Kalitec

MATIRA

Anterior Cervical System®

SURGICAL TECHNIQUE GUIDE

About Kalitec

At Kalitec, we translate our passion for product development with relentless commitment and attention to detail to create the next successful product. We conduct business to ensure the highest standard for product quality, abidance to ethical conduct, and compliance with government regulations in order to continually improve product and process efficacy, safety, and cost containment objectives currently impacting our industry.

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MATIRA
Anterior Cervical System®

TABLE OF CONTENTS

MATIRA
Anterior Cervical System

INTRODUCTION

Description

The Matira Anterior Cervical System components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion.

The Matira Anterior Cervical System consists of a variety of shapes and sizes of bone plates, screws (available in self-drilling or self-tapping configurations), and associated instruments.

Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The Matira Anterior Cervical System implant components are made from Ti-6Al-4V ELI titanium alloy in accordance with ASTM F136. Do not use any of the Matira Anterior Cervical System components with the components from any other system or manufacturer.

Indications

The Matira Cervical System is intended for anterior interbody screw fixation of the cervical spine from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine as an adjunct to fusion for patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures and dislocations), tumors, spondylolisthesis, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions. This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Contraindications

Contraindications for use of the Matira Anterior Cervical System include:

- Infection, local to the operative site
- Local inflammation, with or without fever or leukocytosis
- Pregnancy
- Diseases or conditions other than those specifically described in the Indications section
- Use in the posterior elements (pedicles) of the cervical, thoracic, or lumbar vertebrae
- Where attempted correction exceeds the limits of physiological conditions
- Uncooperative patient or patient with neurologic disorders rendering the patient incapable of following instructions
- Metabolic disorders that may impair bone formation
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
- Any case not needing a bone graft and fusion or where fracture healing is not required
- Inability to restrict high activity level
- Any time implant utilization would interfere with anatomical structures or expected physiological performance
- Obesity
- Poor prognosis for good wound healing (e.g., decubitis ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition)
- Any medical or surgical condition, which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Suspected or documented metal allergy or intolerance

Contraindications may be relative or absolute and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

Possible Adverse Effects

Complications and adverse reactions have been reported with the use of similar spinal instrumentation systems. These adverse effects, including the possibility of death, should be discussed with the patient prior to surgery. Possible operative/postoperative adverse reactions that may require medical or surgical intervention (e.g., implant removal with or without re-instrumentation) include:

- Loosening, disassembly, bending, breakage and/or migration of any or all of the components.
- Foreign body (allergic) reactions to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing implant or graft extrusion through the skin, irritation, and/or pain.
- Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
- Collapse of a fracture and/or fusion site.
- Device failure.
- Attachment device pullout, especially with short constructs and osteoporotic bone.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Wound infection, deep or superficial, which may require implant removal and/or other medical interventions.
- Laminar erosion.
- Dural tears leading to cerebrospinal fluid fistula or pseudo meningocele.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation. Delayed onset has occurred even when evoked potential was unaffected during surgery.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise. Urinary tract infection.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.

- Non-union (or pseudarthrosis). Delayed union. Malunion.
- Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, epidural bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility, impotency, and/or loss of consortium.
- Development of respiratory problems, deep vein thrombosis, thrombophlebitis, and/or pulmonary embolism that may be fatal; may be due to patient position and/or length of the surgical procedure.
- Change in mental status.
- Pain, possibly severe in nature.
- Death.

Note: *Additional surgery may be necessary to correct some of these anticipated adverse events.*

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 Matira Anterior Cervical System is a temporary internal fixation device. 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 should be removed. Implant removal should be followed by adequate postoperative management to avoid fracture or refracture. 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. Bone grafting must be part of the spinal fusion procedure in which the Matira Anterior Cervical System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful.

This spinal implant cannot 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 planning 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 Matira Anterior Cervical 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 and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. The implants are not prostheses.

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: *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:

Some metals, polymers, chemicals, and other materials utilized with orthopedic implants have been known to cause cancer and other adverse body reactions, or reports in the literature have suggested such causation. Any factor that causes chronic damage to tissues may be oncogenic. Cancer can metastasize from soft tissue sites (lung, breast, digestive system, and others) to bone, including areas adjacent to implants, or it can be seeded to these locations during operative and diagnostic procedures (such as biopsies). Paget's disease has been reported to progress to cancer; surgical candidates suffering from this disease should be warned accordingly.

Implantation foreign material in tissues can elicit an inflammatory reaction. Current literature suggests that wear debris (including metal, polyethylene, ceramic, and cement particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening.

Metal sensitivity has been reported following exposure to orthopedic implants.

The Matira Anterior Cervical System instrumentation should only be used after the surgeon has had adequate training in this method of fixation and has become thoroughly knowledgeable about the spinal anatomy and biomechanics. A surgical technique for the Matira Anterior Cervical System is available upon request. This technique is not a substitute for training and is for general informational purposes only.

Components from other anterior cervical plating systems should not be used with the Matira Anterior Cervical System because compatibility has not been established.

Do not use implants made from dissimilar metals (such as cobalt chromium-molybdenum alloy or stainless steel) in contact with components of the Matira Anterior Cervical System; otherwise, galvanic corrosion may occur.

If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant(s) surface. The plates must not be repeatedly or excessively bent. Do not reverse bend the plate.

All implants and some instruments are intended for single use only; refer to the product label to determine if the instrument is intended for single use only. Single use devices should not be re-used. Possible risks associated with re-use of single use devices include mechanical malfunction and transmission of infectious agents.

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

The Matira Anterior Cervical System has not been evaluated for safety and compatibility within the MR environment. The Matira Anterior Cervical System has not been tested for heating or migration in the MR environment. The safety of Matira Anterior Cervical System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

SURGICAL TECHNIQUE

Plate Size Determination

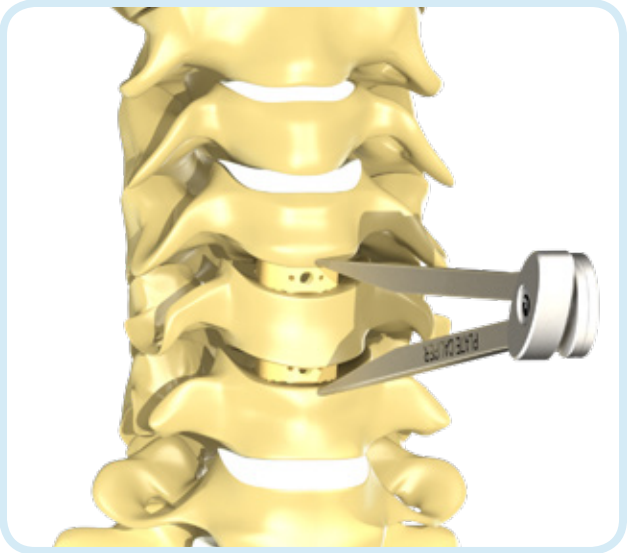


Figure 1

Step 1:
Select appropriate plate length utilizing the Plate Caliper. Turn the oval knob clockwise to lock Caliper in position.

Note: *Plate lengths are measured from end to end.*

Plate Contouring (Optional)

Figure 2

Step 2:
If Plate contouring is required, the Plate Bender may be used to increase or decrease the lordotic curvature.

To contour, insert the Plate into the Bender while aligning the viewing window with the center fulcrum. Squeeze the handles of the Plate Bender to contour between the screw holes.

Note: *Use caution to align the center fulcrum at the center of the viewing window. Bending outside of this area can compromise the Screw insertion and locking mechanism.*

INSTRUMENTS

Plate Caliper

Plate Bender

Plate Positioning

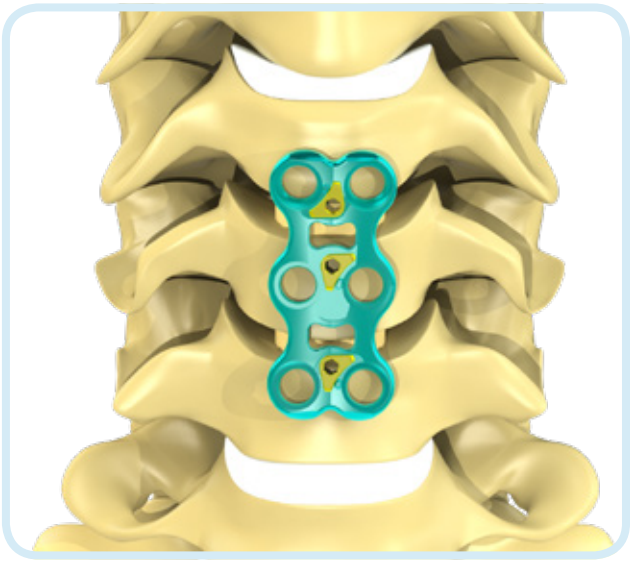


Figure 3.1

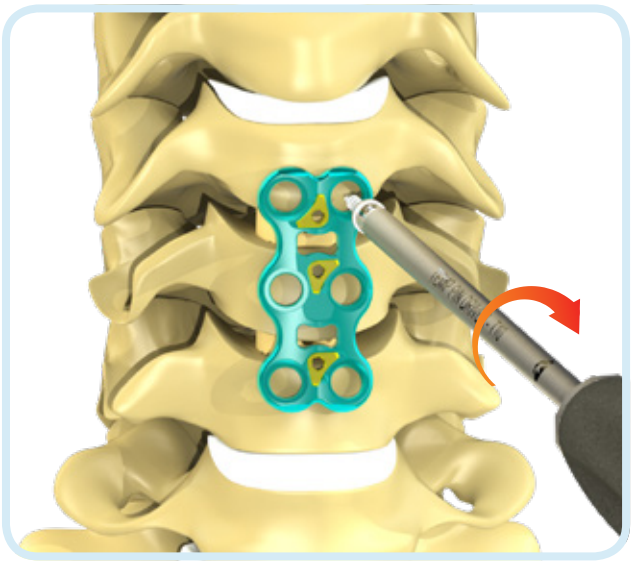


Figure 3.2

Step 3a:
Position Plate onto the anterior cervical spine. Fluoroscopy may be used, if needed, to verify length and anatomical fit.

Note: *The removal of anterior osteophytes, if present, may aid in Plate positioning and fit.*

Step 3b (Optional):
If desired, use Temporary Fixation Pins to stabilize position of Plate. Insert the Pin Holder into the Fixation Pin; while applying downward pressure onto the Pin, insert the Draw Rod and turn clockwise until light resistance is felt and the Pin is sufficiently fixated on the Pin Holder. Insert the Fixation Pin in the desired screw hole by applying slight pressure and turning the handle clockwise. Back out draw rod to remove from Pin.

Notes: *Do not over-tighten the Draw Rod - It is not necessary to screw flush with the Pin Holder handle.*

The Temporary Fixation Pin Holder is not to be used as a screwdriver or screw remover for damage to the instrument may occur - Use only with Temporary Fixation Pins.

INSTRUMENTS

Temporary Fixation Pin Draw Rod

Temporary Fixation Pin Holder

Temporary Fixation Pin

Pilot Hole Preparation

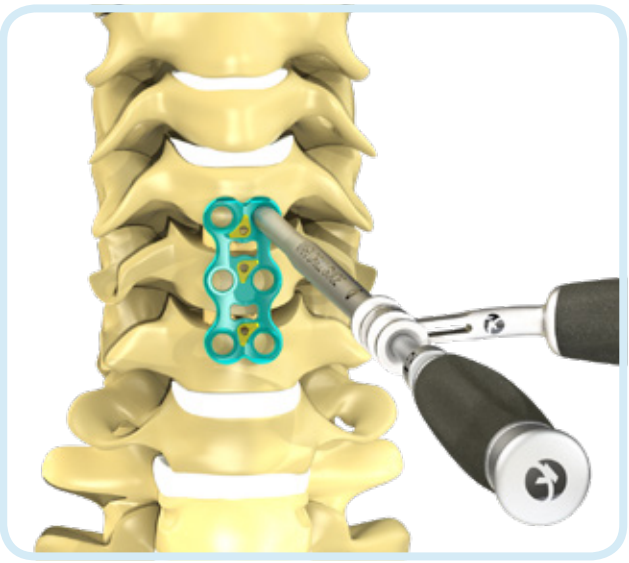


Figure 4.1

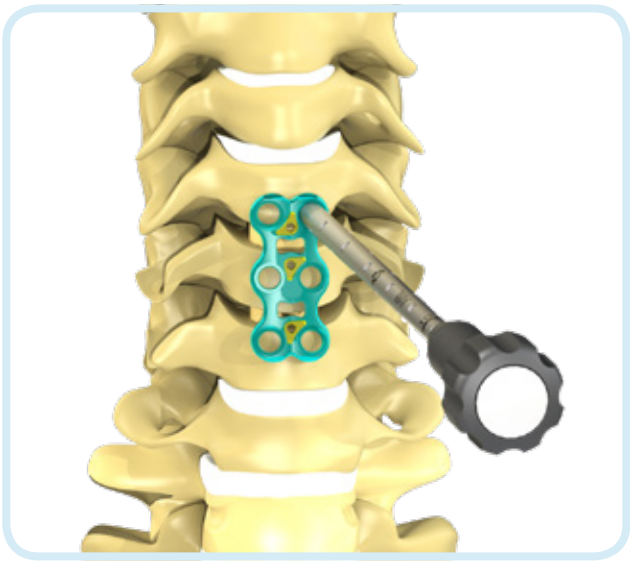


Figure 4.2

Step 4 – Option 1: Variable/Fixed Angle Drill Guide

Attach the Offset Angled Handle to the Variable or Fixed Angle Drill Guide, then attach the Drill to the AO Handle. Position the Variable or Fixed Guide into the desired screw hole, then insert the Drill through the Guide. Turn the AO handle clockwise while applying light pressure to break the cortex. The Drill has a positive stop collar at the indicated drill depth.

Step 4 – Option 2: Spring-Loaded Awl

Position the variable angle Spring-Loaded Awl into the desired screw hole. While keeping the awl in position with one hand, apply light pressure to the handle using your other hand to break the cortex. The Awl has a positive stop at 10mm depth.

Note: *A 4mm Tap may be used following any of the 4 Pilot Hole Preparation options listed in Step 4. The Tap is undersized 0.25mm*

INSTRUMENTS

Variable Angle Drill Guide

Fixed Angle Drill Guide

Offset-Angled Handle

Drill, 10-18mm

AO Handle

Spring-Loaded Awl

Pilot Hole Preparation

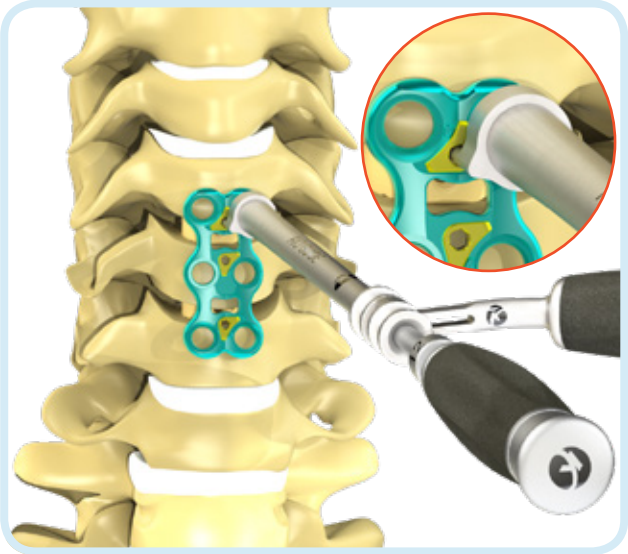


Figure 4.3

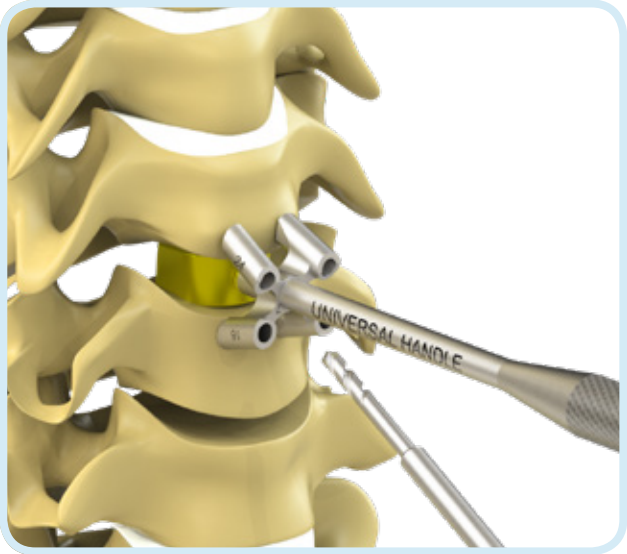


Figure 4.4

Step 4 – Option 3: All-In-One Guide

Attach the Offset Angled Handle to the All-In-One Guide, then attach the Drill to the AO Handle. Position the AIO Guide into the desired screw hole by inserting the distal post into the adjacent locking cam hole. A second alignment point is achieved by engaging the distal tip of the AIO Guide with the "ledge" that surrounds the screw hole. Once positioned, insert the drill through the Guide. Turn the AO handle clockwise while applying light pressure to break the cortex. The Drill has a positive stop collar at the indicated drill depth.

You may also tap and insert a Screw through the AIO Guide. For proper Screw insertion, refer to Steps 5 and 6 while holding Guide in position.

Step 4 – Option 4: Trial Drill Guide

Assemble the Trial Drill Guide(s) by threading them onto the Universal Handle until they are firmly fixed. Trial the intervertebral disc space sequentially until desired implant height is determined. Ensure Guide is oriented with correct angulation (16° or 24°), then insert Drill through Guide. Turn Drill Handle clockwise while applying light pressure to break cortex. The Drill has a positive stop collar at the indicated drill depth.

Note: *A 4mm Tap may be used following any of the 4 Pilot Hole Preparation options listed in Step 4. The Tap is undersized 0.25mm*

INSTRUMENTS

All-In-One Guide

Offset-Angled Handle

Drill, 10-18mm

AO Handle

Universal Slim Handle

Trial Drill Guide, 5-8mm

Screw Size/Type Determination

Screw Length	
Length (mm)	**Head Color**
10	Seafoam
12	Magenta
14	Light Blue
16	Green
18	Vector Purple

Primary vs. Rescue / Variable vs. Fixed			
Diameter (mm)	**Type**	**Thread Color**	**Example**
4.0	Variable	Same As Head	
	Fixed	Silver	
4.5	Variable	Gold	
	Fixed	Grey	

Figure 5

Step 5:

Figure 5 above shows a complete listing of Screw options. Self-Drilling Screws will have a sharp tip and the Self-Tapping Screws will have a blunt tip.

The Matira System can be configured in several Plate/Screw combinations to obtain patient-specific construct rigidities: Variable, Fixed, or Hybrid.

Attach the Split-Tip Driver Shaft (T10) to the AO Handle and attach to desired Screw when ready.

Note: *Upon special request and approval, odd numbered length Screws may be ordered. Odd length Screws come in sizes 11-17mm with head colors medium blue, teal, bronze, and aqua, respectfully.*

INSTRUMENTS

Split-Tip Driver Shaft, T10

AO Handle

Screw Insertion

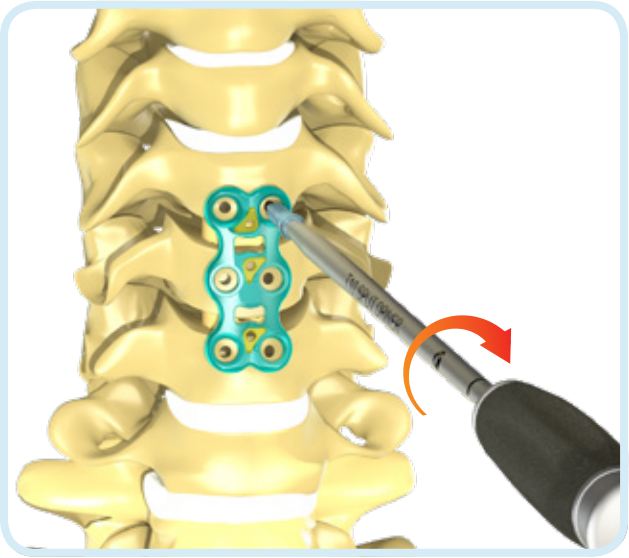


Figure 6

Engage Locking Cam

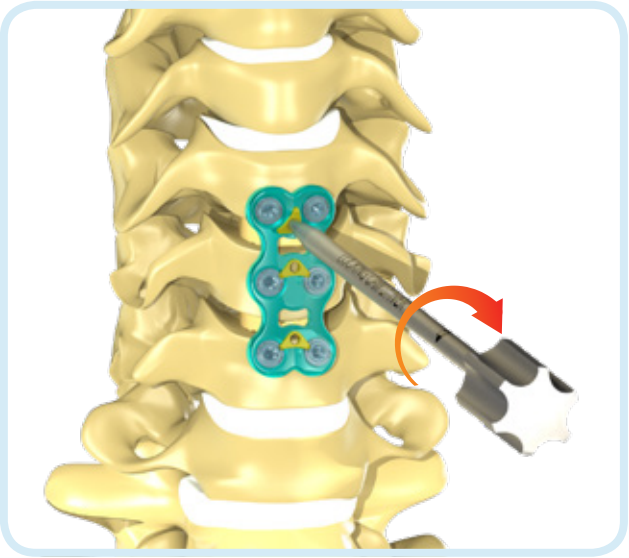


Figure 7

Step 6:

Attach the Split-Tip Driver Shaft or the Retaining Driver Shaft to the AO Handle. Select the desired Screw type and length (see Step 5). Apply light pressure to handle to engage the Driver Shaft into the Screw. Apply light pressure while turning clockwise until Screw has been has been engaged into the previously created pilot hole and nearly seated. To fully tighten and seat the screw into the bone, the T10 Final Driver Shaft should then be used.

Note: *Take caution when using the Split-Tip Driver shaft. If no pilot hole is created with either the awl or the drill, or if used for final seating, excess torque could be placed on the tip resulting in damage to the instrument.*

Step 7:

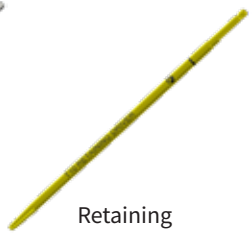
Once the Screws are completely seated into the Plate, Insert the Locking Cam Driver into the Plate locking mechanism. Turn handle clockwise until positive stop is seen and felt. Repeat until all Plate locking mechanisms are fully locked and visually covering Screws.

Note: *The locking mechanism cam may safely be cycled up to three times during a surgical procedure. One cycle is considered rotating from an unlocked position to a locked position, then back to an unlocked position.*

Do not over-torque the locking mechanism or damage to the mechanism may occur.

INSTRUMENTS

Split-Tip Driver Shaft, T10



Retaining Driver Shaft, T10

Final Driver Shaft, T10

AO Handle

Locking Cam Driver

SYSTEM CONFIGURATION

SCREW OPTIONS

Item #	Catalog #	Description
4.0MM SELF DRILLING, FIXED		
1	07-SDF-4010	Screw, 4x10mm SD Fixed
2	07-SDF-4012	Screw, 4x12mm SD Fixed
3	07-SDF-4014	Screw, 4x14mm SD Fixed
4	07-SDF-4016	Screw, 4x16mm SD Fixed
5	07-SDF-4018	Screw, 4x18mm SD Fixed
4.0MM SELF TAPPING, FIXED		
6	07-STF-4010	Screw, 4x10mm ST Fixed
7	07-STF-4012	Screw, 4x12mm ST Fixed
8	07-STF-4014	Screw, 4x14mm ST Fixed
9	07-STF-4016	Screw, 4x16mm ST Fixed
10	07-STF-4018	Screw, 4x18mm ST Fixed
4.0MM SELF DRILLING, VARIABLE		
11	07-SDV-4010	Screw, 4x10mm SD Vari
12	07-SDV-4012	Screw, 4x12mm SD Vari
13	07-SDV-4014	Screw, 4x14mm SD Vari
14	07-SDV-4016	Screw, 4x16mm SD Vari
15	07-SDV-4018	Screw, 4x18mm SD Vari
4.0MM SELF TAPPING, VARIABLE		
16	07-STV-4010	Screw, 4x10mm ST Vari
17	07-STV-4012	Screw, 4x12mm ST Vari
18	07-STV-4014	Screw, 4x14mm ST Vari
19	07-STV-4016	Screw, 4x16mm ST Vari
20	07-STV-4018	Screw, 4x18mm ST Vari

Item #	Catalog #	Description
4.5MM SELF DRILLING, FIXED		
21	07-SDF-4510	Screw, 4.5x10mm SD Fixed
22	07-SDF-4512	Screw, 4.5x12mm SD Fixed
23	07-SDF-4514	Screw, 4.5x14mm SD Fixed
24	07-SDF-4516	Screw, 4.5x16mm SD Fixed
25	07-SDF-4518	Screw, 4.5x18mm SD Fixed
4.5MM SELF TAPPING, FIXED		
26	07-STF-4510	Screw, 4.5x10mm ST Fixed
27	07-STF-4512	Screw, 4.5x12mm ST Fixed
28	07-STF-4514	Screw, 4.5x14mm ST Fixed
29	07-STF-4516	Screw, 4.5x16mm ST Fixed
30	07-STF-4518	Screw, 4.5x18mm ST Fixed
4.5MM SELF DRILLING, VARIABLE		
31	07-SDV-4510	Screw, 4.5x10mm SD Vari
32	07-SDV-4512	Screw, 4.5x12mm SD Vari
33	07-SDV-4514	Screw, 4.5x14mm SD Vari
34	07-SDV-4516	Screw, 4.5x16mm SD Vari
35	07-SDV-4518	Screw, 4.5x18mm SD Vari
4.5MM SELF TAPPING, VARIABLE		
36	07-STV-4510	Screw, 4.5x10mm ST Vari
37	07-STV-4512	Screw, 4.5x12mm ST Vari
38	07-STV-4514	Screw, 4.5x14mm ST Vari
39	07-STV-4516	Screw, 4.5x16mm ST Vari
40	07-STV-4518	Screw, 4.5x18mm ST Vari

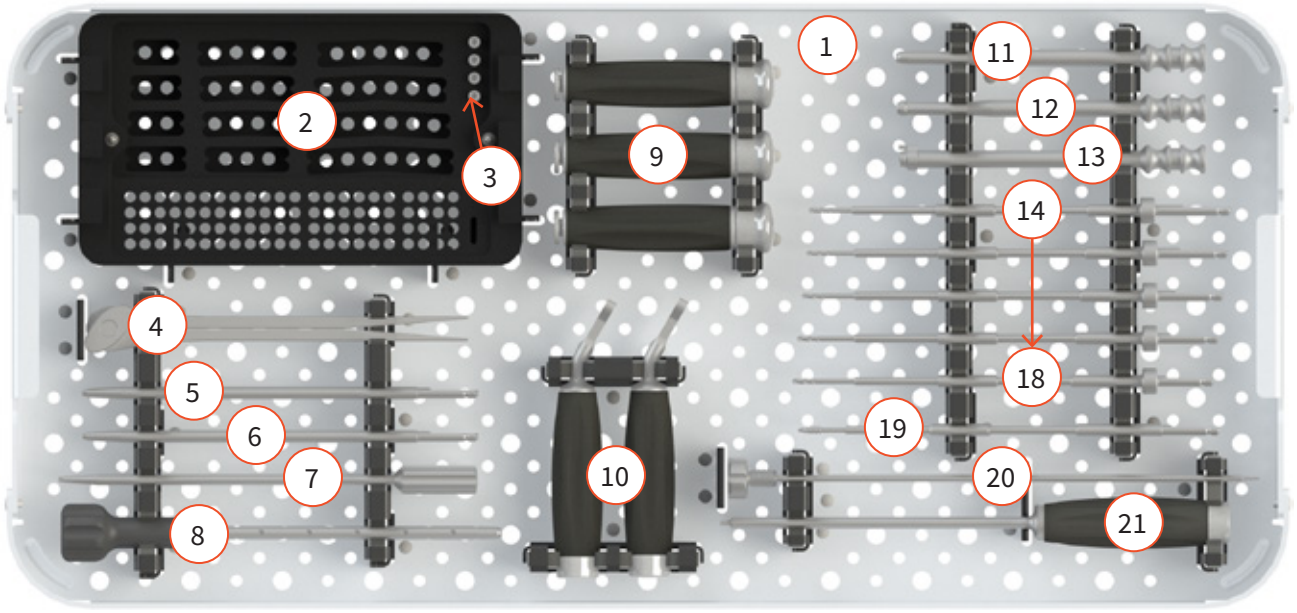
PLATE OPTIONS

1-LEVEL 2-LEVEL 3-LEVEL 4-LEVEL

Level(s)	Catalog #	Description
1	07-CPR-0118	Plate, 18mm 1L
	07-CPR-0120	Plate, 20mm 1L
	07-CPR-0122	Plate, 22mm 1L
	07-CPR-0124	Plate, 24mm 1L
	07-CPR-0126	Plate, 26mm 1L
	07-CPR-0128	Plate, 28mm 1L
	07-CPR-0130	Plate, 30mm 1L
2	07-CPR-0234	Plate, 34mm 2L
	07-CPR-0236	Plate, 36mm 2L
	07-CPR-0238	Plate, 38mm 2L
	07-CPR-0240	Plate, 40mm 2L
	07-CPR-0242	Plate, 42mm 2L
	07-CPR-0244	Plate, 44mm 2L
	07-CPR-0246	Plate, 46mm 2L
	07-CPR-0248	Plate, 48mm 2L

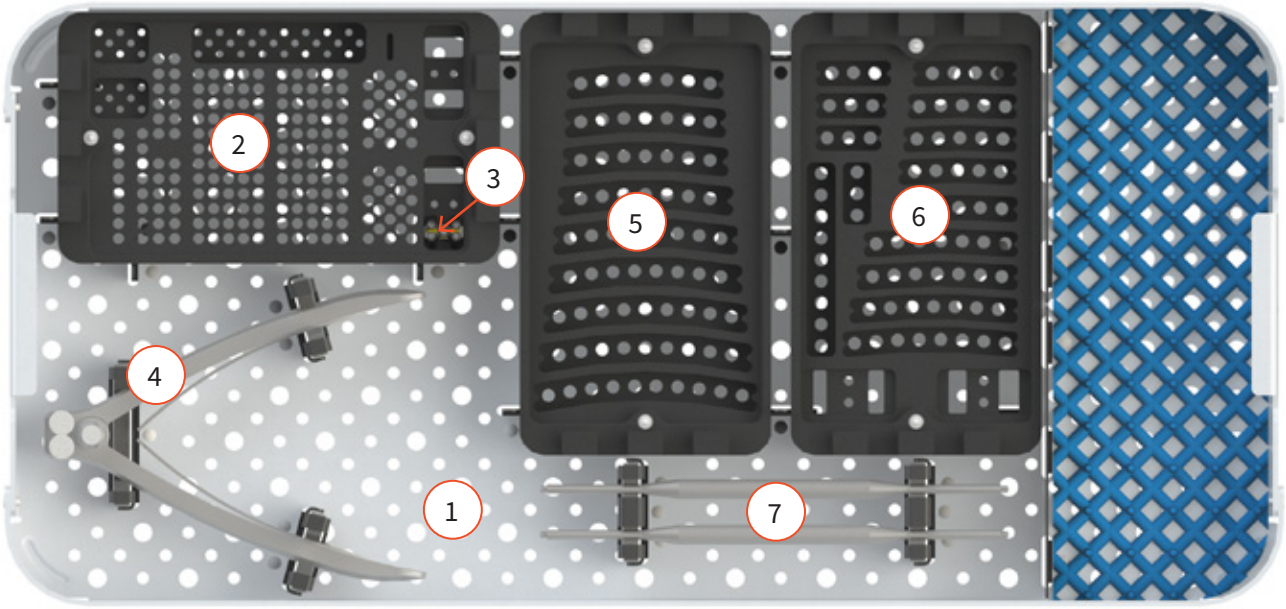
Level(s)	Catalog #	Description
3	07-CPR-0348	Plate, 48mm, 3L
	07-CPR-0351	Plate, 51mm, 3L
	07-CPR-0354	Plate, 54mm, 3L
	07-CPR-0357	Plate, 57mm, 3L
	07-CPR-0360	Plate, 60mm, 3L
	07-CPR-0363	Plate, 63mm, 3L
	07-CPR-0366	Plate, 66mm, 3L
	07-CPR-0369	Plate, 69mm, 3L
	07-CPR-0372	Plate, 72mm, 3L
4	07-CPR-0466	Plate, 66mm, 4L
	07-CPR-0468	Plate, 68mm, 4L
	07-CPR-0472	Plate, 72mm, 4L
	07-CPR-0476	Plate, 76mm, 4L
	07-CPR-0480	Plate, 80mm, 4L
	07-CPR-0484	Plate, 84mm, 4L
	07-CPR-0488	Plate, 88mm, 4L
	07-CPR-0492	Plate, 92mm, 4L

TOP TRAY INSERT



Item #	Description	Qty
1	Tray Insert, Level 1	1
2	Caddie, Common Plates & Screws	1
3	Temporary Fixation Pin	4
4	Plate Caliper	2
5	Driver Shaft, T10	2
6	Split-Tip Driver Shaft, T10	2
7	Locking Cam Driver	2
8	Spring Loaded Awl, 10mm	1
9	AO Handle	2
10	Offset-Angled Handle	2
11	Variable Angle Drill Guide	1
12	Fixed Angle Drill Guide	1
13	All-In-One Guide	1
14-18	Drills, 10-18mm	2 ea.
19	Tap, 4.0mm	1
20	Temporary Fixation Pin Draw Rod	1
21	Temporary Fixation Pin Driver, T10	1

BOTTOM TRAY INSERT



Item #	Description	Qty
1	Tray Insert, Level 2	1
2	Caddie, Screws	1
3	Trial Drill Guide, 5-8mm	1 ea.
4	Plate Bender	1
5	Caddie, 4L Plates	1
6	Caddie, 1-3L Plates (Uncommon)	1
7	Universal Slim Handle	1

NOTES:

NOTES:

For instrument part numbers, please contact Kalitec or your local distributor.

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