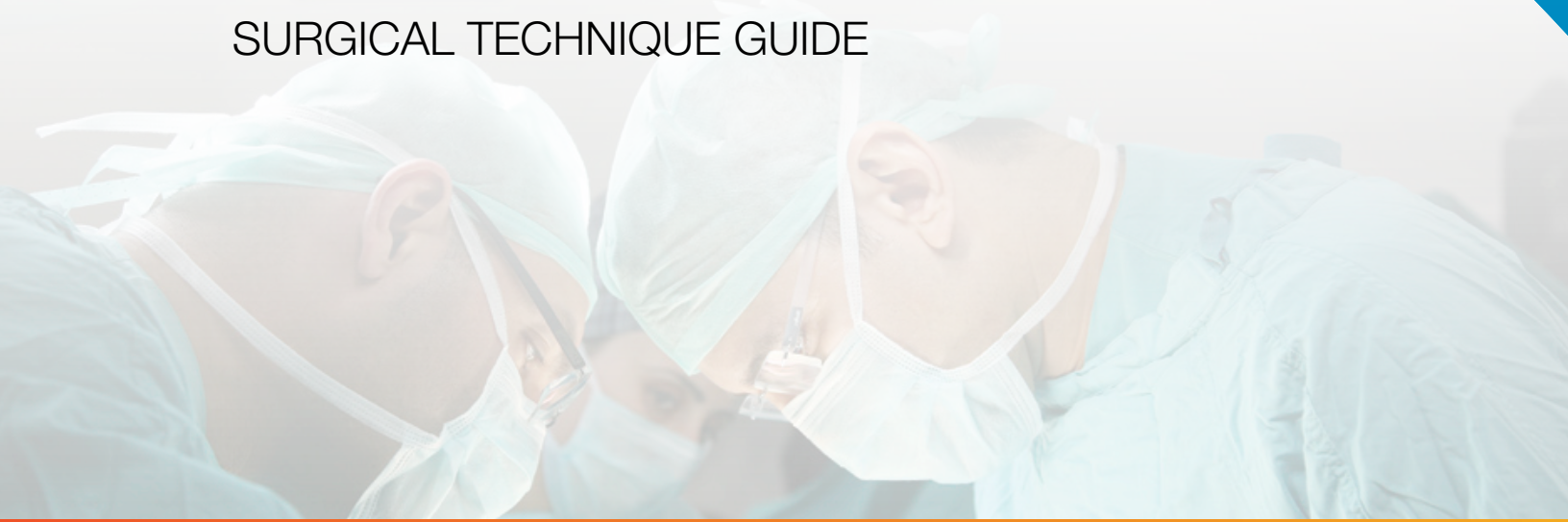

Kalitec

# INTESS® Lumbar Interbody 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**

618 E. South Street, Suite 500

Orlando, FL 32801 USA

407-545-2063

kalitecmed.com

# INTESS® Lumbar
## Interbody System

## TABLE OF CONTENTS



# INTESS Lumbar

## Interbody System

## INTRODUCTION

### Description:

The Kalitec INTESS Lumbar Cage Interbody System is used to maintain disc space distraction in skeletally mature adults requiring an intervertebral body fusion. It is designed to be used in conjunction with supplemental spinal fixation instrumentation. The implant is available in a range of footprints and heights to suit each individual's pathology and anatomical conditions of the patient. The implant has a hollow center to allow placement of autogenous bone graft to promote intervertebral body fusion. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent implant migration and/or expulsion.

The Kalitec INTESS Lumbar Cage Interbody System is made from the Zeniva® ZA500 PEEK polymer radiolucent material with embedded tantalum radiographic markers as specified in ASTM F2026 and ASTM F560, respectively.

### 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 INTESS Lumbar Cage must not be reused under any circumstances.** The INTESS Lumbar Cage is not a standalone device and must be utilized in conjunction with supplemental fixation. These instructions for use are designed to assist in use of the INTESS Lumbar Cage and are not a reference for surgical techniques.

### Indications:

The INTESS Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). INTESS Lumbar Cage implants are to be used with autogenous bone graft and implanted via a transforaminal approach, or an open posterior or lateral approach. The INTESS Lumbar Cage implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

### Contraindications:

- Spondylolisthesis higher than grade I (not for the use with a pedicle screw fixation system).
- Reduced bone density, which does not guarantee a sufficient resting stability (e. g. osteoporosis).
- Fractures.
- Tumors.
- Scoliosis.
- Active infection.
- Allergy to tantalum or PEEK.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing a fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.

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 Effects:

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

- Bending or fracture of 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.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Nerve damage due to surgical trauma

or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.

- Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
- Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- Bursitis.
- Paralysis.
- Death.
- Spinal cord impingement or damage.
- Fracture of bony structures.
- Reflex sympathetic dystrophy.
- If a pseudarthrosis occurs coupled with the Kalitec INTESS Lumbar Cage, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.
- Degenerative changes or instability in segments adjacent to fused vertebral levels.

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

## Warnings and Precautions:

The INTESS Lumbar Cage is intended to be used to augment the development of a spinal fusion by providing temporary stabilization while a solid fusion mass forms. This device is not intended to be the sole means of spinal support. The use of autogenous bone graft must be part of the spinal fusion procedure in which the INTESS Lumbar Cage 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, loosening, disassembly and/or breakage of the device will eventually occur. The risk of device expulsion and migration is higher without the use of supplemental fixation. 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 INTESS Lumbar Cage 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. Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery. An entirely satisfactory result is not always achieved in every surgical case. This particularly applies to spinal surgery, in which numerous external factors may compromise the results.

The implantation of the Interbody System should be performed only by experienced spinal surgeons with specific training in the use of lumbar cage systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

***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.*

***CAUTION:*** *The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. The physician should always consider a variety of patient conditions including but not limited to the levels of implantation, patient weight, and patient activity level, which may have an impact on the performance of the Interbody System.*

# SURGICAL TECHNIQUE

## Patient Positioning and Exposure

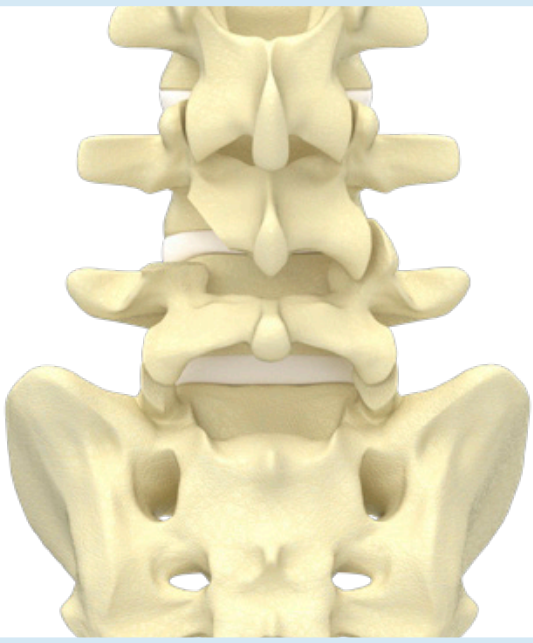


*Figure 1*

***Step 1:***

a. Place patient in the prone position.

b. Identify the disc space at the level to be instrumented using manual palpation and intraoperative imaging.

c. Make a midline incision and dissect to locate the spinous process, lamina, and nerve roots of the appropriate level(s).

***Step 2:***

a. Perform a laminotomy, laminectomy, and/or facetectomy, in order to secure sufficient unilateral transforaminal access to the disc space. Ensure that the neurogenic structures are spared as much as possible.

b. Using a nerve root retractor, expose the annulus of the disc space with care taken not to over-retract the nerve root.

## Discectomy

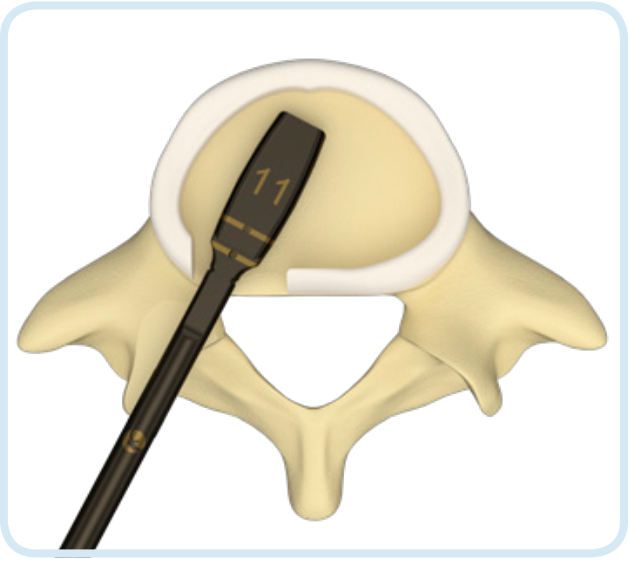


*Figure 2*

## Implant Size Determination

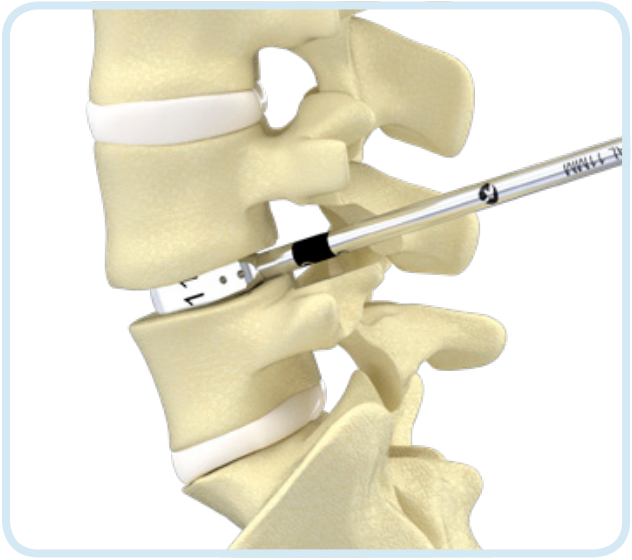


*Figure 3*

***Step 3:***

a. Perform a discectomy using the Open and/or Closed Shavers through the incision window, leaving the anterior and lateral annulus intact. Remove the superficial layers of the cartilaginous endplates down to bleeding bone.

***Note:*** *The Open and Closed Shavers feature bi-directional cutting flutes to allow for cutting in the clockwise and counter clockwise directions.*

***Note:*** *Appropriate cleaning of the endplates is important for the vascularization of the bone graft material. Excessive cleaning, on the other hand, can weaken the endplate. Removal of the entire endplate can result in subsidence and loss of segmental stability.*

***Step 4:***

a. Using either the Paddle Distractors or Implant Trials, insert into disc space. Repeat sequentially until appropriate implant size has been determined.

***Note:*** *Attempting to insert too large of an implant into the disc space may cause damage to the implant and/or instrument*

INSTRUMENTS


## Implant Inserter Assembly

*Figure 4*

## Implant Insertion

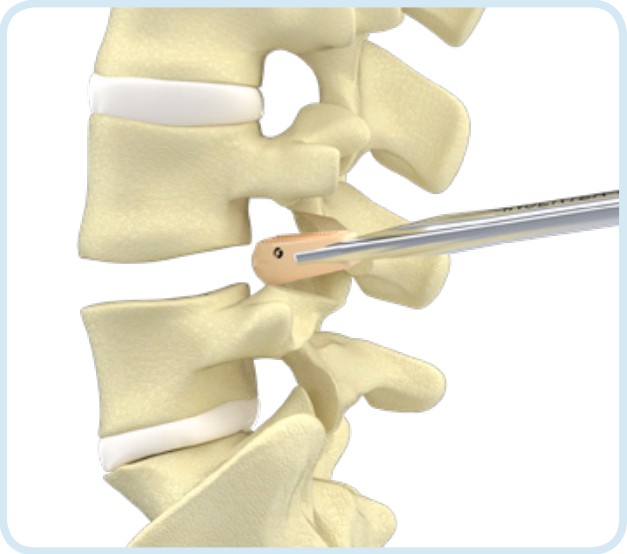


*Figure 5*

***Step 5:***

a. Once Implant size is determined, choose the corresponding Implant Inserter (ex: If Implant size is 13mm then you would need the 11-13mm Inserter).

b. Attach the Inserter to the T-Handle as shown. Make sure the T-Handle is in line with the anti-migration surfaces of the implant.

c. Insert the Draw Rod through the cannulated Inserter, slide the posterior portion of the Implant between the Inserter tongs, and thread the Draw Rod into the Implant.

***Step 6:***

a. Once the Cage is completely filled with bone graft, insert Cage into intervertebral disc space by gentle impaction.

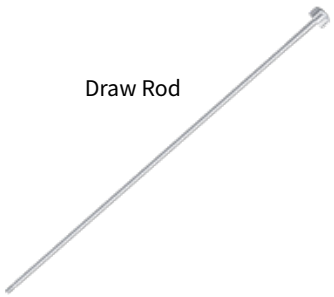
b. Once the Implant is in the desired position, unthread Draw Rod from Implant and remove Inserter.

c. Depending on surgeon preference, a bilateral cage may be inserted.

***Note:*** *Implants and Instruments are not designed for turn and rotate implantation methods - damage to implants or instruments may occur.*

INSTRUMENTS

Draw Rod



T-Handle

Sleeveless Implant Inserter

## Implant Insertion (Cont.)

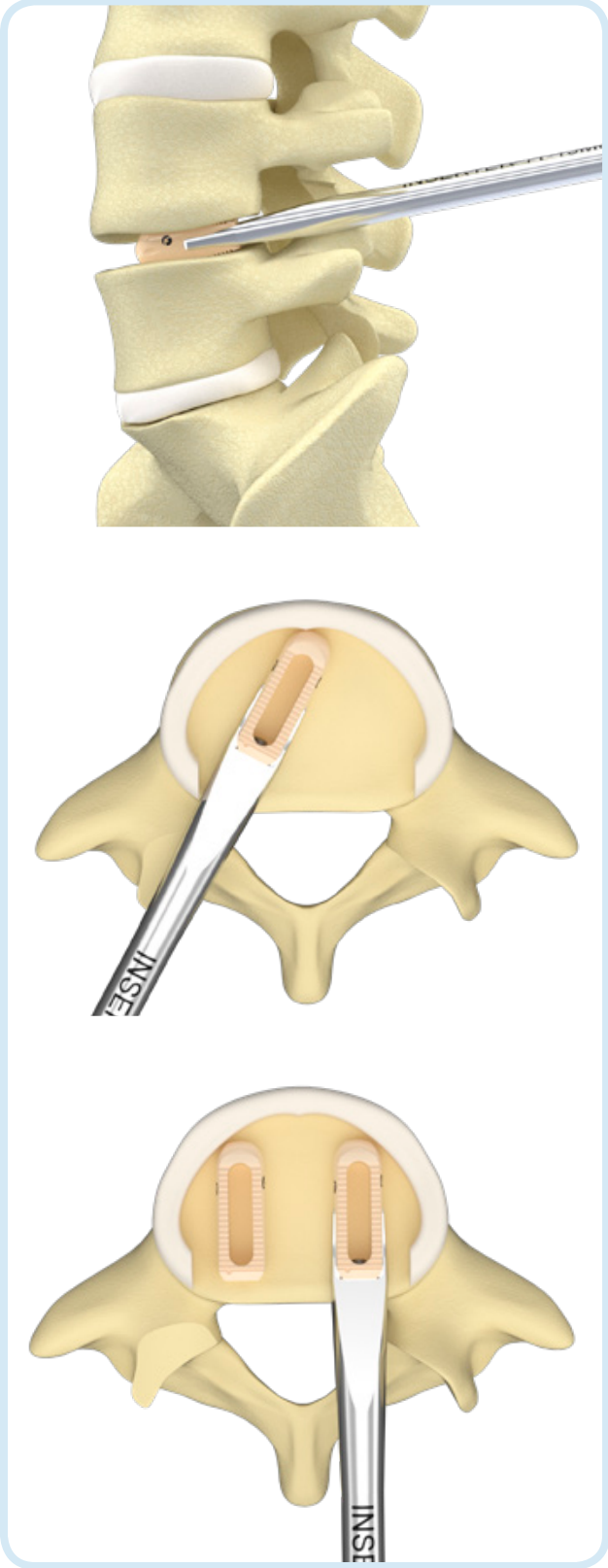


*Figure 5*

## Supplemental Fixation

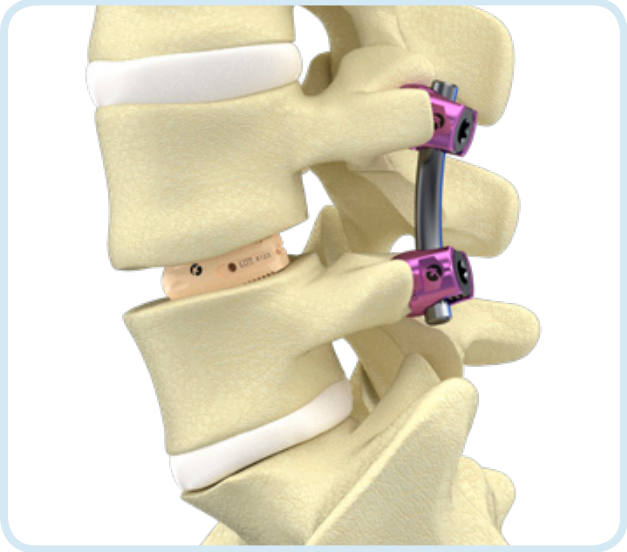


*Figure 6*

***Step 7:***
Please refer to the CosmoLock® Surgical Technique for instructions on Rod and Locking Cap insertion and compression of each instrumented disc space.

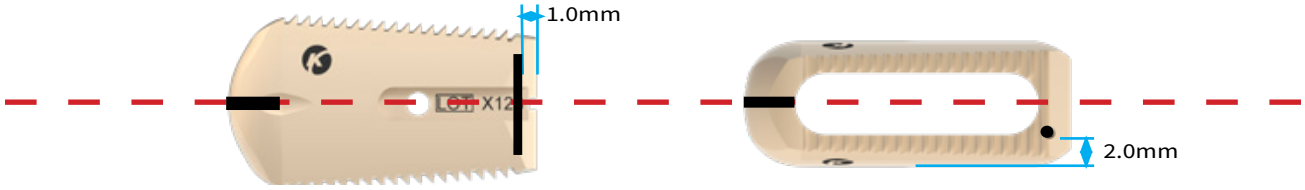
# TANTALUM MARKER LOCATIONS

*Tantalum Marker Locations are applicable for 21, 26, and 30mm cage lengths as well as parallel (0°), lordotic taper (8°), and lordotic extra-taper (12°) cages.*

## CAGE DIMENSIONS: (H)8-10MM X (W)8MM


## CAGE DIMENSIONS: (H)11-13MM X (W)9MM


## CAGE DIMENSIONS: (H)14-16MM X (W)10MM




***Disclaimer:*** *All Dimensions listed above have been rounded to the nearest 0.5mm*

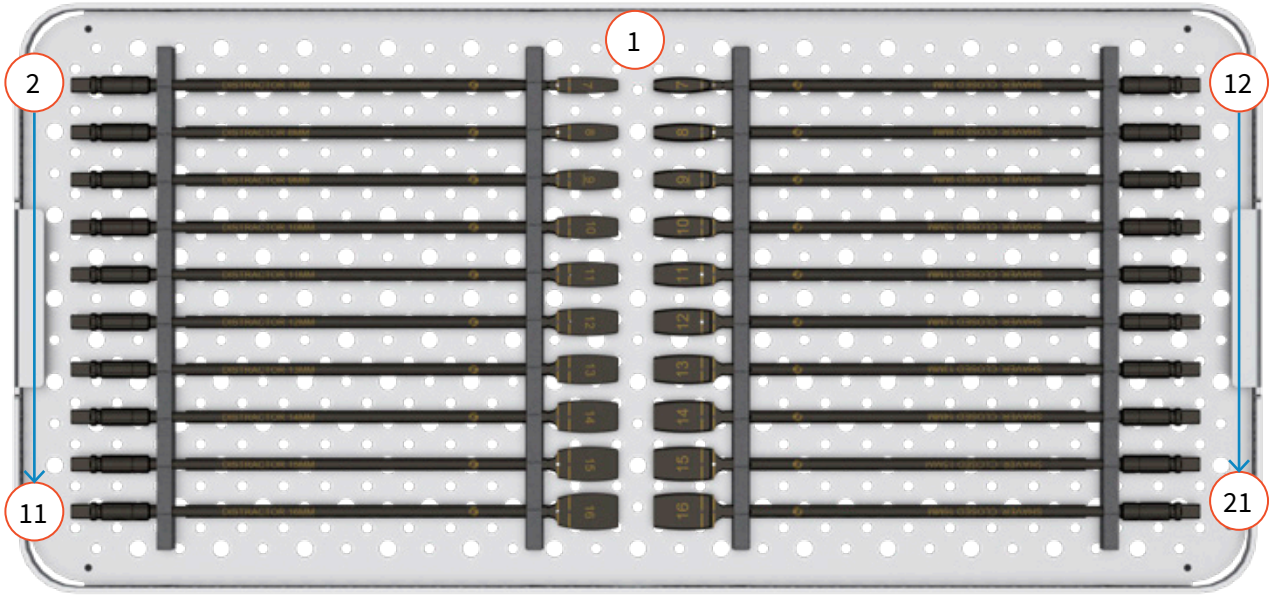
# SYSTEM CONFIGURATION

## IMPLANT OPTIONS

| 21mm Footprint | |
|---|---|
| **Catalog #** | **Description** |
| 12-PCN-2108 thru 12-PCN-2116 | Cage, 21x8-16mm, 0° NT Str |
| 12-PCT-2108 thru 12-PCT-2116 | Cage, 21x8-16mm, 8° TA Str |
| 12-PCX-2108 thru 12-PCX-2116 | Cage, 21x8-16mm, 12° TA Str |
| **26mm Footprint** | |
| 12-PCN-2608 thru 12-PCN-2616 | Cage, 26x8-16mm, 0° NT Str |
| 12-PCT-2608 thru 12-PCT-2616 | Cage, 26x8-16mm, 8° TA Str |
| 12-PCX-2609 thru 12-PCX-2616 | Cage, 26x9-16mm, 12° TA Str |
| **30mm Footprint** | |
| 12-PCN-3008 thru 12-PCN-3016 | Cage, 30x8-16mm, 0° NT Str |
| 12-PCT-3009 thru 12-PCT-3016 | Cage, 30x9-16mm, 8° TA Str |
| 12-PCX-3010 thru 12-PCX-3016 | Cage, 30x10-16mm, 12° TA Str |

# SYSTEM CONFIGURATION

## TRAY INSERT 1



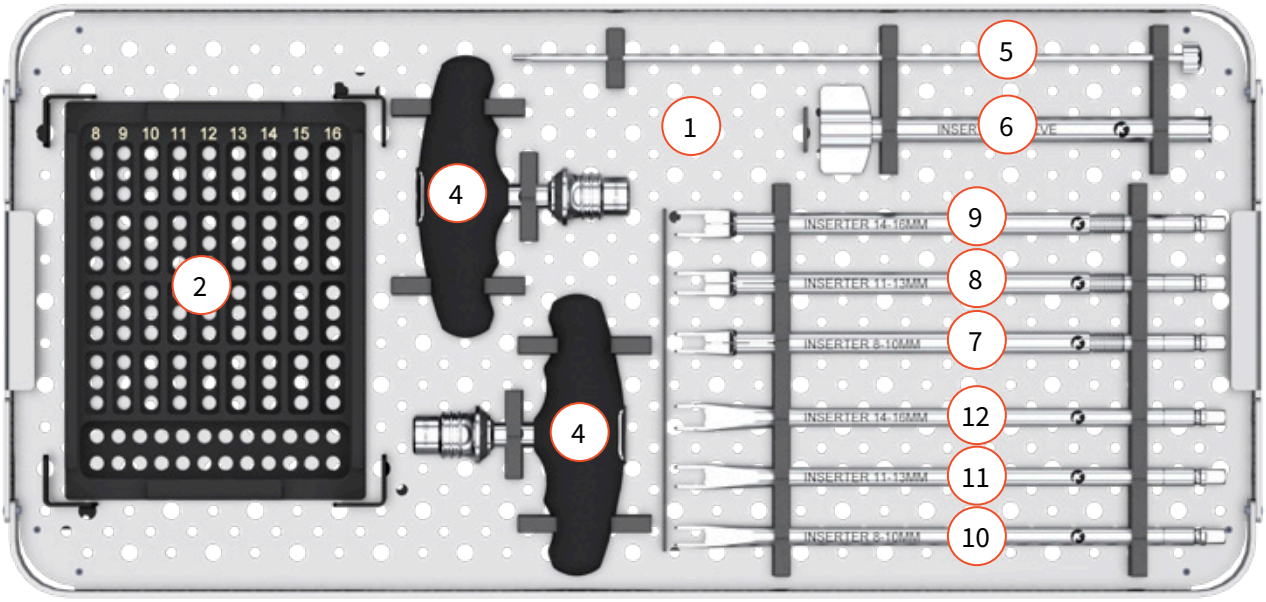

| Item # | Description | Qty |
|---|---|---|
| 1 | Tray Insert 1 | 1 |
| 2 | Distractor, Smooth Paddle 7mm | 1 |
| 3 | Distractor, Smooth Paddle 8mm | 1 |
| 4 | Distractor, Smooth Paddle 9mm | 1 |
| 5 | Distractor, Smooth Paddle 10mm | 1 |
| 6 | Distractor, Smooth Paddle 11mm | 1 |
| 7 | Distractor, Smooth Paddle 12mm | 1 |
| 8 | Distractor, Smooth Paddle 13mm | 1 |
| 9 | Distractor, Smooth Paddle 14mm | 1 |
| 10 | Distractor, Smooth Paddle 15mm | 1 |
| 11 | Distractor, Smooth Paddle 16mm | 1 |
| 12 | Shaver, Closed 7mm | 1 |
| 13 | Shaver, Closed 8mm | 1 |
| 14 | Shaver, Closed 9mm | 1 |
| 15 | Shaver, Closed 10mm | 1 |
| 16 | Shaver, Closed 11mm | 1 |
| 17 | Shaver, Closed 12mm | 1 |
| 18 | Shaver, Closed 13mm | 1 |
| 19 | Shaver, Closed 14mm | 1 |
| 20 | Shaver, Closed 15mm | 1 |
| 21 | Shaver, Closed 16mm | 1 |
| *22 | Shaver, Open 7mm | 1 |

| Item # | Description | Qty |
|---|---|---|
| *23 | Shaver, Open 8mm | 1 |
| *24 | Shaver, Open 9mm | 1 |
| *25 | Shaver, Open 10mm | 1 |
| *26 | Shaver, Open 11mm | 1 |
| *27 | Shaver, Open 12mm | 1 |
| *28 | Shaver, Open 13mm | 1 |
| *29 | Shaver, Open 14mm | 1 |
| *30 | Shaver, Open 15mm | 1 |
| *31 | Shaver, Open 16mm | 1 |

**Not shown, optional Open Shavers*

# SYSTEM CONFIGURATION

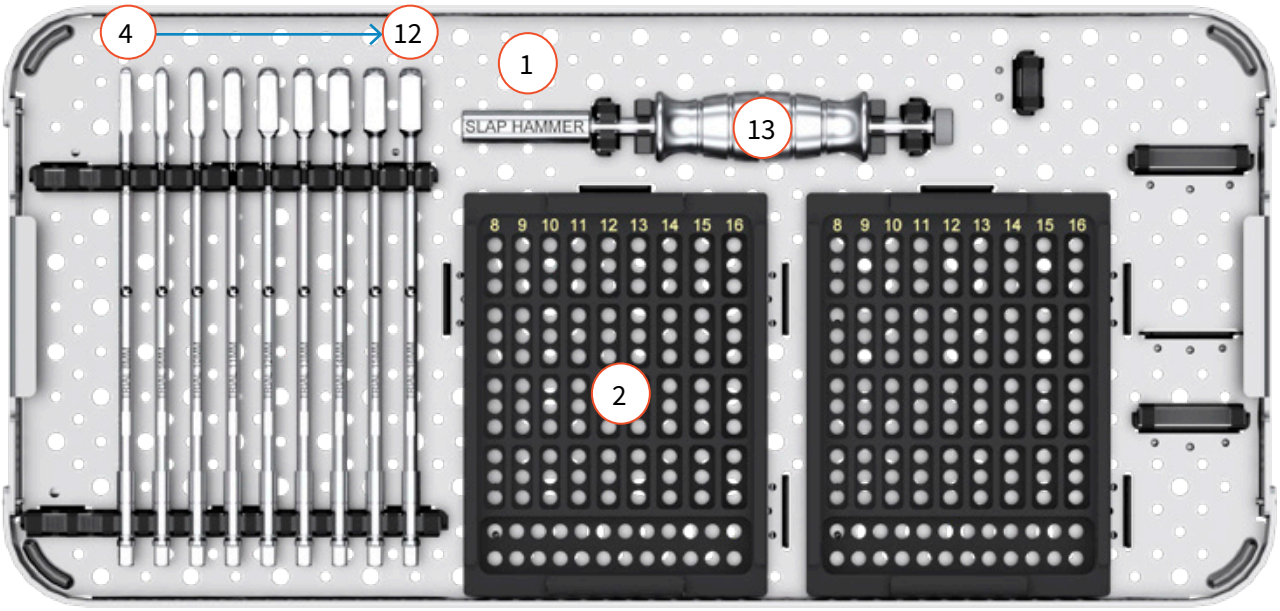
## TRAY INSERT 2




| Item # | Description | Qty |
|---|---|---|
| 1 | Tray Insert 2 | 1 |
| 2 | Caddie, Implants 21-30mm | 1 |
| 3 | Caddie Lid (Not shown) | 1 |
| 4 | T-Handle | 2 |
| 5 | Draw Rod | 1 |
| 6 | Inserter Sleeve, Universal | 1 |
| 7 | Implant Inserter, 8-10mm Sleeved | 1 |
| 8 | Implant Inserter, 11-13mm Sleeved | 1 |
| 9 | Implant Inserter, 14-16mm Sleeved | 1 |
| 10 | Implant Inserter, 8-10mm Sleeveless | 1 |
| 11 | Implant Inserter, 11-13mm Sleeveless | 1 |
| 12 | Implant Inserter, 14-16mm Sleeveless | 1 |

# SYSTEM CONFIGURATION

## TRIAL TRAY INSERT




| Item # | Description | Qty |
|---|---|---|
| 1 | Tray Insert, Trials | 1 |
| 2 | Caddie, Implants 21-30mm | 2 |
| 3 | Caddie Lid (Not shown) | 2 |
| 4 | Trial, 26x8mm, 8º TA Str | 1 |
| 5 | Trial, 26x9mm, 8º TA Str | 1 |
| 6 | Trial, 26x10mm, 8º TA Str | 1 |
| 7 | Trial, 26x11mm, 8º TA Str | 1 |
| 8 | Trial, 26x12mm, 8º TA Str | 1 |
| 9 | Trial, 26x13mm, 8º TA Str | 1 |
| 10 | Trial, 26x14mm, 8º TA Str | 1 |
| 11 | Trial, 26x15mm, 8º TA Str | 1 |
| 12 | Trial, 26x16mm, 8º TA Str | 1 |
| 13 | Slap Hammer | 1 |

*Note: Tray insert has space to accommodate the paddle distractors, open shavers, or closed shavers 7-16mm in place of Trials.*

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

**Kalitec Medical**
618 E. South Street, Suite 500
Orlando, FL 32801 USA

info@kalitecmed.com
(407) 545-2063

12-SRG-0000 | REV_F 07/21