LPlate™ MIS Fusion System
Surgical Technique Guide

The following general 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 carefully executed surgical technique is required. Only those individuals with specialized training and experience in spinal surgery should attempt use of the Biomet Spinal Fixation System. Refer to the Instructions for Use for a detailed list of indications, contraindications, warnings, cautions and other information about the system.

Note: Interbody fusion technique is not covered in this technique guide. If performing an interbody fusion, disc preparation and interbody spacer placement are performed prior to placement of the LPlate device.

Patient Preparation and Surgical Access
1) Position the patient in the prone position on the operating table.
2) Identify the spinous processes of the level to be instrumented, using manual palpation and intraoperative imaging.
3) Make a midline incision about 3cm in length to expose the spinous processes at the correct level.
4) Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina. Depending on the surgeon’s preferred technique, the supraspinous ligament may be left intact, reflected or removed entirely.

Preparation of the Implant Site
5) Clear the fusion site of connective and soft tissues, lightly decorticating the bone surfaces. If fusing through the spinous processes, a burr, ronguer or rasp may be used to remove the interspinous ligament. If not using interspinous bone graft, the interspinous ligament may optionally be incised/dilated without complete removal.
6) If a decompression procedure is desired, perform a conservative laminotomy, partial facetectomy, foraminotomy or other decompression procedure as needed.
   Caution: Do not remove excessive amounts of bone, particularly from the base of the spinous processes and midline lamina. Weakening the posterior arch by aggressive bone removal may increase the risk of intraoperative or postoperative fracture of the adjoining spinous processes or posterior arch.
7) If the facets are hypertrophied and do not allow for proper anterior placement of the implant, the facets may be trimmed. Do not perform a complete bilateral facetectomy. Preserving a sufficient portion of the facets to preserve biomechanical stability for axial rotation and transverse shear loads is required.

8) If the interspinous ligament has not been excised, insert the first dilator and puncture the interspinous ligament, placing it as far anterior as possible.

**Caution:** Do not over-dilate the implant space. Excessive force may fracture the spinous processes.

**Inserting the Implant**

9) Attach the posted side of the implant to the plate-post body inserter. The small pins on the inserter tip engage the slots along the posterior aspect of the spiked plate. Once the tips are positioned, the adjuster knob must be tightened fully to secure the implant to the inserter.

10) Place the plate-post body along the spinous processes, with the central post lying in the space between the spinous processes.

11) Attach the mating lock plate to the lock plate inserter. The peg of the inserter fits inside the set screw while the curved portion surrounds the set screw housing. Note: It is important to ensure that the set screw has been adequately backed up, flush with the top of the lock plate, to allow the plates to slide together.

12) Slide the mating lock plate over the central post and along the spinous processes. See Figure A.

**Optional Technique:** If the supraspinous ligament has been reflected or removed, and the interspinous ligament excised, the implant assembly may be inserted from the posterior midline position, rather than individually placing the plates from a lateral position.

13) Before compressing the plates and tightening the set screw, ensure that the device is placed as far anteriorly as possible, and that the plate does not protrude above the lumbodorsal fascia. Also confirm position in the sagittal plane, ensuring that the fixation spikes will securely engage both spinous processes. The lock plate will angulate up to ±10° in the coronal plane, to accommodate the bony anatomy. Confirm correct placement with radiograph.

14) Align the conical tips of the compressors into the lateral divots in each plate. Prior to applying compression, take a lateral x-ray to confirm proper positioning and remove the inserters.

15) Using the compressors, clamp the plates against the spinous processes, slowly driving the spikes into the bone. Squeeze both compressors simultaneously or alternate back and forth, just enough to ensure the spikes seat properly in both the inferior and superior spinous processes. Visually confirm that the spikes are fully seated in the bone, with good apposition of the plates against the sides of the spinous processes – if the base of the spikes are still visible, apply more compression until the plates are fully seated. See Figure B.

16) Tighten the locking set screw with the 30 in-lb preset-torque driver, while maintaining compression on the plates. To ensure proper screw torque, tighten until the driver clicks twice. Note: To ensure that the plates and set screw are fully engaged at the interconnection, visually confirm that the post protrudes beyond the lateral face of the lock plate by at least one plate thickness (3 mm).

17) Remove the compressors. Visually and manually inspect the plate to confirm secure fixation. Check placement of the device using x-ray or guidance equipment as needed.
Figure A: Inserting the LPlate™ spinous process fusion plate over the spinous processes

Figure B: Crimping the plates against the spinous processes, to seat the spikes in the bone
Bone Grafting and Closure
The LPlate MIS Fusion System is intended for use with bone graft material, not intended for stand-alone use.

Interbody bone grafting technique is not covered in this technique guide. If performing an interbody fusion, disc preparation and interbody spacer placement are typically performed prior to the placement of the LPlate device.

18) If not previously performed, decorticate the bone surfaces, prepare the fusion site for grafting and place the bone graft material in the usual manner.

When fusing through the spinous processes, bone graft may be placed anterior to the device in the interspinous space before placement of the LPlate device.

If the supraspinous ligament was resected, bone graft may be packed posterior to the device between the tips of the spinous processes.

If fusing through the facets decorticate articular surfaces and place bone graft in the usual manner. If desired, additional posterior bone grafting material may be placed around the implant, in the posterolateral gutter and/or across the interlaminar space.

19) After the construct is implanted and bone graft completed, close the surgical site using standard techniques. If the supraspinous ligament was reflected, it may be sutured back to the tips of the spinous processes. The fascia may be closed back to the supraspinous ligament.

20) The LPlate device is intended for use with bone graft material, not intended for stand-alone use.
**Removal of the Implant**

1) The LPlate spinous process fusion plate construct can be removed if necessary.

2) Use the driver to loosen the locking set screw.

3) The plates can then be separated with a Cobb elevator or similar instrument and removed from the spinous processes.

**IMPORTANT INFORMATION ON THE LPLATE™ MIS FUSION SYSTEM**

**DEVICE DESCRIPTION**

The LPlate system is a posterior attachment spinal fixation system composed of spinous process plates, dedicated surgical instruments, and sterilization cases. The components are used to build a construct to provide stabilization of spinal segments in the thoracic, lumbar and sacral spine to support fusion. The LPlate device is part of the Biomet Spinal Fixation System, which offers the surgeon a variety of implant components from which to assemble a suitable construct according to each individual patient’s needs and requirements. It is essential to use the Lanx implants with their specifically designed instruments. After a solid fusion occurs, the system serves no functional purpose and should be removed. Removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. However, any decision to remove the device must be made by the physician and the patient, taking into consideration the patient’s general medical condition and the potential risk to the patient of a second surgical procedure.

**INDICATIONS FOR USE**

The Biomet Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The system is intended for use with autograft or allograft.

The Biomet Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, 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); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

The LPlate device is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes 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 LPlate device is intended for use with bone graft material, not intended for stand-alone use.

**CONTRAINDICATIONS**

Contraindications may be relative or absolute. The choice of a particular 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:

- An allergy to titanium or cobalt chrome alloys, or foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to implantation.

- Known or suspected infection/immune system incompetence. Acute or chronic infectious diseases of any etiology or localization.
• Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, active infection at the site or certain metabolic disorders affecting osteogenesis.

• Morbid Obesity. An overweight or obese patient can produce loads on the spinal system, which can lead to failure of the fixation of the device or failure of the device itself.

• Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.

• Open Wounds.

• Pregnancy.

• Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.

• Any case requiring the mixing of components from other manufacturers’ systems.

• Any case requiring the mixture of stainless steel with titanium, or stainless steel with cobalt chrome implant components.

• Fever or leukocytosis.

• Signs of local infection or inflammation.

• Previous history of infection.

• Alcoholism or heavy smoking.

• Senility, mental illness or substance abuse, of a severity that the patient may ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.

• Any patient unwilling to follow post-operative instructions.

• Inadequate tissue coverage over the operative site.

• The LPlate device is also contraindicated for incompetent or missing posterior arch (e.g., laminectomy, pars defect, severe osteoporosis).

POSSIBLE COMPLICATIONS
Possible complications specific to the device may include:

• Early or late implant bending, breakage, failure, loosening or movement/migration

• Bone and/or spinous process fracture

• Allergic reaction to implant material

Other general complications associated with any spinal surgical procedure may include: non-union or delayed union, pseudarthrosis; pain; second surgery; bleeding; infection, early and late; tissue or nerve damage, including dural tears or other neurological problems; incisional complications; scar formation; damage to blood vessels and cardiovascular system compromise; changes in mental status; damage to internal organs and connective tissue; complications due to the use of bone grafting, including graft donor site complications; respiratory problems; reactions to anesthesia and/or death.

WARNINGS
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery, where many extenuating circumstances may compromise the results.

PRECAUTIONS

• The LPlate implants are for single use only. Never reuse any implant even if it appears unmarked or undamaged. Reuse of the implant components may result in reduced mechanical performance, malfunction, or failure of the device. Any implant implanted and then removed must be discarded. Use only new implants for each case.

• The implantation of spinal fixation systems must only be performed by experienced spinal surgeons with specific training in the use of this system due to the technically demanding procedure presenting a risk of serious injury to the patient.

• Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

• Preoperatively: The surgeon must be fully conversant with all aspects of the surgical
technique and know the indications and contraindications of this type of implant. The surgeon must have acquainted himself before the operation with the specific technique for insertion of the product, which is available from the manufacturer. As part of the preoperative examination, the surgeon must check that no biological, biomechanical or other factors will affect the correct conduct of the operation and the postoperative period. An appropriate range of implant sizes must be available at the time of the operation.

- Intraoperatively: The correct selection of the type and size of implant appropriate to the patient and the positioning of the implant are extremely important.

- Postoperatively: Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that regular postoperative follow-up is undertaken to detect early signs of failure of the implants and to consider the action to be taken. Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implants. The implant can be removed after bony healing.

- The LPlate device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The LPlate device has not been tested for heating or migration in the MR environment.

PRODUCT COMPLAINTS — Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to BIOMET SPINE by email: spinecomplaints@biomet.com or phone: 866.956.7579. When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint, surgeon name and the date you became aware of the complaint. Sterilize and return all component(s) to your local BIOMET SPINE representative. Notify BIOMET SPINE immediately of an incident resulting in patient death or serious injury.

If further directions for use of this system are needed, contact BIOMET SPINE Customer Service by email: spinecustomerservice@biomet.com, phone: 866.378.4195 or fax: 303.443.7501.