CAYMAN®
LATERAL

Surgical Technique

cayman



CAYMAN® Lateral Plate System



K2M
COMPLEX SPINE INNOVATIONS™

As Described By:

John Kostuik, MD
Professor Emeritus Orthopaedics & Neurosurgery,
Johns Hopkins University

The K2M Board of Scientific Advisors

Surgical Technique

Dear Colleagues,

Welcome to K2M, Inc. As we continue our commitment to achieve the highest level of excellence in the treatment of spinal pathologies, we are pleased to introduce the CAYMAN® Lateral Plate System. The system has been designed through an innovative, collaborative approach, which includes spinal surgery opinion leaders, experienced biomechanical engineers, independent testing laboratories, and the K2M product development team.

CAYMAN Lateral is highlighted by a range of Thoracolumbar Plates that are designed to address a number of spinal pathologies. Similar to the PYRENEES® Cervical Plate Systems, the CAYMAN Plate Systems, which also include CAYMAN Anterior and CAYMAN Buttress, incorporate the revolutionary *tifix*® Locking Technology. With *tifix*, each screw head forms an autogenic lock to the plate upon insertion requiring no additional locking mechanism.

We look forward to sharing this system with you.

Sincerely,

John Kostuik, MD

Chairman & Chief Medical Officer and Professor Emeritus – Johns Hopkins University Orthopaedics and Neurosurgery
Past President – Scoliosis Research Society and North American Spine Society

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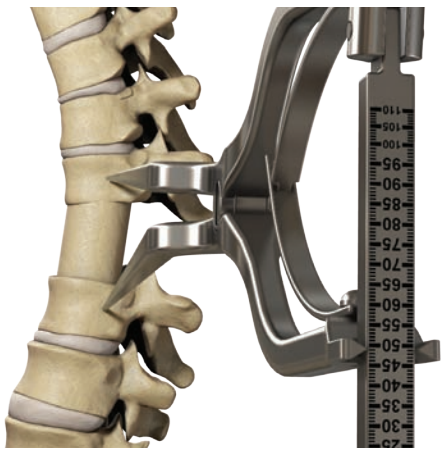
STEP 1



EXPOSURE AND VERTEBRAL BODY PREPARATION

PREPARE THE LATERAL SURFACE OF THE vertebral body to achieve a smooth surface. This will allow the plate to sit flush to the bone.

STEP 2



THORACOLUMBAR PLATE SELECTION

SELECT THE APPROPRIATE PLATE LENGTH BY placing the tips of the 110 mm Caliper on the vertebral bodies at the anticipated plate length. The Caliper measures the plate length from end to end. Be sure that the plate does not extend over the adjacent disc spaces and allows access to the screw holes at the ends of the plate.

STEP 3



PLATE INTRODUCTION AND FIXATION

PLACE THE PLATE HOLDER IN ONE of the holes on the plate and turn the proximal thumbwheel clockwise to fix the holder to the plate. If used in conjunction with the Screw Thru Drill Guide, position the Plate Holder and the drill guide in adjacent holes at the end of the plate. Smooth or Threaded Temporary Fixation Pins may be used to temporarily secure the plate to the vertebra. To engage a pin in the Temporary Pin Inserter, pull back on the shaft of the instrument. Once inserted, repeat to disengage the pin.

STEP 4



CREATE PILOT HOLE AND DRILL VERTEBRAL BODY

THE 20 MM SPRING LOADED AWL, FIXED AWL, or Freehand Awl may be used to perforate the vertebral body. To prepare for bicortical screw placement, select the Ø3.5 mm or Ø4.5 mm x 65 mm Drill and attach it to the aqua-colored Ratcheting Hudson Handle. Proceed to drill the screw hole through the Fixed, Variable, or Screw Thru Drill Guide. If a power drill is required, the Hudson Adapter may be used to connect the drill bit to the power drill.

STEP 5



SCREW PREPARATION AND INSERTION

SCREW SIZE MAY BE DETERMINED BY inserting the 100 mm Depth Gauge into the pilot hole. The screws are self-tapping; however, the Ø6.0 mm Tap may be inserted through the drill guide into the pilot hole at the same angle at which it was drilled to tap the vertebral bodies. Next, insert the appropriately sized screw through the plate using the Size 25 Driver attached to the Ratcheting Hudson Handle, and preliminarily tighten the screw. Follow the same procedure to insert the remaining screws.



NOTE: The screws can be inserted at a conical angulation of 15°, or up to 7.5° in any direction, and will lock to the plate.

STEP 6



FINAL LOCKING

FINAL SCREW LOCKING SHOULD ONLY BE performed once the plate and screw positions have been verified via intraoperative radiographs. Once the screws are tightened, they will become locked to the plate.

Use the Size 25 Driver attached to the black Torque Limiting Handle to final tighten the screws to 35 in-lbs.



When the screw head engages on the locking lip of the plate, the plate will lag down to the bone and the revolutionary *tifix*® Locking Technology will commence. Due to a difference in material hardness and design, the screw head begins to reshape the lip of the plate, the metals bind, and an autogenic lock is formed. The Torque Limiting Handle emits an audible "click" at 35 in-lbs to signify the screw has formed an autogenic lock with the plate. Use of the Torque Limiting Handle further ensures that the screw is not over tightened. No additional locking step is required.

NOTE: If realignment of the screw is necessary after final locking, the screw may be unlocked using the Ratcheting Hudson Handle and Size 25 Driver and locked again up to three times without compromising the locking mechanism.

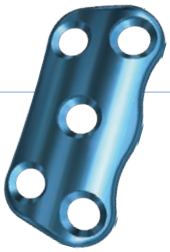
STEP 7



WOUND CLOSURE

WHEN THE CONSTRUCT IS COMPLETE, perform a standard, multi-layer wound closure.

IMPLANTS



THORACOLUMBAR PLATES

Lengths: 34 mm - 109 mm in 3 mm increments



Ø6.0 mm SCREWS

Lengths: 24 mm - 60 mm in 4 mm increments



Ø7.0 mm SCREWS

Lengths: 24 mm - 60 mm in 4 mm increments

IMPLANTS

DESCRIPTION	LENGTHS
Thoracolumbar Plates	34 mm - 109 mm
Ø6.0 mm Screws	24 mm - 60 mm
Ø7.0 mm Screws	24 mm - 60 mm

Unique catalog numbers exist for each screw length in each diameter and for each plate length. Please contact your local sales representative with any questions you may have about the CAYMAN Lateral Plate System.

INSTRUMENTS



RATCHETING HUDSON HANDLE

20 mm SPRING LOADED AWL

20 mm FIXED AWL

20 mm FREEHAND AWL

Ø3.5 & Ø4.5 x 20 mm DRILL

Ø3.5 & Ø4.5 x 65 mm DRILL

Ø3.5 & Ø4.5 x 30 mm UNIVERSAL DRILL

SIZE 25 DRIVER

SIZE 25 UNIVERSAL DRIVER

Ø6.0 mm TAP

FIXED DRILL GUIDE

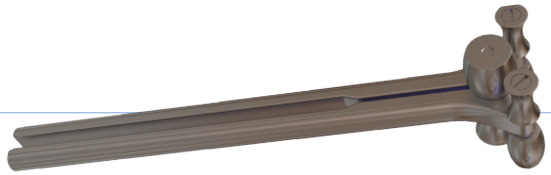
VARIABLE DRILL GUIDE

SCREW THRU DRILL GUIDE

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER	DESCRIPTION	CATALOG NUMBER
Ratcheting Hudson Handle	1208-90012	Ø3.5 x 30 mm Universal Drill	1208-90032
20 mm Spring Loaded Awl	1208-90038	Ø4.5 x 30 mm Universal Drill	1208-90033
20 mm Fixed Awl	1208-90037	Size 25 Driver	1208-90004
20 mm Freehand Awl	1408-90003	Size 25 Universal Driver	1208-90005
Ø3.5 x 20 mm Drill	1208-90000	Ø6.0 mm Tap	1208-90039
Ø4.5 x 20 mm Drill	1208-90001	Fixed Drill Guide	1208-90056
Ø3.5 x 65 mm Drill	1208-90002	Variable Drill Guide	1208-90057
Ø4.5 x 65 mm Drill	1208-90003	Screw Thru Drill Guide	1208-90017

INSTRUMENTS



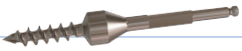
LUMBAR PLATE BENDER



PLATE HOLDER



TEMPORARY PIN INSERTER



THREADED TEMPORARY FIXATION PIN



SMOOTH TEMPORARY FIXATION PIN



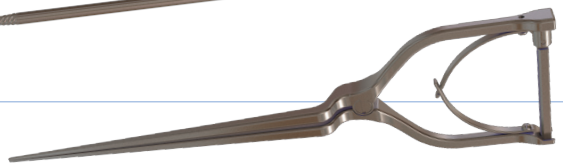
TORQUE LIMITING HANDLE, 35 IN-LBS



100 mm DEPTH GAUGE



SCREW EXTRACTOR



110 mm CALIPER



HUDSON ADAPTER

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER	DESCRIPTION	CATALOG NUMBER
Lumbar Plate Bender	1208-90014	Torque Limiting Handle, 35 in-lbs	1208-90029
Plate Holder	1208-90007	100 mm Depth Gauge	1208-90035
Temporary Pin Inserter	1208-90058	Screw Extractor	1208-90016
Threaded Temporary Fixation Pin	1208-90010	110 mm Caliper	1208-90034
Smooth Temporary Fixation Pin	1208-90041	Hudson Adapter	1208-90036

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT
This booklet is designed to assist in using the CAYMAN® Lateral Plate System. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

INDICATIONS
The CAYMAN Buttress Plates are intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.
The CAYMAN Thoracolumbar Plates are indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures (L1-S1). The CAYMAN Thoracolumbar Plate System is intended to provide temporary stabilization during fusion using autograph or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities and deformities: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h) lordotic deformities of the spine, i) thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy.

MATERIALS
All implant components are manufactured from CP Titanium and Ti6Al4V per ASTM and ISO standards.

CLEANING/REPROCESSING OF K2M SURGICAL INSTRUMENTS
K2M surgical instruments are supplied non-sterile. While it is recommended that the following steps are included in a decontamination/ reprocessing protocol the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for K2M implants or disposable surgical instruments.
Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean K2M surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of 1 minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water. Automatic cleaning may be used in addition to manual cleaning. Do not ultrasonically clean torque limiting handles.

STERILIZATION
Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The following steam autoclave cycles are recommended, however sterilization should be in accordance with the institution's usual and customary procedures for assuring sterility.

AUTOCLAVE CYCLES:
Prevacuum
Temperature: 270°F - 275°F (132°C - 135°C)
Time: 20 minutes
Use caution during sterilization and storage. Do not allow contact with metal or other hard objects that could damage the finish or prevent proper use. (See Preoperative Warnings and Precautions).

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prion decontamination protocol. K2M recommends contacting the Centers for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

INSTRUCTIONS FOR USE
The CAYMAN Plate System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. For complete instructions refer to the CAYMAN Plate System surgical technique provided by your local K2M sales representative.

CONTRAINDICATIONS
1. The CAYMAN Plate System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissuecoverage, drug/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity,patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2.. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. This device is not intended for use except as indicated.

POTENTIAL ADVERSE EVENTS
1. Potential adverse events associated with spinal fusion procedures include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
2. Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

WARNINGS AND PRECAUTIONS
1. The CAYMAN Plate System is intended for use for the indications listed. Safety and effectiveness of the implants have not been established for other applications. The implants are for single use only and are not designed to be combined with devices from other manufacturers.
2. For optimum results careful preoperative diagnosis and planning, meticulous surgical technique and extended postoperative care by experienced spinal surgeons are essential. Prior to use the surgeon should be specifically trained in the use of this spinal system and the associated instrumentation to facilitate correct selection and placement of the implants. The size and shape of bones and soft tissue place limitations on the size and strength of the implants and proper selection will reduce the risk of neurological injury during implantation as well as metal fatigue leading to bending or breakage of the device.
3. Patient selection and compliance is extremely important. Spinal implant surgery on patients with conditions listed under Contraindications may not be candidates for this procedure. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
4. Potential risks identified with the use of this device system which may require additional surgery include device component failure, loss of fixation, non-union, fracture of the vertebra, and neurological, vascular or visceral injury.
5. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Especially avoid sharp or reverse bends and notches.
6. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
7. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids and alkalis which can cause corrosion. Putting dissimilar metals in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys. Fretting or wear at the interface between components of a device may also accelerate the corrosion process and may lead to the generation of wear debris which has been associated with localized inflammatory response.
8. Implants used in spinal fusion procedures are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.

PREOPERATIVE
1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
2. Preoperative testing (simple bend and where necessary, stretch testing) should identify degree of correction possible without neurological damage and levels to be spanned using techniques similar to other spinal fusion procedures.
3. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
4. An adequate inventory of implant sizes should be available at the time of the surgery.
5. All components should be cleaned and sterilized before use.
6. Before the initial experience we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device.

OPERATIVE
1. The primary goal of spinal fusion surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. Plates used in spinal fusion procedures may be prebent to the degree of correction determined by preoperative testing however reverse bends should be avoided.
3. The placement of screws should be checked radiographically.
4. Care should be taken when positioning the implants to avoid neurological damage.
5. Use of bone cement will make removal of the implants difficult and should be avoided.

POSTOPERATIVE
1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.
2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
3. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
4. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
5. Surgical implants must never be reused. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

Notes

CAYMAN® Lateral Plate System

The CAYMAN Thoracolumbar Plates are indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures (L1-S1). The CAYMAN Thoracolumbar Plate System is intended to provide temporary stabilization during fusion using autograph or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities and deformities: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h) lordotic deformities of the spine, i) thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy.

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U.S. Patent 6,332,562 and patents pending

tifix® TECHNOLOGY
MULTIDIRECTIONAL LOCKING SCREW

CODE OF ETHICS SUPPORTER