Kalitec

OCATA
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.

Kalitec Medical

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oCATA
Anterior Cervical System®

TABLE OF CONTENTS

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INTRODUCTION

Description

The Ocata 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 Ocata 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 Ocata 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 Ocata Anterior Cervical System components with the components from any other system or manufacturer.

Indications

The Ocata 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 Ocata 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.

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- 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 Ocata 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 Ocata 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 Ocata 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 Ocata 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 Ocata 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 Ocata 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 Ocata 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

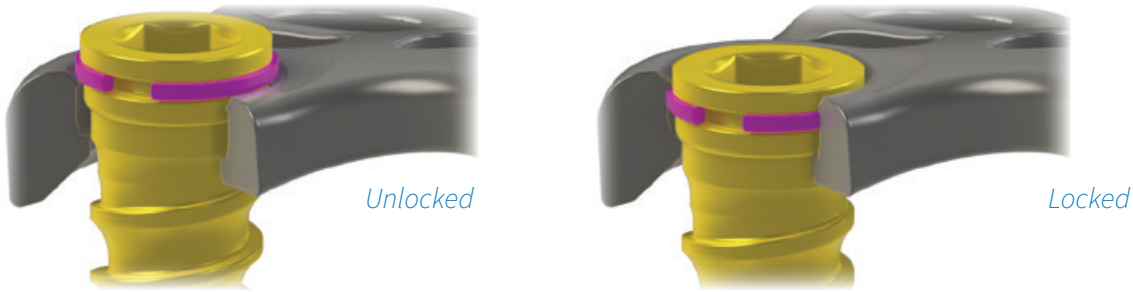
Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, etc. which may impact the performance of the system.

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

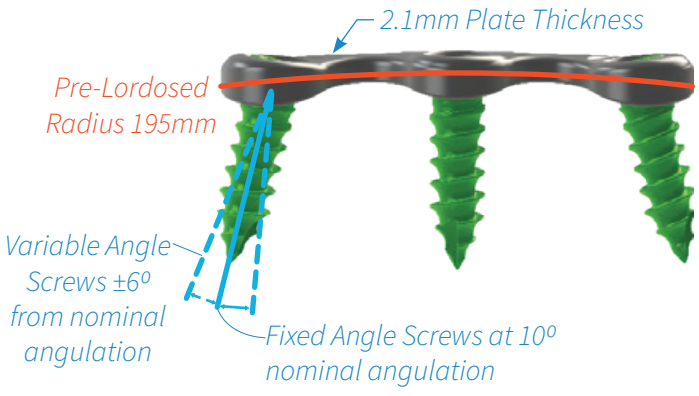
FEATURES

Self-Drilling or Self-Tapping Screws available in Fixed and Variable Options

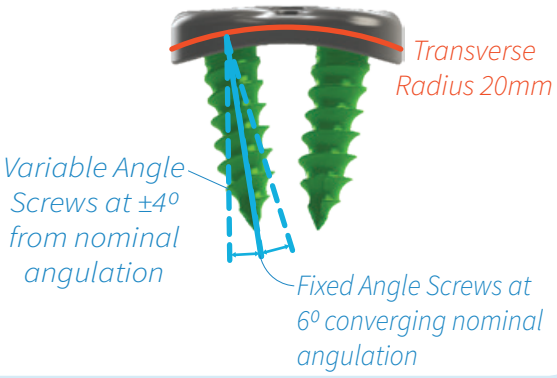
Self-Actuating Locking Mechanism with Visual and Tactile Indication



Screw Angulation – Cephalad/Caudal



Screw Angulation – Medial



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SURGICAL TECHNIQUE

Plate Size Determination

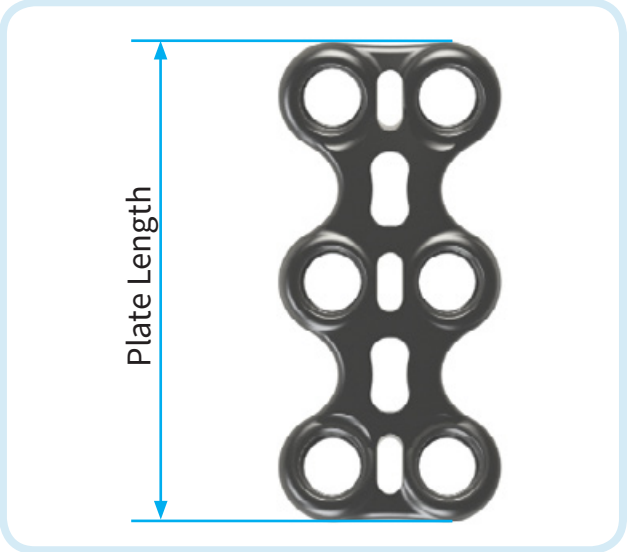

Figure 1

Step 1:
Select appropriate plate length based on number of levels and patient anatomy.

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

Plate Contouring (Optional)

Figure 2

Step 2:
If countouring of the Plate 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: *Be careful 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 Bender

Plate Positioning

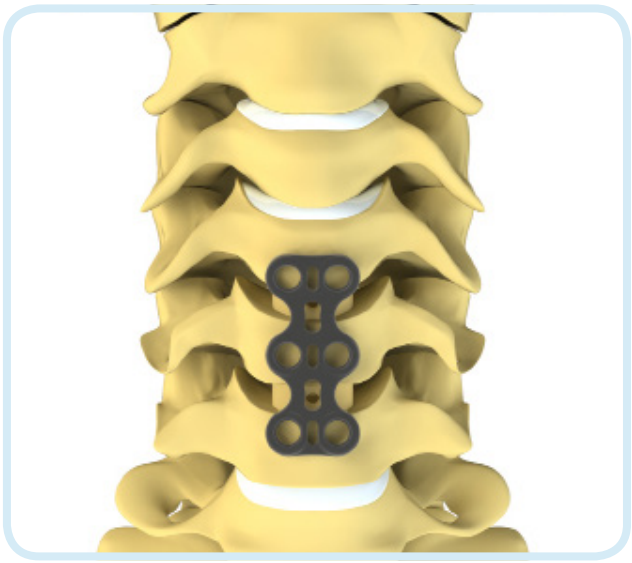

Figure 3

Screw Size/Type Determination

Figure 4

Step 3a:
Position Plate onto the anterior cervical spine. Fluoroscopy may be used if needed to verify length and antomical 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. Pull back on the collar of the Pin Holder shaft and insert hex into the Fixation Pin. Insert the Fixation Pin in the desired Plate hole by applying slight pressure and turning the handle clockwise.

Step 4:
The Ocata System can be configured in several Plate/Screw combinations to obtain patient-specific construct rigidities: Variable, Fixed, or Hybrid.

INSTRUMENTS

Temporary Fixation Pin Holder

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Pilot Hole Preparation

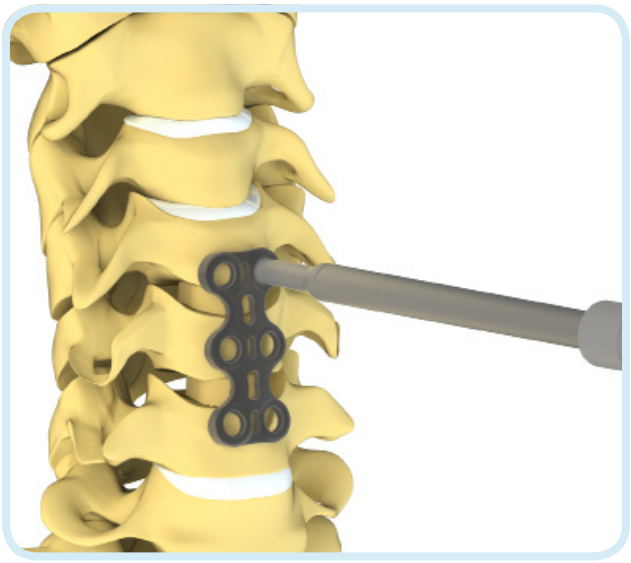

Figure 5 - Option 1

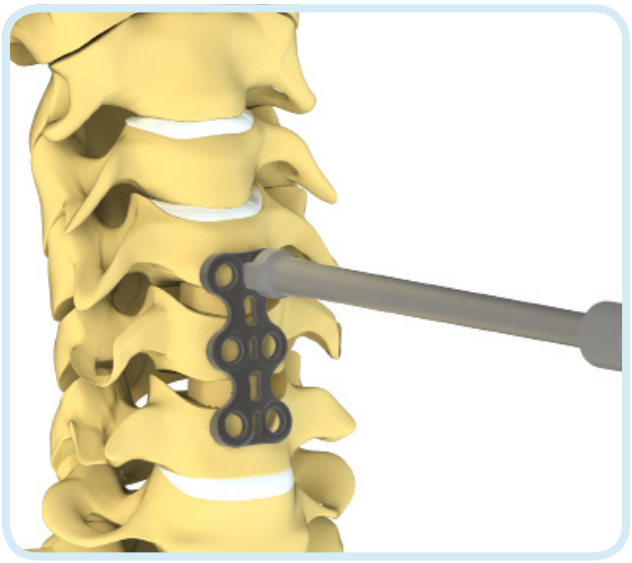

Figure 5 - Option 2

Step 5 – Option 1: Variable Drill Guide

Attach the Drill to the AO Handle and insert through the Drill Guide. Turn Handle clockwise while applying slight pressure to break the cortex. The Drill has a collar to positively stop in the Drill Guide at 12mm depth.

Step 5 – Option 2: Fixed All-in-One Guide

Position the oblong extruded track into the medial slot. Attach the Drill to the AO Handle and insert through the All-in-One Guide. Turn the Handle clockwise while applying slight pressure to break the cortex. The Drill has a collar to positively stop in the Guide at 12mm depth.

Note: *It is not advised to free-hand Drills, Taps, and Screws. In the case that a Screw is over-angulated, the retaining ring will not engage into the Plate and may become seperated from the screw.*

INSTRUMENTS

Variable Drill Guide

Fixed All-In-One Guide

12mm Drill

AO Handle

Screwdriver Assembly

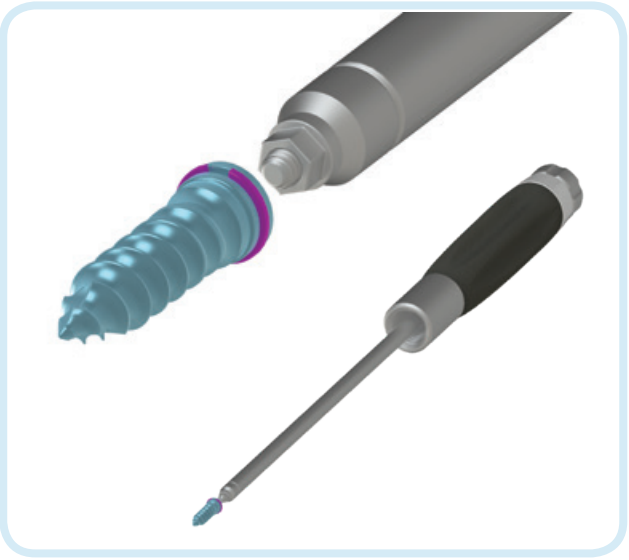

Figure 6

Screw Insertion

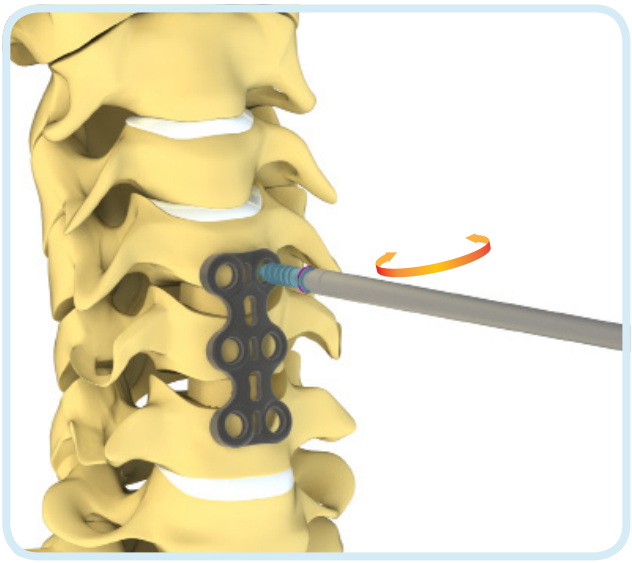

Figure 7

Step 6:
Insert the Draw Rod into the proximal end of the Screwdriver and turn clockwise until seated for Screw attachment. Position Screwdriver tip into desired Screw. While keeping slight downward pressure on the Screwdriver, thread the Draw Rod clockwise into the Screw until secured. The Screw is now ready for insertion.

NOTE: *Use caution when inserting the screw to ensure that as the screw is seated in the plate the locking ring does not get pinched by the plate and becomes separated from the screw. If this occurs replace the screw and ensure the separated ring is retreived.*

Step 7 – Option 1: Variable Screw Insertion
Following Step 5 - Option 1, apply slight pressure to the handle of the Screwdriver to insert Screw. Once the Screw is seated at its desired depth, turn the Draw Rod counter-clockwise from the Screw and remove the Screwdriver.

Step 7 – Option 2: Fixed All-In-One Guide
Following Step 5 - Option 2, keep the Guide in place and insert the Screwdriver. Apply slight pressure to the handle of the Screwdriver while turning clockwise to insert Screw. Once Screw is at its desired depth, turn the Draw Rod counter-clockwise from the Screw and remove the Screwdriver.

INSTRUMENTS

Screwdriver

Draw Rod

Fixed All-In-One Guide

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Final Tightening

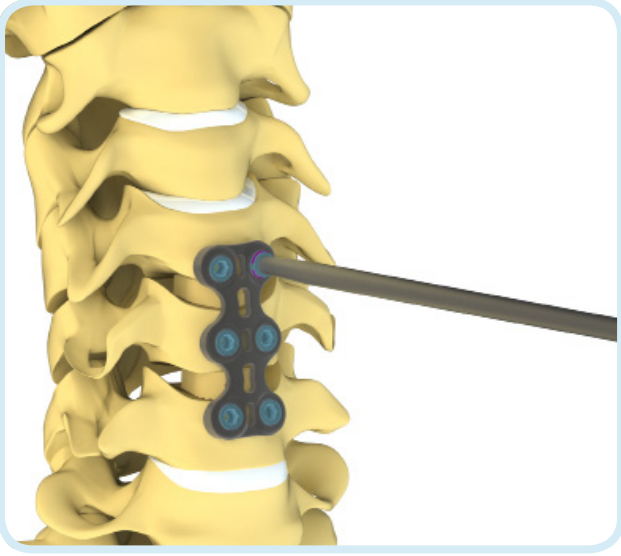
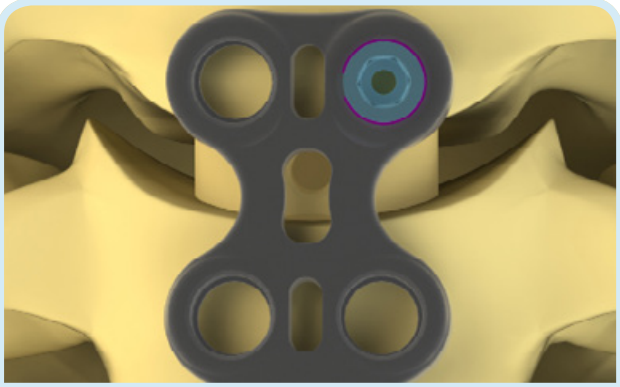


Figure 8a

Step 8:
If additional tightening is needed to fully seat and lock Screws into the Plate, the Final Tighten Driver Shaft may be used. Attach the Final Driver Shaft to the AO Handle, position in the Screw, and apply slight pressure while turning clockwise until Screw has been completely seated into the Plate.

When a Screw is final tightened and locked, a tactile click may be felt (see figure 8b).



UNLOCKED

LOCKED

Figure 8b

INSTRUMENTS

Final Tighten Driver Shaft

AO Handle

SCREW REMOVAL

Removal Sleeve Assembly

Figure 9

Screw Extraction

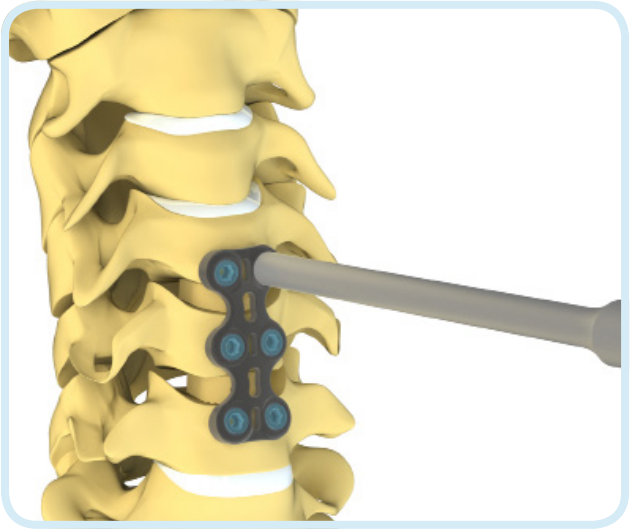


Figure 10

Step 9a:
Slide the Removal Sleeve over the Screwdriver. While holding the handle of the Screwdriver, thread the Removal Sleeve counter-clockwise until it is fully seated onto the Screwdriver.

Step 9b:
Insert the Screwdriver tip into the Screw. While applying slight downward pressure, thread the Draw Rod clockwise into the Screw until secured.

While holding the handle of the Screwdriver stationary, turn the Removal Sleeve clockwise until securely tightened against the Plate surface. Hold the Removal Sleeve stationary and turn the handle of the Screwdriver counter-clockwise until a tactile click is felt (click indicates disengagement of Retaining Ring from Plate). Release hand from Removal Sleeve and continue turning the handle of the Screwdriver counter-clockwise until Screw is completely extracted.

INSTRUMENTS

Screwdriver

Draw Rod

Removal Sleeve

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SYSTEM CONFIGURATION

SCREW OPTIONS

Self-Drilling, Fixed (1-11)

Self-Tapping, Fixed (12-22)

Self-Drilling, Variable (23-33)

Self-Tapping, Variable (34-44)

Item #	Catalog #	Description
SELF DRILLING, FIXED		
1	08-SDF-4010	Screw, 4x10mm SD Fixed
2	08-SDF-4011	Screw, 4x11mm SD Fixed
3	08-SDF-4012	Screw, 4x12mm SD Fixed
4	08-SDF-4013	Screw, 4x13mm SD Fixed
5	08-SDF-4014	Screw, 4x14mm SD Fixed
6	08-SDF-4015	Screw, 4x15mm SD Fixed
7	08-SDF-4016	Screw, 4x16mm SD Fixed
8	08-SDF-4017	Screw, 4x17mm SD Fixed
9	08-SDF-4018	Screw, 4x18mm SD Fixed
10	08-SDF-4019	Screw, 4x19mm SD Fixed
11	08-SDF-4020	Screw, 4x20mm SD Fixed
SELF TAPPING, FIXED		
12	08-STF-4010	Screw, 4x10mm ST Fixed
13	08-STF-4011	Screw, 4x11mm ST Fixed
14	08-STF-4012	Screw, 4x12mm ST Fixed
15	08-STF-4013	Screw, 4x13mm ST Fixed
16	08-STF-4014	Screw, 4x14mm ST Fixed
17	08-STF-4015	Screw, 4x15mm ST Fixed
18	08-STF-4016	Screw, 4x16mm ST Fixed
19	08-STF-4017	Screw, 4x17mm ST Fixed
20	08-STF-4018	Screw, 4x18mm ST Fixed
21	08-STF-4019	Screw, 4x19mm ST Fixed
22	08-STF-4020	Screw, 4x20mm ST Fixed

Item #	Catalog #	Description
SELF DRILLING, VARIABLE		
23	08-SDV-4010	Screw, 4x10mm SD Vari
24	08-SDV-4011	Screw, 4x11mm SD Vari
25	08-SDV-4012	Screw, 4x12mm SD Vari
26	08-SDV-4013	Screw, 4x13mm SD Vari
27	08-SDV-4014	Screw, 4x14mm SD Vari
28	08-SDV-4015	Screw, 4x15mm SD Vari
29	08-SDV-4016	Screw, 4x16mm SD Vari
30	08-SDV-4017	Screw, 4x17mm SD Vari
31	08-SDV-4018	Screw, 4x18mm SD Vari
32	08-SDV-4019	Screw, 4x19mm SD Vari
33	08-SDV-4020	Screw, 4x20mm SD Vari
SELF TAPPING, VARIABLE		
34	08-STV-4010	Screw, 4x10mm ST Vari
35	08-STV-4011	Screw, 4x11mm ST Vari
36	08-STV-4012	Screw, 4x12mm ST Vari
37	08-STV-4013	Screw, 4x13mm ST Vari
38	08-STV-4014	Screw, 4x14mm ST Vari
39	08-STV-4015	Screw, 4x15mm ST Vari
40	08-STV-4016	Screw, 4x16mm ST Vari
41	08-STV-4017	Screw, 4x17mm ST Vari
42	08-STV-4018	Screw, 4x18mm ST Vari
43	08-STV-4019	Screw, 4x19mm ST Vari
44	08-STV-4020	Screw, 4x20mm ST Vari

SCREW OPTIONS

Self-Drilling, Fixed (1-11)

Self-Tapping, Fixed (12-22)

Self-Drilling, Variable (23-33)

Self-Tapping, Variable (34-44)

Item #	Catalog #	Description
SELF DRILLING, FIXED		
1	08-SDF-4510	Screw, 4.5x10mm SD Fixed
2	08-SDF-4511	Screw, 4.5x11mm SD Fixed
3	08-SDF-4512	Screw, 4.5x12mm SD Fixed
4	08-SDF-4513	Screw, 4.5x13mm SD Fixed
5	08-SDF-4514	Screw, 4.5x14mm SD Fixed
6	08-SDF-4515	Screw, 4.5x15mm SD Fixed
7	08-SDF-4516	Screw, 4.5x16mm SD Fixed
8	08-SDF-4517	Screw, 4.5x17mm SD Fixed
9	08-SDF-4518	Screw, 4.5x18mm SD Fixed
10	08-SDF-4519	Screw, 4.5x19mm SD Fixed
11	08-SDF-4520	Screw, 4.5x20mm SD Fixed
SELF TAPPING, FIXED		
12	08-STF-4510	Screw, 4.5x10mm ST Fixed
13	08-STF-4511	Screw, 4.5x11mm ST Fixed
14	08-STF-4512	Screw, 4.5x12mm ST Fixed
15	08-STF-4513	Screw, 4.5x13mm ST Fixed
16	08-STF-4514	Screw, 4.5x14mm ST Fixed
17	08-STF-4515	Screw, 4.5x15mm ST Fixed
18	08-STF-4516	Screw, 4.5x16mm ST Fixed
19	08-STF-4517	Screw, 4.5x17mm ST Fixed
20	08-STF-4518	Screw, 4.5x18mm ST Fixed
21	08-STF-4519	Screw, 4.5x19mm ST Fixed
22	08-STF-4520	Screw, 4.5x20mm ST Fixed

Item #	Catalog #	Description
SELF DRILLING, VARIABLE		
23	08-SDV-4510	Screw, 4.5x10mm SD Vari
24	08-SDV-4511	Screw, 4.5x11mm SD Vari
25	08-SDV-4512	Screw, 4.5x12mm SD Vari
26	08-SDV-4513	Screw, 4.5x13mm SD Vari
27	08-SDV-4514	Screw, 4.5x14mm SD Vari
28	08-SDV-4515	Screw, 4.5x15mm SD Vari
29	08-SDV-4516	Screw, 4.5x16mm SD Vari
30	08-SDV-4517	Screw, 4.5x17mm SD Vari
31	08-SDV-4518	Screw, 4.5x18mm SD Vari
32	08-SDV-4519	Screw, 4.5x19mm SD Vari
33	08-SDV-4520	Screw, 4.5x20mm SD Vari
SELF TAPPING, VARIABLE		
34	08-STV-4510	Screw, 4.5x10mm ST Vari
35	08-STV-4511	Screw, 4.5x11mm ST Vari
36	08-STV-4512	Screw, 4.5x12mm ST Vari
37	08-STV-4513	Screw, 4.5x13mm ST Vari
38	08-STV-4514	Screw, 4.5x14mm ST Vari
39	08-STV-4515	Screw, 4.5x15mm ST Vari
40	08-STV-4516	Screw, 4.5x16mm ST Vari
41	08-STV-4517	Screw, 4.5x17mm ST Vari
42	08-STV-4518	Screw, 4.5x18mm ST Vari
43	08-STV-4519	Screw, 4.5x19mm ST Vari
44	08-STV-4520	Screw, 4.5x20mm ST Vari

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PLATE OPTIONS

1 LEVEL 

2 LEVEL 

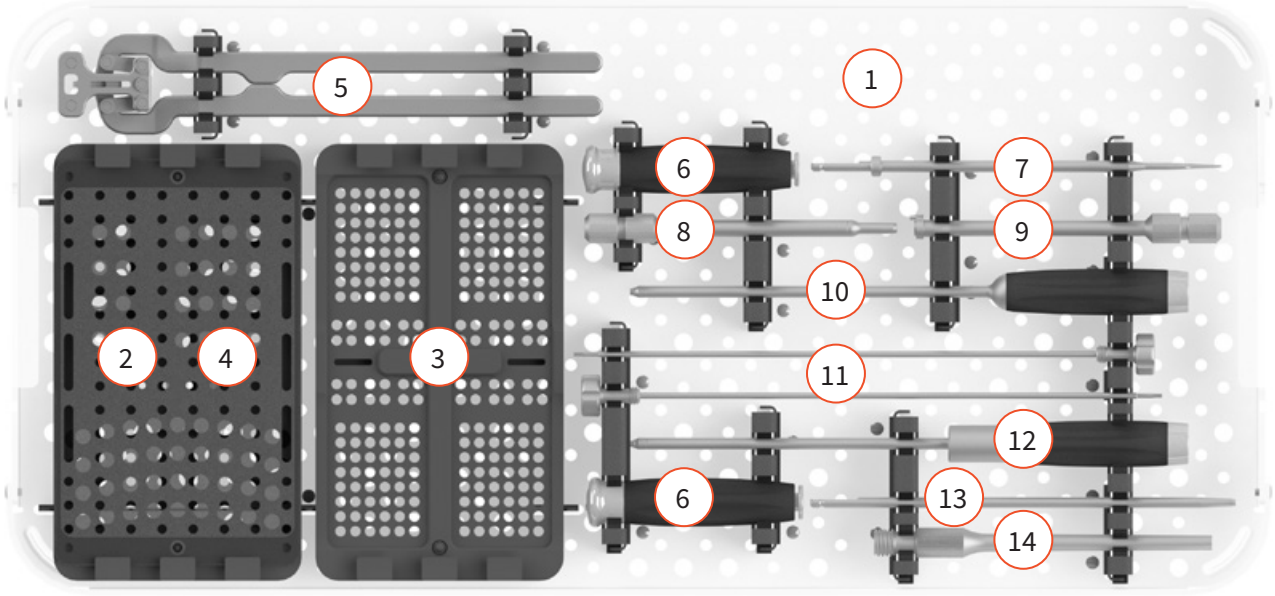
3 LEVEL 

4 LEVEL 

Level(s)	Catalog #	Description
1	08-CPR-0118	Plate, 18mm 1L
	08-CPR-0120	Plate, 20mm 1L
	08-CPR-0122	Plate, 22mm 1L
	08-CPR-0124	Plate, 24mm 1L
	08-CPR-0126	Plate, 26mm 1L
	08-CPR-0128	Plate, 28mm 1L
	08-CPR-0130	Plate, 30mm 1L
	08-CPR-0132	Plate, 32mm 1L
	08-CPR-0134	Plate, 34mm 1L
2	08-CPR-0234	Plate, 34mm 2L
	08-CPR-0237	Plate, 37mm 2L
	08-CPR-0240	Plate, 40mm 2L
	08-CPR-0243	Plate, 43mm 2L
	08-CPR-0246	Plate, 46mm 2L
	08-CPR-0249	Plate, 49mm 2L
	08-CPR-0252	Plate, 52mm 2L
	08-CPR-0255	Plate, 55mm 2L

Level(s)	Catalog #	Description
3	08-CPR-0348	Plate, 48mm, 3L
	08-CPR-0351	Plate, 51mm, 3L
	08-CPR-0354	Plate, 54mm, 3L
	08-CPR-0357	Plate, 57mm, 3L
	08-CPR-0360	Plate, 60mm, 3L
	08-CPR-0363	Plate, 63mm, 3L
	08-CPR-0366	Plate, 66mm, 3L
	08-CPR-0369	Plate, 69mm, 3L
	08-CPR-0372	Plate, 72mm, 3L
4	08-CPR-0464	Plate, 64mm, 4L
	08-CPR-0466	Plate, 66mm, 4L
	08-CPR-0468	Plate, 68mm, 4L
	08-CPR-0472	Plate, 72mm, 4L
	08-CPR-0476	Plate, 76mm, 4L
	08-CPR-0480	Plate, 80mm, 4L
	08-CPR-0484	Plate, 84mm, 4L
	08-CPR-0488	Plate, 88mm, 4L
	08-CPR-0492	Plate, 92mm, 4L

TRAY INSERT



Item #	Description	Qty
1	Tray Insert, Level 1	1
2	Caddie, Plates	1
3	Caddie, Screws	1
4	Caddie Lid, Plates & Screws	2
5	Plate Bender	1
6	AO Handle	2
7	12mm Drill	2
8	Variable Drill Guide	1
9	Fixed All-In-One Guide	1
10	Temporary Fixation Pin Driver	1
11	Draw Rod	2
12	Screwdriver	1
13	Final Tighten Driver Shaft	2
14	Removal Sleeve	1

Kalitec Medical | 618 E. South Street, Suite 500 Orlando, FL 32801 USA | 407-545-2063

NOTES:

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

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