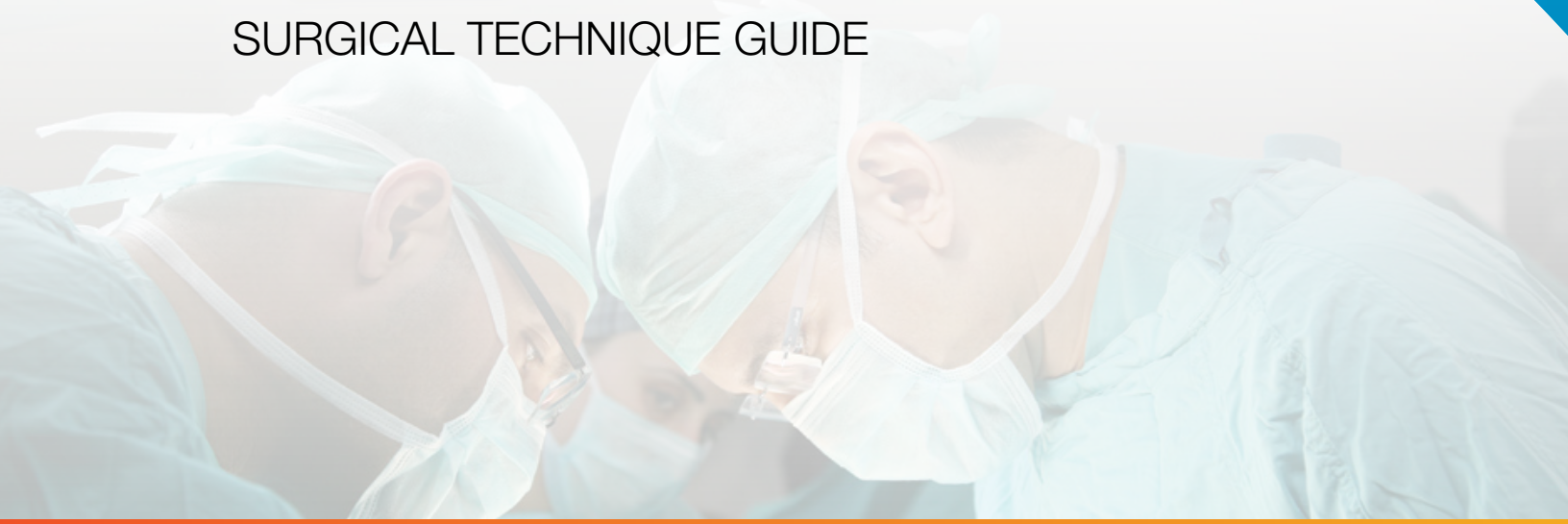
Kalitec

INTESS® Cervical 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.

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INTESS® Cervical
Interbody System

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INTESS Cervical

Interbody System

INTRODUCTION

Description:

The INTESS Cervical 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 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 INTESS Cervical 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 INTESS Cervical Cage must not be reused under any circumstances.

The INTESS Cervical Cage is not a stand-alone device and must be utilized in conjunction with supplemental anterior cervical plate fixation. These instructions for use are designed to assist in use of the INTESS Cervical Cage and are not a reference for surgical techniques.

Indications:

The INTESS Cervical Cage is intended for anterior interbody spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-T1). Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This device is intended for use with supplemental internal fixation systems and autogenous bone graft implanted via an open, anterior approach. Patients should have at least six weeks of non-operative treatment prior to treatment with intervertebral cage.

Contraindications:

- Acute or chronic infectious diseases of any etiology and localization
- Signs of local inflammation
- 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.
- Grossly distorted anatomy due to congenital abnormalities
- 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 medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- 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.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance, or if the patient has grossly distorted anatomy caused by congenital abnormalities.
- Symptomatic cardiac disease.
- Systemic or terminal illness.
- Prior fusion at the level to be treated.

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.
- 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.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Dural tears.
- 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, 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.
- 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.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- 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, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status.
- Non-union (or pseudarthrosis). Delayed union. Mal-union.
- 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.
- Paralysis.
- Death.

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

Warnings and Precautions:

The INTESS Cervical 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 Cervical 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. 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 Cervical 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 level to be treated may have different clinical outcomes compared to those without a previous surgery.

The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of cervical 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.*

The INTESS Cervical Cage has not been evaluated for safety and compatibility within the MR environment. The INTESS®Cervical Cage has not been tested for heating or migration in the MR environment.

SURGICAL TECHNIQUE

Patient Positioning and Exposure

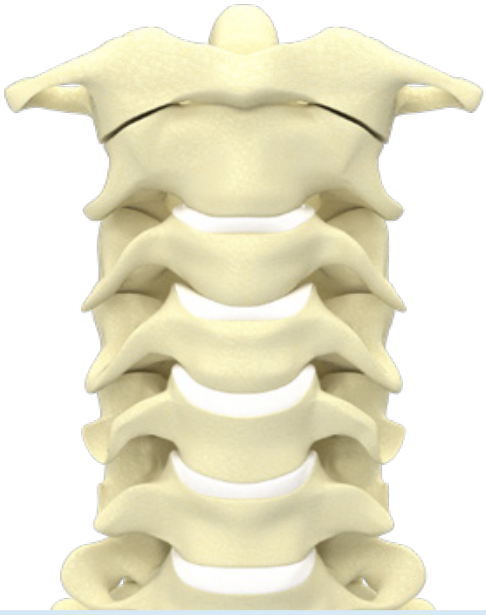


Figure 1

Step 1:

a. Prior to skin incision, radiographic imaging can be used to determine indicated cervical levels and proper incision site.

b. With the patient in the supine position, perform the anterior cervical dissection for exposure to the required cervical level utilizing the standard surgical technique ensuring complete anterior access to the appropriate disc.

c. Remove all disc material at the indicated cervical level ensuring all cartilaginous end plate disc material is removed.

Vertebral Endplate Preparation

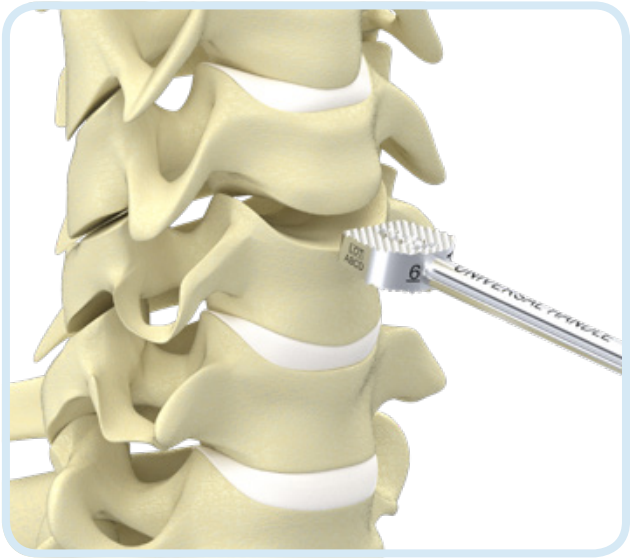


Figure 2

Implant Size Determination

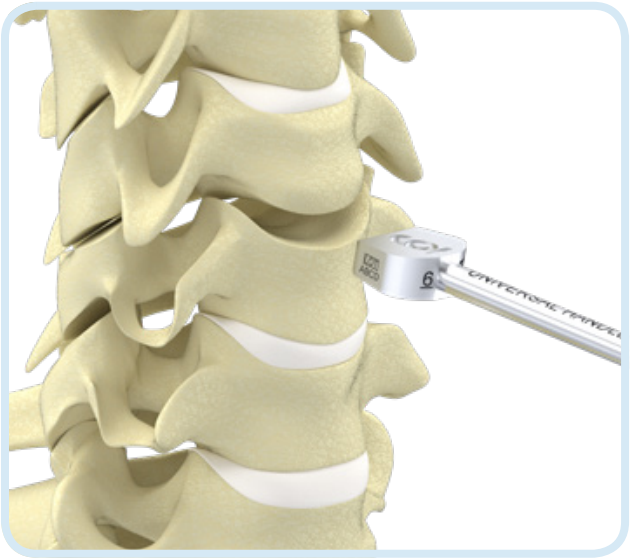


Figure 3

Step 2:

a. Rasps may be used to assist in preparing the cervical end plates.

b. Choose desired Rasp and thread onto either end of the Universal Handle. Rotate the Rasp clockwise until it is firmly fixed .

c. To remove a Rasp from the Universal Handle, firmly rotate the Rasp counter-clockwise until it is released.

Step 3:

a. Determine the depth and width of the desired Implant. Four different footprints are available (Width X Depth: 14X11mm, 15x12mm, 16x14mm, 19x15mm) in 0° non-tapered and 7° tapered.

b. Once footprint and taper are determined, assemble Trial(s) by threading them onto the Universal Handle until they are firmly fixed. Trial disc space sequentially until desired height is determined. An Impactor Cap may be placed on the opposite end of the Universal Handle if preferred.

INSTRUMENTS

Rasp

Universal Handle

Trial

Implant Inserter Assembly

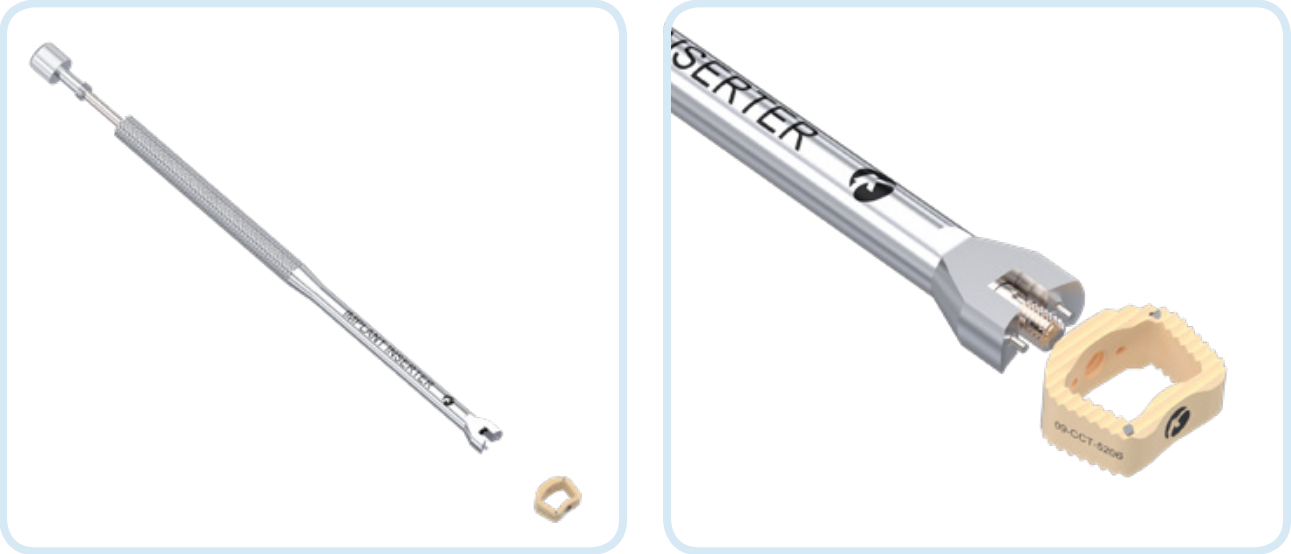


Figure 4

Step 4:

a. Once the Implant size is determined, confirm that the proper cervical Implant matches with the Trial size used to achieve desired disc height restoration.

b. Align the Draw Rod into the proximal end of the Implant Inserter and thread clockwise until in place.

c. Load the Implant on the Inserter by placing the two prongs of the Inserter directly into the two small holes on the anterior face of the Implant.

d. While applying slight downward pressure on the Implant, turn the Draw Rod clockwise until the Implant is completely fixed to the Inserter. The Draw Rod knob should be flush with the proximal end of the Implant Inserter body when fully fixed to the Implant.

Note: *Use caution when tightening the Inserter to the Implant to prevent the threads from stripping.*

INSTRUMENTS

Draw Rod

Implant Inserter

Implant Insertion

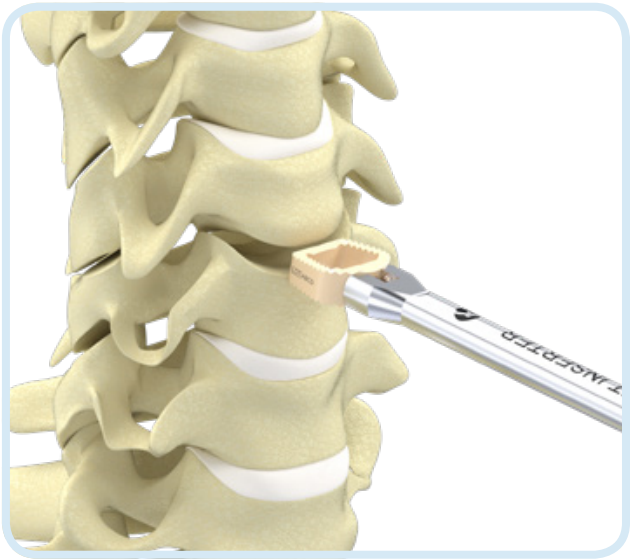


Figure 5

Verify Implant Positioning

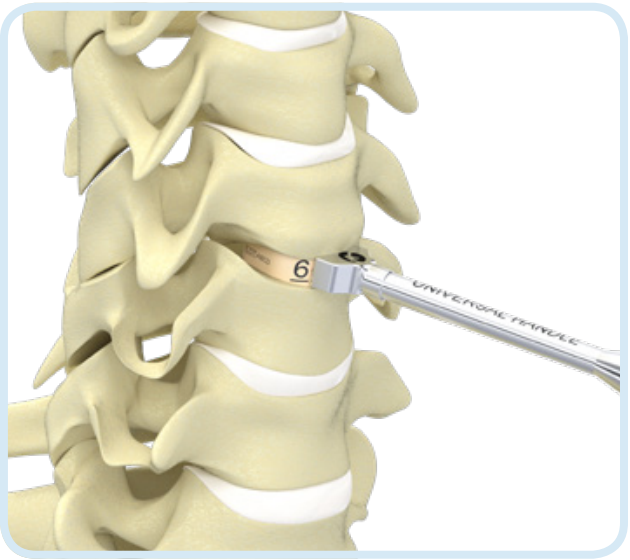


Figure 6

Step 5:

a. Load the Implant with desired bone graft. Once the central cavity is completely filled, insert the Implant into the intervertebral disc space by gentle impaction with a mallet. Radiographic confirmation is recommended to ensure proper implant position.

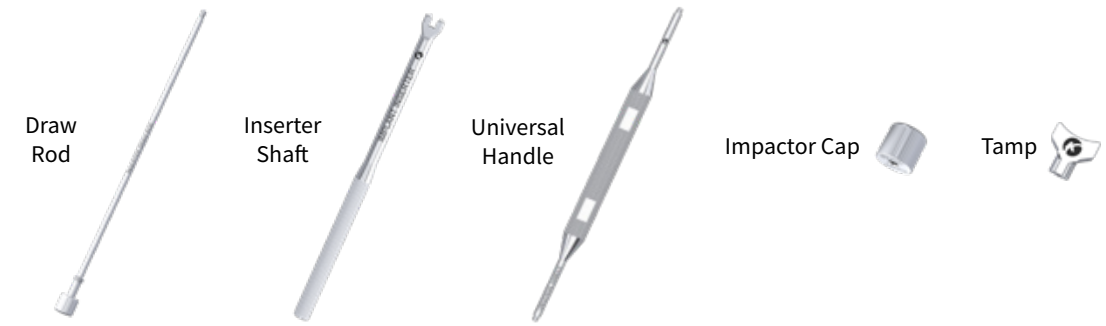
b. Once positioned, turn the Draw Rod counter-clockwise while holding the Inserter stationary until the Inserter has been released from the implant. Gently lift the Inserter away from the implant to ensure complete detachment.

Step 6:

a. Verify proper Implant position prior to supplemental fixation. If further Implant adjustment is required, attach the Tamp and Impactor Cap by threading clockwise to the Universal Handle until they are firmly fixed to both ends.

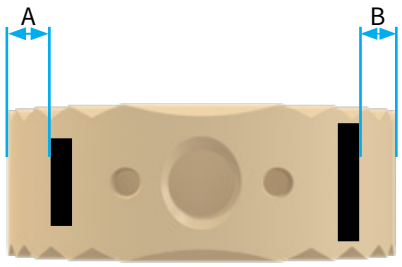
b. Using a mallet and fully assembled Tamp with Impactor Cap, gently impact the implanted Cage into the desired position. Use radiography to confirm Implant positioning.

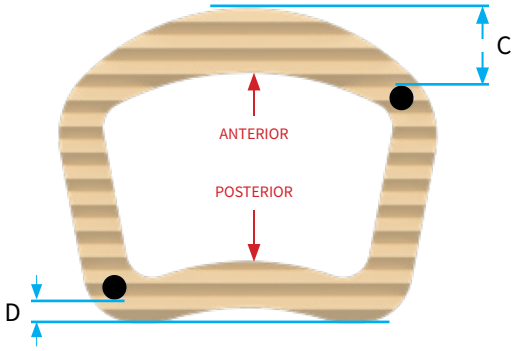
INSTRUMENTS



TANTALUM MARKER LOCATIONS

DIMENSIONS



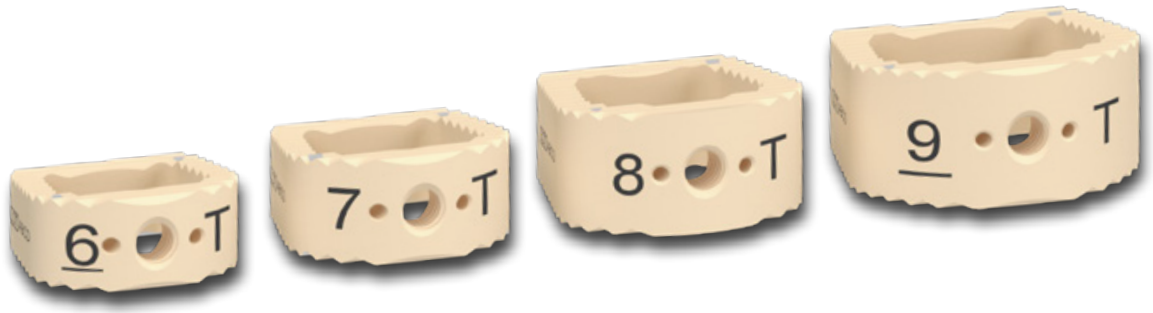


Disclaimer: *All Dimensions listed above have been rounded to the nearest 0.5mm*

Footprint (mm)	Dim "A" (mm)	Dim "B" (mm)	Dim "C" (mm)	Dim "D" (mm)
14 x 11	1.5	1.0	2.5	1.0
15 x 12	1.5	1.0	3.0	1.0
16 x 14	2.5	1.5	3.0	1.0
19 x 15	2.5	1.5	4.0	1.0

SYSTEM CONFIGURATION

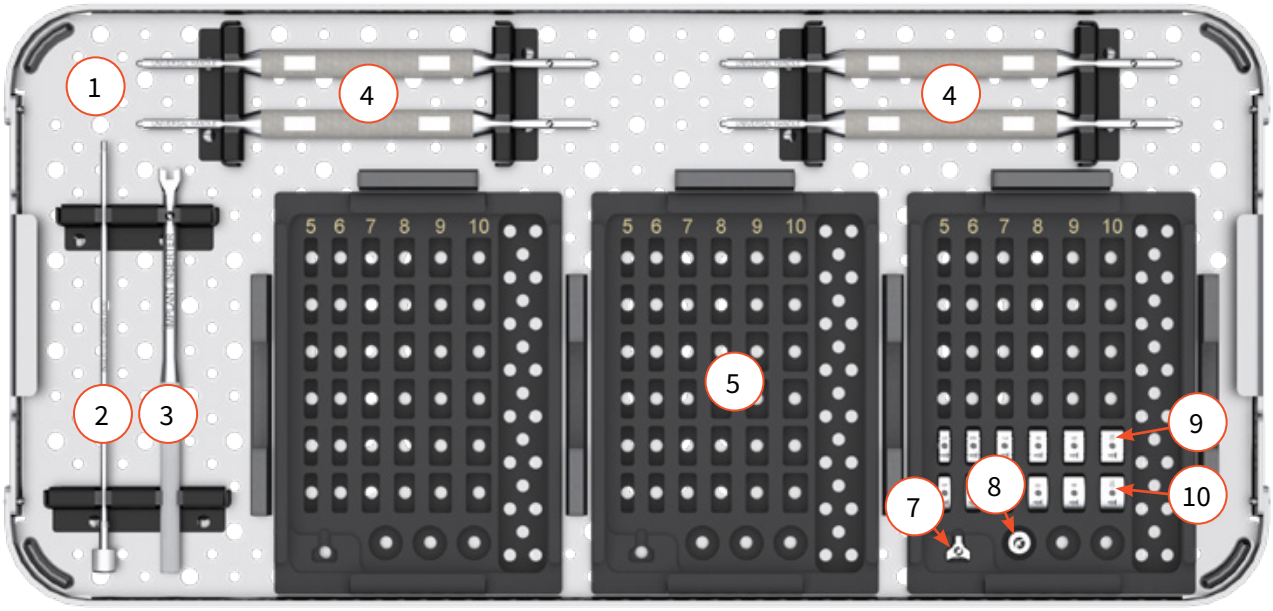
IMPLANTS



Catalog #	Description
09-CCN-4105 thru 09-CCN-4110	Cage, 14x11, 5mm thru 10mm, 0° NT
09-CCT-4105 thru 09-CCT-4110	Cage, 14x11, 5mm thru 10mm, 7° TA
09-CCN-5205 thru 09-CCN-5210	Cage, 15x12, 5mm thru 10mm, 0° NT
09-CCT-5205 thru 09-CCT-5210	Cage, 15x12, 5mm thru 10mm, 7° TA
09-CCN-6405 thru 09-CCN-6410	Cage, 16x14, 5mm thru 10mm, 0° NT
09-CCT-6405 thru 09-CCT-6405	Cage, 16x14, 5mm thru 10mm, 7° TA
09-CCN-9505 thru 09-CCN-9510	Cage, 19x15, 5mm thru 10mm, 0° NT
09-CCT-9505 thru 09-CCT-9510	Cage, 19x15, 5mm thru 10mm, 7° TA

SYSTEM CONFIGURATION

TRAY INSERT



Item #	Description	Qty
1	Tray Insert	1
2	Draw Rod	1
3	Implant Inserter	1
4	Universal Handle	4
5	Caddie, Cervical Implants & Trials	1-3
6	Caddie Lid (Not Shown)	1-3
7	Tamp	1
8	Impactor Head	1-3
9	Rasp, 5mm thru 10mm, 0° NT or 7° TA	6
10	Trial, 5mm thru 10mm, 0° NT or 7° TA	6

NOTES:

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

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