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Dear Colleagues,

Welcome to K2M and the PYRENEES® Cervical Plate Systems! With these breakthrough technologies, K2M strives to attain the highest level of excellence in the orthopaedic industry. The systems have been designed by surgeons and engineers with the ultimate objective of providing you with a revolutionary locking mechanism, requiring no additional locking step.

PYRENEES is named after a range of mountains in southwest Europe, forming a natural border between France and Spain. The systems incorporate the revolutionary *tifix*® Locking Technology, whereby each screw head forms an autogenic lock to the plate upon insertion.

The implant and instrument technology is state-of-the-art with several enhancing features to facilitate more efficient intraoperative use of the systems. The multidirectional screws can be inserted conically up to 30° and lock upon insertion. In addition, repeated screw adjustment or realignment up to three times can be achieved without compromising the locking feature. The Translational Plate allows for up to 2 mm of uni-directional translation at each level.

A significant investment has been made in the instrument design in an effort to provide you with multiple options during surgery. These designs incorporate several new and innovative ideas for simplifying surgical application of the implants.

The PYRENEES Cervical Plate Systems are, in my opinion, a step forward in the design of cervical plate systems for the treatment of our patients. The following surgical technique clearly outlines the procedural details and options and offers a reference to help explain the many features of these systems for use in treating patients as indicated.

Sincerely,

John P. Kostuik, MD

Co-Founder, Past Chairman, & Chief Scientific Officer – K2M, Inc.
Professor Emeritus – Johns Hopkins University, Orthopaedics & Neurosurgery
Past President – Scoliosis Research Society (SRS) & North American Spine Society (NASS)

PYRENEES® Translational Cervical Plate System

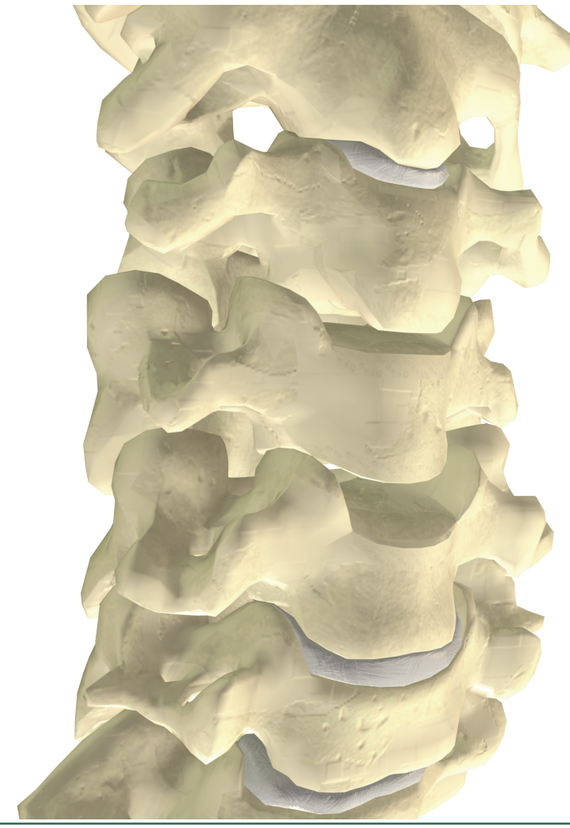
DRILL GUIDES

IMPLANTS

- Uni-directional Translational Plates
- Ratchets 2 mm per Level in 1 mm Increments
- Revolutionary *tifix*® Locking Technology
- Flexibility to Insert Screws Conically up to 30°
- Screws Lock to the Plate Upon Insertion, No Additional Locking Mechanism Needed
- 1 – 4 Level Color-coded Plates
- Screw Sizes of 4.0 mm Diameter; Self-Tapping & Self-Starting, Ranging From 12 to 16 mm Lengths
- Rescue Screws of 4.35 & 4.5 mm Diameter
- Color-coded Screws by Length for Easy Intraoperative Identification

INSTRUMENTATION

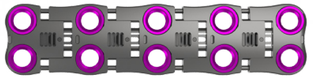
- Modular Trays for More Streamlined Ordering
- 4 Available Drill Guides: Fixed & Variable Drill Guides, Screw-Thru Fixed Drill Guide, & a FAST Drill Guide
- Color-coded Tips Identify Translational Instrumentation



DISCECTOMY/ CORPECTOMY

Perform the discectomy or corpectomy with grafting, as indicated for the patient. Remove all osteophytes from the anterior surface of the vertebrae to allow the plate to sit flush against the vertebral bodies.

levels being fused.

PYRENEES CONSTRAINED		PYRENEES TRANSLATIONAL
	1 LEVEL	
	2 LEVEL	
	3 LEVEL	
	4 LEVEL	
	5 LEVEL	Not Available

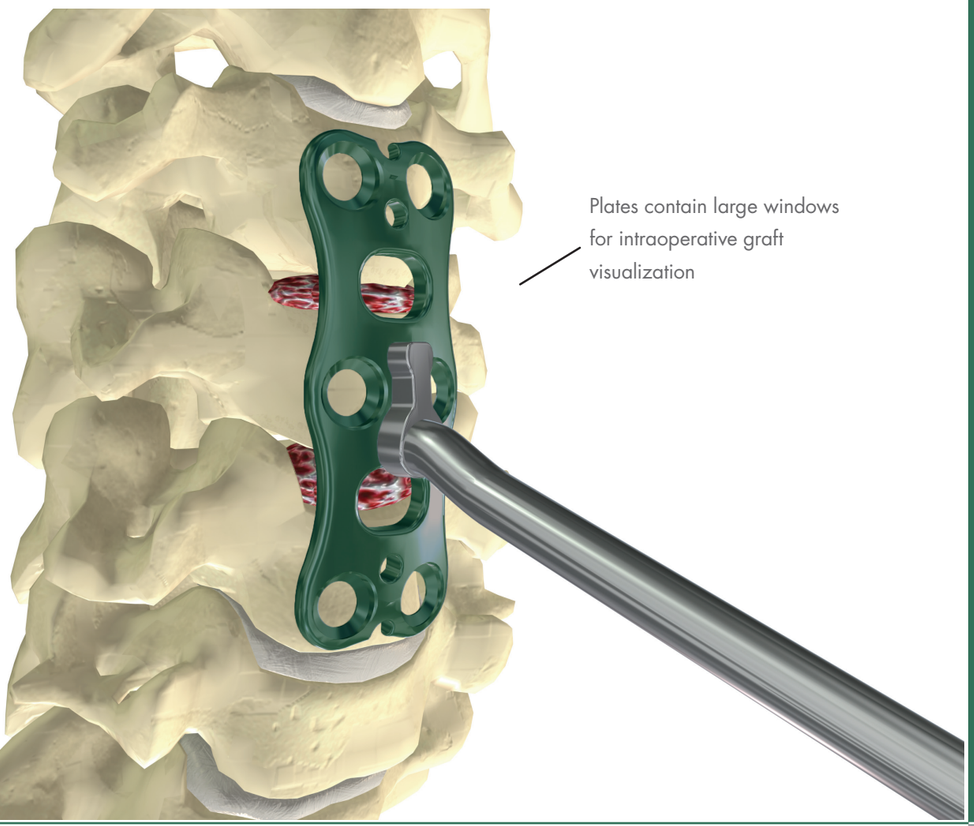
PYRENEES Constrained Cervical Plate System Table of Implants	
PYRENEES Cervical Plate	Lengths*
1 Level	18 – 36 mm
2 Level	34 – 54 mm
3 Level	48 – 78 mm
4 Level	61 – 101 mm
5 Level	95 – 110 mm

PYRENEES Translational Cervical Plate System Table of Implants	
PYRENEES Cervical Plate	Lengths*
1 Level	23 – 37 mm
2 Level	38 – 52 mm
3 Level	53 – 71 mm
4 Level	68 – 92 mm

Be sure the plate does not extend over the adjacent disc spaces. A properly sized plate will allow access to both screw holes at each end of the plate.

*Some plate lengths are available by request

PYRENEES PLATE HOLDER



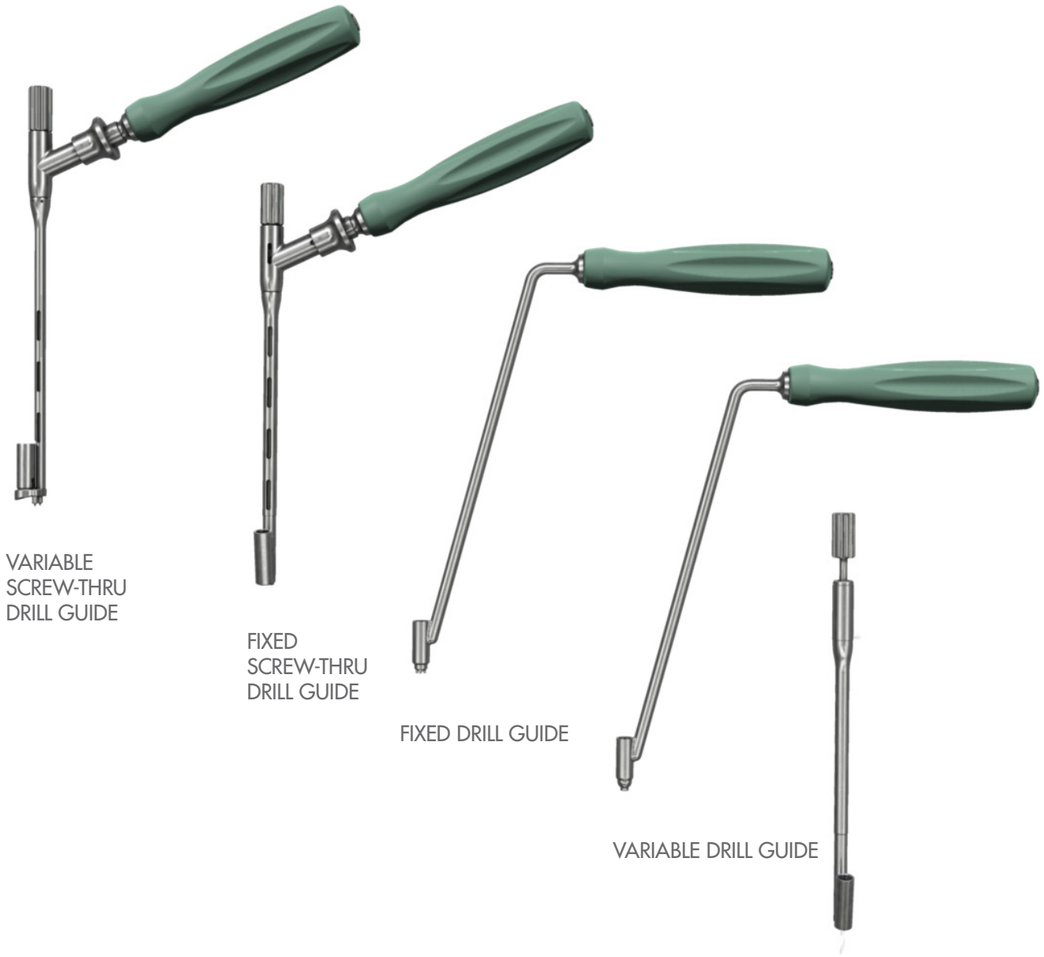
Plates contain large windows for intraoperative graft visualization

PLATE INTRODUCTION & "OPTIONAL STEP" TEMPORARY FIXATION

Use the PYRENEES Plate Holder (available by request) or any of the Screw-Thru Drill Guides to place the cervical plate into the wound. If using the Screw-Thru Drill Guides, the two locating pins on the bottom of the Drill Guide provide positive fixation to the plate.

DRILL GUIDES

Five drill guides are available for use: a Fixed Drill Guide, a Variable Drill Guide, a Fixed Screw-Thru Drill Guide, a Variable Screw-Thru Drill Guide, and a Fast Drill Guide. All Drill Guides, except the Variable Screw-Thru Drill Guide, are available for both PYRENEES Constrained and PYRENEES Translational. The Variable Screw-Thru Drill Guide is only available for PYRENEES Constrained. The Translational Drill Guides are annodized gold at the tip.



DRILL GUIDES

The Fixed Screw-Thru Drill Guide can be used to tap, drill and insert screws at a fixed trajectory of 12° and, along with the Variable Screw-Thru Drill Guide, provides a positive docking onto the plate. The Variable Screw-Thru Drill Guide provides the surgeon with 30° conical range of motion to tap, drill, and insert screws. The Fixed and Variable Drill Guides have slim barrels to allow for improved visualization. The Variable Drill Guide provides 30° conical range of motion used to drill.

AO SPIN TOP HANDLE

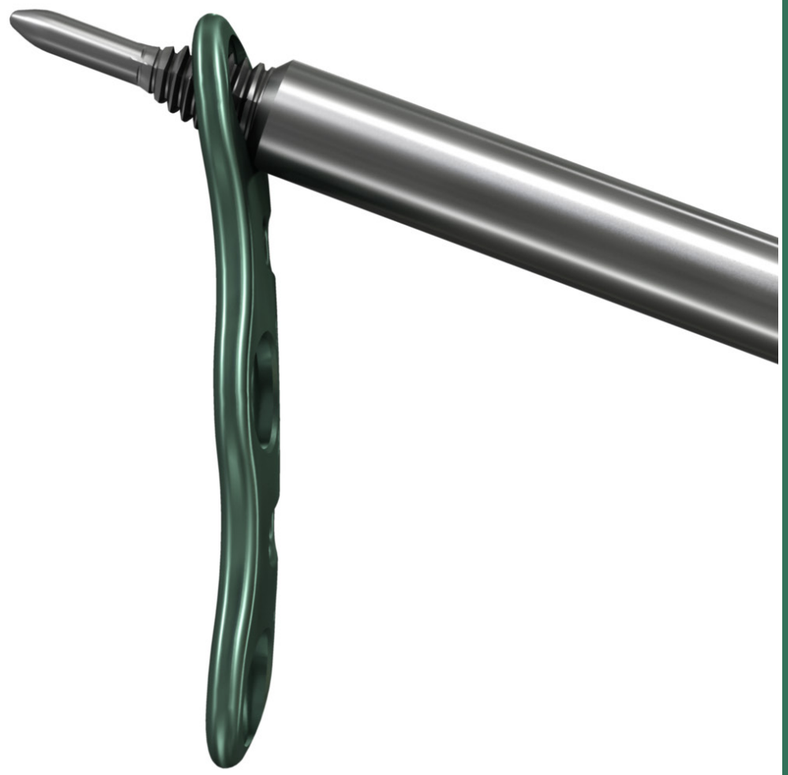
2.3 mm STOP DRILL, 14 mm

SELECT STOP DRILL

Insert the selected Stop Drill (12, 14, or 16 mm) into the AO Spin Top Handle. These Drills are color-coded to match the screw colors.

THREAD FORMER

AO SPIN TOP HANDLE



"OPTIONAL STEP" THREAD FORMER

NOTE: This step is for PYRENEES Constrained only and is NOT INTENDED FOR USE ON TRANSLATIONAL PLATES.

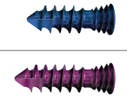
If even greater angles must be obtained past 30°, the Thread Former may be used. This device prepares the plate to permit 45° conical angulation. After drilling the appropriate length, insert the Thread Former (up to 22.5° in any direction) to prepare a pathway through the plate to accept the bone screw. Use of the Thread Former will help the screw sit flush in the plate.

12°, the Variable Screw-Thru Drill

SELF-STARTING SCREWS

	4.0 x 12 mm
	4.0 x 14 mm
	4.0 x 16 mm

SELF-TAPPING SCREWS

	4.0 x 10 mm		4.35 x 10 mm		
	4.0 x 12 mm		4.35 x 12 mm		4.5 x 12 mm
	4.0 x 14 mm		4.35 x 14 mm		4.5 x 14 mm
	4.0 x 16 mm		4.35 x 16 mm		

Both the Taps have a positive stop at 10 mm. If preferred, self-starting screws may be used, which do not require any drilling or tapping.

SIZE 10 TAPERED DRIVER

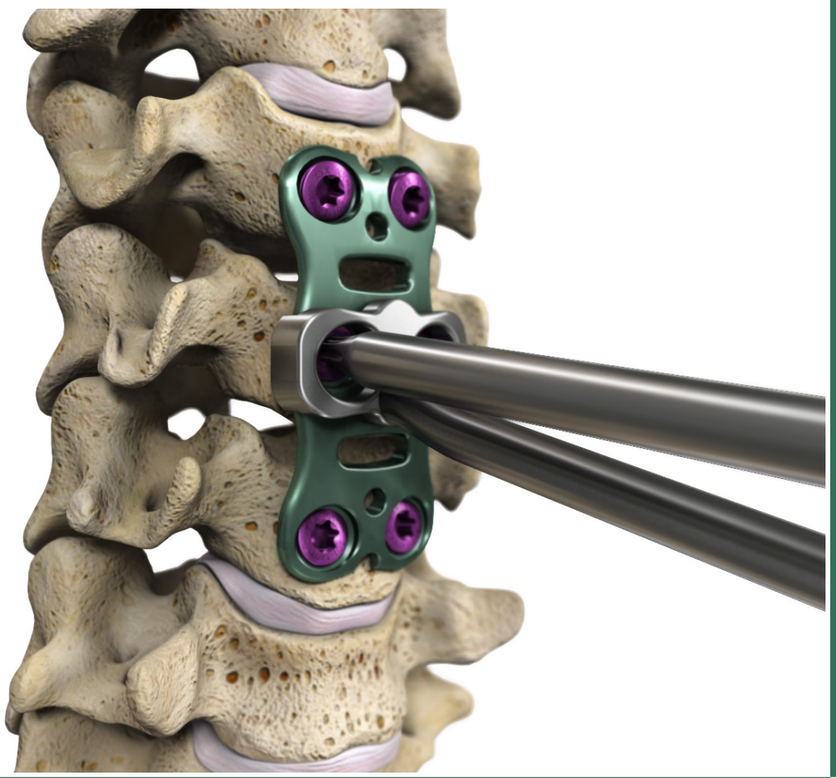
AO SPIN TOP HANDLE

Repeat this procedure for the remaining screws.

ANTI-TORQUE

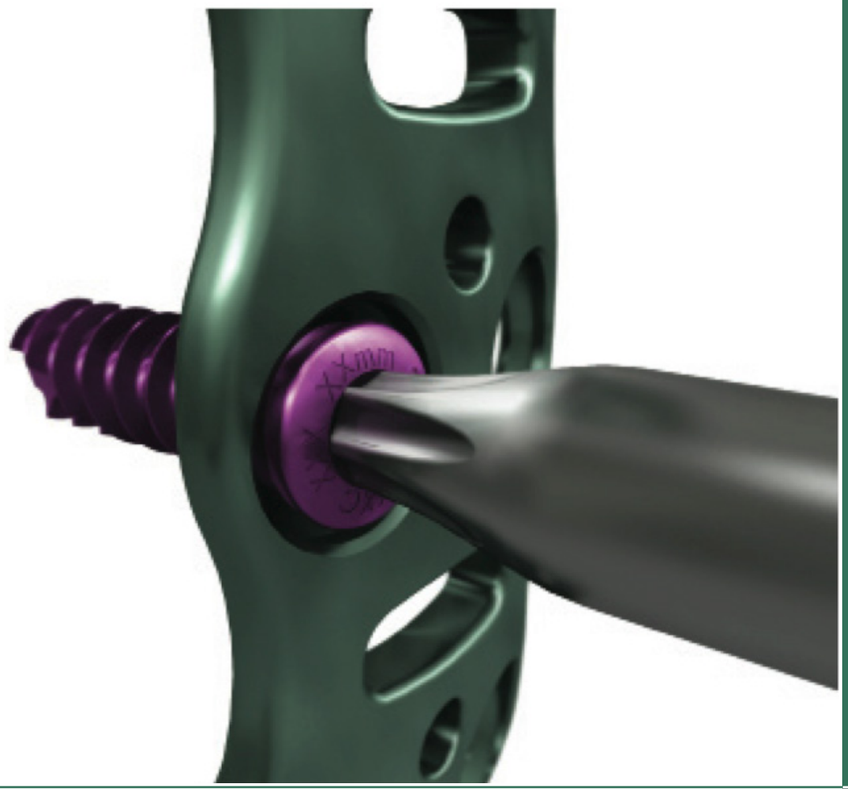
TORQUE LIMITING HANDLE

SIZE 10 NON-TAPERED TORQUE DRIVER

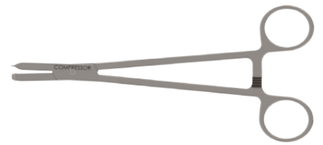


FINAL TIGHTENING

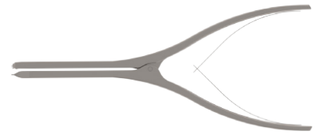
After all the *tifix* Bone Screws have been secured, utilize the Torque Limiting Handle in conjunction with the Torque Limiting Hexalobe Shaft for final tightening of the bone screws. The Torque Limiting Screwdriver will provide a locking torque of 20 in-lbs (2.26 Nm) and ensure the *tifix* Locking Technology is fully engaged and not over tightened. The Anti-Torque instrument is available for both PYRENEES Constrained and Translational. This instrument docks onto the plate and is used as an Anti-Torque device when final tightening.



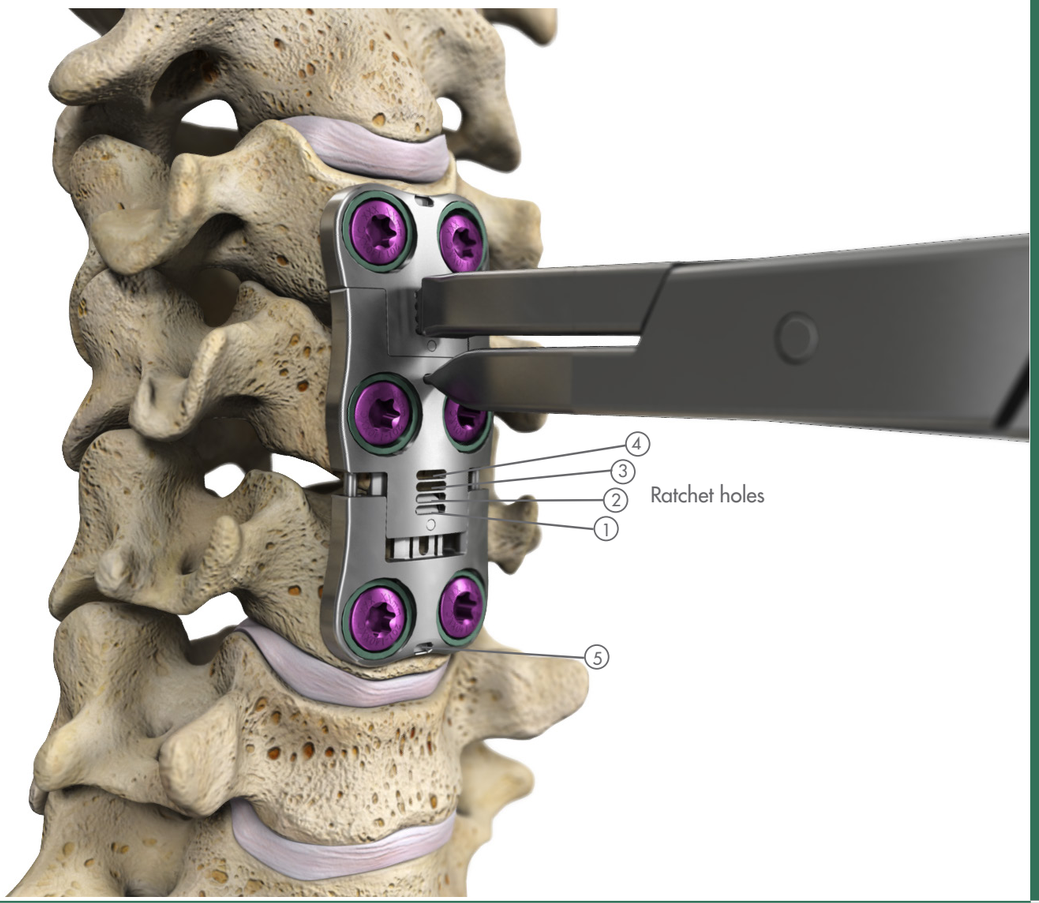
Realignment of a screw can be repeated up to three times without compromising the locking feature.



COMPRESSOR



DISTRACTOR



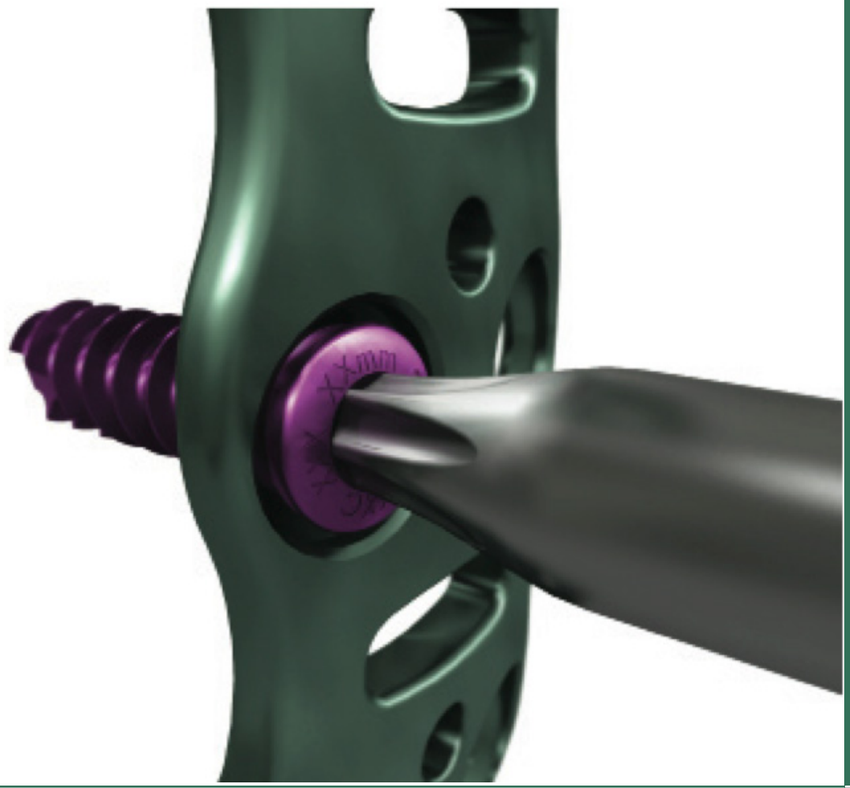
keep the plate extended in its maximum

further compression be desired, the Compressor may again be used to fully compress the plate.

COMPRESSION/ DISTRACTION

NOTE: This step is for PYRENEES Translational only

If in-situ compression is preferred once the screws have been inserted and final tightened and the 1 or 2 mm clips have been removed, align the distal teeth of the Compressor in the ratchet holes 1, 2, and 3, then place the adjacent end of the Compressor in the notch across the level of compression, 5. Put light, downward pressure on the Compressor, and squeeze to collapse the plate. Once the plate is collapsed, it will not reopen without use of a Distractor. The Distractor may be used in the same manner as the Compressor. With all clips removed, align the distal teeth of the Distractor in ratchet holes 2, 3, and 4, and place the adjacent end of the Distractor in the notch across the level of distraction, 5. Put light, downward pressure on the Distractor, and squeeze to distract the plate open.



SCREW OR PLATE REMOVAL

If a screw needs to be removed, re-engage the Size 10 Driver onto the head of the screw to disengage the screw from the plate. The screw can be locked and unlocked up to three times before replacing the plate.

If the plate needs to be removed, first unlock all screws, then proceed to remove all screws from the vertebral bodies.

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PYRENEES® CONSTRAINED AND TRANSLATIONAL PRODUCT CATALOG

CONSTRAINED PLATES

LENGTHS (mm) 18, 20, 22, 24, 26, 28, 30, 32, 34, 36

LENGTHS (mm) 36, 38, 40, 42, 44, 46, 48, 50, 52, 54

34 mm available by request only

LENGTHS (mm) 54, 57, 60, 63, 66, 69, 72, 75, 78

48 & 51 mm available by request only

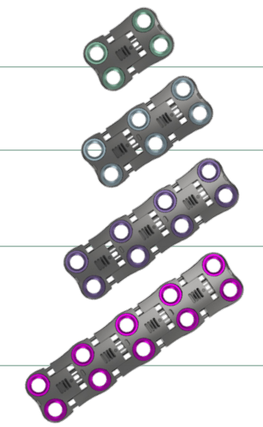
LENGTHS (mm) 69, 73, 77, 81, 85, 89, 93, 97, 101

Available by request only

LENGTHS (mm) 95, 100, 105, 110

Available by request only

TRANSLATIONAL PLATES



LENGTHS (mm) 23, 25, 27, 29, 31, 33, 35, 37

LENGTHS (mm) 38, 40, 42, 44, 46, 48, 50 52

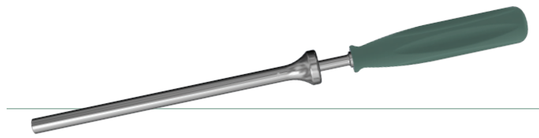
LENGTHS (mm) 53, 56, 59, 62, 65, 68, 71

LENGTHS (mm) 68, 72, 76, 80, 84, 88, 92

Available by request only

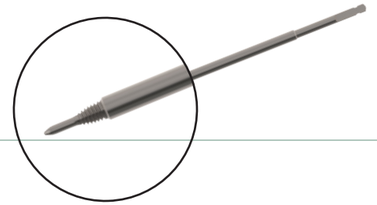
CERVICAL PLATES

Unique catalog numbers exist for each plate. Please contact your local sales consultant with any questions you may have about ordering the PYRENEES Cervical Plate Systems.



TEMPORARY FIXATION PIN HOLDER

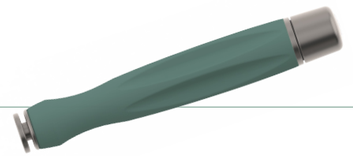
TEMPORARY FIXATION PIN



AO CONNECT THREAD FORMER

PREPARATION & PLACEMENT

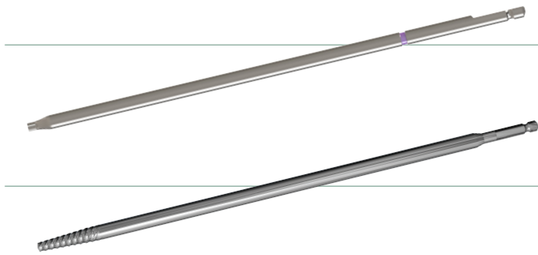
DESCRIPTION	CATALOG NUMBER
Temporary Fixation Pin Holder	201-90111
Temporary Fixation Pin	201-90026
AO Connect Thread Former	201-90102



AO SPIN TOP HANDLE

SIZE 10 TAPERED DRIVER

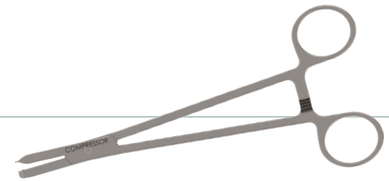
TORQUE LIMITING HANDLE 20 IN-LBS



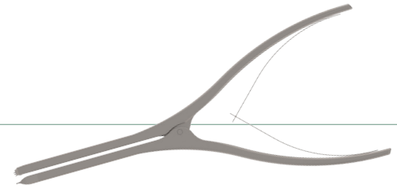
SIZE 10 NON TAPERED TORQUE DRIVER

SCREW EXTRACTOR

DESCRIPTION	CATALOG NUMBER
AO Spin Top Handle	201-90173
Size 10 Tapered Driver	201-90118
Torque Limiting Handle 20 in-lbs	201-90140
Size 10 Non-Tapered Torque Driver	201-90133
Screw Extractor	201-90120



COMPRESSOR



DISTRACTOR

TRANSLATIONAL FIXED DRILL GUIDE

TRANSLATIONAL FIXED SCREW-THRU DRILL

TRANSLATIONAL FAST DRILL GUIDE

TRANSLATIONAL ANTI-TORQUE

DESCRIPTION	CATALOG NUMBER
Compressor	201-90254
Distractor	201-90253
Translational Anti-Torque	201-90250
Translational Fixed Drill Guide	201-90185
Translational Fixed Screw-Thru Drill Guide	201-90252
Translational FAST Drill Guide	201-90251

damage the finish or prevent proper use. (See Preoperative Warnings and Precautions).

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. Based on fatigue testing results, K2M Cervical Plate Systems have been determined to be substantially equivalent to predicate devices however when using these systems, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of these systems. 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 an 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 (e.g. titanium and stainless steel) 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. The implants 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.
9. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

PREOPERATIVE

1. The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions.
2. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
3. 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.
4. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
5. An adequate inventory of implant sizes should be available at the time of the surgery.
6. All components should be cleaned and sterilized before use.
7. 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 this surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. Plates 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 prior to assembly of the rod construct.
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. 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 recomended 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 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.

SYMBOL KEY


Caution: Consult Accompanying Documentation


Consult Instructions For Use


Do Not Reuse

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