Kalitec

InSePtion®

Interspinous MIS Fixation Device

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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SURGICAL TECHNIQUE GUIDE

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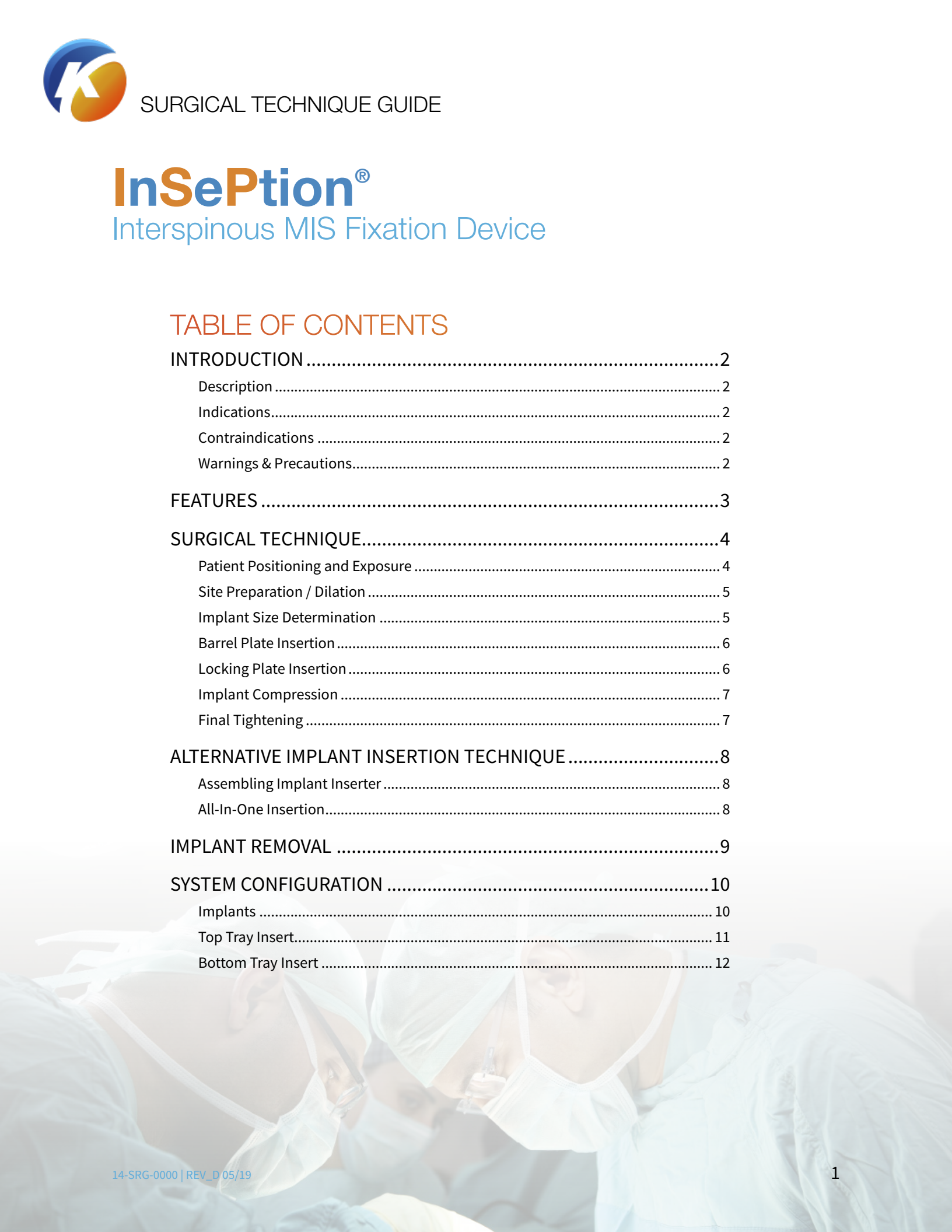


InSePtion®
Interspinous MIS Fixation Device
INTRODUCTION

Description:

The Kalitec Medical InSePtion MIS Fixation System is a minimally invasive posterior attachment spinal fixation system manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and designed to be an alternative to pedicle screw fixation for the described indications. The system is composed of spinous process plates, dedicated surgical instruments and sterilization cases. The components are used to build a construct to provide stabilization of spinal segment in the thoracic, lumbar and sacral spine to support fusion.

Indications, Contraindications, and Possible Adverse Effects:

Indications:

The Kalitec Medical InSePtion MIS Fixation System is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The system is intended for use with autograft or allograft.

The Kalitec Medical InSePtion MIS Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), and/or tumor. The Kalitec Medical InSePtion MIS Fixation System is not intended for standalone use.

Contraindications:

- Acute or chronic infectious diseases of any etiology or localization
- Signs of local inflammation
- Open wounds
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Metal/polymer sensitivity/allergies to the implant materials
- Mental illness, alcoholism, heavy smoking, drug abuse
- Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery
- Incompetent or missing posterior arch (e.g., laminectomy, pars defect severe osteoporosis)
- 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
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period
- Any case requiring the mixing of components from other manufacturers systems
- Any case requiring the mixture of stainless steel with titanium or stainless steel with cobalt chrome implant components
- Previous history of infection

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.

Potential 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 pseudarthrosis), 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

Warnings and Precautions:

The safety and effectiveness of spinal fixation 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 (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. The implantation of the Kalitec Medical InSePtion MIS Fixation 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. 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.

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.

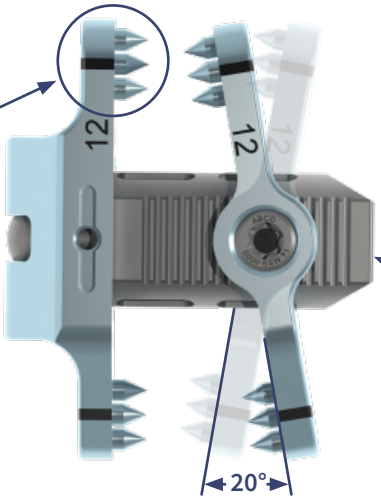
PHYSICIAN NOTE: *Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.*

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

MRI Safety Information:

The Kalitec Medical InSePtion MIS Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Kalitec Medical InSePtion MIS Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

FEATURES

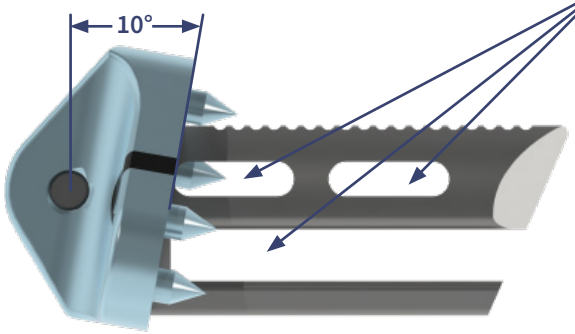


Spikes
Allow for secure implant fixation

Bullet Tip
Simplifies insertion

20° Coronal Angulation
Accommodates varying patient bony anatomy

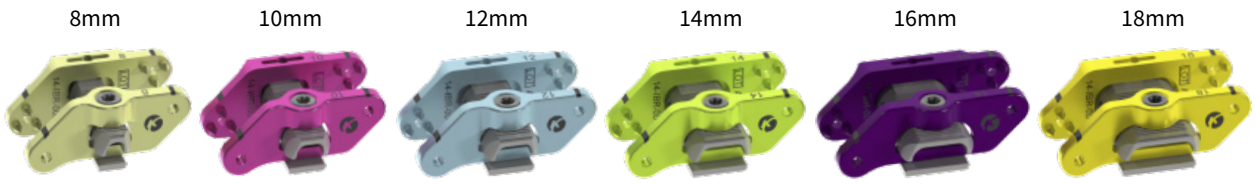
Up to 10° Transverse Angulation
Accommodates varying patient bony anatomy



Large Graft Windows
Maximizing area for bony fusion

Color Coded Implants

Sizes range 8 to 18mm in 2mm increments.
All implants are manufactured from Titanium Alloy (Ti-6Al-4V ELI)



SURGICAL TECHNIQUE

Patient Positioning and Exposure

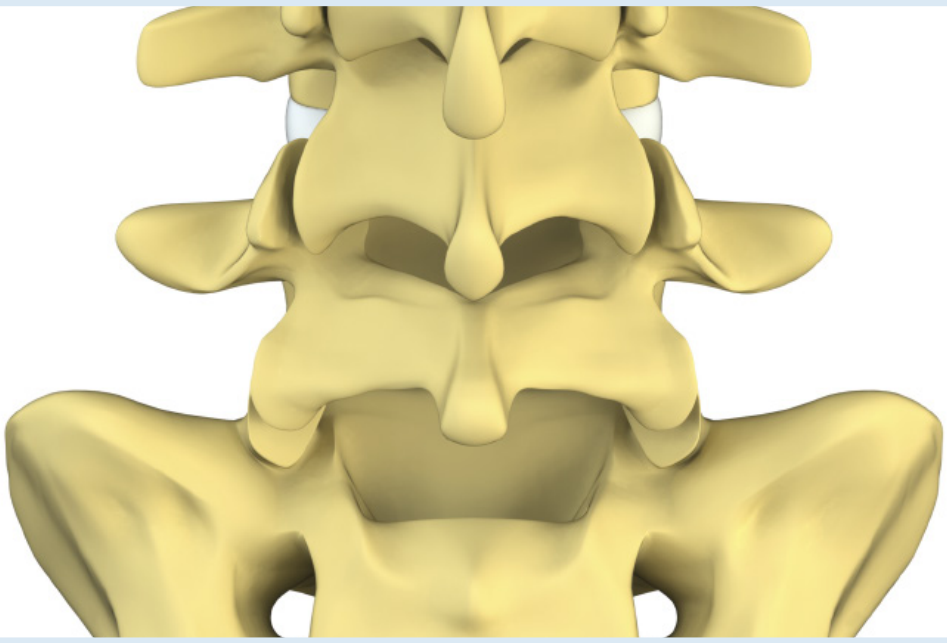


Figure 1

Step 1a:
Place patient in the prone position.

Step 1b:
Identify the spinous processes at the level to be instrumented using manual palpation and intraoperative imaging.

Step 1c:
Make a midline incision at the indicated level to expose the spinous processes.

Step 1d:
Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joints. Depending on the surgeon's preferred technique, the supraspinous ligament may be left intact, reflected, or removed entirely.

Step 1e:
Clear the fusion site of connective and soft tissues and lightly decorticate the bony surfaces. When fusing through the spinous processes, a burr, ronguer or rasp may be used to remove the interspinous ligament. The interspinous ligament may optionally be incised/dilated without complete removal.

Step 1f:
If neural decompression procedure is desired, perform a conservative laminotomy, partial facetectomy, foraminotomy or other decompression procedure as needed per surgeons preferred technique, using care to leave the spinous processes intact.

Note: *Do not perform a complete facetectomy. Preserving a sufficient portion of the facets to provide biomechanical stability for axial rotation and transverse shear loads is required.*

Site Preparation / Dilation

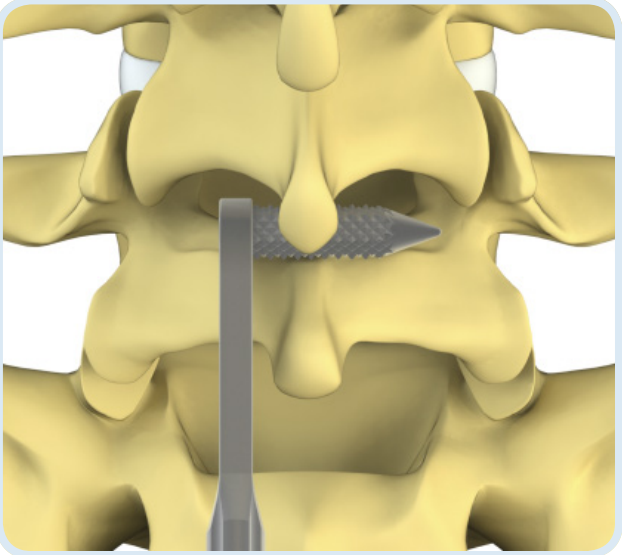


Figure 2

Implant Size Determination

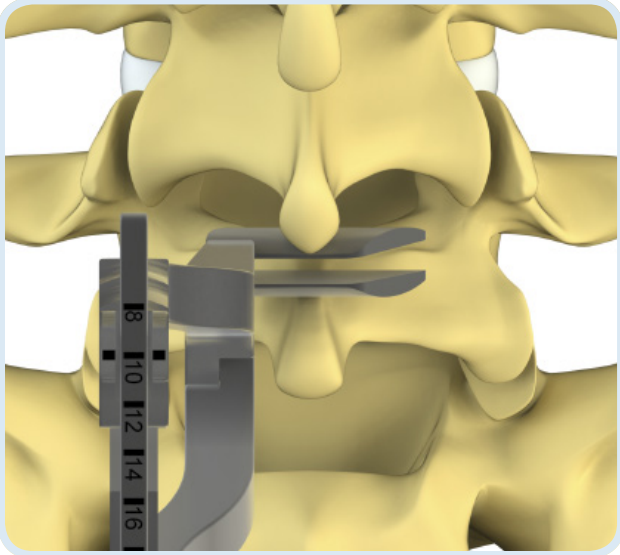


Figure 3

Step 2a:
If the interspinous ligament has been left intact, utilize the Double-Ended Punch to penetrate the interspinous ligament, placing it as far anterior as possible.

Step 2b (Optional):
While maintaining an anterior instrument position sequentially dilate with the Double-Ended Rasp until sufficient decortication is achieved and appropriate implant size becomes apparent.

Step 3:
Utilizing the Rasp and/or Smooth Ratcheting Sizer, insert into the prepared surgical site. Squeeze the handle until the desired distraction is achieved and Implant size can be determined. Implant Barrel should interface directly with decorticated spinous processes over the largest surface area possible.

INSTRUMENTS

Punch/Rasp,
Double-Ended 6 to 18mm

Rasp or Smooth
Ratcheting Sizer

Barrel Plate Insertion

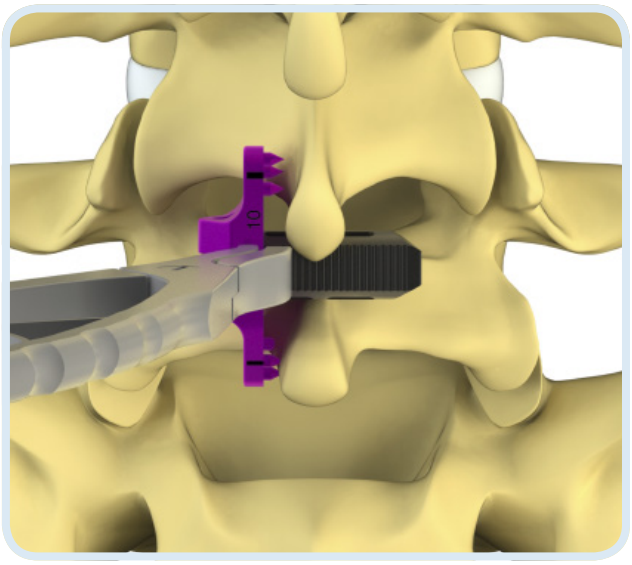


Figure 4

Locking Plate Insertion

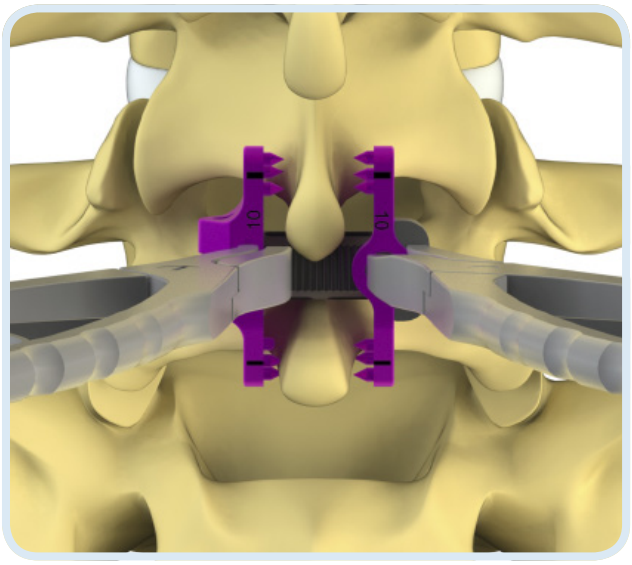


Figure 5

Step 4a:
Apply autograft and/or allograft inside Implant prior to placement. Additional autograft and/or allograft may be placed around prepared Implant site after implantation.

Note: *Manual distraction of spinous processes with towel clip or laminar spreader may be needed to aid with insertion.*

Optional: *For All-In-One Inserter instructions, proceed to page 8 and skip steps 4b, 5a, and 5b.*

Step 4b:
Utilizing the Barrel Plate Inserter, position the Barrel Plate as far anterior as possible between the spinous processes.

Step 5a:
Prior to attaching Locking Plate to Inserter, ensure the Set Screw is slightly proud from top surface of plate.

Step 5b:
Slide same color-coded Locking Plate over the Barrel until it comes in contact with the spinous processes.

INSTRUMENTS

Barrel Plate Inserter

Locking Plate Inserter

Implant Compression

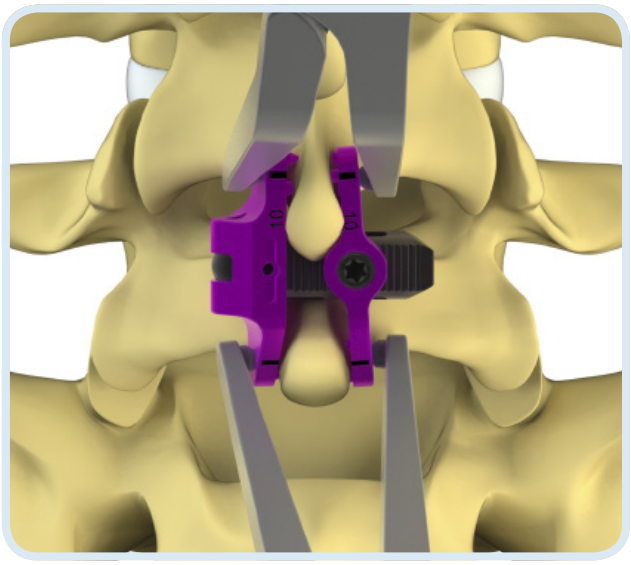


Figure 6

Step 6:
Remove Implant Inserters and apply both Compressors to the Implant. The Compressor tips fit into the lateral cephalad and caudal holes on the Implant, indicated by the black laser-marked visual indicators. Compress the Implant to fully seat the fixation spikes into the bony anatomy. After achieving desired compression, provisionally tighten the Set Screw.

Final Tightening

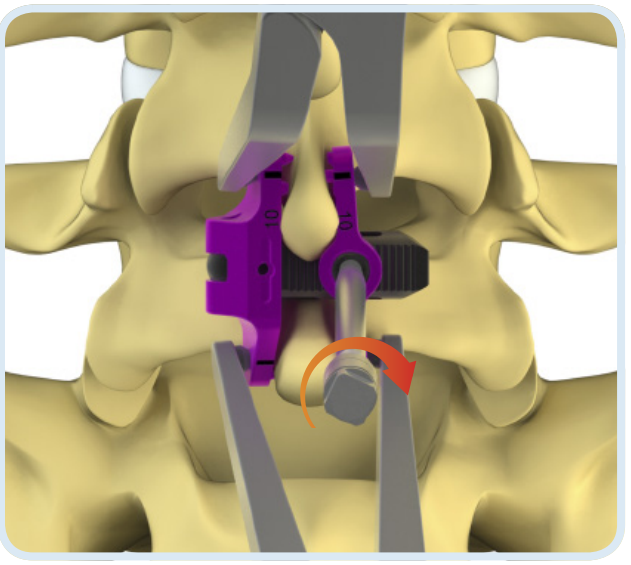


Figure 7

Step 7:
While maintaining desired compression, utilize the Torque Limiting Driver (30in-lbs) and insert the Driver Shaft into the Set Screw and turn the Handle clockwise until it clicks.

Note: *Visually and manually confirm the fixation and position of the implant using fluoroscopy.*

Notice: *Torque Limiting Handle not shown for visual purposes.*

INSTRUMENTS

Compressor

Torque Limiting Handle (30in-lbs)

Set Screw Driver Shaft (T15)

ALTERNATIVE IMPLANT INSERTION TECHNIQUE

Assembling Implant Inserter

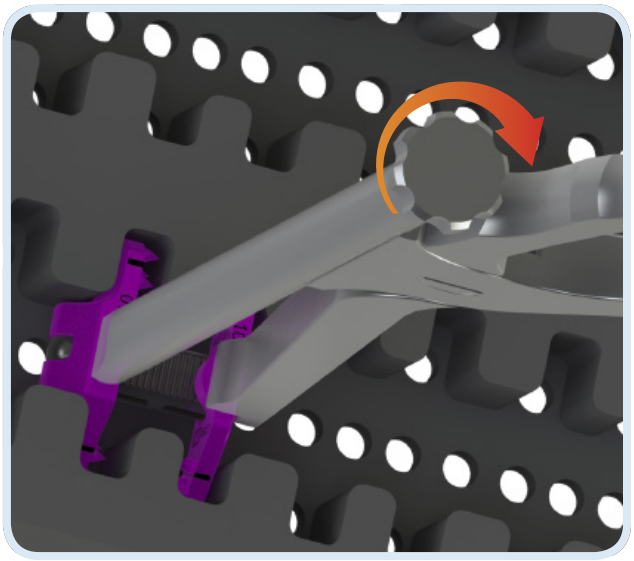


Figure 8

Note: *This technique replaces Steps 4b, 5a, and 5b from the standard two-piece insertion technique.*

Step 1:

Assemble All-In-One Implant Inserter onto the desired implant. Turn the Draw Rod Knob clockwise until it is fully seated into the Barrel Plate.

Note: *A small portion of the cephalad spinous process may need to be removed to aid all-in-one implant insertion.*

All-In-One Insertion

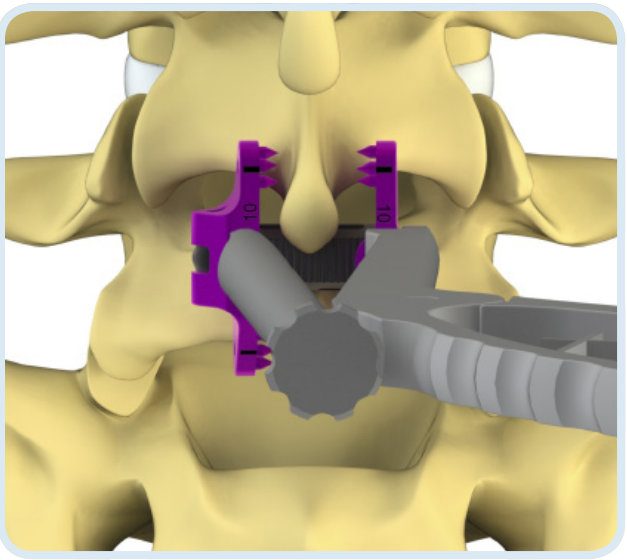


Figure 9

Step 2a:

The supraspinous and interspinous ligaments must be removed prior to utilizing the All-In-One Inserter.

Step 2b:

Position the implant as far anterior as possible between the spinous processes. Proceed to step 6 & 7 for instruction on Implant compression and Set Screw final tightening.

INSTRUMENTS

All-in-One Inserter

IMPLANT REMOVAL

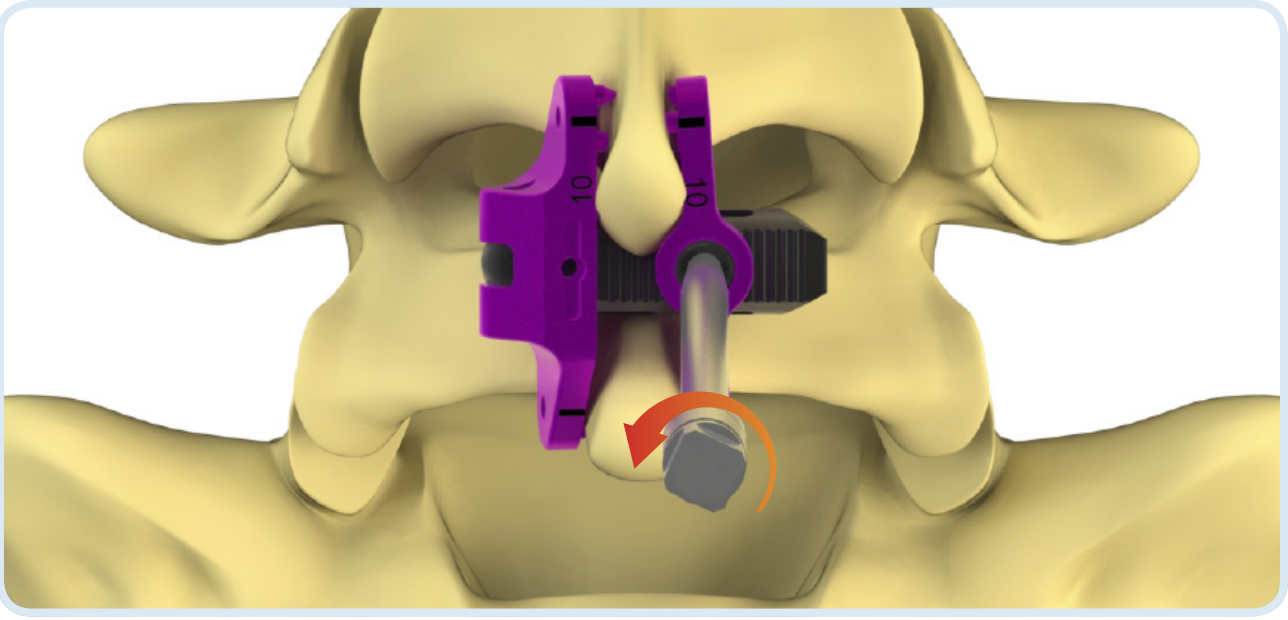


Figure 10

Step 1:
Insert the Driver Shaft with Torque Limiting Handle into the Set Screw and turn counter clockwise to loosen. Separate the Locking and Barrel Plate using an Elevator or Forceps and carefully remove the Implant.

Note: *Torque Limiting Handle not shown for visual purposes.*

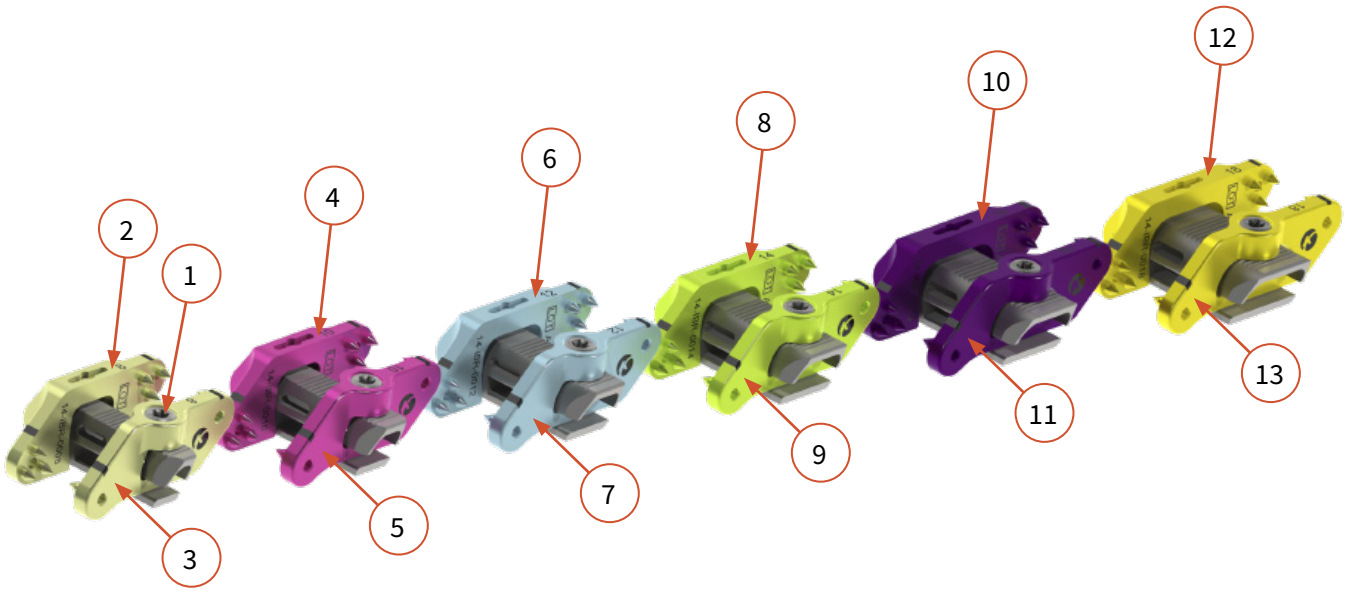
INSTRUMENTS

Torque Limiting
Handle (30in-lbs)

Set Screw Driver
Shaft (T15)

SYSTEM CONFIGURATION

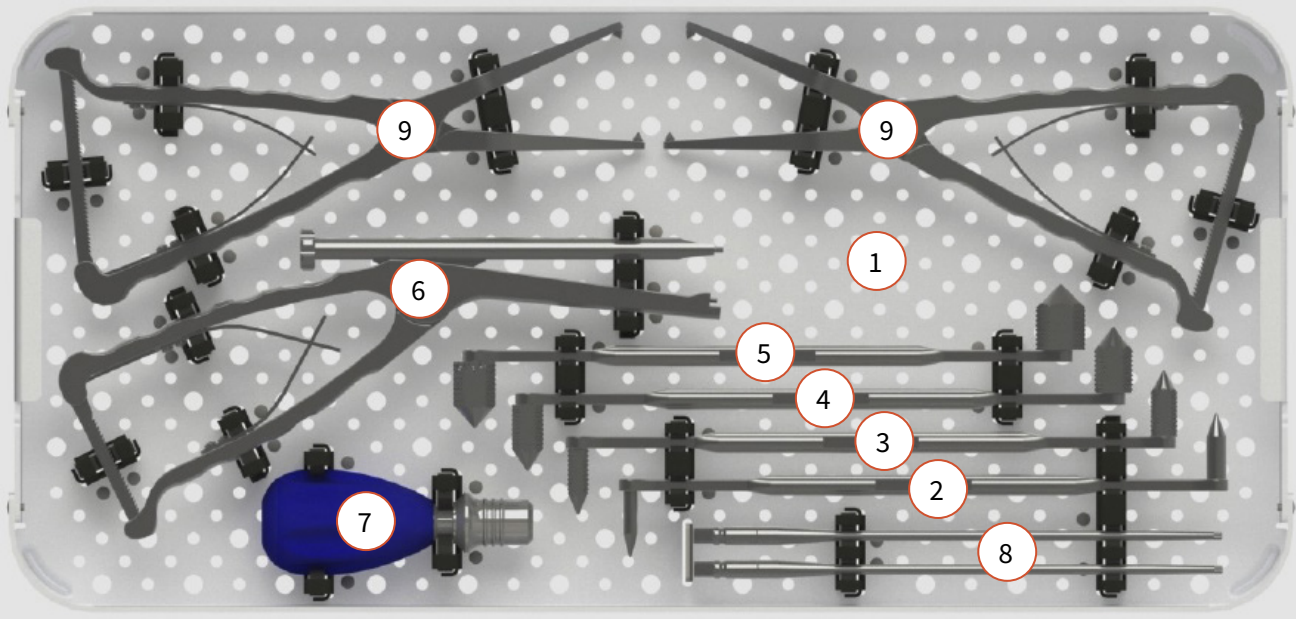
IMPLANTS



ITEM #	CATALOG #	DESCRIPTION	QTY / CADDIE
1	14-MSS-0000	Set Screw, Locking Plate	12
2	14-IBR-0008	Barrel Plate, 8mm	2
3	14-ILP-0008	Locking Plate, 8mm	2
4	14-IBR-0010	Barrel Plate, 10mm	2
5	14-ILP-0010	Locking Plate, 10mm	2
6	14-IBR-0012	Barrel Plate, 12mm	2
7	14-ILP-0012	Locking Plate, 12mm	2
8	14-IBR-0014	Barrel Plate, 14mm	2
9	14-ILP-0014	Locking Plate, 14mm	2
10	14-IBR-0016	Barrel Plate, 16mm	2
11	14-ILP-0016	Locking Plate, 16mm	2
12	14-IBR-0018	Barrel Plate, 18mm	2
13	14-ILP-0018	Locking Plate, 18mm	2

SYSTEM CONFIGURATION

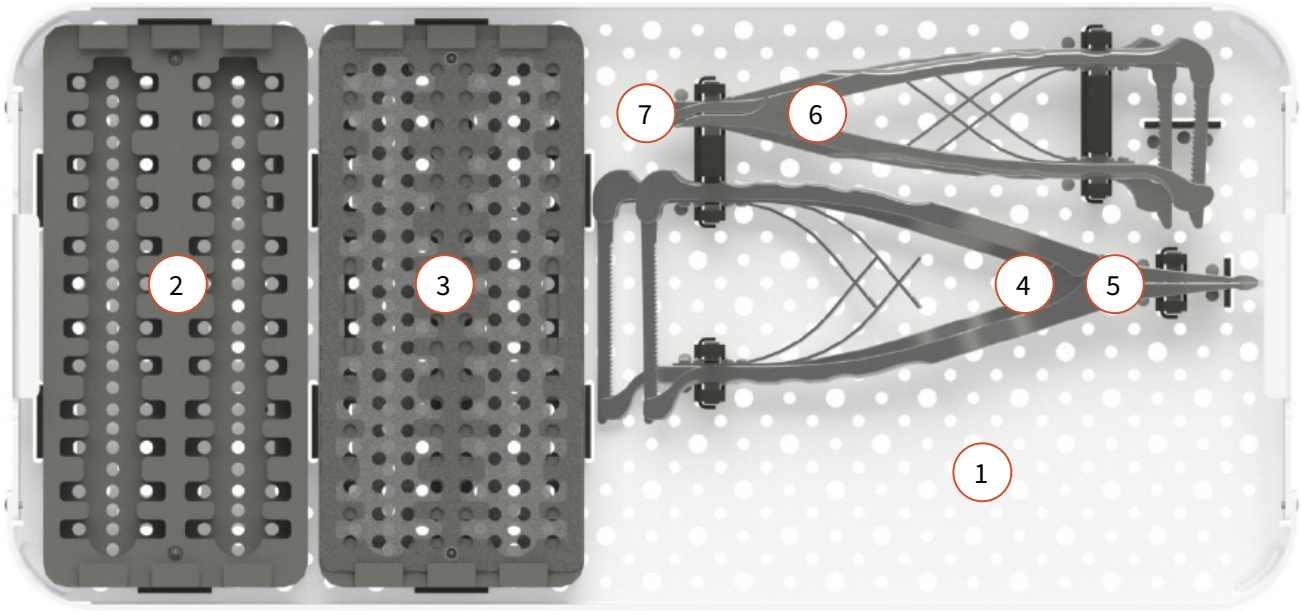
TOP TRAY INSERT



ITEM #	DESCRIPTION	QTY
1	Tray Insert, ISP Instrument Prep	1
2	Punch, 6 & 8mm	1
3	Rasp, 8 & 10mm	1
4	Rasp, 12 & 14mm	1
5	Rasp, 16 & 18mm	1
6	All-In-One Inserter	1
7	Torque Limiting Handle (30in-lbs)	1
8	Set Screw Driver Shaft (T15)	2
9	Compressor	2

SYSTEM CONFIGURATION

BOTTOM TRAY INSERT



ITEM #	DESCRIPTION	QTY
1	Tray Insert, ISP Implant	1
2	Implant Caddie	2
3	Caddie Lid	2
4	Rasp Ratcheting Sizer	1
5	Smooth Ratcheting Sizer	1
6	Barrel Plate Inserter	1
7	Locking Plate Inserter	1

NOTES:

Kalitec

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

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