage to vital soft tissue and ensure guide wires are not implanted too deep per the preplanned location. Ensure during procedure that the guide wire does not advance further than the planned location. If guide wire is inadvertently removed during procedure, reinsert by repeating surgical steps in surgical technique guide.
PrimaLOK™ FF 4.5mm Facet Fixation screws are available in 25, 30, 35, 40, and 45mm lengths to accommodate variations in vertebral body sizes, and pedicle.
SURGICAL TECHNIQUE

PATIENT POSITIONING

Position the patient prone on a radiolucent table. Ensure adequate clearance around the surgical table for movement of the fluoroscopic C-arm.

If possible, use bi-planar fluoroscopy to make the surgery quicker and smoother. If the room set up allows, bring the lateral c-arm from the foot of the bed, and the AP c-arm should come in obliquely from the head of the bed.
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.

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 PrimaLOK™ FF access needle.
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 thru the center of the pedicle into the vertebral body.

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.
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°.

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.

Once precise placement is confirmed, tap the access needle into the cortex of the superior facet.
DILATION & CANNULA INSERTION

At this point the access needle can be carefully advanced through 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 through 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.

Advancement of the guide wire should be accompanied by a series of fluoroscopy images to insure the wire does not change trajectory as it passed across the facet joint and into the pedicle. Once the guide wire is placed remove the access needle.
DILATION & CANNULA INSERTION

With the guide wire placed, extend the skin incision and facial incisions to 15 mm for placement of the dilator and working cannula. The facial incision needs to be incised inferiorly to the skin incision to allow proper placement of the cannula introducer.

Prepare the cannula introducer by sliding the gold cannula over the dilator shaft while the knob is in position #2. Lock the cannula into place by turning the knob to position #1.

The cannula introducer is placed over the guide wire and advanced until the dilator is docked on the facet.
DILATION & CANNULA INSERTION

1. With the dilator docked on the facet turn the knob to position #2. This unlocks the cannula.

2. Press the handle down, sliding the cannula into place.
3. With downward pressure, hold the gold 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.

4. The working cannula is now placed and is a clear working channel to drill, tap the facet, and place the implant.
DRILLING

The cannulated drill is placed on the handle and passed over the guide wire. Confirm with fluoroscopy the trajectory and depth as drilling.

*Note: This can also be done under power using the cannulated power drill. Make sure the drill doesn’t advance the guide wire as the drill advances.*

Advance the drill roughly 30mm, to the junction of the pedicle and the vertebral body.
NOTE: Tapping is optional. The PrimaLOK™ FF Facet Screw is self tapping.

Seat the tap into the handle, pass over the guide wire, and tap to the desired depth. Tapping needs to be done by hand. Confirm with fluoroscopy the trajectory and depth as 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. This can help the surgeon confirm the desired screw length.
IMPLANT PLACEMENT

Attach the desire implant to the screw driver. The screw driver inner shaft is designed with a threaded distal tip to retain the screw to the 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.

Pass the screw and driver over the guide wire. The guide wire can be removed once the screw is into the vertebral body.

NOTE: 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.
IMPLANT PLACEMENT

Confirm with fluoroscopy the trajectory and depth as the screw is advanced over the guide wire. Careful not to advance the guide wire as the screw is advanced.

Placement of the implant should be confirmed using a series of fluoroscopy images.
Once screw placement has 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.
To remove the PrimaLOK™ FF Facet Screw use the Removal Driver seated into the Ratcheting Driver Handle. Gain access to the head of the screw through a small incision.

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 Implant Driver Shaft to remove a screw. Do not try and 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. If the threaded tip of the implant driver shaft breaks in the screw, the screw can be still be removed using the implant driver without the implant driver shaft.
INSTRUMENTATION

800-1211  PrimaLOK™ FF Implant Driver
800-1212  PrimaLOK™ FF Threaded Implant Driver Shaft - Cannulated (single use)
800-1213  PrimaLOK™ FF Threaded Implant Driver Shaft - Solid
800-1210  PrimaLOK™ FF Cannula Inserter
800-1205  PrimaLOK™ FF Standard Cannula
800-1206  PrimaLOK™ FF EMG Cannula
800-1215  PrimaLOK™ FF Ratcheting Driver Handle
800-1201  PrimaLOK™ FF 3.0mm Cannulated Drill
800-1221  PrimaLOK™ FF 3.0mm Cannulated Power Drill
800-1202  PrimaLOK™ FF 4.5mm Cannulated Tap
800-1203  PrimaLOK™ FF Removal Driver
800-1204  PrimaLOK™ FF Guide Wire Stiffener
800-1207  PrimaLOK™ FF Access Needle
800-1200  PrimaLOK™ FF Guide Wire 20" x .053"
CONTRAINDICATIONS AND COMPLICATIONS

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 are not limited to:

- Allergy or sensitivity to Titanium or Titanium Alloy
- Active or suspected infection
- Patients who are immune-compromised
- 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.
- Morbid obesity
- Signs of local infection or inflammation.
- 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.
- Spondylolisthesis > grade 1
- Alcoholism or heavy smoking
- Pregnancy
- Any case requiring the mixing of metals from two different systems.
- Any patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation screw implants.

COMPLICATIONS

Possible complications specific to the device may include:
- Implant breakage, failure, loosening, or migration
- Bone fracture or fracture to the spinous process
- Allergic reaction to the implant material

Other general complications associated with any spinal surgery may include:
- Pseudoarthrosis
- Pain
- Revision surgery
- Bleeding
- Infection, early or late
- Tissue or nerve damage
- Spinal fluid leakage
- Scar formation
- Complications due to the use of bone grafting, including donor site complications
Circumstances listed below may reduce the chance of a successful outcome. Contraindications may be relative or absolute. The choice to implant the Facet Fixation System is to be carefully weighed against the patient’s overall evaluation. Contraindications include:

1. Allergy or sensitivity to Titanium or Titanium Alloy
2. Bone fracture or fracture to the spinous process
3. Patients who are immune-compromised
4. Prior radiation therapy to the area
5. Circumstances that may affect the process of normal bone remodeling, including, but not limited to osteoporosis, bone absorption, osteopenia, or certain metabolic disorders affecting osteogenesis
6. OsteoMed single use devices cannot be reused and/or reprocessed. The device has been sterilized and implant removal driver. Instruments which are faulty, damaged, or suspect OsteoMed medical products and techniques.

Instructions for Use, PrimaLOK™ FF Facet Fixation System

1. To remove the PrimaLOK™ FF Screw use the Removal Driver seated into the Ratcheting Driver Handle. Gently Access to the head of the screw through a small incision.

2. 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, the initial torque generated is in the direction of the screw.

3. Note: The Removal Driver is a non-cannulated instrument. Do not use the PrimaLOK™ FF Instrument Driver and Threaded shaft to remove the screw. Do not try to re-engage the threads of the Threaded Instrument Driver Shaft with the thread of the head of the screw, as cross threading may occur, damaging the Threaded Instrument Driver Shaft.

4. The tip of the internal implant driver shaft breaks in the screw, the implant can be removed by using the implant driver without the Threaded Instrument Driver Shaft.

5. Instruments must be carefully cleaned prior to sterilization. Trained personnel must perform and maintain the sterilization process.

6. Compromise is required with the equipment manufacturer’s user instructions (manual and/or machine, cleaning, ultrasound, treatment, etc.) and recommendations for chemical sterilization. Each implant system, the following parameters should be used:

7. PrimaLOK™ FF Facet Fixation System has not been evaluated for safety and performance in the MR environment. The PrimaLOK™ FF Facet Fixation System has not been tested for heating or migration in the MR environment.

8. Caution, Consult the OsteoMed website for proper cleaning and sterilization instructions. This material is intended for use only with OsteoMed sterilization methods. Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed medical products and techniques.

9. The PrimaLOK™ FF Facet Fixation System is contraindicated in contexts in which the physician administrator in a sterile environment.

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 the implant system.

13. Complications due to the use of bone grafting, including donor site complications.

14. Scar formation

15. Full evidence in the literature that the implant will not affect the performance of the system.

16. Potential for cross-infection via donor site contamination.

17. Removal of the implant system.

18. Symptoms of local infection or inflammation.

19. Symptoms of the facet joint and into the pedicle.

20. The procedure of the implantation technique and the size of the implant is to be carefully weighed against the patient’s overall evaluation.

21. Failure to use dedicated, unique OsteoMed™ Spinal System Instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient failure. Failed devices may require reoperation and removal.

22. OsteoMed recommends the following cleaning and sterilization instructions for

23. OsteoMed recommends the following cleaning and sterilization instructions for

24. Patients who are immune-compromised

25. Prior radiation therapy to the area

26. Circumstances that may affect the process of normal bone remodeling, including, but not limited to osteoporosis, bone absorption, osteopenia, or certain metabolic disorders affecting osteogenesis

27. OsteoMed single use devices cannot be reused and/or reprocessed. The device has been sterilized and implant removal driver.

28. Instruments which are faulty, damaged, or suspect OsteoMed medical products and techniques.

29. The tip of the internal implant driver shaft breaks in the screw, the implant can be removed by using the implant driver without the Threaded Instrument Driver Shaft.

30. Infection, osteopenia

31. Bone fracture or fracture to the spinous process

32. Patients who are immune-compromised

33. Pri...