Kalitec

Navagio™

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

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INTRODUCTION

Description:

The Kalitec Medical Navagio Lumbar Cage intervertebral body fusion device 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, lengths, and heights to suit each individual's pathology and anatomical conditions. 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 implant help prevent implant migration and/or expulsion.

The Kalitec Medical Navagio Lumbar Cage intervertebral body fusion device 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 Navagio Lumbar Cage must not be reused under any circumstances. The Navagio Lumbar Cage is not a stand-alone device and must be utilized in conjunction with supplemental fixation. These instructions for use are designed to assist in use of the Navagio Lumbar Cage and are not a reference for surgical techniques.

Indications:

The Navagio 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). Navagio 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 Navagio 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 Events:

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 Medical Navagio 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 Navagio 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 Navagio 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 Navagio 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 intervertebral body fusion device 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 intervertebral body fusion device.

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.

The Navagio Lumbar Cage has not been evaluated for safety and compatibility in the MR environment. The Navagio Lumbar Cage has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Navagio Lumbar Cage in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Discectomy

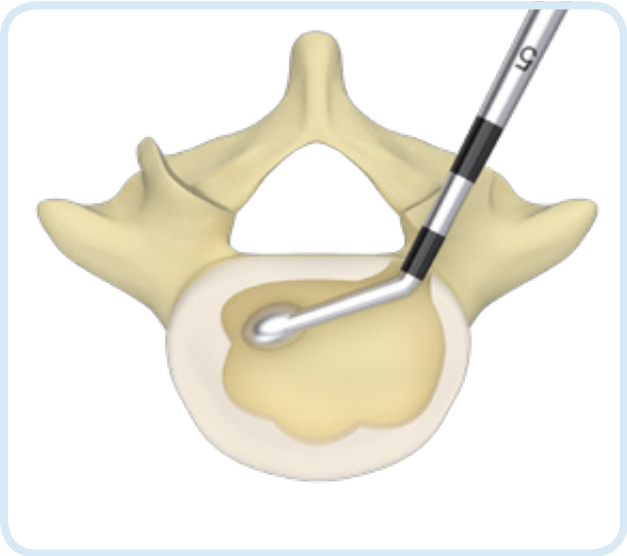


Figure 1

Endplate Preparation

Figure 2

Step 1:

a. Adequately remove disk material with the provided disc preparation instruments.

b. Gently expose the endplates utilizing a curette, shaver, or rasp.

Note: Distraction may be required prior to discectomy if a disk collapse is significant, making the disk material difficult to remove.

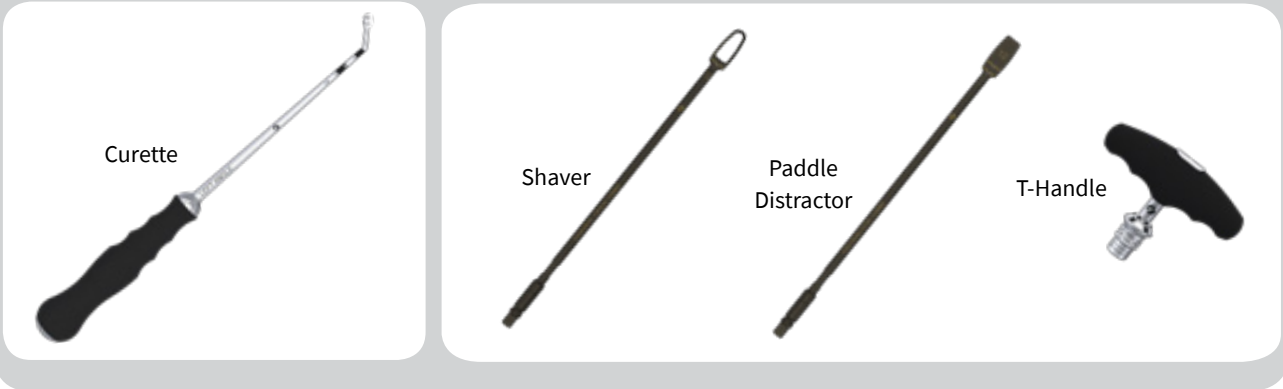
Step 2:

a. Utilize optional paddle distractors to prepare the endplate and determine implant sizing.

b. Insert the paddle distractor into the disk space and rotate to distract for optimal annular tension.

c. To increase annular tension, sequentially increase the size of the distractor.

INSTRUMENTS



Trial Sizing

Figure 3

Trial Removal

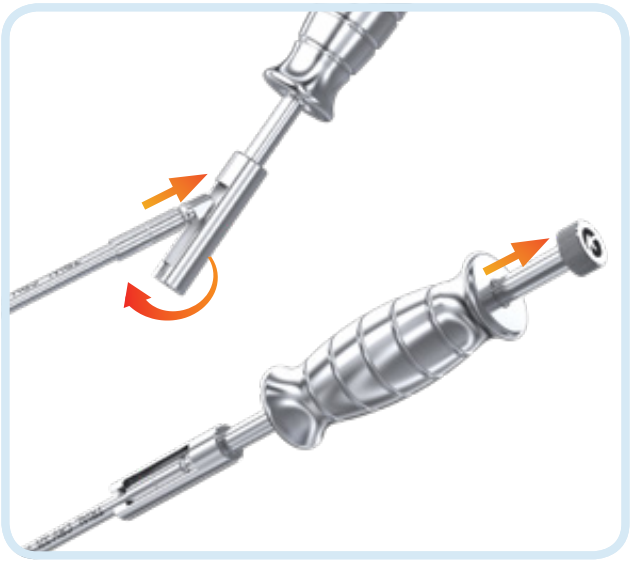


Figure 4

Step 3 (Optional):

a. Insert the trial into the disk space.

b. If the trial fits with little to no excess space between it and the endplates, choose the corresponding implant size for insertion. Otherwise, continually increase in trial size until the excess space is reduced to as little as possible.

Note: Trials match the total implant geometry.

Note: The 2mm diameter hole drilled through the trial is placed 26mm from the trial tip, representing 25mm length from the closest point of the hole, and 27mm length from the furthest.

Step 4:

a. Remove the T-handle from the trial.

b. Attach the slap hammer by inserting the end of the 1/4" square adapter of the trial into the slap hammer's open connector and then rotating the connector to hook under the trial's ledge.

INSTRUMENTS

Implant Attachment

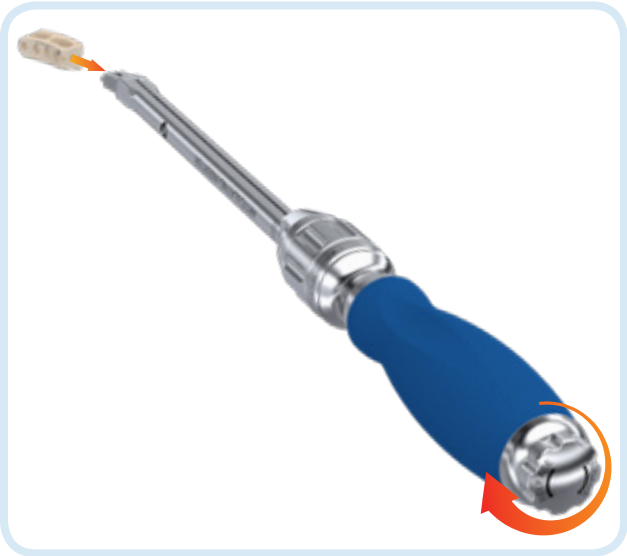


Figure 5

Implant Insertion

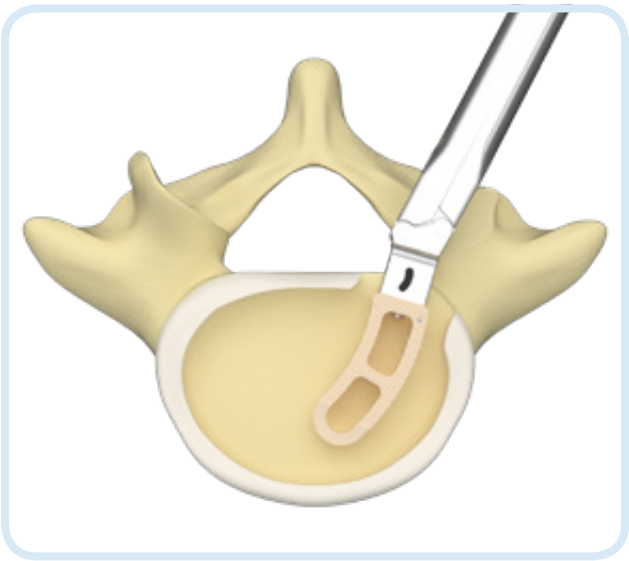


Figure 6

Step 5:

a. Align the curvature of the implant so that it matches the curvature of the laser marking on the tip of the inserter (applies to curved implants and Articulating Inserter only).

b. While aligning the grooves in the implant with the tabs of the inserter tip, rotate the rear-most knob clockwise until the implant becomes fully threaded onto the end of the inserter.

Note: Using excessive torque to attach implant to the inserter may cause damage to implant threading.

Step 6:

a. Once the implant is completely filled with bone graft, guide the implant towards the disk space.

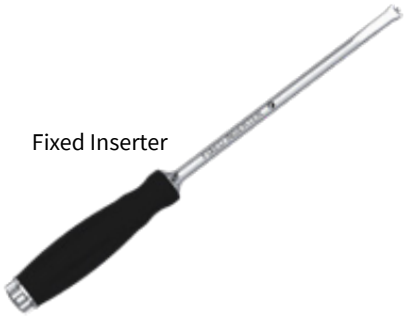
b. Use a mallet to gently tap on the rear of the inserter to move the implant into the desired position.

Note: Excessive malleting force may cause damage to the implant and/or inserter.

INSTRUMENTS

Articulating Inserter

Fixed Inserter



Inserter Articulation

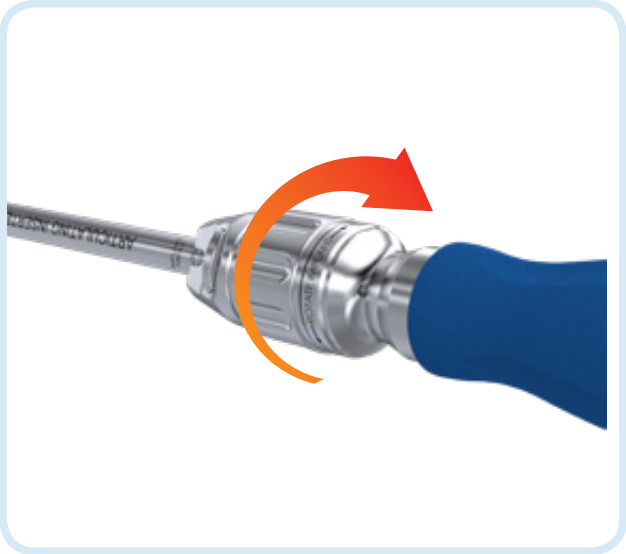


Figure 7

Step 7 (Optional):

a. When using the Articulating Inserter, use the adjustment knob to vary the angle of the implant relative to the inserter.

Implant Release

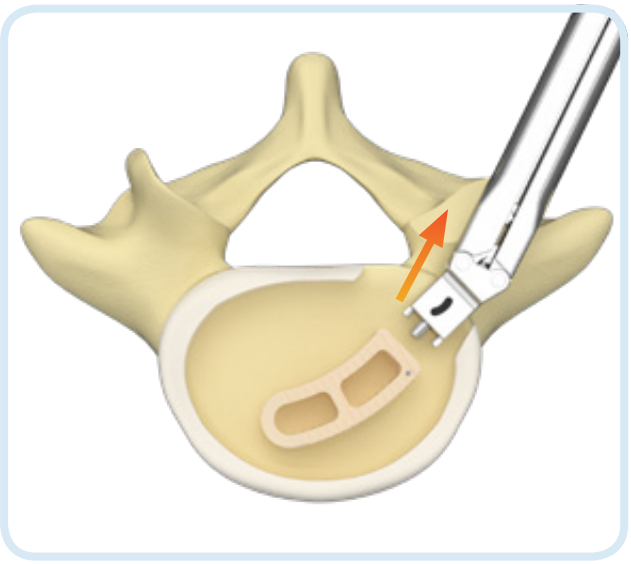


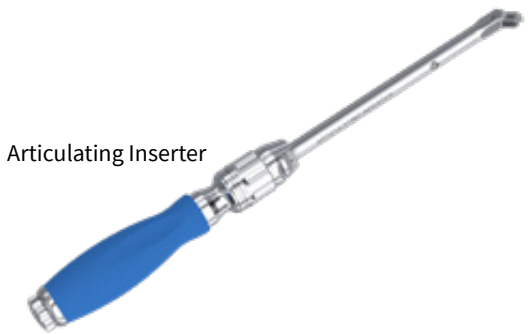
Figure 8

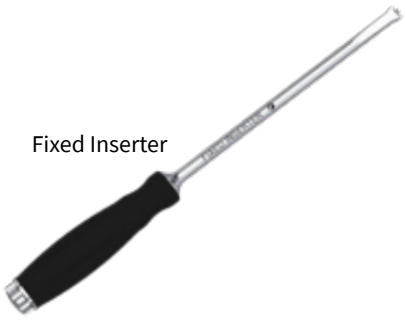
Step 7:

a. Hold the inserter in place and unthread the implant from the inserter by rotating the rear-most knob counter-clockwise.

b. Once fully unthreaded from the implant, remove the inserter from the disc space.

INSTRUMENTS





Implant Adjustment

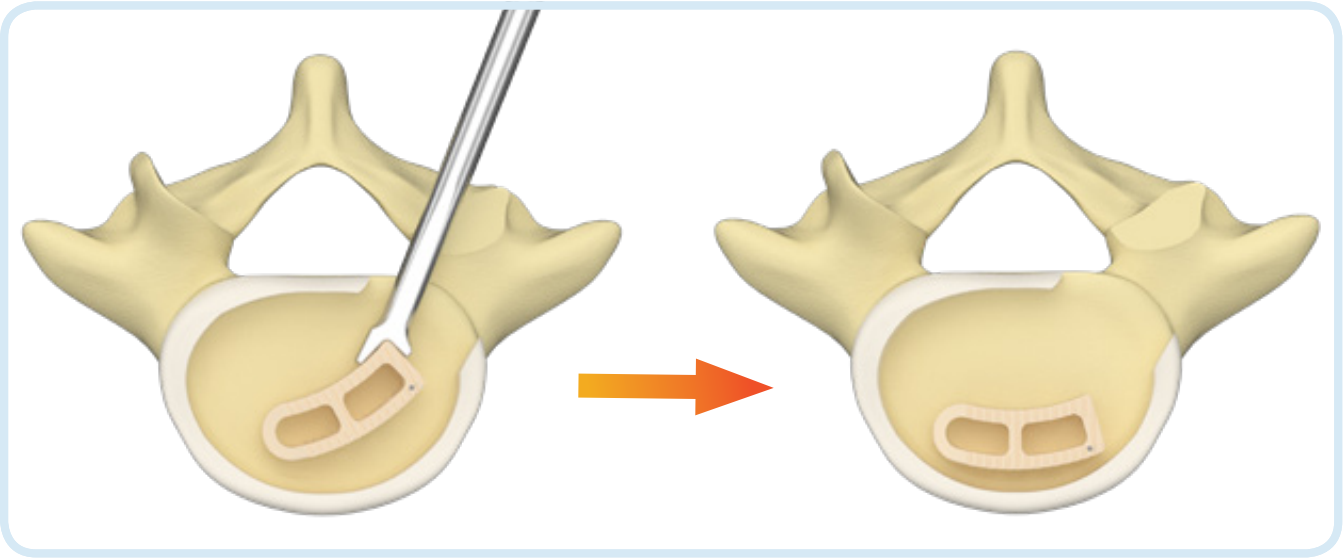


Figure 9

Step 9:

a. Using the selection of tamps, gently impact the implant into its final position.

INSTRUMENTS

Implant Removal Instructions

Removal:

a. Expose the operative site and threads of the implant.

b. Thread the Removal Tool into the implant. The nipple on the tip of the Removal Tool can be used to help locate and orient the implant's threaded attachment point.

c. Attach the Slap Hammer onto the end of the Removal Tool. While holding the connection point of the two instruments, move the weight up and away from the adapter, striking the knurled cap at the end of the slide. Repeat this step until the implant is freed from the disk space.

INSTRUMENTS

Removal Tool

Slap Hammer

Articulating Inserter Disassembly Instructions

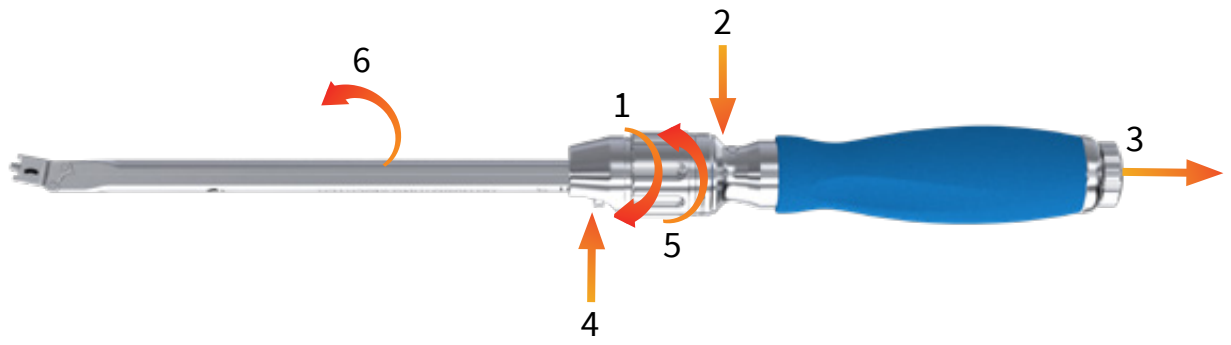


Figure 9

Step 1: Rotate the articulating knob counter-clockwise until the implant angle reads zero on the articulating arm.

Step 2: Locate the first button closest to the handle.

Step 3: While holding the button from step 2, remove the draw rod entirely from the inserter.

Step 4: Locate the second button near the angle measurement markings.

Step 5: While holding down the button from step 4, rotate the articulating knob clockwise until the knob slides down and off of the arm.

Step 6: Unfold the the articulating arm to expose the interior of the instrument.

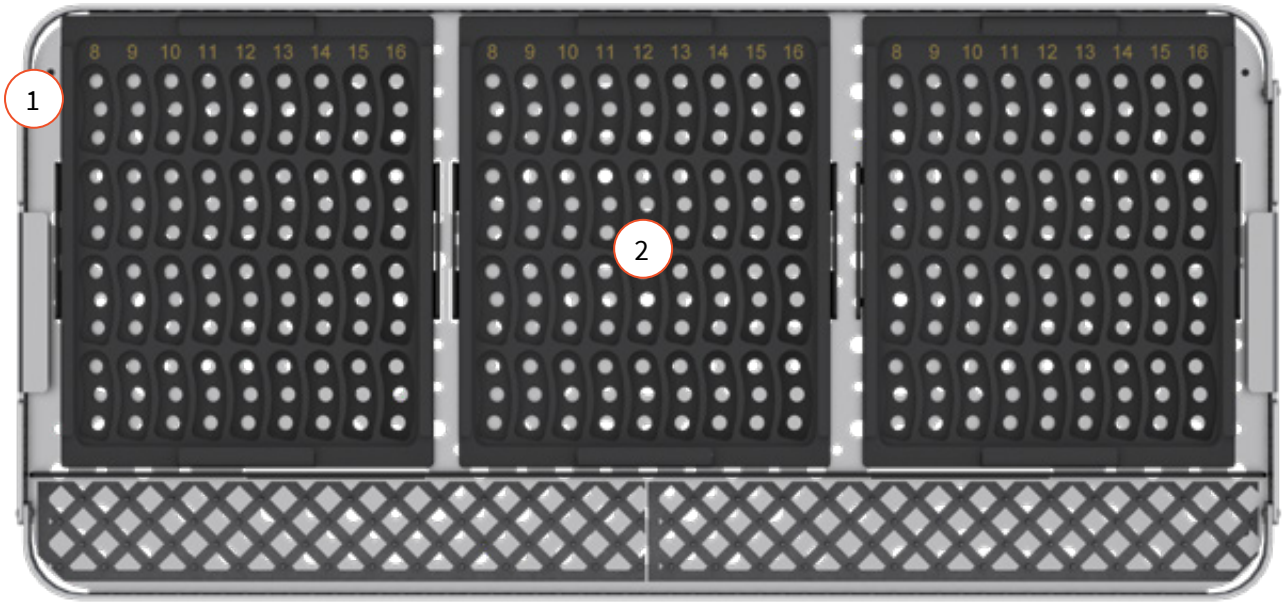
SYSTEM CONFIGURATION

IMPLANTS

Catalog #	Description
30-PNS-2508 thru 30-PNS-2516	Cage, Straight 0°, 25 x 8 thru 16mm
30-PTS-2508 thru 30-PTS-2516	Cage, Straight 7°, 25 x 8 thru 16mm
30-PES-2509 thru 30-PES-2516	Cage, Straight 14°, 25 x 9 thru 16mm
30-TNS-2708 thru 30-TNS-2716	Cage, Straight 0°, 27 x 8 thru 16mm
30-TTS-2708 thru 30-TTS-2716	Cage, Straight 7°, 27 x 8 thru 16mm
30-TES-2709 thru 30-TES-2716	Cage, Straight 14°, 27 x 9 thru 16mm
30-TNS-3208 thru 30-TNS-3216	Cage, Straight 0°, 32 x 8 thru 16mm
30-TTS-3209 thru 30-TTS-3216	Cage, Straight 7°, 32 x 9 thru 16mm
30-TES-3210 thru 30-TES-3216	Cage, Straight 14°, 32 x 10 thru 16mm
30-TNC-2708 thru 30-TNC-2716	Cage, Curved Oblique 0°, 27 x 8 thru 16mm
30-TTC-2708 thru 30-TTC-2716	Cage, Curved Oblique 7°, 27 x 8 thru 16mm
30-TEC-2709 thru 30-TEC-2716	Cage, Curved Oblique 14°, 27 x 9 thru 16mm
30-TNC-3208 thru 30-TNC-3216	Cage, Curved Oblique 0°, 32 x 8 thru 16mm
30-TTC-3209 thru 30-TTC-3216	Cage, Curved Oblique 7°, 32 x 9 thru 16mm
30-TEC-3210 thru 30-TEC-3216	Cage, Curved Oblique 14°, 32 x 10 thru 16mm
30-TTA-2708 thru 30-TTA-2716	Cage, Curved AP 7°, 27 x 8 thru 16mm
30-TEA-2708 thru 30-TEA-2716	Cage, Curved AP 14°, 27 x 8 thru 16mm
30-TTA-3208 thru 30-TTA-3208	Cage, Curved AP 7°, 32 x 8 thru 16mm
30-TEA-3208 thru 30-TEA-3216	Cage, Curved AP 14°, 32 x 8 thru 16mm
30-TTA-3608 thru 30-TTA-3616	Cage, Curved AP 7°, 36 x 8 thru 16mm
30-TEA-3608 thru 30-TEA-3616	Cage, Curved AP 14°, 36 x 8 thru 16mm

SYSTEM CONFIGURATION

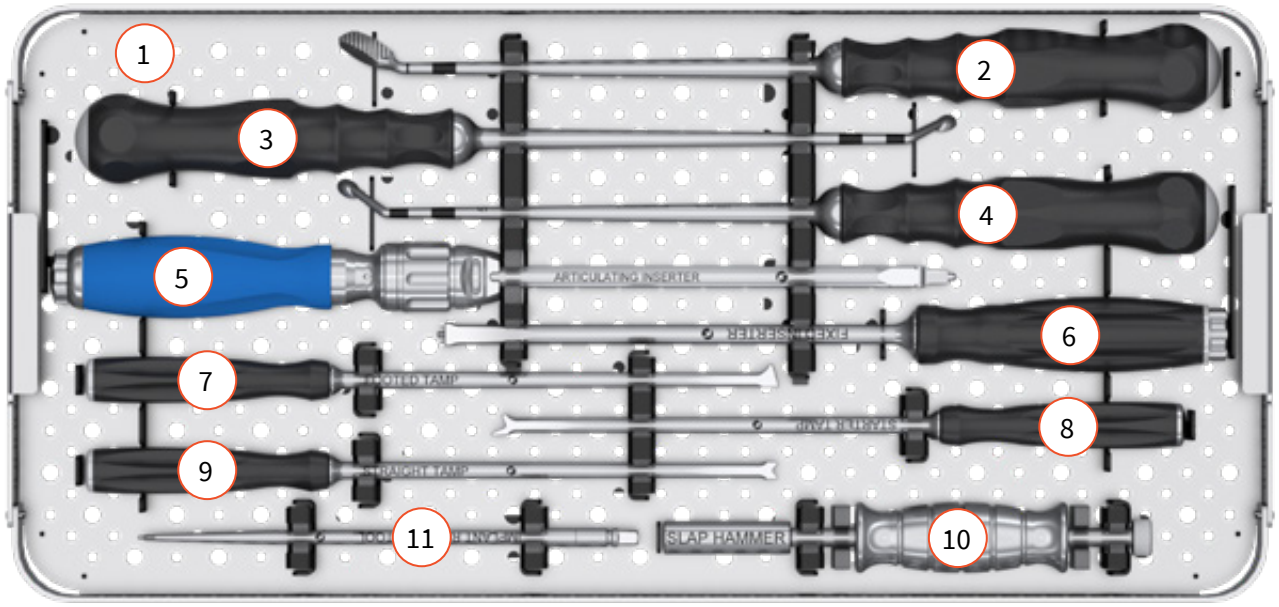
IMPLANT TRAY



Item #	Description	Qty/Set
1	Implant Tray	1
2	Implant Caddie	3
3	Caddie Lid (Not Shown)	3

SYSTEM CONFIGURATION

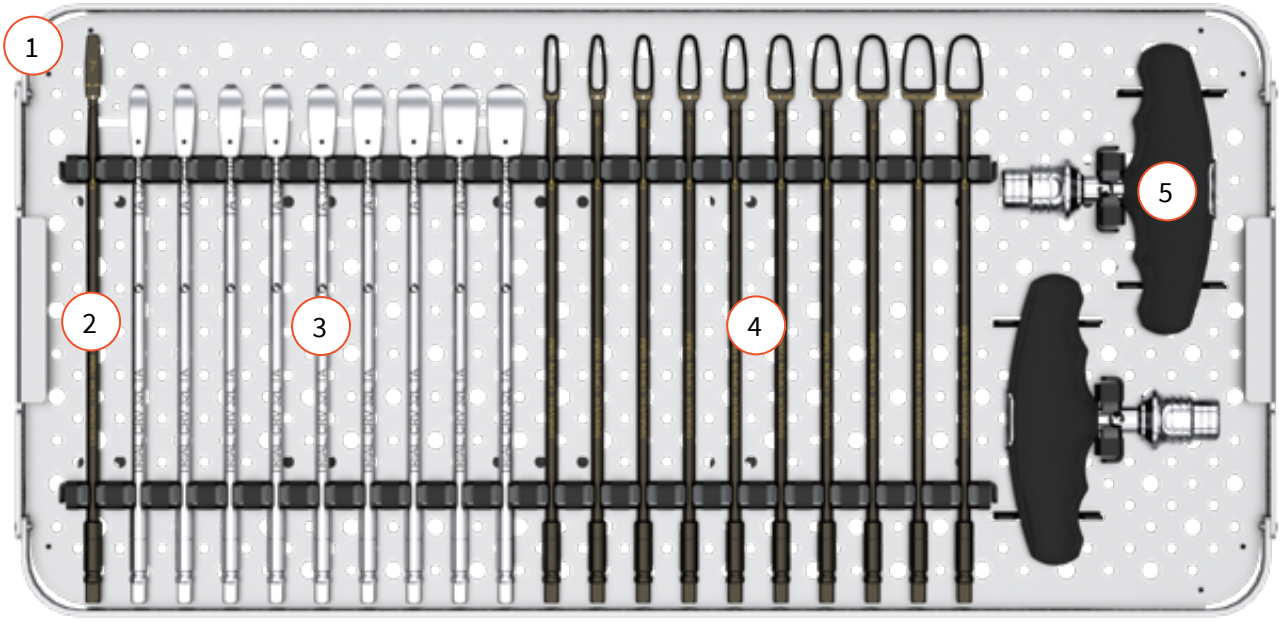
TRAY INSERT 1



Item #	Description	Qty/Set
1	Tray Insert 1	1
2	Rasp, Angled	1
3	Curette, Right Angle #5	1
4	Curette, Left Angle #5	1
5	Inserter, Articulating	1
6	Inserter, Fixed	1
7	Tamp, Footed	1
8	Tamp, Starter	1
9	Tamp, Straight	1
10	Slap Hammer	1
11	Removal Tool	1

SYSTEM CONFIGURATION

TRAY INSERT 2



Item #	Description	Qty/Set
1	Tray Insert 2	1
2	Paddle Distractor, 7mm	1
3	Fixed Trial, 8-16mm	9
4	Open Shaver, 7-16mm	10
5	T-Handle	2

Note: 8-16mm Paddle Distractors may be substituted for Trials. 7-16mm Closed Shavers may be substituted for Open Shavers.

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

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

sales@kalitecmed.com
(407) 545-2063

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