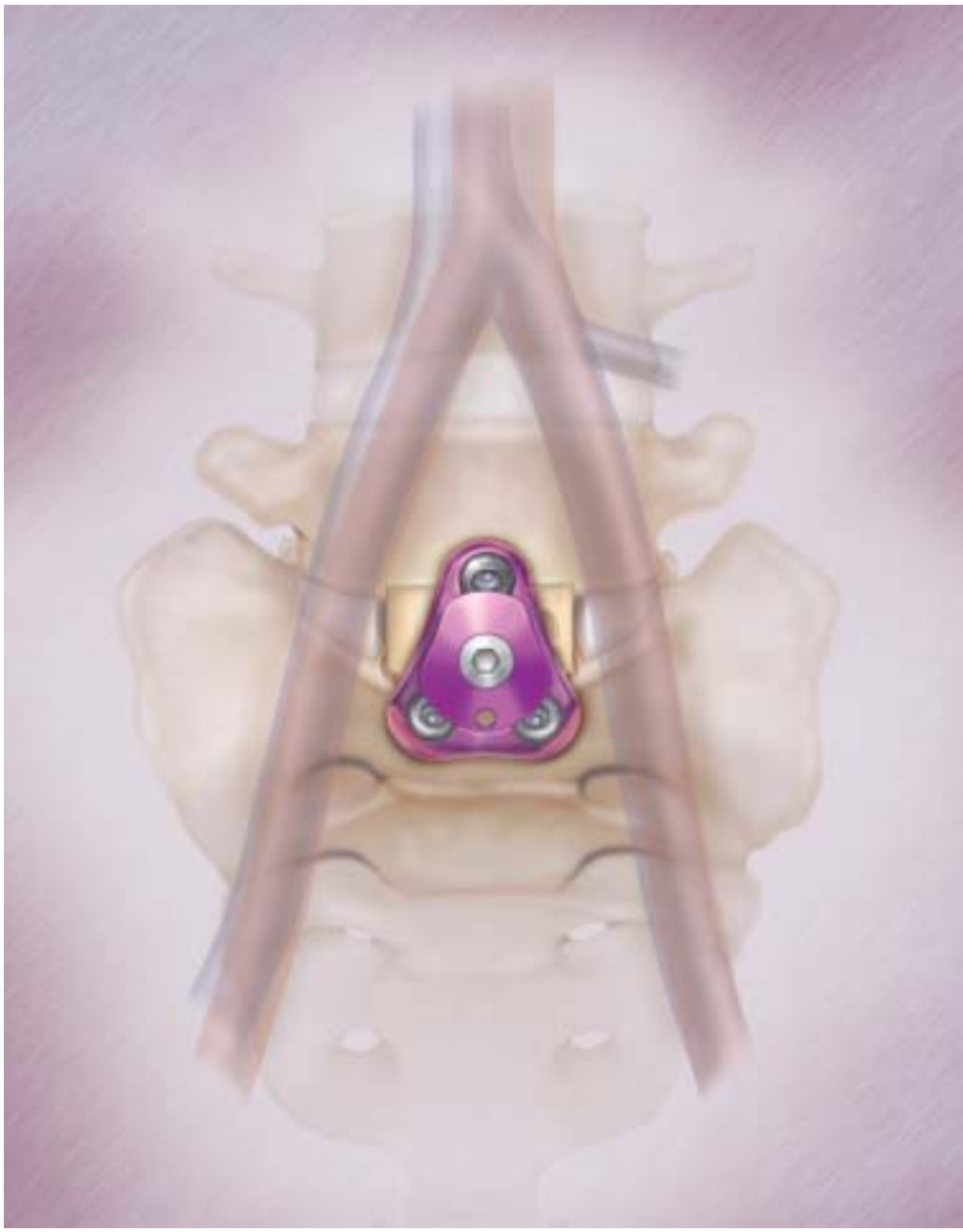
Medtronic
SOFAMOR DANEK

PYRAMID™

Anterior Lumbar Plate Surgical Technique



as described by:

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PYRAMID™

ADVANTAGES

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.

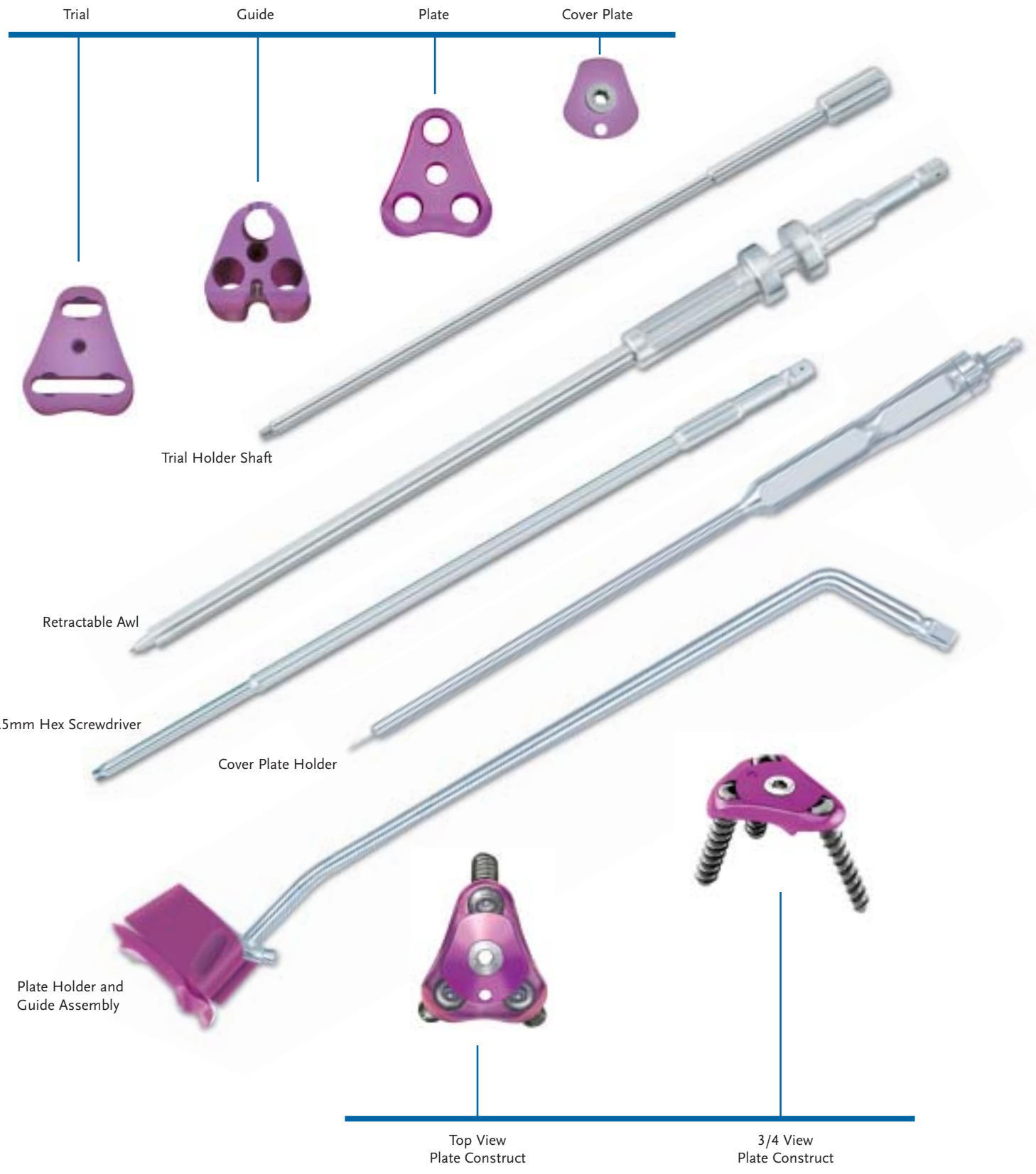
"This meticulously designed and anatomically streamlined implant system uniquely permits anterior supplemental fixation to be performed at L5-S1 to augment an interbody fusion construct. This precludes the need for a combined anterior – posterior approach for a 360° fusion. Stable, rigid segmental fixation 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

INSTRUMENTS



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.

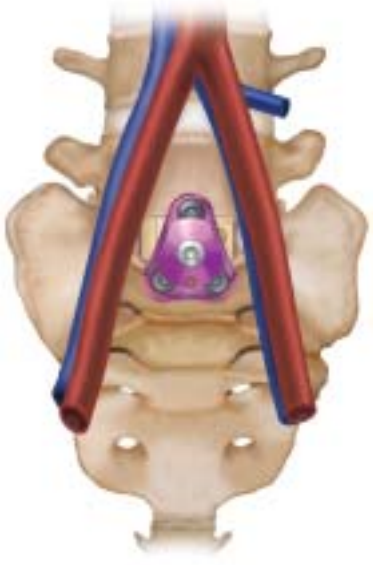
The primary design considerations for a rigid anterior lumbosacral fixation device are to protect the major vascular anatomy anterior to the lumbosacral spine and to help achieve internal fixation of the spine that is comparable to the fixation achieved with pedicle screws.

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.



1 PREOPERATIVE PREPARATION

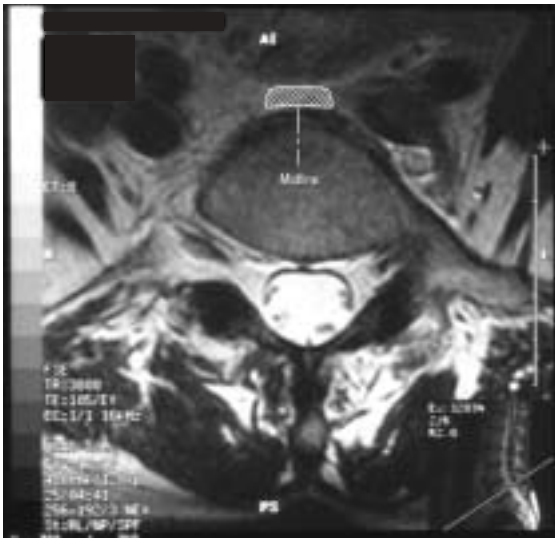


Figure 1

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.

2 INTRAOPERATIVE PREPARATION

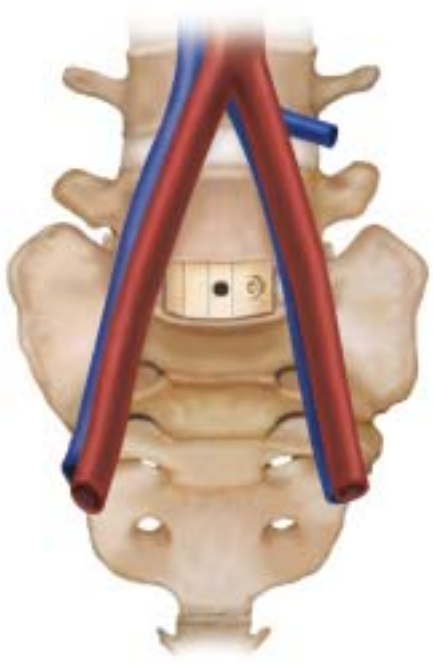


Figure 2

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.

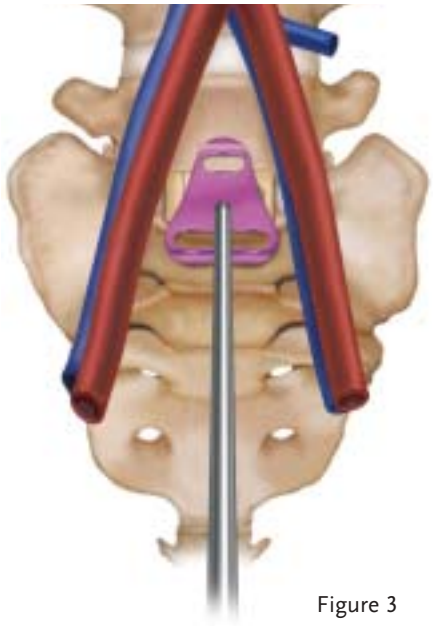


Figure 3

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.

Figure 4

Figure 5

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).

SCREW PREP & PLACEMENT 5

Figure 6

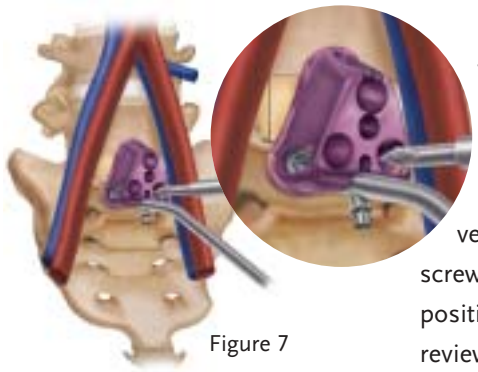


Figure 7

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

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 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.

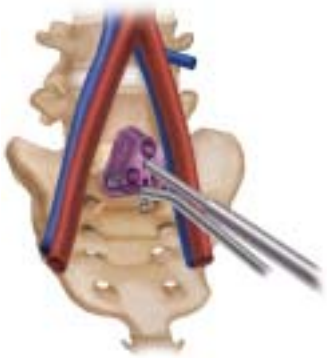


Figure 8

COVER PLATE INSTALLATION 6

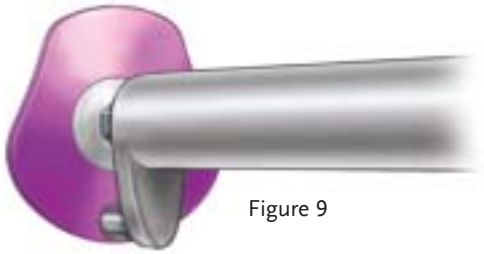


Figure 9

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.

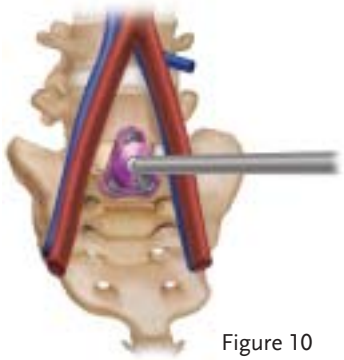
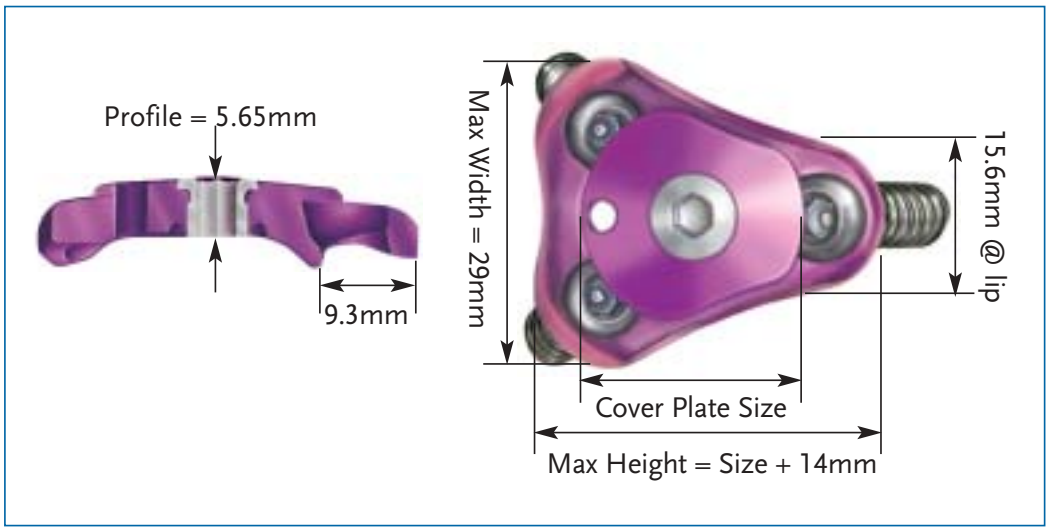


Figure 10

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



Part #	Description
8969119	19mm PYRAMID™ Plate
8969121	21mm PYRAMID™ Plate
8969123	23mm PYRAMID™ Plate
8969125	25mm PYRAMID™ Plate
8969219	19mm PYRAMID™ Cover Plate & Set Screw
8969221	21mm PYRAMID™ Cover Plate & Set Screw
8969223	23mm PYRAMID™ Cover Plate & Set Screw
8969225	25mm PYRAMID™ Cover Plate & Set Screw
8968625	Bone Screw D=6.5mm L=25mm
8968630	Bone Screw D=6.5mm L=30mm
8968635	Bone Screw D=6.5mm L=35mm

D = Diameter L = Length

Pyramid Plate Dimensions

Plate Color	Plate Size	Max Height	Max Width	Avg. L5 Width	Plate Profile	L5 Height
	19mm	33mm	29mm	15.6mm	5.65mm	9.3mm
	21mm	35mm	29mm	15.6mm	5.65mm	9.3mm
	23mm	37mm	29mm	15.6mm	5.65mm	9.3mm
	25mm	39mm	29mm	15.6mm	5.65mm	9.3mm

IMPORTANT INFORMATION FOR PYRAMID™ ANTERIOR LUMBAR PLATE

PURPOSE:
The PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System is a temporary implant used for the correction and stabilization of the spine. The 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 of plates, and screws, as well as ancillary products and instrument sets. The PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System components can be locked into a variety of configurations, with each construct being tailor-made for the individual case. As with all orthopedic and neurosurgical implants, none of the PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System components should ever be reused under any circumstances. PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System implant components are made of titanium alloy (Ti-6A1-4V) described by such standards as ASTM Standard F136 or ISO 5832-3. Stainless steel and titanium implant components must not be used together in a construct. Medtronic Sofamor Danek expressly warrants that these devices are fabricated from the foregoing material specification. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. **See the MSD Catalog for further information about warranties and limitations of liability.**

INDICATIONS:
The Medtronic Sofamor Danek PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures. When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include: 1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); 2) Pseudoarthrosis; 3) Spondylolysis; 4) Spondylolisthesis; 5)Fracture; 6) Neoplastic disease; 7) Unsuccessful previous fusion surgery; 8) Lordotic deformities of the spine; 9) Idiopathic thoracolumbar or lumbar scoliosis; 10) Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele; and/or 11) Neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity.

CONTRADICTIONS:
Contraindications include, but are not limited to:
1. Infection, local to the operative site.
2. Fever or leukocytosis.
3. Morbid obesity.
4. Pregnancy.
5. Mental illness.
6. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
7. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
8. Suspected or documented metal allergy or intolerance.
9. Any case needing to mix metals from different components.
10. Any case not needing a bone graft and fusion or requiring fracture healing.
11. Any patient having inadequate tissue coverage over the operative site, or inadequate bone stock or bone quality such as in the sacrum.
12. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
13. Any patient who will not follow postoperative instructions, such as drug/alcohol abuse patients, and are unwilling to restrict postoperative activities.
14. Any case not described in the Indications.
15. Any patient unwilling to follow the postoperative instructions.

Contraindications of this device are consistent with those of other anterior spinal instrumentation systems.
This spinal implant system is not designed, intended, or sold for uses other than those indicated.
Possible Adverse Effects:
1. Early or late loosening of the components.
2. Implant migration.
3. Disassembly, bending, loosening, slippage, and/or breakage of any or all of the components or instruments.
4. Foreign body reaction to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring.
5. Pressure on the skin possibly resulting in skin breakdown from component parts where there is inadequate tissue coverage over the implant. Implant or graft extrusion through the skin. Wound complications.
6. Loss of proper spinal curvature, correction, height, and/or reduction.
7. Infection.
8. Bone fracture or stress shielding at, above, or below the level of surgery.
9. Non-union (or pseudoarthrosis).
10. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis or other types of serious injury. Cerebral spine fluid leakage.
11. Gastrointestinal, urological, and/or reproductive system compromise, including sterility, impotency, and/or loss of consortium.
12. Hemorrhage of blood vessels and/or hematomas.
13. Cessation of growth of the fused portion of the spine.
14. Discitis, arachnoiditis, and/or other types of inflammation.
15. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
16. Bone graft donor site pain.
17. Inability to resume activities of normal daily living.
18. Death.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse reactions.

Warnings and Precautions:
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. The PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System components are only temporary implants used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.
Preoperative and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion. The use of allograft material may not give as good a result as pure autograft.
PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.
CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.
CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
Other preoperative, intraoperative, and postoperative warnings are as follows:

IMPLANT SELECTION:
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design 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.
Preoperative:
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predisposition such as those addressed in the aforementioned contraindications should be avoided.
3. Care should 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. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. PYRAMID™ System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. Unless sterile packaged, all parts should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:
1. Any instruction manuals 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. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring is gradual and great care is used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent in the same location.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
5. To assure proper fusion below and around the location of the instrumentation, a bone graft should be used.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
7. Before closing, all of the screws should be seated onto the plate. **Caution:** Do not over tighten so as to prevent stripping of the threads.

POSTOPERATIVE:
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely 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 breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result: the patient or device should not be 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 twisting motions and any type of sport participation. The patient should be advised not to smoke during the bone graft healing process.
3. The patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. If a non-union develops 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 excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the fracture or surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is achieved.
5. PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and must be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain, (2) Migration of implant position resulting in injury, (3) Risk of additional injury from postoperative trauma, (4) Bending, loosening and/or breakage, which could make removal impractical or difficult, (5) Pain, discomfort, or abnormal sensations due to the presence of the device, (6) Possible increased risk of infection, and (7) Bone loss due to stress shielding. Implant removal, should be followed by adequate postoperative management to avoid fracture or refracture.
6. 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.

PACKAGING:
Packages for each of the components should be intact upon receipt. If a loaner, earn-out or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to Medtronic Sofamor Danek.

CLEANING AND DECONTAMINATION:
Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments and implants must be disassembled and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic Sofamor Danek. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.
Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.
All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION:
Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. For a 10^{-6} Sterility Assurance Level, these products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	30 Minutes
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

Note: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment. *For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS:
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Medtronic Sofamor Danek. Further, if any of the implanted PYRAMID™ ANTERIOR LUMBAR PLATE Fixation System component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Medtronic Sofamor Danek product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION:
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact Medtronic Sofamor Danek:

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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