as described by:

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Trial

Guide

Plate

Cover Plate

IMPLANTS & INSTRUMENTS

Trial Holder Shaft

Tapered Awl

3.5mm Hex Screw Driver

Plate Holder and Guide Assembly

Top View Plate Construct

3/4 View Plate Construct
PREFACE

“Anterior Lumbar Interbody Fusion (ALIF) is a versatile and useful technique. Traditionally, when segmental spinal instability is present and an ALIF has been employed, a 360° approach adding pedicle screws has been previously required.

The XANTUS Plate is a uniquely designed, anatomically streamlined, Variable Screw Plate ideally suited for rigid anterolateral lumbar fixation at L4–L5 and above. This rigid fixation supplements the anterior interbody construct and precludes the need for combined anterior and posterior approaches for a 360° fusion. The XANTUS Plate is a useful and versatile option for spine surgery. The smooth, low profile design enables placement adjacent to the vasculature and lumbrosacral plexus without impingement.”

Sincerely,

Curtis A Dickman, M.D.    Jean–Charles LeHuec, M.D. Ph.D.

ADVANTAGES

• Compatible with adjacent vasculature and neural structures
• Low profile
• Variable angle screws
• Locking screw plate
• Smooth contours
• Single stage approach for ALIF and supplemental fixation
• Minimal blood loss
• Preserving normal posterior spinal anatomy
ANATOMY-SURGICAL SUGGESTIONS

The L5 vertebral body has a unique triangular shape that differs from the oval shape of the other lumbar vertebrae (Fig. 1 and Fig. 2). This triangular shape needs to be considered when positioning Screws and Plates in L5. If using the Screw Guide for L5 screws, then the L5 screw trajectory may be aimed toward the spinal canal or toward the neural foramen. Adjust the screw trajectory so that the Screws are coronally oriented (Fig. 2).

Also, at L5, the iliac vessels must be sufficiently ventral, to permit lateral Plate placement without impinging on the vessels. This can be assessed preoperatively on CT or MRI Studies.

Anomalous vasculature, a very thick iliopsoas muscle, or a wide iliac wing could potentially interfere with the ability to satisfactorily approach the segment from a lateral retroperitoneal approach or to fit a Screw Plate in satisfactory position. The regional anatomy can be assessed preoperatively with X–rays, MRI and CT scans.
1 SURGICAL APPROACH/EXPOSURE

- The patient is positioned in a true lateral decubitis position on the operating table with the left side up.
- A left sided lateral retroperitoneal approach is performed to expose the spinal segment of interest.
- The peritoneal contents, ureter and great vessels are retracted medially and anteriorly, away from the spine.
- The vasculature is mobilized to permit exposure of the spine. At L5 and rostral levels, the iliolumbar and segmental spinal vessels are ligated.
- Subperiosteal exposure of the spine is performed and the psoas muscle is gently retracted, along its medial border, in a posterior direction.
- The nerve roots are preserved and protected, and the neural foramen is identified.
- The interbody procedure is performed using the surgeon’s preferred technique and interbody construct.

Note: The technique described is for a lateral retroperitoneal approach at L4-L5 and for the rostral lumbar (or thoracic) disc levels.

2 TEMPLATING

- The proper size construct should be selected by comparing the various size Trials to the patient’s effected segment.
- Thread the Trial onto the Holder and place inside the incision.
- The XANTUS Plate should contact only the surfaces of the vertebral bodies that are to be fixated and should NOT be in contact with the adjacent healthy discs. Complete visualization of the superior and inferior vertebral bodies should be seen through the screw trial slots. (Fig. 3)
- The trials are inserted to determine appropriate size construct.
- Use the smallest XANTUS Plate possible to ensure that the plate does not contact the adjacent healthy discs.
• Attach the selected XANTUS Plate to the Plate Holder by tightening the Plate Holder Screw with the 3.5mm Hex Screw Driver.

• Attach the appropriate color-coded Guide to the Plate and Plate Holder (above the fastened Plate) and secure it by tightening the Screw in the center of the Guide with the 3.5mm Hex Screw Driver. Ensure that all holes are adequately aligned.

• Position the XANTUS Plate against the lateral surface of the vertebral bodies and ensure that the screw holes are in full contact with the vertebral bodies. Center the XANTUS Plate laterally over the vertebral bodies and interbody construct with the narrowest portion of the Plate anterior and the widest portion posterior. (Fig. 4)

• AP and Lateral Fluoroscopic guidance is used to judge the trajectory, depth and positioning of the Screws during the procedure.

• Using the Awl, puncture the cortical surface of the vertebral body through one of the guide holes.

• Engage a screw onto the 3.5mm Hex Screw Driver and thread it into the piloted hole until it engages the XANTUS Plate. (Fig. 5)

• Repeat the steps above working diagonally in the adjacent vertebrae until all four Screws have been placed. (Fig. 6)

*Note:* Due to the triangular shape of the L5 vertebral body, take caution when using the Guide at this level to ensure the screw trajectory is NOT angled toward the neural foramen. If trying to achieve longer screw fixation, place the Screws using a freehand technique and angle the Screws with a trajectory in the coronal plane, parallel to the spinal canal.
COVER PLATE PLACEMENT

- Detach the Plate Holder and Guide Assembly by loosening the Plate Holder Screw with the 3.5mm Hex Screw Driver.
- Final tightening should only be done when all Screws are in place. (Fig. 7)
- Attach the size specific Cover Plate to the Plate Holder with the 3.5mm Hex Screw Driver. (Fig. 8)
- Position the Cover Plate on top of the secured XANTUS Plate.
- Using the 3.5mm Hex Screw Driver thread the Cover Plate Set Screws into the XANTUS Plate until fully tightened.

FINAL CONSTRUCT

- The construct should be inspected to assess the final position of the XANTUS Plate. Ensure that the XANTUS Plate is flush with the vertebral body and that there is no impingement on the adjacent vessels after retraction is released. (Fig. 9)
- Prior to closing, final AP and lateral X-rays should be obtained to assess the final screw position. (Fig. 10 and Fig. 11)
REMOVAL OF HARDWARE

• If removal is necessary, use the 3.5mm Hex Screw Driver to disengage the Cover Plate Set Screws from the XANTUS Plate. (Fig. 13)

• Remove the Cover Plate.

• Use the 3.5mm Hex Screw Driver to unthread and remove each Screw.

• Remove the XANTUS Plate from the incision.

CONTRAINDICATIONS

• Morbid obesity

• Abnormal anatomy that would prevent placing a screw plate in satisfactory position. The regional anatomy can be assessed preoperatively with X-rays, MRI and CT sans.

• Severe osteoporosis is an important contraindication. The ALIF construct could subside, or screw purchase could be insufficient.

See the XANTUS Package Insert at the end of this surgical technique for a complete listing of indications and contraindications.
## Plate Images

![Profile](image)

![Anterior Height](image)

![Posterior Height](image)

![Width](image)

## Plate Dimensions

<table>
<thead>
<tr>
<th>Plate Color</th>
<th>Plate Size</th>
<th>Posterior Height</th>
<th>Anterior Height</th>
<th>Width</th>
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Exposure Time: 30 minutes

In Cycle: Gravity to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent

breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

1. Only patients that meet the criteria described in the indications should be selected.

2. Conditions to be considered may include: (a) the aforementioned conditions should be avoided.

3. Care must be used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.

4. The type of construct to be assembled for the case should be determined prior to beginning the surgery.

5. For surgical purposes, use of the equipment and should be familiar with the various components before using.

6. Sterile, packaged, all parts must be cleaned and sterilized before use. Additional sterile components should be available in case of an emergency.

Intraoperative:

1. All meniscal tears should be carefully followed.

2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.

3. Where the configuration of the joint cannot be filled with an available temporary internal fixation device, and continuing is absolutely necessary, it is recommended that such contouring is gradual and great care is used to avoid rotational or scrubbing the surface of the implant against the bone in the insertion area or excessively bent any other than absolutely necessary. The components should not be reversed in the same location.

4. The implant surfaces should not be scratched or nicked, since such actions may reduce the functional and results.

5. To assure proper fusion between and around the location of the instrumentation, a bone graft should be used.

6. Bone graft should not be used since this material will make removal of the components difficult and impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

7. Before closing, all of the screws or nuts should be seated onto the plate. Caution: Do not over tighten so as to prevent stripping of the threads. All of the nuts should be tightened firmly onto the bolts (if used) with a torque wrench.

8. Recheck the tightness of all nuts after finishing to make sure that none have loosened during the tightening of the other nuts. Failure to do so may cause loosening.

Postoperative:

The physician's postoperative directions and warnings to the patient and the corresponding patient care are important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, or displacement of the bone is complete or unstable may occur as a result of a minor injury.

2. The risk of bending, loosening, or breaking of a temporary internal fixation device during postoperative rehabilitation may be minimal if bending is avoided. The patient should be strongly advised not to do intraoral or extraoral weight supporting devices. The patient should be warned to avoid falls or sudden jerks in spinal position.

3. The patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate by allowing 90% permanent restriction in body motion and to limit and restrict physical activities, especially lifting and lifting motions and any type of sport participation. The patient should be advised of this advice in a written form.

4. The patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate by allowing 90% permanent restriction in body motion and to limit and restrict physical activities, especially lifting and lifting motions and any type of sport participation. The patient should be advised of this advice in a written form.

5. Any patient unwilling to follow the postoperative instructions, such as described by ASTM Standard F136 or ISO 5832-3. Stainless steel and titanium implant components must not be used such as described by ASTM Standard F136 or ISO 5832-3. Stainless steel and titanium implant components must not be used.

6. Any patient having inadequate tissue coverage over the operative site, or inadequate bone stock or bone quality such as in rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication to stress shielding. Implant removal, should be followed after the maximum chances for a successful surgical result: the patient on device or implant is exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and lifting motions and any type of sport participation. The patient should be advised of this advice in a written form.

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