Surgical Technique

Kodiak C Spinal Implant System

STG-07 Rev C
11-15-2023

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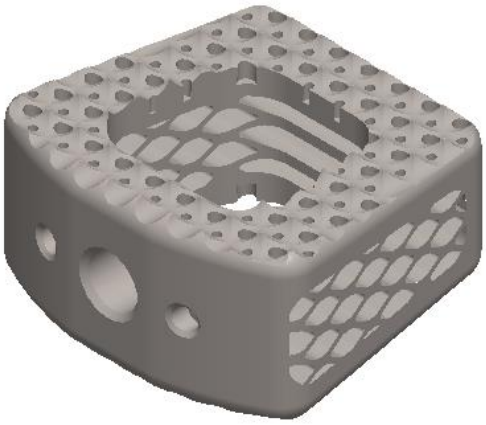
PRODUCT OVERVIEW

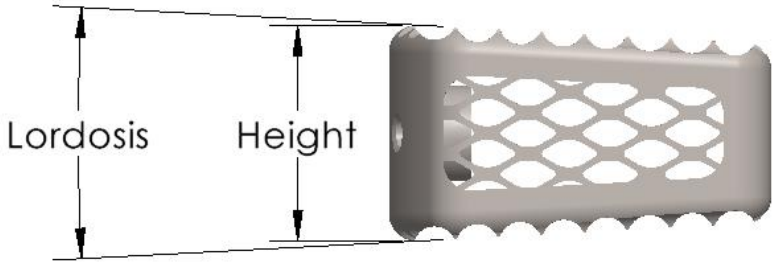
The Met One Technologies Kodiak C Cervical Cage is a cervical intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. The implants are available in a variety of heights, footprints, and lordotic configurations to suit individual patient anatomy.

The Met One Technologies Kodiak C Corpectomy Cage is a thoracolumbar vertebral body replacement device (VBR) that is implanted to achieve anterior decompression of the spinal cord and neural tissues and to restore the height of a collapsed vertebral body.

The Kodiak C cages have a central cavity to permit the packing of autograft and/or allograft bone, teeth on the superior and inferior surfaces to resist expulsion, and lattice windows for radiographic visualization.

The Kodiak C Spinal Implant System cages are manufactured from Ti-6Al-4V Eli, in compliance with ASTM F3001.





FEATURES

- Unique lattice design allows for bone growth through implant without compromising strength
- Large graft windows create maximum contact between the graft and endplate
- Textured superior/inferior surfaces prevent expulsion in any direction
- Superior instrumentation for the most efficient application of implants
- Quick-release inserter prevents cage cross threading and allows for easier implant insertion
- Sizes available for all surgical needs

KODIAK C CERVICAL CAGE OVERVIEW

Footprints: 12mm x 14mm, 14mm x 16mm
Lordosis angles: parallel (0°), 6°

Footprint

Height (mm)	12 mm x 14 mm	14 mm x 16 mm
5	•	•
6	•	•
7	•	•
8	•	•
9	•	•
10	•	•
11	•	•

KODIAK C CORPECTOMY CAGE OVERVIEW

Footprints: 12mm x 14mm, 14mm x 16mm
Lordosis angles: parallel (0°), 6°

Footprint

Height (mm)	12 mm x 14 mm	14 mm x 16 mm
10	•	•
11	•	•
12	•	•
13	•	•
14	•	•
15	•	•
16	•	•
17	•	•
18	•	•
19	•	•
20	•	•
21	•	•
22	•	•
23	•	•
24	•	•
25	•	•
26	•	•
27	•	•
28	•	•
29	•	•
30	•	•
31	•	•
32	•	•
33	•	•
34	•	•

Footprint

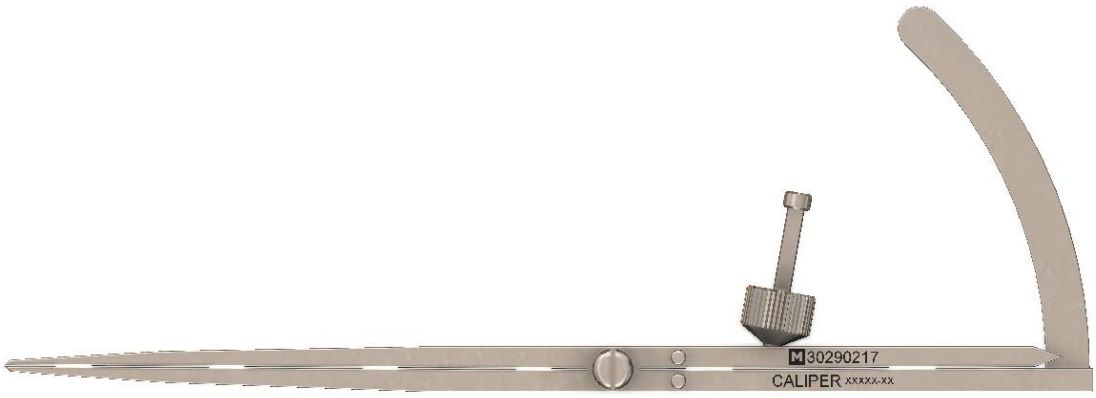
Height (mm)	12 mm x 14 mm	14 mm x 16 mm
35	•	•
36	•	•
37	•	•
38	•	•
39	•	•
40	•	•
41	•	•
42	•	•
43	•	•
44	•	•
45	•	•
46	•	•
47	•	•
48	•	•
49	•	•
50	•	•
51	•	•
52	•	•
53	•	•
54	•	•
55	•	•
56	•	•
57	•	•
58	•	•
59	•	•
60	•	•

INSTRUMENT OVERVIEW

30290209 Lever Inserter

30290211 Tamp

30290217 Caliper



07-0011F – 07-0012F 0° Corpectomy Trials

07-0013F – 07-0014F 6° Corpectomy Trials

07-0015H – 07-0028H 12x14, 0° & 6° Cervical Trials

07-0029J – 07-0035J 14x16, 0° & 6° Cervical Trials

EXPOSURE

Locate the correct operative level using radiographic assistance. Expose the intervertebral disc and adjacent bodies through a standard anterior approach to the cervical spine. Carefully place retractors to provide sufficient access to the intervertebral space.

DISCECTOMY

Perform a complete discectomy at the desired level employing rongeurs and curettes as appropriate. Remove posterior rim and/or osteophytes as necessary. Take care to avoid damaging the vertebral body endplates to minimize the probability of implant subsidence.

Cervical spine before discectomy

Cervical spine after discectomy

DISTRACTION

Place distraction screws in the adjacent vertebral bodies and attach a Caspar distractor.

Distraction

DETERMINE IMPLANT SIZE

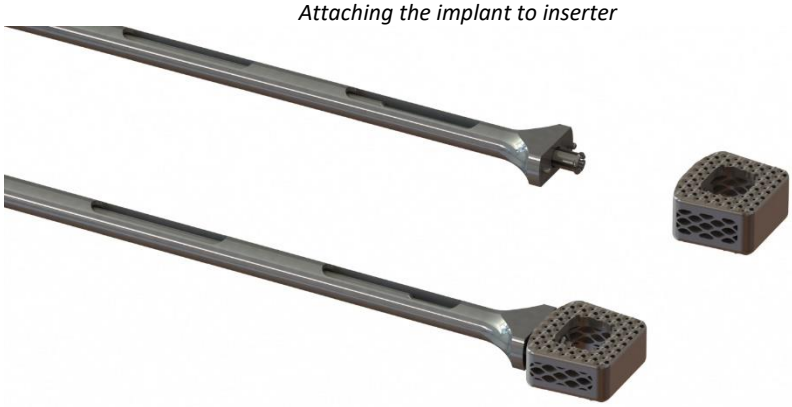
After ensuring proper distraction of the intervertebral space with a Caspar distractor, use the provided implant trials to determine the appropriate implant size for the procedure. Be sure to note the size marked on the trial. Slight impaction may be used to introduce the trial into the intervertebral space. Use a smaller trial if the fit is deemed too tight, or a larger trial if the fit it deemed too loose. Confirm fit of the trial radiographically.

Trialing implant size

IMPLANT SELECTION AND PREPARATION

Select the implant that matches the appropriate implant trial. Attach the selected implant to the inserter, check again that it is the appropriate size and place it in the graft loading block. Fill the implant with bone graft or bone graft substitute and pack it down with the tamp. Do not use a mallet for packing down the bone graft as this may damage the structural integrity of the implant.

Attaching the implant to inserter



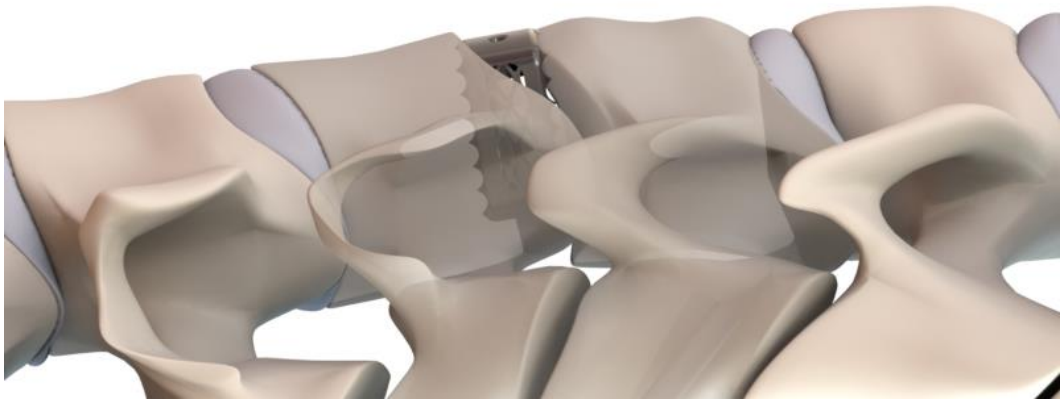
Attaching implant to insterter

Implant packed with bone graft or bone graft substitute

IMPLANT INSERTION

Align the implant to the prepared intervertebral space and carefully insert the implant. Proper positioning may be facilitated by using slight impaction. Confirm the location of the implant radiographically. Once proper positioning has been achieved, disconnect the inserter from the implant and remove from the surgical site. Also remove the Caspar distractor and distractor pins. Verify correct positioning of the implant radiographically again.

Implant insertion



Typical final position of implant

CERVICAL PLATE

Implant an approved cervical plate and screw system at the appropriate level to provide additional stabilization.

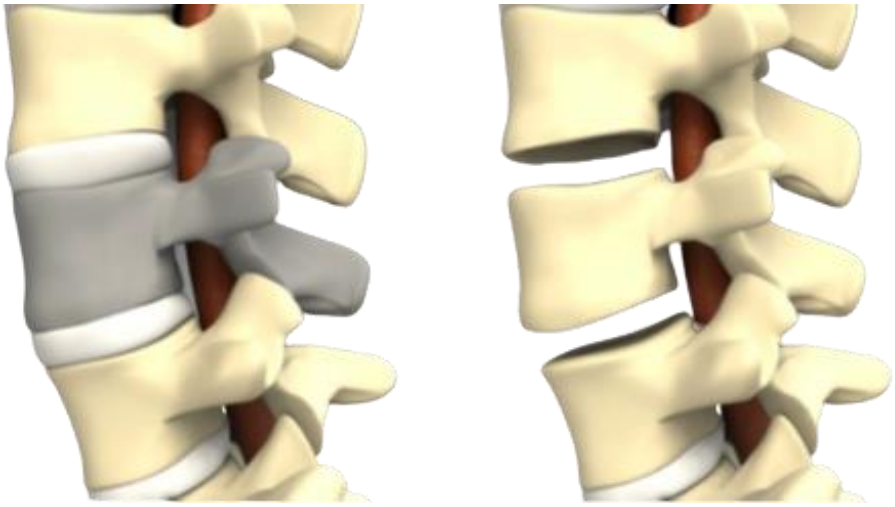
Cervical plate and screw system (example)

EXPOSURE OF THE INTERVERTEBRAL SPACE

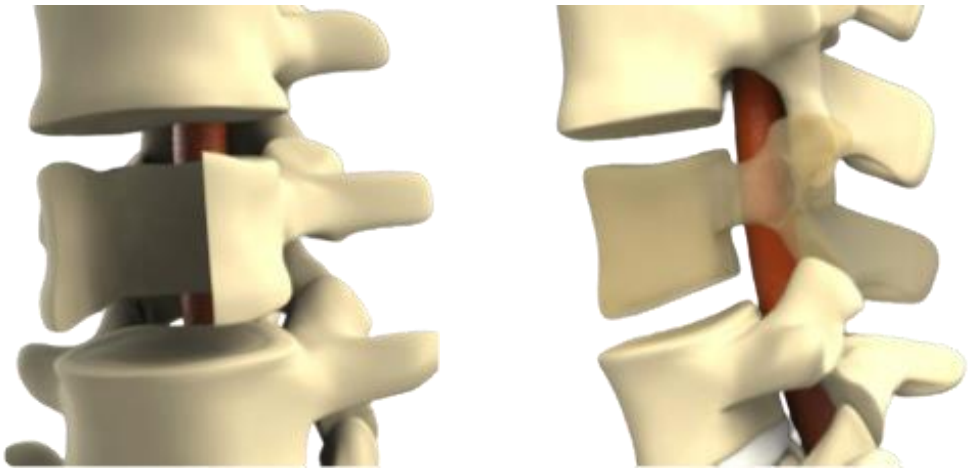
Locate the correct operative level using radiographic assistance. Expose the vertebral body being replaced as well as the adjacent vertebral discs via a standard anterior approach to the lumbar spine. Carefully place retractors to provide sufficient access to the surgical area.

DISCECTOMY AND CORPECTOMY

Perform a complete discectomy on the adjacent intervertebral discs employing rongeurs and curettes as appropriate. Take care to avoid damaging the endplates of the adjacent vertebral bodies in order to minimize the probability of implant subsidence.



Identify target vertebral body (highlighted body shown) and perform discectomies on caudal and cephalad intervertebral discs.

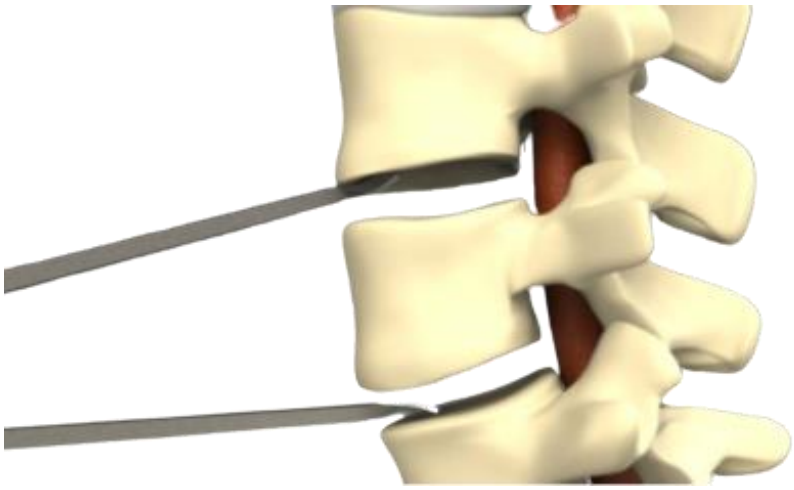


Perform corpectomy as necessary (corpectomy shown is for illustrative purposes only, actual procedures may have more or less bone removed).

DETERMINE IMPLANT SIZE

Determining the appropriate implant size may be achieved by employing the measurement caliper provided in the instrument set. Measure the distance from the endplates of the superior and inferior intact vertebrae respectively. If desired, the surgeon may apply traction to the spinal column to achieve proper spacing between intact vertebrae. Note the distance indicated on the measurement caliper and select the appropriately sized implant.

Measurement Caliper

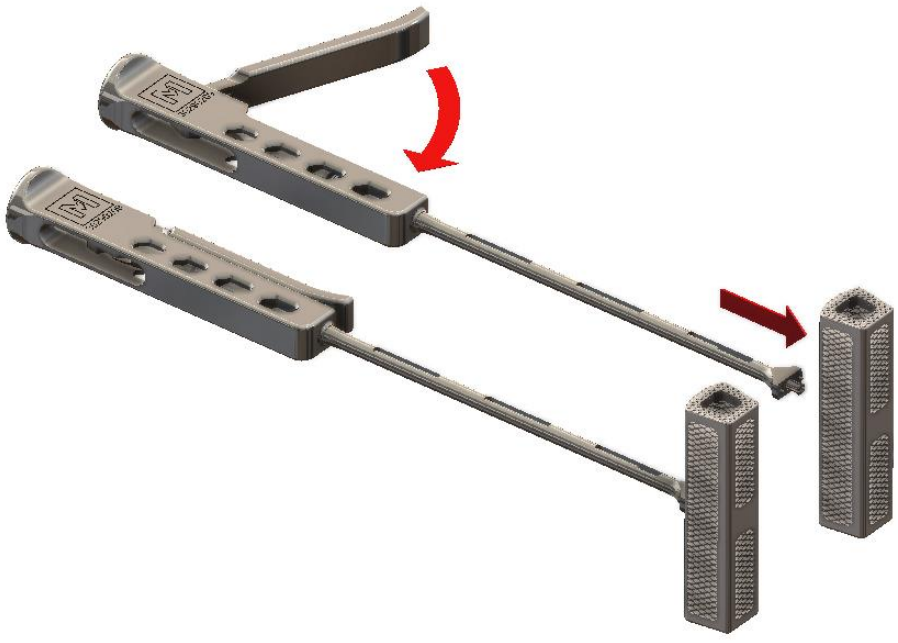


Employing caliper to measure space

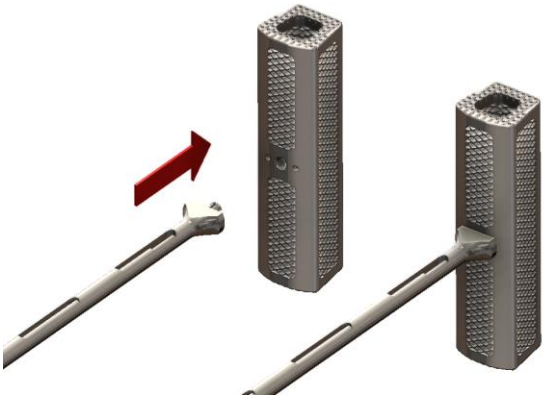
Reading Caliper

IMPLANT SELECTION AND PREPARATION

Select the implant that matches the appropriate implant trial. Attach the selected implant to the inserter, check again that it is the appropriate size and fill the implant with bone graft or bone graft substitute and pack it down with the impactor tool. Do not use a mallet for packing down the bone graft as this may damage the structural integrity of the implant.



Attaching implant to inserter, locking inserter

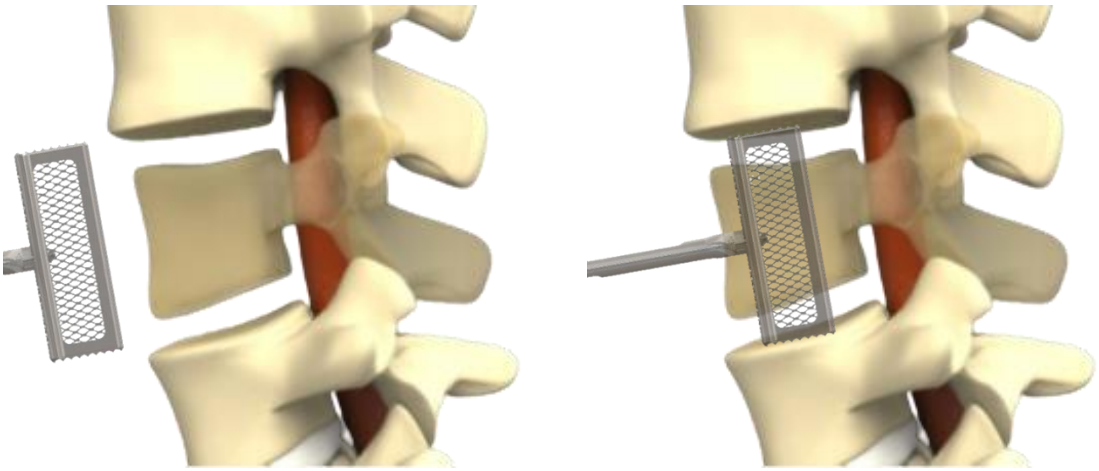


Attaching implant to inserter

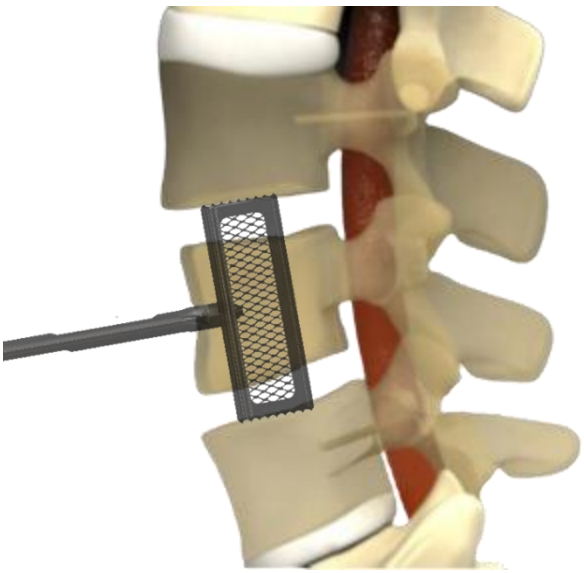
Packing bone graft in implant

IMPLANT INSERTION

Align the implant to the prepared space and carefully insert the implant. If desired, the surgeon may apply traction to the spinal column to distract the space between intact vertebrae. Proper positioning may be facilitated by using slight impaction. Confirm the location of the implant radiographically, being sure to identify the radiographic markers in the implant. Once proper positioning has been achieved, disconnect the inserter from the implant remove from the surgical site. Verify correct positioning of the implant radiographically again.



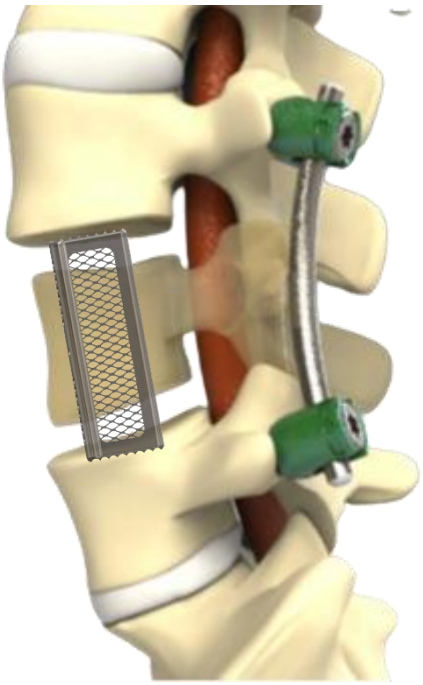
Insert implant – approach and final position



Radiographic check of implant position

SUPPLEMENTAL FIXATION

Supplemental posterior fixation is achieved through the use of an approved pedicle screw system as shown.



Final construct with pedicle screw in place.
(L4 vertebral body transparent for illustrative purposes.)

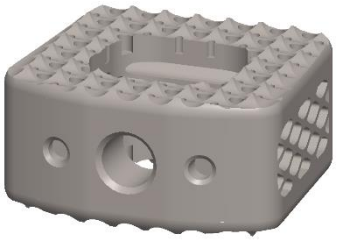
IMPLANT REMOVAL

This procedural step is only to be conducted if it is necessary to remove the implant from the intervertebral space. Being careful not to push the implant any further into the intervertebral space, attach the implant inserter to the implant ensuring that the alignment holes are engaged. Close the lever to ensure proper attachment of the instrument to the inserter. Applying an upward force and being careful not twist or bend the attachment between the implant and the inserter, remove the implant from the intervertebral space. Gentle tapping from a tap hammer is permissible.

Implant Removal

CERVICAL CAGES

DESCRIPTION	CATALOG #	IMPLANT SIZE
Kodiak C Cervical Cage	31052400K	12X14X5, 0°
Kodiak C Cervical Cage	31062400K	12X14X6, 0°
Kodiak C Cervical Cage	31072400K	12X14X7, 0°
Kodiak C Cervical Cage	31082400K	12X14X8, 0°
Kodiak C Cervical Cage	31092400K	12X14X9, 0°
Kodiak C Cervical Cage	31102400K	12X14X10, 0°
Kodiak C Cervical Cage	31112400K	12X14X11, 0°
Kodiak C Cervical Cage	31054600K	14X16X5, 0°
Kodiak C Cervical Cage	31064600K	14X16X6, 0°
Kodiak C Cervical Cage	31074600K	14X16X7, 0°
Kodiak C Cervical Cage	31084600K	14X16X8, 0°
Kodiak C Cervical Cage	31094600K	14X16X9, 0°
Kodiak C Cervical Cage	31104600K	14X16X10, 0°
Kodiak C Cervical Cage	31114600K	14X16X11, 0°
Kodiak C Cervical Cage	31052406K	12X14X5, 6°
Kodiak C Cervical Cage	31062406K	12X14X6, 6°
Kodiak C Cervical Cage	31072406K	12X14X7, 6°
Kodiak C Cervical Cage	31082406K	12X14X8, 6°
Kodiak C Cervical Cage	31092406K	12X14X9, 6°
Kodiak C Cervical Cage	31102406K	12X14X10, 6°
Kodiak C Cervical Cage	31112406K	12X14X11, 6°
Kodiak C Cervical Cage	31054606K	14X16X5, 6°
Kodiak C Cervical Cage	31064606K	14X16X6, 6°
Kodiak C Cervical Cage	31074606K	14X16X7, 6°
Kodiak C Cervical Cage	31084606K	14X16X8, 6°
Kodiak C Cervical Cage	31094606K	14X16X9, 6°
Kodiak C Cervical Cage	31104606K	14X16X10, 6°
Kodiak C Cervical Cage	31114606K	14X16X11, 6°



Kodiak C Cervical Cage

CORPECTOMY CAGES

DESCRIPTION	CATALOG #	IMPLANT SIZE
Kodiak C Corpectomy Cage	41102400K	12X14X10, 0°
Kodiak C Corpectomy Cage	41122400K	12X14X12, 0°
Kodiak C Corpectomy Cage	41142400K	12X14X14, 0°
Kodiak C Corpectomy Cage	41162400K	12X14X16, 0°
Kodiak C Corpectomy Cage	41182400K	12X14X18, 0°
Kodiak C Corpectomy Cage	41202400K	12X14X20, 0°
Kodiak C Corpectomy Cage	41222400K	12X14X22, 0°
Kodiak C Corpectomy Cage	41242400K	12X14X24, 0°
Kodiak C Corpectomy Cage	41262400K	12X14X26, 0°
Kodiak C Corpectomy Cage	41282400K	12X14X28, 0°
Kodiak C Corpectomy Cage	41302400K	12X14X30, 0°
Kodiak C Corpectomy Cage	41322400K	12X14X32, 0°
Kodiak C Corpectomy Cage	41342400K	12X14X34, 0°

IMPLANT OVERVIEW

DESCRIPTION	CATALOG #	IMPLANT SIZE
Kodiak C Corpectomy Cage	41362400K	12X14X36, 0°
Kodiak C Corpectomy Cage	41382400K	12X14X38, 0°
Kodiak C Corpectomy Cage	41402400K	12X14X40, 0°
Kodiak C Corpectomy Cage	41422400K	12X14X42, 0°
Kodiak C Corpectomy Cage	41442400K	12X14X44, 0°
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Kodiak C Corpectomy Cage	41542400K	12X14X54, 0°
Kodiak C Corpectomy Cage	41562400K	12X14X56, 0°
Kodiak C Corpectomy Cage	41582400K	12X14X58, 0°
Kodiak C Corpectomy Cage	41602400K	12X14X60, 0°
Kodiak C Corpectomy Cage	41104600K	14X16X10, 0°
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Kodiak C Corpectomy Cage	41164600K	14X16X16, 0°
Kodiak C Corpectomy Cage	41184600K	14X16X18, 0°
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Kodiak C Corpectomy Cage	41284600K	14X16X28, 0°
Kodiak C Corpectomy Cage	41304600K	14X16X30, 0°
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Kodiak C Corpectomy Cage	41344600K	14X16X34, 0°
Kodiak C Corpectomy Cage	41364600K	14X16X36, 0°
Kodiak C Corpectomy Cage	41384600K	14X16X38, 0°
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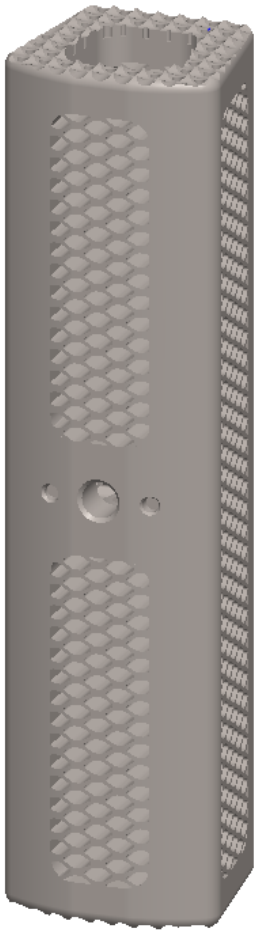

Kodiak C Corpectomy Cage

IMPLANT OVERVIEW

DESCRIPTION	CATALOG #	IMPLANT SIZE
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Kodiak C Corpectomy Cage	41262406K	12X14X26, 6°
Kodiak C Corpectomy Cage	41282406K	12X14X28, 6°
Kodiak C Corpectomy Cage	41302406K	12X14X30, 6°
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Kodiak C Corpectomy Cage	41402406K	12X14X40, 6°
Kodiak C Corpectomy Cage	41422406K	12X14X42, 6°
Kodiak C Corpectomy Cage	41442406K	12X14X44, 6°
Kodiak C Corpectomy Cage	41462406K	12X14X46, 6°
Kodiak C Corpectomy Cage	41482406K	12X14X48, 6°
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Kodiak C Corpectomy Cage	41602406K	12X14X60, 6°
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Kodiak C Corpectomy Cage	41504606K	14X16X50, 6°
Kodiak C Corpectomy Cage	41524606K	14X16X52, 6°
Kodiak C Corpectomy Cage	41544606K	14X16X54, 6°
Kodiak C Corpectomy Cage	41564606K	14X16X56, 6°
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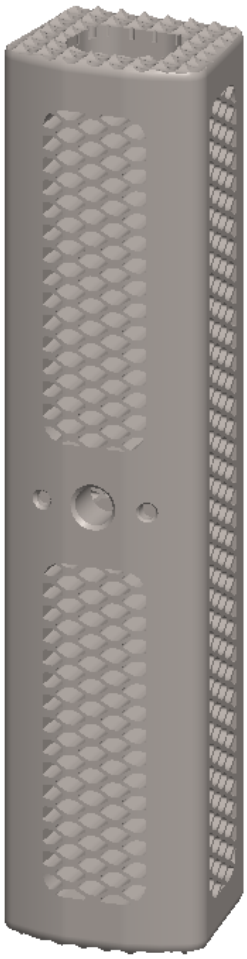
Kodiak C Corpectomy Cage	41604606K	14X16X60, 6°



Kodiak C Corpectomy Cage

EXCEPTIONAL SERVICE. SUPERIOR PRODUCTS. INNOVATIVE MINDS.

The physicians we work with are Renaissance thinkers. Their mastery, scientific insight and innovative minds inspire our product development. Met One puts advanced technology to work for physicians who artfully transform patients' lives.

INDICATIONS FOR USE

The Kodiak C Cervical Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine (C2-T1). The Kodiak C Cervical Cages are intended to be used with autograft and/or allograft bone (allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The Kodiak C Cervical Cages are intended to be used with an FDA cleared cervical supplemental fixation system. Patients should receive 6 weeks of non-operative treatment prior to treatment.

The Kodiak C Corpectomy Cages are indicated for use in the thoracolumbar spine (T1-L5) for partial or total replacement of a damaged, collapsed, or unstable vertebral body due to trauma/fracture or tumor, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Kodiak C Corpectomy Cages are intended to be used with autograft and/or allograft bone. The Kodiak C Corpectomy Cages are intended to be used with an FDA cleared supplemental fixation device such as a lumbar pedicle screw system.

For additional product information including warnings, precautions and adverse effects concerning spinal fixation implants refer to the product insert.

CONTRAINDICATIONS

The AUDERE II Lumbar Spacer System is contraindicated for use in patients with the following:

1. Active infectious process or significant risk of infection (immunocompromised)
2. Signs of local inflammation
3. Fever or leukocytosis
4. Osteoporosis or similar loss of bone density
5. Morbid obesity
6. Pregnancy
7. Gross distorted anatomy caused by congenital abnormalities
8. Suspected or documented metal allergy or intolerance

9. Prior fusion at the level being treated
10. Any case not described in the indications

WARNINGS

Potential risks identified with the use of this intervertebral body-fusion device, which may require additional surgery, include device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and vascular or visceral Injury.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Never reuse an internal fixation device under any circumstances.

Only surgeons trained in and experienced with spinal-fusion and bone-grafting techniques should use the Kodiak C Spinal Implant System. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants, are essential considerations in the utilization of this device.

Do not reuse implants. Discard used, damaged or otherwise suspect implants. AN IMPLANT SHOULD NEVER BE REUSED. Any implant, once used, should be discarded.

PRECAUTIONS

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the intervertebral body-fusion device.

The implantation of the intervertebral body-fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device, as this is a technically demanding procedure presenting a risk of serious injury to the patient.

Accepted medical practices, in addition to any local and national requirements, should be employed in the handling and disposal of all contaminated implants.

Caution: Federal law restricts this device to sale by or on the order of a licensed physician.

MRI SAFETY INFORMATION

The Kodiak C Spinal Implant 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 the Kodiak C Spinal Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING

Implants are provided clean but not sterile. ISO 8828 or ACORN recommended practices for in-hospital sterilization should be followed for all components.

Once an implant comes in contact with any human tissue or bodily fluid, it should not be resterilized and used. Please discard all contaminated implants.

1. Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions.
2. Immediately after the procedure, soak and manually agitate the soiled instruments in the solution for the minimum recommended time specified by the solution manufacturer or 10 minutes, whichever is longer.
3. Using a soft bristle scrub brush, scrub instruments to remove all traces of blood and debris from the instrument surfaces. Employ a soft bristle brush or pipe cleaner to reach the entire length of all instrument lumens.
4. Rinse instruments with warm 85°F-104°F (36°C-46°C) tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. Pay particular attention to flushing all instrument lumens.
5. Ultrasonically clean the instruments for 10 minutes in a neutral pH detergent, prepared in accordance with the manufacturer's instructions.
6. Rinse instruments with warm 85°F-104°F (36°C-46°C) tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. Pay particular attention to flushing all instrument lumens.
7. Dry the instruments immediately after final rinse with a clean towel or clean, dry compressed air until visibly dry.

INSPECTION

1. Carefully inspect all instruments before sterilization to ensure all visible blood and soil have been removed from surfaces, lumens, holes and moveable parts.
2. If damage or biological residue is observed on an implant, the implant must be discarded.

STERILIZATION

All implants should be placed in the provided implant caddies. All instruments should be placed in their appropriate locations within the instrument case(s).

Instrument case(s) to be double wrapped with FDA approved 1-ply polypropylene wrap (Kimguard KC600 or equivalent) with a surgical towel placed between the tray and the wrap.

Sterilization type:	Pre-vacuum
Exposed Temperature:	270°F (132°C)
Full Cycle Time:	4 min.
Minimum Dry Time:	20 min

LIMITED WARRANTY

Met One Technologies products are sold with a limited warranty to the original purchaser against defects in the workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than two years have elapsed between the date of issue/revision of this insert and the date of consultation, contact Met One Technologies for current information.

MANUFACTURED BY

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