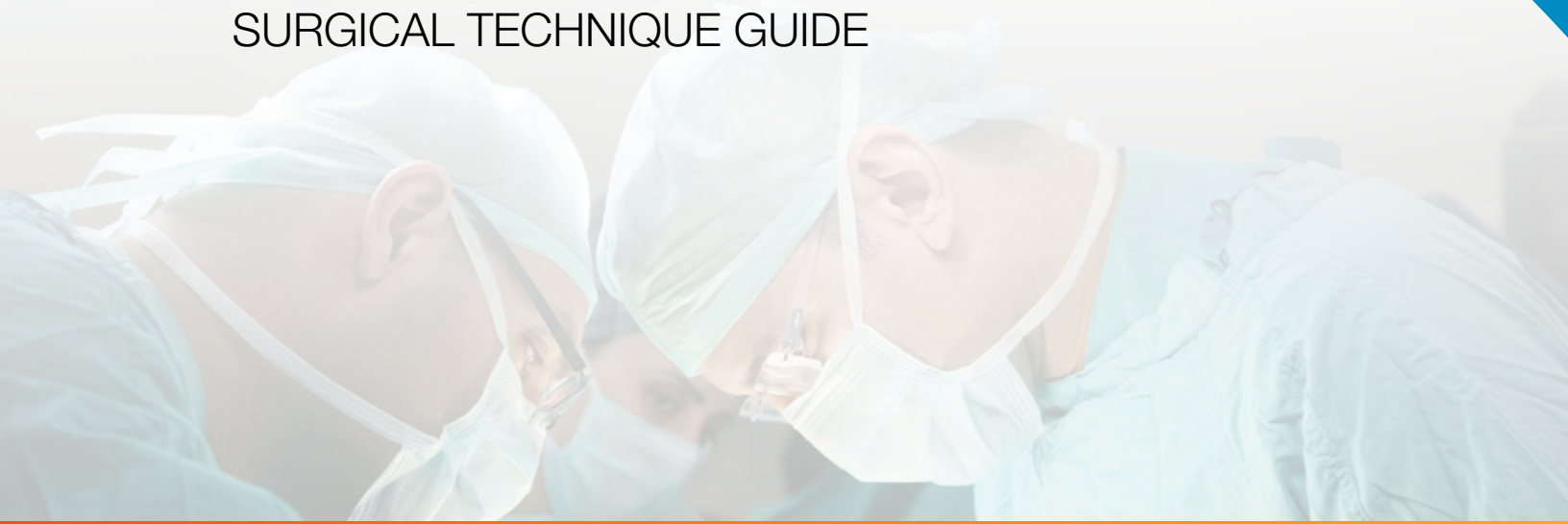
Kalitec

CosmoLock®
Pedicle Screw 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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CosmoLock®
Pedicle Screw System

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CosmoLock
Pedicle Screw System

INTRODUCTION

Description:

The Kalitec CosmoLock Pedicle Screw System is used as a non-cervical spinal fixation device intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The CosmoLock Pedicle Screw System is comprised of various types and sizes of screws, rods, and connectors. The implant components are selected for the individual case, being placed in a variety of configurations. The CosmoLock Pedicle Screw System is made from medical implant grade titanium alloy Ti-6Al-4V (ELI) per ASTM F-136, and cobalt chrome alloy per ASTM F-1537.

Caution:

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

All implants are intended for single use only. The CosmoLock Pedicle Screw System should not be reused under any circumstances. Do not use the CosmoLock Pedicle Screw System components in conjunction with components from any other system or manufacturer. These instructions are designed to assist in the use of the CosmoLock Pedicle Screw System and are not a reference for surgical techniques.

The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.

Indications:

The CosmoLock Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

The CosmoLock Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis; and failed previous fusion.

Contraindications:

- Acute or chronic infectious diseases of any etiology and localization
- Signs of local inflammation
- Open wounds
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Metal/polymer sensitivity/allergies to the implant materials
- Mental illness, alcoholism, drug abuse
- Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any condition that totally precludes the possibility of fusion (i.e. cancer, kidney dialysis).
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Symptomatic cardiac disease.
- Systemic or terminal illness.

These contraindications can be absolute or relative and must be taken into account by the physician when making surgical decisions.

The list above is not exhaustive.

Possible Adverse Events:

A listing of possible adverse events includes, but is not limited to:

- Bending, disassembly, or fracture of any or all components of the implant.
- Loosening of the implant.
- Implant material sensitivity, or allergic reaction to a foreign body.

• Infection, early or late.

• Decrease in bone density due to stress shielding.

• Increased biomechanical stress on adjacent levels.

• Pain, discomfort, or abnormal sensations due to the presence of the device.

• Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Tissue damage caused by improper positioning and placement of implants or instruments.

• Loss of correction, curvature, height, and/or reduction.

• Dural tear and/or leak.

• 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.

• 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.

• Scar formation possibly causing neurological compromise around nerves and/or pain.

• Fracture, micro-fracture, 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.

• Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.

• Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.

• Graft donor site complications including pain, fracture, or wound healing problems.

• Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.

• Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.

• Development of respiratory problems (i.e. pulmonary embolism, bronchitis, pneumonia, etc.).

• Non-union (or pseudoarthrosis), delayed union and/or mal-union.

• Cessation of any potential growth of the operated portion of the spine.

• Loss of spinal mobility or function.

• Death.

Note: Re-operation or revision may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions:

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

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. The implantation of the CosmoLock Pedicle Screw System should be performed only by experienced spine surgeons with specific training in the use of spinal pedicle screw instrumentation because this is a technically demanding procedure presenting a risk of serious injury to the patient.

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.

If a reusable device is/was used in a patient with, or suspected of having, Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize and eliminate the risk of cross-contamination.

Use of instrumentation on patients with very hard bone may lead to damage to instruments or implants.

The CosmoLock Pedicle Screw System has not been evaluated for safety and compatibility within the MR environment. The CosmoLock Pedicle Screw System has not been tested for heating or migration in the MR environment.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

SURGICAL TECHNIQUE

Patient Positioning and Exposure

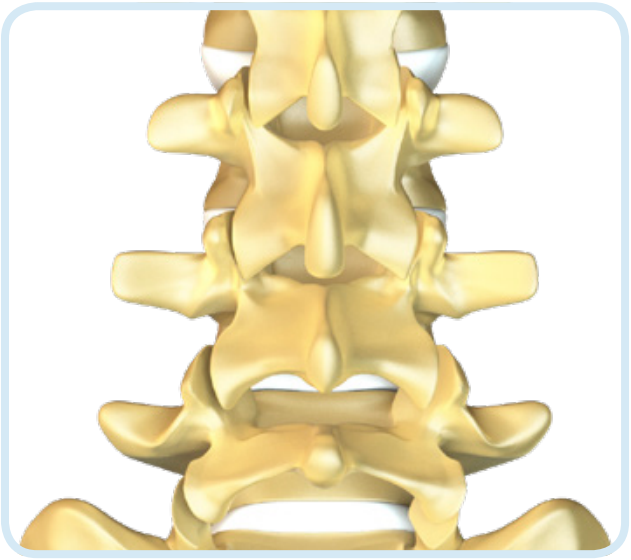


Figure 1

Pedicle Preparation

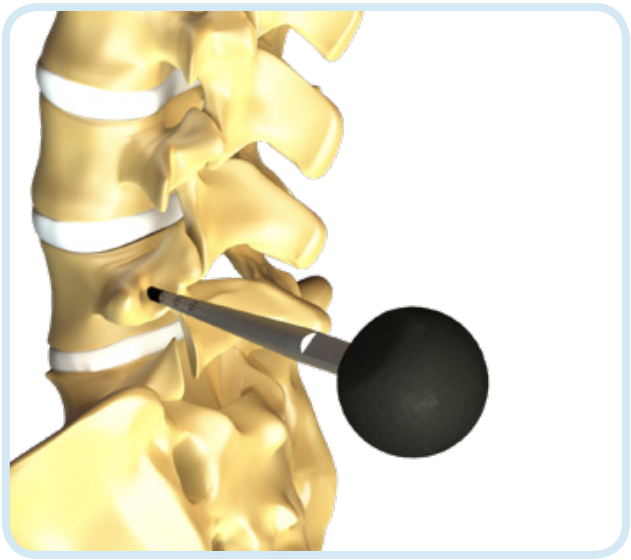


Figure 2

Step 1:

a. Place patient in the prone position.

b. Identify the appropriate level(s) to be instrumented using manual palpation and intraoperative imaging.

c. Make an incision and expose all levels to be treated.

Step 2:

a. Using a motorized burr or manual Bone Awl with depth stop, prepare the pedicle entry point.

b. Utilizing a Bone Probe, prepare the proper trajectory within the pedicle, ensuring not to disturb the pedicle walls.

INSTRUMENTS

Pedicle Trajectory Verification

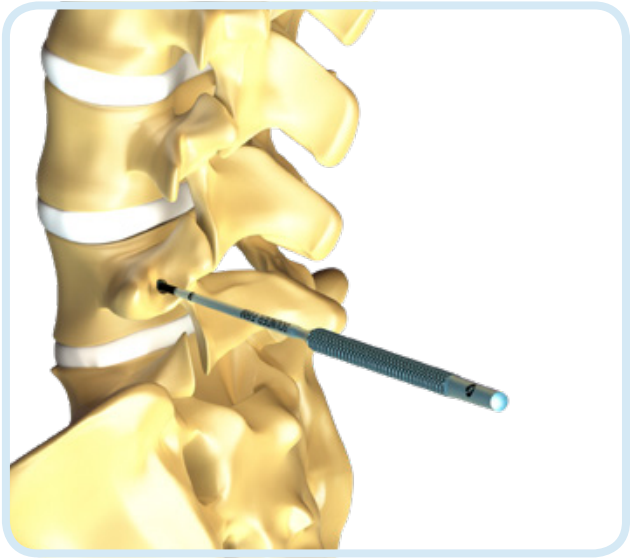


Figure 3

Tapping

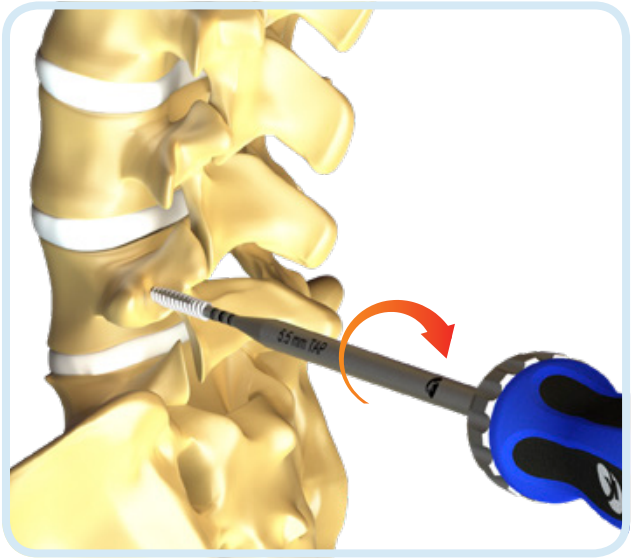


Figure 4

Step 3:

a. Using the Ball Tip Sounder, confirm the integrity of all aspects of each pedicle wall.

b. Additionally, confirm the integrity of all aspects of the vertebral body walls.

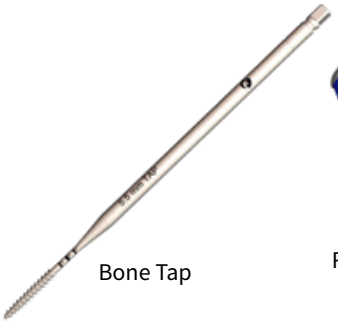
Step 4:

a. CosmoLock Pedicle Screws have a fully threaded, tapered tip minimizing the need to Tap. Taps are undersized 0.5mm to optimize screw purchase.

Note: *Under-tapping is not recommended due to the potential of screw breakage or instrument damage. Tapping should always be performed when dense hard bone is present.*

INSTRUMENTS

Ball Tip Sounder



Bone Tap

Ratcheting Handle

Screw Loading

Figure 5

Screw Insertion

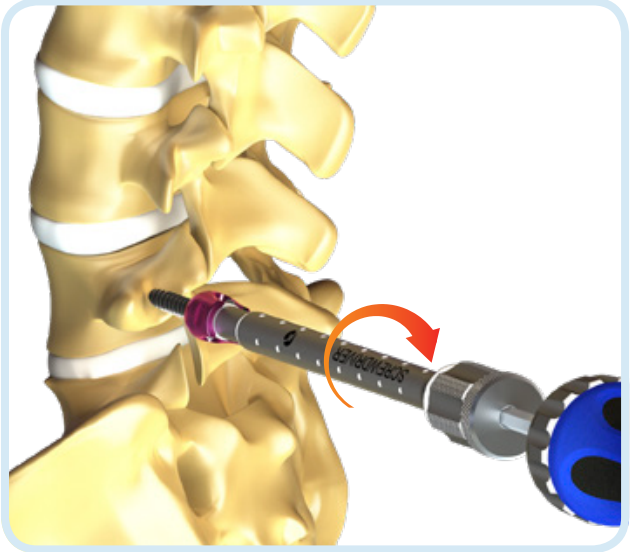


Figure 6

Step 5:

a. Insert Polyaxial Screwdriver Shaft into Ratcheting Handle. Alignment ring at the base of the Screwdriver should not be visible when properly seated and shaft should not move in any direction when handle is in the middle neutral, non-ratcheting position.

b. Remove the appropriate size screw from the screw caddie and firmly attach to the Screwdriver by releasing the Screwdriver locking ring and tightening the knob on the Screwdriver shaft. Ensure that the Screwdriver tip is fully seated into the screw. When holding the knob, the distal screw threads should not rotate when the Screwdriver is properly engaged.

c. Fully seat the Screwdriver locking ring into the knob.

Step 6:

a. Turn the Ratcheting Handle into the forward advancing position.

b. Insert the screw into the prepared pedicle. Additional Screwdriver support may be achieved by holding the free-floating Screwdriver sleeve.

c. Once the screw is properly seated, raise the Screwdriver Locking Ring and turn the Screwdriver knob counterclockwise to release the Screw.

INSTRUMENTS

Polyaxial Screwdriver

Ratcheting Handle

Screw Positioning

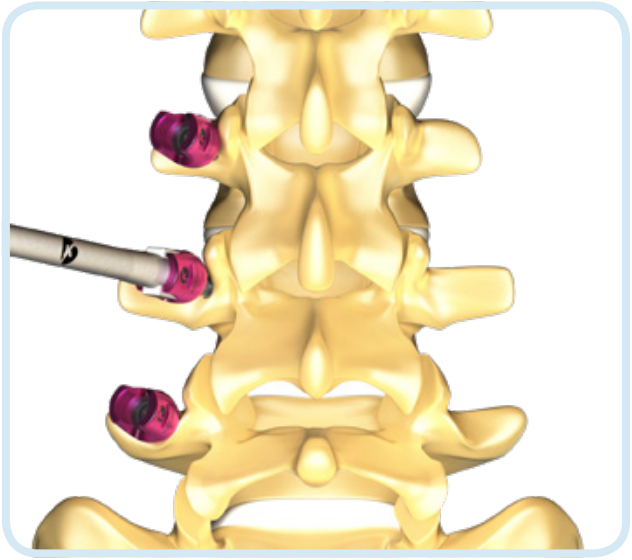


Figure 7

Rod Placement

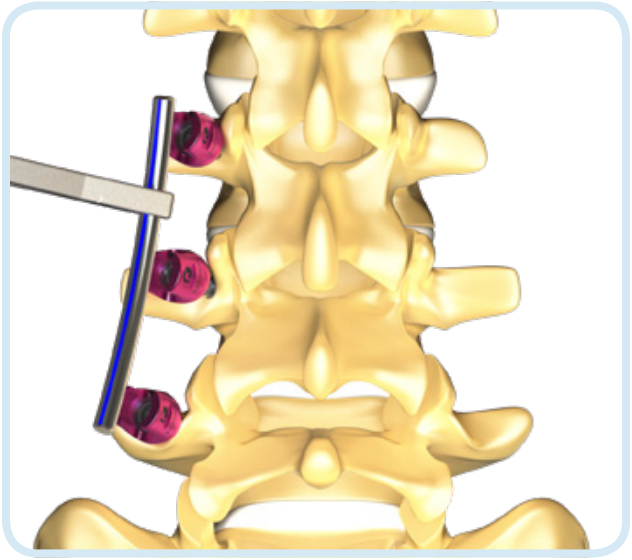


Figure 8

Step 7:

a. ***Height Adjustment:*** The screw height may be adjusted utilizing the fixed Screw Height Adjuster T-Handle.

b. ***Screw Head Alignment:*** The screw heads may be aligned with the fixed Screw Head Persuader T-Handle.

Note: *When using Screw Head Persuader, take caution to avoid placing excessive force on the Screw head that would cause an over angulation greater than 35° in any direction as this could cause a potential separation from the Screw shank.*

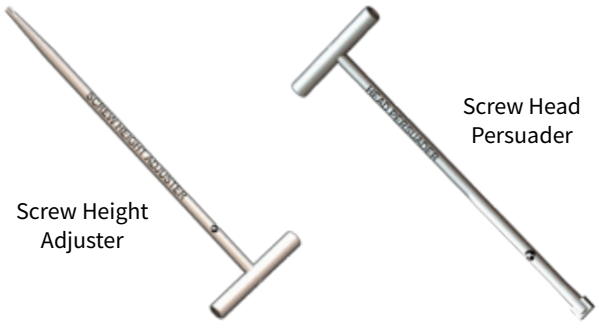
Step 8:

a. Select the appropriate length 5.5mm rod and if necessary, contour the rod utilizing the Adjustable Rod Bender or Coronal Rod Benders.

b. Utilizing the Rod Holder or Small Vise Grip, place the rod into the aligned screw heads. Ensure that the rod extends beyond the top and bottom screw heads.

Note: *Repetitive or acute angle rod bending may decrease overall rod fatigue strength.*

INSTRUMENTS



Rod Reduction & Cap Insertion

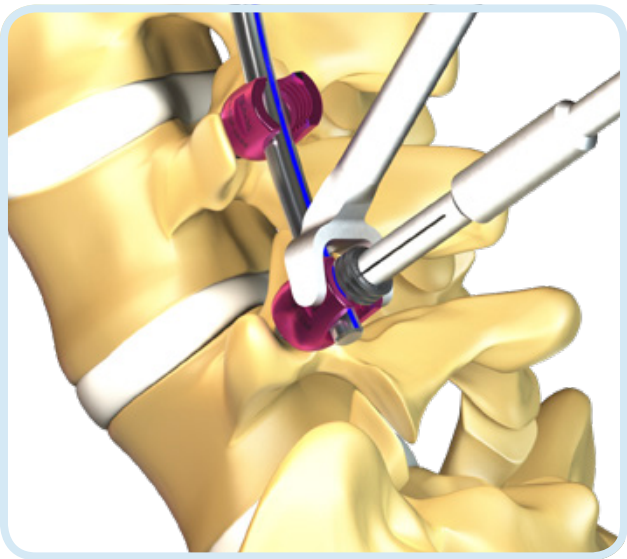


Figure 9 - Option 1

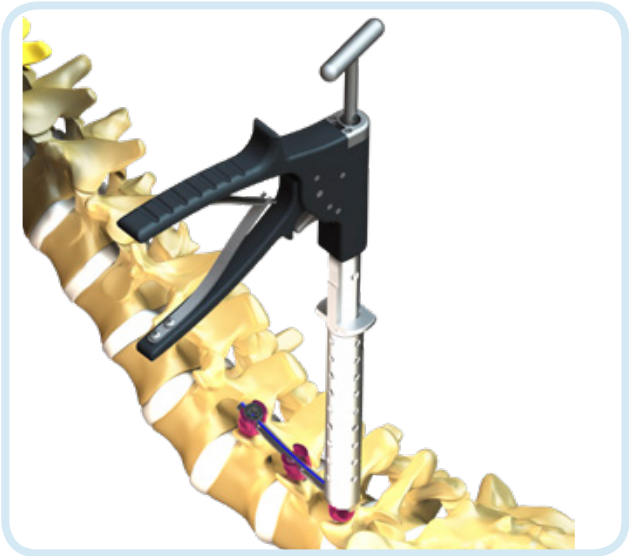


Figure 9 - Option 2

Step 9:

a. Utilizing the Split Tip Cap Starter T-Handle, firmly seat the T-Handle into a locking cap. Additional locking caps may be loaded onto the other supplied T-Handles to expedite locking cap placement.

b. Align the laser mark on the locking cap with the laser mark on the screw head and slowly rotate in the clockwise direction until the locking cap is tracking properly within the screw head.

c. If additional rod reduction is needed, the Fixed, Adjustable, and Ratcheting Rod Reducers may be utilized.

Note: *Cross-threading may lead to damage to the locking cap and/or screw head that may go unnoticed and could compromise the final locking functionality.*

Step 9 continued:

Option 1: One-Piece or Hinged Rocker – To use the One-Piece Rocker, slide it to the center of the screw head then push the Rocker handle anteriorly. To use the Hinged Rocker, close the Rocker in the center of the screw head. Secure the locking arm on the backside of the handle, then push the Rocker anteriorly.

Option 2: Ratcheting Rod Reducer – Align the arms of the Ratcheting Rod Reducer with the sides of the screw head. Fully squeeze the handle assembly twice. If properly engaged, the Rod Reducer will not disengage when pulled in the upward direction after two cycles. Actuate the handle as need to fully seat the rod. Insert a loaded Locking Cap Starter through the inner channel of the Rod Reducer until the screw head is felt. Slowly rotate clockwise until locking cap is tracking properly. The Ratcheting Rod Reducer release mechanism is the trigger located just above the handle assembly.

INSTRUMENTS

One-Piece Rocker

Split Tip Cap Starter (T30)

Ratcheting Rod Reducer

Compression or Distraction (Optional)

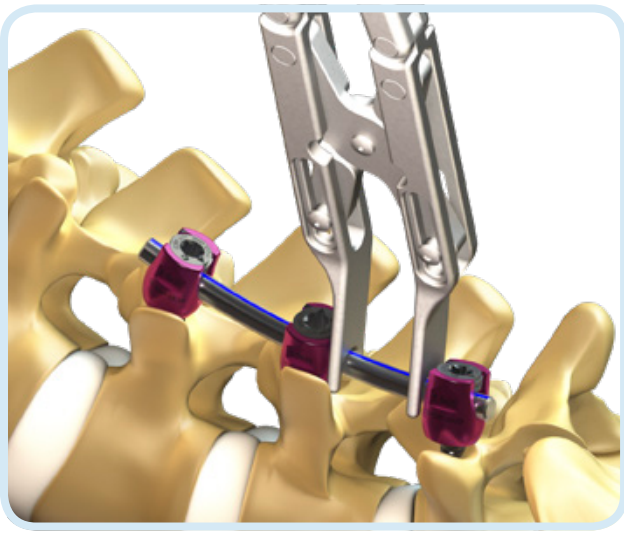


Figure 10

Step 10:

a. If Compression or Distraction of the screws is needed, provisionally lock one locking cap. Utilizing the dual action Compressor or Distractor, compress or distract as needed.

b. Once the desired Compression or Distraction is achieved, provisionally lock the adjacent locking cap that is under compression or distraction.

Final Tightening

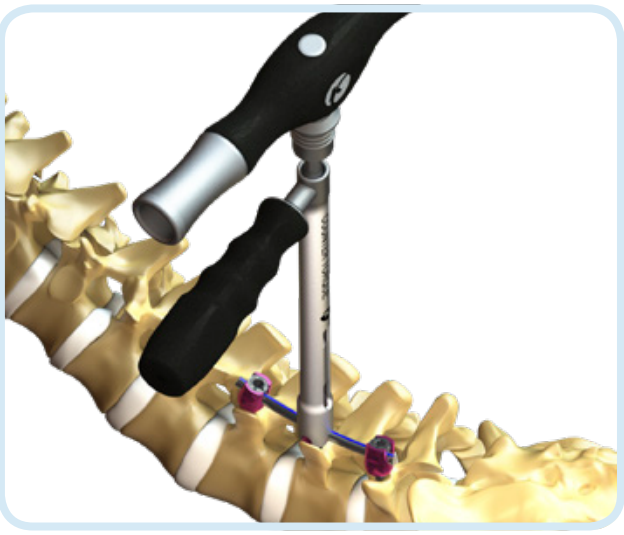


Figure 11

Step 11:

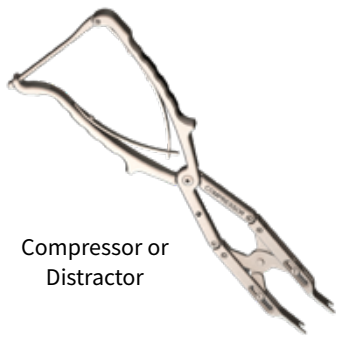
a. Assemble the Torque Limiting T-Handle (90 in-lbs) to the Locking Cap Final Driver shaft (T30).

b. Slide the Counter Torque over each screw head until the rod is engaged. Insert the Locking Cap Final Driver shaft and Torque Limiting T-Handle assembly through the Counter Torque and engage the locking cap.

c. While providing counter resistance with the Counter Torque, rotate the Torque Limiting T-Handle clockwise until the tactile break away click is achieved. Each tactile break away click indicates that the required 90in-lbs of torque to each locking cap has been achieved.

d. Repeat this process for each of the remaining screws in the construct.

INSTRUMENTS



Compressor or Distractor

Counter Torque

Locking Cap Final Driver (T30)

Torque Limiting T-Handle (90in-lbs)

CrossLink Placement

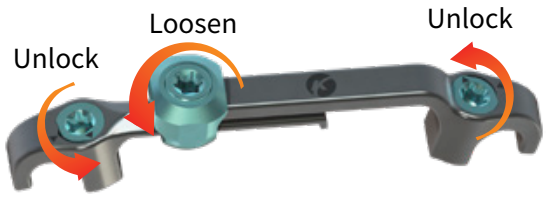


Figure 12

Step 12:

a. Adjustable CrossLinks are available in four sizes: Extra Small (30-37mm), Small (38-48mm), Medium (46-60mm), & Large (58-72mm).

b. Before placing appropriate CrossLink on the rods, ensure that both locking cams have been rotated fully open in the counterclockwise direction. Additionally, ensure that the center locking screw is loose to maximize angulation.

CrossLink Final Tightening

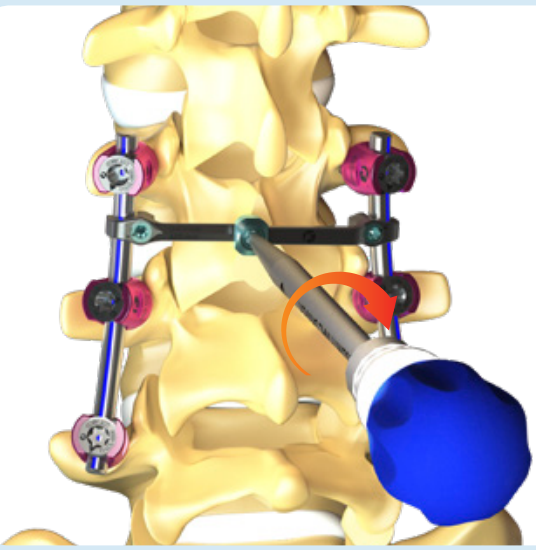


Figure 13

Step 13:

a. Once the CrossLink has been placed across the rods, turn the locking cams clockwise about a quarter turn. When the CrossLink cams are tightened properly, the laser markings on the CrossLink should be aligned.

b. Utilizing the assembled blue Torque Limiting Egg Handle (30in-lbs) and CrossLink Final Driver (T15), turn the center locking screw clockwise until the tactile break away click is achieved. Each tactile break away click indicates that the required 30in-lbs of torque on the center locking screw has been achieved.

INSTRUMENTS

CrossLink
Final Driver (T15)

Torque Limiting
Egg Handle (30in-lbs)

Implant Construct Removal

Removal:

a. Expose all implants to be removed.

b. Utilizing a standard T15 removal driver, loosen the CrossLink center locking screw by rotating it counterclockwise. Rotate each of the locking cams a quarter turn in the counterclockwise direction.

c. Utilizing a standard T30 removal driver, loosen and remove each of the locking caps from each pedicle screw. Remove rods.

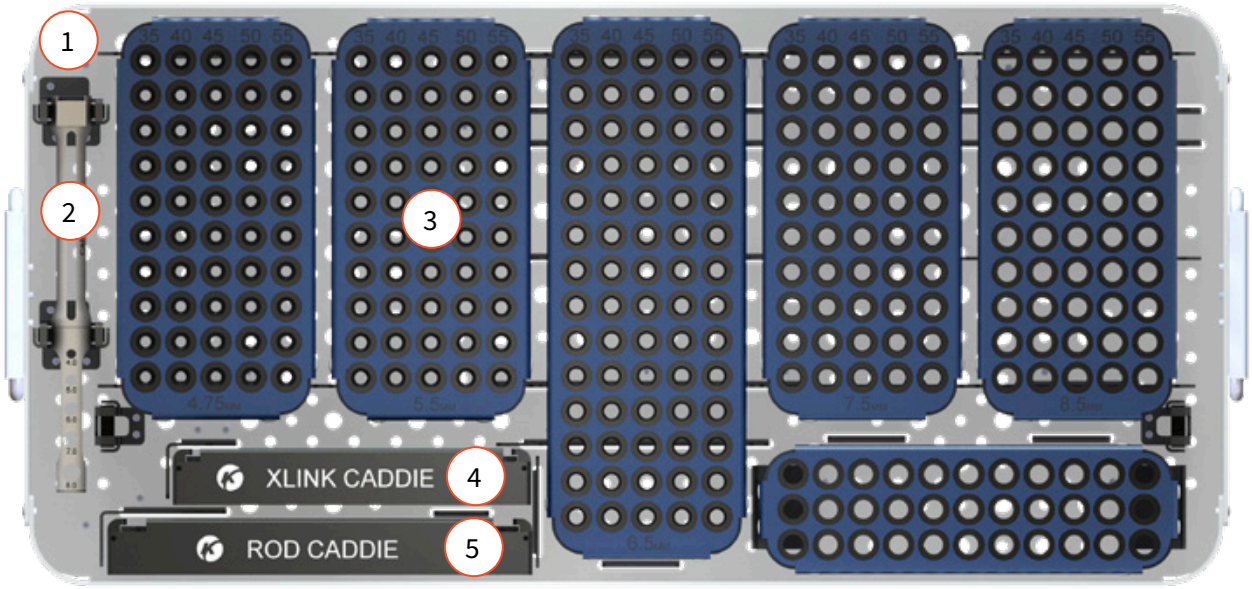
d. Utilizing a standard T25 removal driver, rotate each pedicle screw counterclockwise. ***Note:*** CosmoLock Pedicle Screws have a standard depth screw socket and do not require special instrumentation for removal.

SYSTEM CONFIGURATION

IMPLANTS	
Catalog #	**Description**
11-LCL-0000	Locking Cap
10-SSP-4720 thru 10-SSP-4765	Screw, Poly 4.75 x 20 thru 65mm (5mm increments)
10-SSP-5520 thru 10-SSP-5565	Screw, Poly 5.5 x 20 thru 65mm (5mm increments)
10-SSP-6520 thru 10-SSP-6515	Screw, Poly 6.5 x 20 thru 115mm (5mm increments)
10-SSP-7520 thru 10-SSP-7515	Screw, Poly 7.5 x 20 thru 115mm (5mm increments)
10-SSP-8520 thru 10-SSP-8515	Screw, Poly 8.5 x 20 thru 115mm (5mm increments)
10-SCP-4720 thru 10-SCP-4765	Screw, Poly Cann 4.75 x 20 thru 65mm (5mm increments)
10-SCP-5520 thru 10-SCP-5565	Screw, Poly Cann 5.5 x 20 thru 65mm (5mm increments)
10-SCP-6520 thru 10-SCP-6515	Screw, Poly Cann 6.5 x 20 thru 115mm (5mm increments)
10-SCP-7520 thru 10-SCP-7515	Screw, Poly Cann 7.5 x 20 thru 115mm (5mm increments)
10-SCP-8520 thru 10-SCP-8515	Screw, Poly Cann 8.5 x 20 thru 115mm (5mm increments)
10-SSE-4720 thru 10-SSE-4765	Screw, Ext Tab 4.75 x 20 thru 65mm (5mm increments)
10-SSE-5520 thru 10-SSE-5565	Screw, Ext Tab 5.5 x 20 thru 65mm (5mm increments)
10-SSE-6520 thru 10-SSE-6515	Screw, Ext Tab 6.5 x 20 thru 115mm (5mm increments)
10-SSE-7520 thru 10-SSE-7515	Screw, Ext Tab 7.5 x 20 thru 115mm (5mm increments)
10-SSE-8520 thru 10-SSE-8515	Screw, Ext Tab 8.5 x 20 thru 115mm (5mm increments)
10-SCE-4720 thru 10-SCE-4765	Screw, Ext Tab Cann 4.75 x 20 thru 65mm (5mm increments)
10-SCE-5520 thru 10-SCE-5565	Screw, Ext Tab Cann 5.5 x 20 thru 65mm (5mm increments)
10-SCE-6520 thru 10-SCE-6515	Screw, Ext Tab Cann 6.5 x 20 thru 115mm (5mm increments)
10-SCE-7520 thru 10-SCE-7515	Screw, Ext Tab Cann 7.5 x 20 thru 115mm (5mm increments)
10-SCE-8520 thru 10-SCE-8515	Screw, Ext Tab Cann 8.5 x 20 thru 115mm (5mm increments)
11-RRC-0035 thru 11-RRC-0080	Rod, Curved, 5.5 x 35 thru 80mm (5mm increments)
11-RRC-0090 thru 11-RRC-0120	Rod, Curved, 5.5 x 90 thru 120mm (10mm increments)
11-RRS-0035 thru 11-RRS-0080	Rod, Straight, 5.5 x 35 thru 80mm (5mm increments)
11-RRS-0090 thru 11-RRS-0120	Rod, Straight, 5.5 x 90 thru 120mm (10mm increments)
11-RRS-0250	Rod, Straight, 5.5 x 250mm
11-RRH-0400 thru 11-RRH-0500	Rod, Rigid, 5.5 x 400 thru 500mm (50mm increments)
11-RRH-0600	Rod, Rigid, 5.5 x 600mm
11-RCC-0250	Rod, CoCr, 5.5 x 250mm
11-RCC-0400 thru 11-RCC-0500	Rod, CoCr, 5.5 x 400 thru 500mm (50mm increments)
11-RCC-0600	Rod, CoCr, 5.5 x 600mm
11-RMS-0400 thru 11-RMS-0500	Rod, Malleable, 5.5 x 400 thru 500mm (50mm increments)
11-RMS-0600	Rod, Malleable, 5.5 x 600mm
10-XLV-0004	CrossLink, Adj XSml 30-37mm
10-XLV-0001	CrossLink, Adj Sml 37-51mm
10-XLV-0002	CrossLink, Adj Med 46-60mm
10-XLV-0003	CrossLink, Adj Lrg 58-72mm
10-XLF-0016 thru 10-XLF-0038	CrossLink, Fixed 16 thru 38mm (2mm increments)

SYSTEM CONFIGURATION

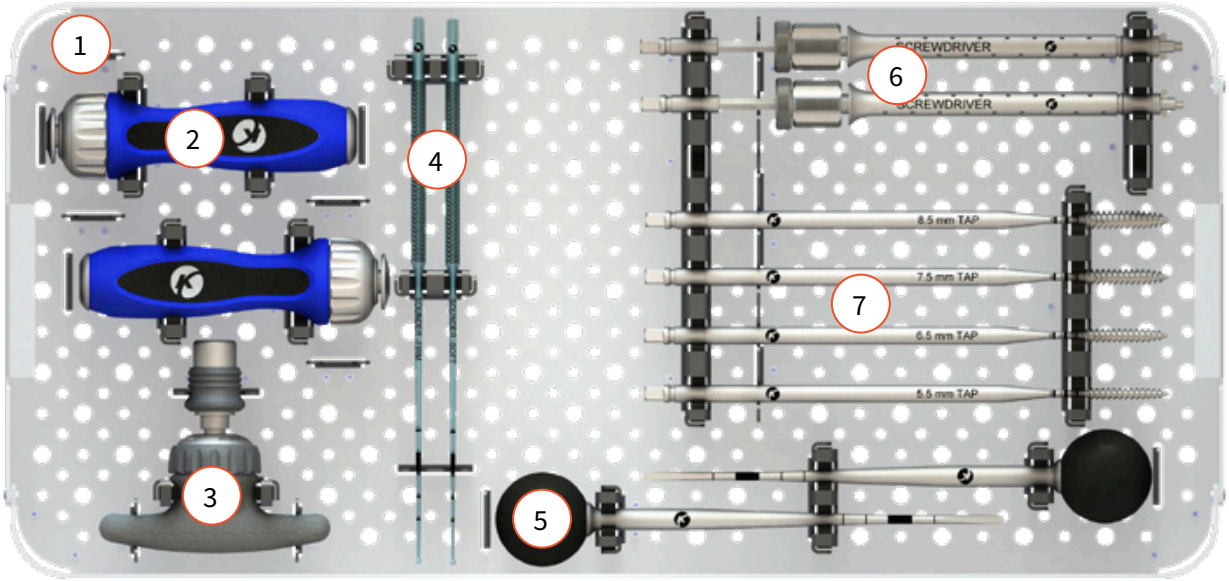
IMPLANT TRAY



Item #	Description	Qty/Set
1	Implant Tray	1
2	Locking Cap Dispenser & Screw Measurement Gauge	1
3	Screw Caddie	6
4	CrossLink Caddie	1
5	Curved Rod Caddie	1

SYSTEM CONFIGURATION

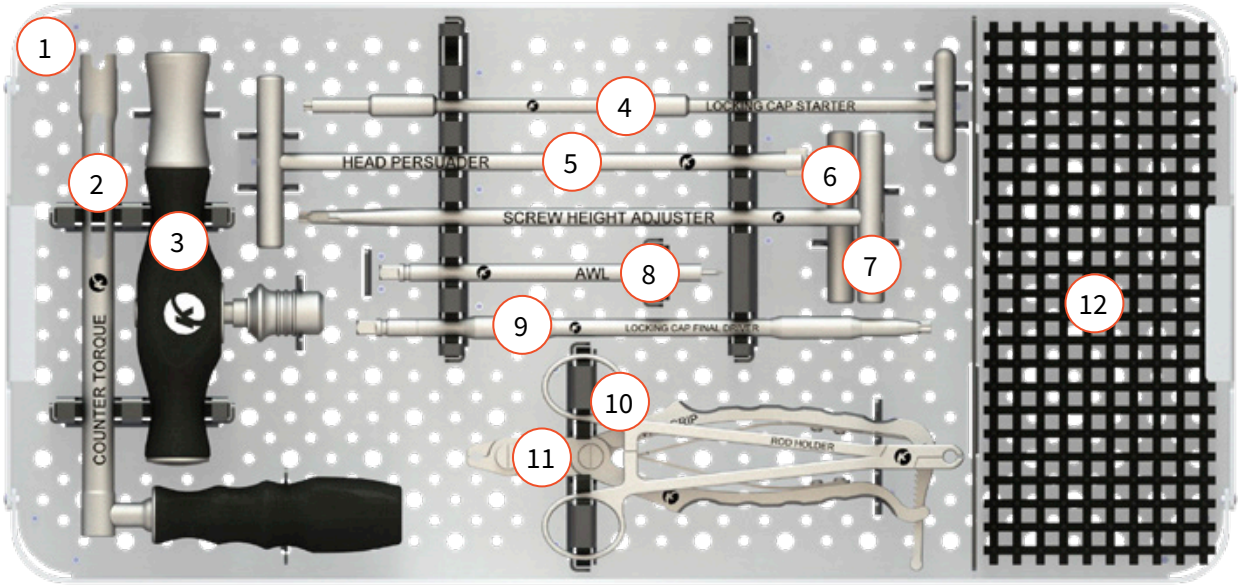
TRAY INSERT 1



Item #	Description	Qty/Set
1	Tray Insert 1	1
2	Inline Ratcheting Handle	2
3	Ratcheting T-Handle	1
4	Sounder, Ball-Tip	2
5	Bone Probe	2
6	Screwdriver, Poly or Ext. Tab Screws	2
7	Bone Taps	4

SYSTEM CONFIGURATION

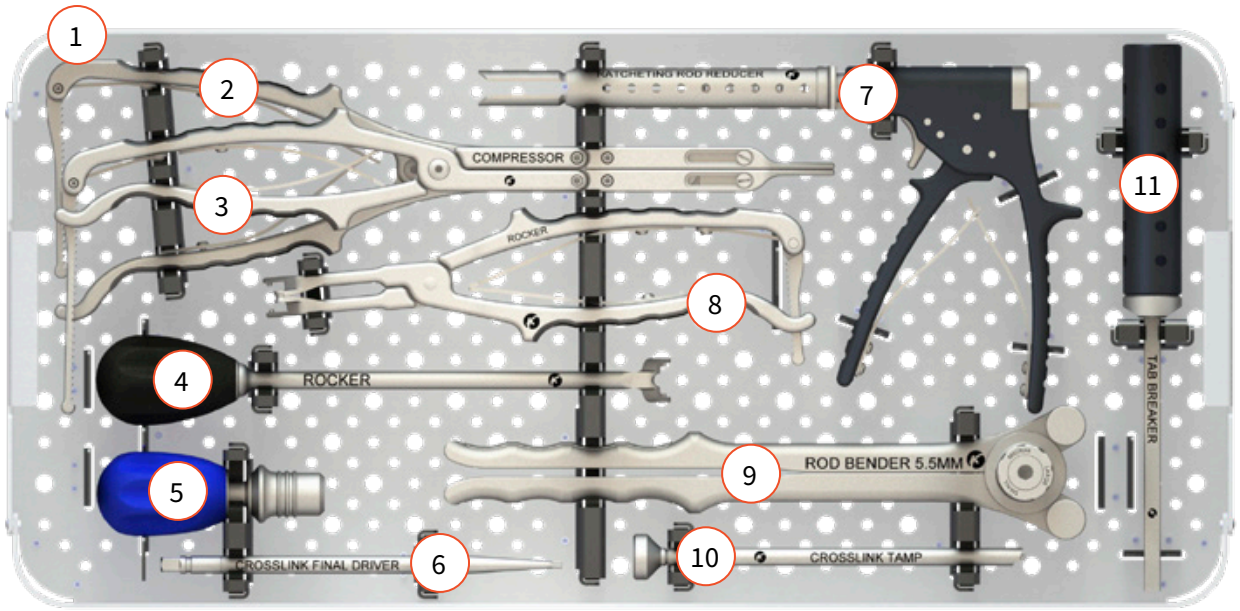
TRAY INSERT 2



Item #	Description	Qty/Set
1	Tray Insert 2	1
2	Counter Torque	1
3	Torque Limiting T-Handle (90in-lb)	1
4	Split-Tip Locking Cap Starter	2
5	Head Persuader	1
6	Locking Cap Adjuster (T30)	1
7	Screw Height Adjuster (T25)	1
8	Bone Awl	1
9	Final Locking Cap Driver (T30)	1
10	Rod Holder, 5.5mm	1
11	Small Vise Grip, 5.5mm	1
12	Nipple Mat	1

SYSTEM CONFIGURATION

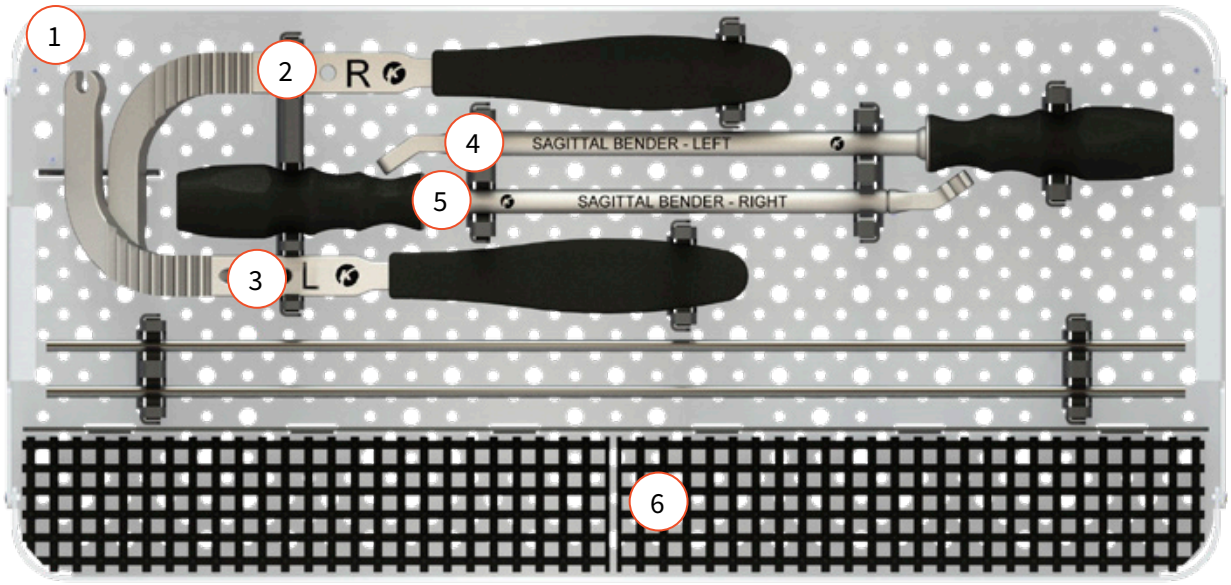
TRAY INSERT 3



Item #	Description	Qty/Set
1	Tray Insert 3	1
2	Distractor	1
3	Compressor	1
4	One-Piece Rocker	1
5	CrossLink Torque Limiting Egg Handle (30in-lb)	1
6	CrossLink Final Driver (T15)	1
7	Ratcheting Rod Reducer	1
8	Hinged Rocker	1
9	Adjustable Rod Bender (5.5mm)	1
10	CrossLink Tamp (Optional)	1
11	Extended Tab Breaker (Optional)	1

SYSTEM CONFIGURATION

TRAY INSERT 4



Item #	Description	Qty/Set
1	Tray Insert 4	1
2	Coronal Rod Bender, Right (Optional)	1
3	Coronal Rod Bender, Left (Optional)	1
4	Sagittal Rod Bender, Left	1
5	Sagittal Rod Bender, Right	1
6	Nipple Mat	1

Kalitec

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

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