as described by:

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Jean-Charles Le Huec, M.D., Ph.D.
“The PYRAMID™ Anterior Lumbar Plate design fits within the patients’ anatomy in the majority of the cases. The key factors of success are:

1. Vigorous pre-operative evaluation of the vascular anatomy to define the safety zone for placement of the implant design.
2. Anatomic, low-profile implant design to minimize risk of contact with the vessels.
3. Appropriate surgical technique to help ensure a successful supplementary fixation.”

Curtis Dickman, M.D.
“This meticulously designed and anatomically streamlined implant system uniquely permits anterior supplemental fixation to be performed at L5-S1 to augment an interbody fusion construct. This precludes the need for a combined anterior – posterior approach for a 360° fusion. Stable, rigid segmental fixation is achieved with comparable stability to that achieved with pedicle screws. The PYRAMID™ Plate is a useful and versatile option for spine surgery.”

ADVANTAGES

△ Smooth, low-profile design specifically accommodates the vascular anatomy at L5-S1

△ Provides added stability to an interbody construct so that a 360° procedure is not necessary

△ Comparable stability to pedicle screws

△ Spiral lock threads secure the unique cover plate mechanism to help prevent screw backout

△ Size-specific Plate Guides help ensure controlled passage of instruments and precise trajectory

△ Simple, integrated instrument system helps ensure a consistent reproducible procedure

△ Color-coded instruments and implants facilitate size-specific device placement

One Plate...One Approach
Trial Holder Shaft
Retractable Awl
3.5mm Hex Screwdriver
Cover Plate Holder
Plate Holder and Guide Assembly
Top View Plate Construct
3/4 View Plate Construct
There are many advantages to the anterior approach for performing lumbar interbody fusion; however, adding supplemental fixation to an anterior interbody construct has previously required a second surgical site to insert pedicle screws from a posterior approach. The ideal solution would be to have an anterior supplemental rigid fixation device that helps provide immediate fixation, which obviates the need for a second surgery posteriorly.

The primary design considerations for a rigid anterior lumbosacral fixation device are to protect the major vascular anatomy anterior to the lumbosacral spine and to help achieve internal fixation of the spine that is comparable to the fixation achieved with pedicle screws.

Anatomical studies and published surgical anatomy literature were reviewed to determine the configuration and variability of the position of the anterior lumbosacral blood vessels. This data was used to determine the feasibility of placing an anterior L5-S1 fixation device, and to establish the ideal geometry of the implant. Eighty percent of patients have a bifurcation of the iliac vessels 1 cm or more above the L5-S1 disc space, with a safe zone that would accommodate an anterior screw plate. The vast majority of patients would be viable candidates for this type of construct.

Preoperative templating and intraoperative sizing are critical to the successful use of the PYRAMID™ Anterior Lumbar Plating System. CT and MRI studies must be reviewed preoperatively to help assess the patient’s unique vascular anatomy (i.e., position of the bifurcation and the iliac vessels). A low bifurcation or an iliac vessel positioned too medially would preclude anterior plate placement.

The dimensions of the ideal zone, which were determined from this anatomical study, were used to design the PYRAMID™ Anterior Lumbar Plating System. The Plate’s triangular design resembles the anatomical space between the iliac vessels after ligating the middle sacral vessels. Sleek, smooth, and contoured plate surfaces and a triangular shape help to ensure preservation of the adjacent blood vessels and soft tissues. Finally, a secure Cover Plate covers the screwheads to help prevent backout.

Biomechanical studies demonstrated that the PYRAMID™ Plate has rigid internal fixation comparable to pedicle screws.
Using MRI or CT scans, obtain an axial view of the great vessels (Figure 1). Identify the position and angle of the bifurcation to determine feasibility of placing the PYRAMID™ Plate. Using the most caudal image of the L5 vertebral body, determine the position of the vascular anatomy relative to the proposed placement of the PYRAMID™ Plate.

If either iliac vein lies across the midline of the affected disc or the lower Vena Cava is too close to the disc, then the PYRAMID™ Plate cannot be used. If an adequate zone exists between the vessels and the disc, the PYRAMID™ Plate is appropriate to use.

The anterior lumbar spine may be approached through either a transperitoneal or a retroperitoneal exposure. The amount of great vessel release and retraction should be limited to that required for insertion of the instruments and construct (Figure 2).

A chosen interbody device is placed in the L5-S1 disc space according to the specific surgical technique for that device. Ensure that the interbody device is adequately recessed within the disc space. Anterior osteophytes adjacent to the interspace MUST be removed in order to ensure accurate seating of the Plate to the vertebral body.
to assist in the ease of identification. The Trial Holder is inserted into the chosen size Trial and threaded clockwise until secure.

The Trial is inserted into the incision with the narrowest portion of the Trial positioned over the L5 vertebral body, and the widest portion of the Trial over the S1 vertebral body (Figure 3).

The Trial should be evaluated on 3 principles:
- Complete visualization of the vertebral bodies through the slots on the Trial
- Proper positioning of the Trial in relation to the vascular anatomy
- Adequate coverage of the interspace

Use the smallest size Plate possible to ensure cortical endplate purchase with the screws.

4 PLATE & GUIDE ASSEMBLY

The Plate Holder is attached to the top of the appropriate size PYRAMID™ Plate by engaging the Plate Holder Screw into the center screw opening of the PYRAMID™ Plate (Figure 4). The screw is tightened down with the 3.5mm Hex Screwdriver.

The corresponding Guide is then positioned over the top of the PYRAMID™ Plate, making sure to align the openings of the Guide with the PYRAMID™ Plate-screw holes. The Guide is fastened to the Plate Holder with the 3.5mm Hex Screwdriver by tightening the Guide Holder Screw located on the back of the Plate Holder Shaft (Figure 5).
The Plate is positioned with the lip against the inferior endplate of the L5 vertebral body (Figure 6). The Awl is introduced through the Guide to puncture the cortical wall of the vertebral body in order to create a pilot hole for screw placement (Figure 7). Proper midline positioning of the Plate and Screws should be reviewed using A/P fluoroscopy. In addition, lateral fluoroscopy should be used throughout screw preparation and placement to judge the depth of penetration into the vertebral bodies.

The corresponding size PYRAMID™ Cover Plate is attached to the Cover Plate Holder by inserting the Hex Shaft into the Cover Plate Set Screw located at the center of the Cover Plate. The cylindrical post on the inferior aspect of the Cover Plate Holder fits into the small opening of the inferior aspect of the PYRAMID™ Cover Plate (Figure 9).

The Cover Plate and Holder are introduced into the incision. The cylindrical post of the Cover Plate Holder is inserted into the small opening on the inferior aspect of the PYRAMID™ Plate. The T-handle of the Cover Plate Holder is rotated clockwise until the Cover Plate is firmly seated onto the PYRAMID™ Plate (Figure 10). Upward motion is applied to the T-handle to disengage the Cover Plate Holder from the PYRAMID™ Plate construct.

The steps above are repeated for the two S1 vertebral body screw holes. Final tightening of ALL Screws should be performed to ensure that the Plate is completely flush with the surfaces of the L5 – S1 vertebral bodies.

The appropriate length Screw is attached to the 3.5mm Hex Screwdriver and is threaded through the prepared guide hole.

The 3.5mm Hex Screwdriver is inserted into the center guide hole and fastened into the Plate Holder Screw (Figure 8). By rotating the Hex Screwdriver counterclockwise, the Plate Holder and Guide are disengaged from the implanted PYRAMID™ Plate and may be removed from the incision.
HARDWARE REMOVAL INSTRUCTIONS

If hardware removal is necessary, complete the following steps. Attach the Hex Screwdriver to the Cover Plate Set Screw and rotate counterclockwise to unthread the Screw. Remove the Cover Plate with the Cover Plate Holder. Attach the Hex Screwdriver to the S1 Screw and unthread with counterclockwise rotations. Repeat for the second Screw at S1 and L5. Remove the Plate from the incision.

PYRAMID™ PLATE DIMENSIONS

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<tr>
<th>Part #</th>
<th>Description</th>
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<tbody>
<tr>
<td>8969119</td>
<td>19mm PYRAMID™ Plate</td>
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<td>8969121</td>
<td>21mm PYRAMID™ Plate</td>
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<td>8969123</td>
<td>23mm PYRAMID™ Plate</td>
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<td>8969125</td>
<td>25mm PYRAMID™ Plate</td>
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<tr>
<td>8969219</td>
<td>19mm PYRAMID™ Cover Plate &amp; Set Screw</td>
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<tr>
<td>8969221</td>
<td>21mm PYRAMID™ Cover Plate &amp; Set Screw</td>
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<td>23mm PYRAMID™ Cover Plate &amp; Set Screw</td>
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<td>25mm PYRAMID™ Cover Plate &amp; Set Screw</td>
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<tr>
<td>8968625</td>
<td>Bone Screw D=6.5mm L=25mm</td>
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<td>8968630</td>
<td>Bone Screw D=6.5mm L=30mm</td>
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<td>8968635</td>
<td>Bone Screw D=6.5mm L=35mm</td>
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D = Diameter  L = Length

Pyramid Plate Dimensions

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<tr>
<th>Plate Color</th>
<th>Plate Size</th>
<th>Max Height</th>
<th>Max Width</th>
<th>Avg. L5 Width</th>
<th>Plate Profile</th>
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The PYRAMID™ ANTerior LUMBAR PLATE Fixation System is a temporary implant used for the correction and stabilization of the spine. This system is also intended to help provide temporary stabilization and to help augment the development of a solid spinal fusion.

**DESCRIPTION:**
The PYRAMID™ ANTerior LUMBAR PLATE Fixation System is a supplemental fixation device consisting of a variety of shapes and sizes, and can also be used as a posterior fixation construct. The implant is made of stainless steel and titanium implant components. The implant components should be locked into a variety of configurations, with each construct being tailor-made for the individual case. As with any orthopedic and neurological surgical procedures, non-sterile instruments should be used. Should a device break, bend, or loosen, it should be replaced as soon as possible to ensure stability and proper function. Reassembly of the device(s) is not intended to be performed.

**PURPOSE:**
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many variables are involved and required in the healing process. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport activities including running and the like. The patient should be warned to avoid falls or sudden jolts in spinal position.

**CLINICAL CONSIDERATIONS:**

**Preoperative:**
1. Only patients that meet the criteria described in the indications should be selected.
2. Infection, local to the operative site.
3. Bone fracture or stress shielding at; above, or below the level of surgery.
4. Neoplasia or neoplastic disease.
5. Pressure on the skin possibly resulting in skin breakdown from component parts where there is inadequate tissue compromising the skin.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible.
7. Loss of proper spinal curvature, correction is neither, and or reduction.
8. Bone fracture or stress shielding at; above, or below the level of surgery.
9. Neoplasia or neoplastic disease.
10. Pressure on the skin possibly resulting in skin breakdown from component parts where there is inadequate tissue compromising the skin.
11. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System components should ever be reused under any circumstances.

**METHOD CYCLE TEMPERATURE EXPOSURE TIME**

- **Steam** 273 oF (134oC)* 20 Minutes*
- **Steam Gravity** 250 oF (121oC) 30 Minutes

**PRODUCT COMPLAINTS:**
1. Failure to report all complaints is extremely important.
2. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System components should ever be reused under any circumstances.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or damaged, and should be stored in a dry environment free from corrosive elements.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. Should a non-union develop, or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in eventual non-union of bone.
5. Pressure on the skin possibly resulting in skin breakdown from component parts where there is inadequate tissue compromising the skin.

**STERILIZATION:**

**METHOD CYCLE TEMPERATURE EXPOSURE TIME**

- **Steam** 273 oF (134oC)* 4 Minutes
- **Steam Gravity** 250 oF (121oC) 25 Minutes

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For product availability, labeling limitations, and/or more information on any Medtronic Sofamor Danek products, contact your MEDTRONIC SOFAMOR DANEK USA, INC. Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA, INC. Customer Service toll free: 800-933-2635.

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