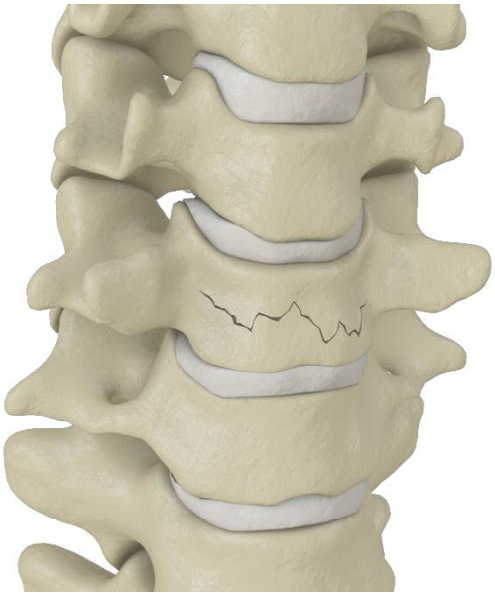
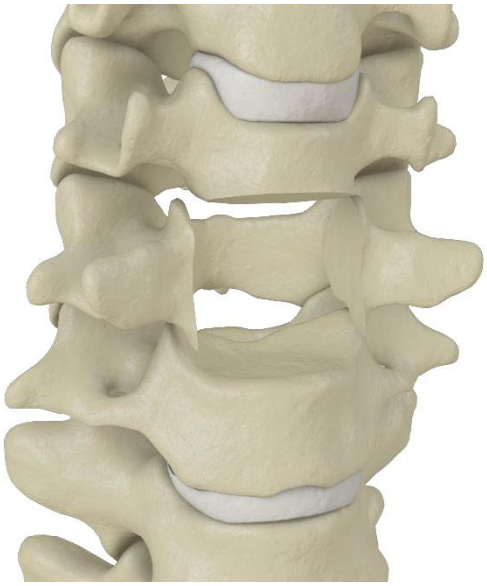
CAPRI® Cervical 3D Expandable Corpectomy Cage System Surgical Technique

I. PATIENT POSITIONING & DISCECTOMY/CORPECTOMY

Perform a standard anterior exposure to the affected spinal level. Using standard disc removal and corpectomy instrumentation, remove the affected vertebrae and discs, and prepare the endplates for fusion.





II: CORPECTOMY CAGE DESIGN

The CAPRI® Cervical 3D Expandable Corpectomy Cage System incorporates K2M's Lamellar 3D Titanium Technology™ and features in-situ height expansion and endplate angulation.

The corpectomy cages are available in 13 x 16 and 14 x 18 mm footprints.

13 x 16 mm

14 x 18 mm

This product is intended for export and is not sold or offered for sale in the United States.

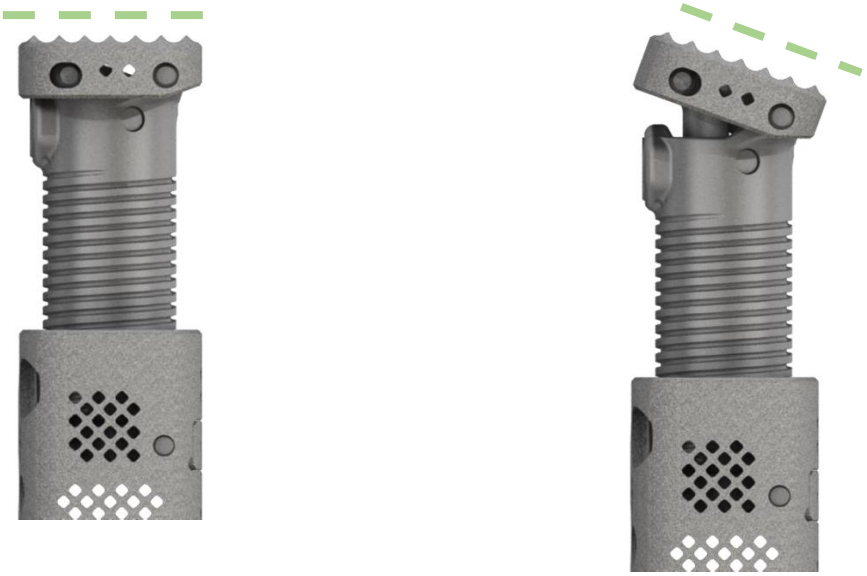
II: CORPECTOMY CAGE DESIGN (CONT.)

Each footprint incorporates a fixed endplate design of either 0°, 5°, or 10°.

0° **5°** **10°**

The articulating endplate allows for continuous endplate angulation adjustments up to 20°. Each footprint ranges in heights from 18–74 mm.

0° **20°**



This product is intended for export and is not sold or offered for sale in the United States.

III. CORPECTOMY CAGE SELECTION

Use the Footprint Trials to identify the footprint size most appropriate for the endplates (Figure 1). To determine the appropriate height for the corpectomy cage, measure the prepared space using the Caliper (Figure 2).

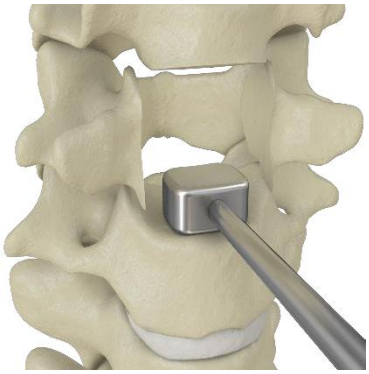


Figure 1

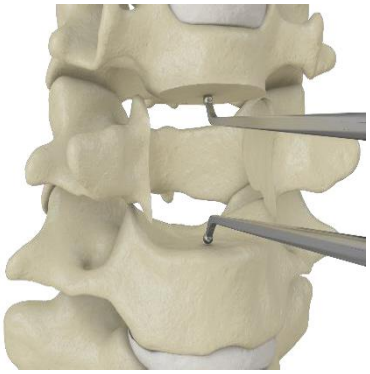
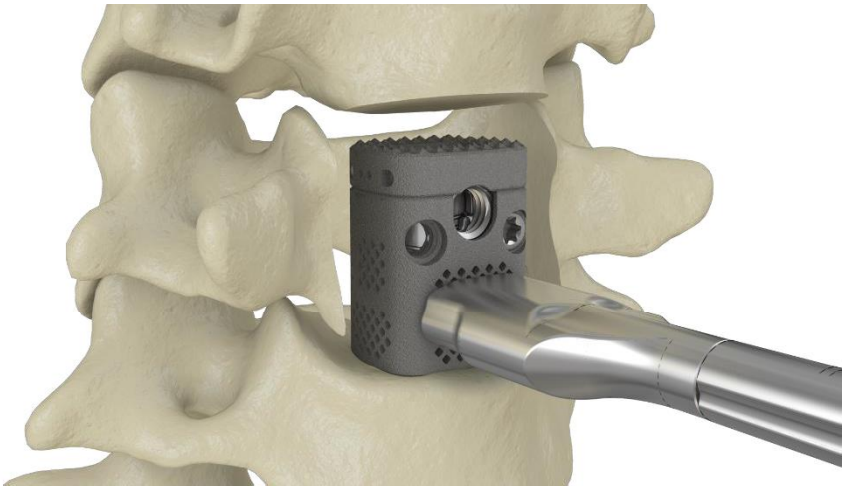


Figure 2

IV. SMALL CORPECTOMY CAGE INSERTION

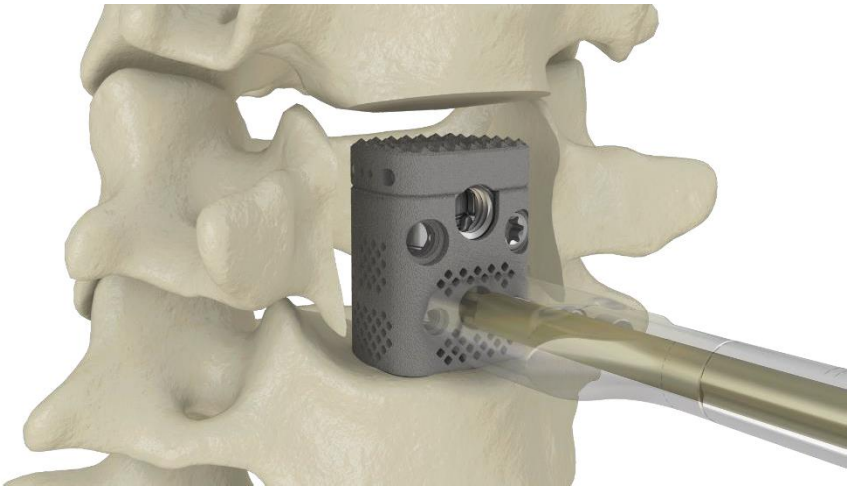
With the desired cage selected, use the Size 10 Non-Tapered Driver attached to the AO Spin Top Handle to thread the Inserter onto the cage and introduce the cage into the site. An optional handle for the Inserter is available if needed. Use the Implant Pusher to assist in positioning the cage.



This product is intended for export and is not sold or offered for sale in the United States.

V. CAGE HEIGHT EXPANSION

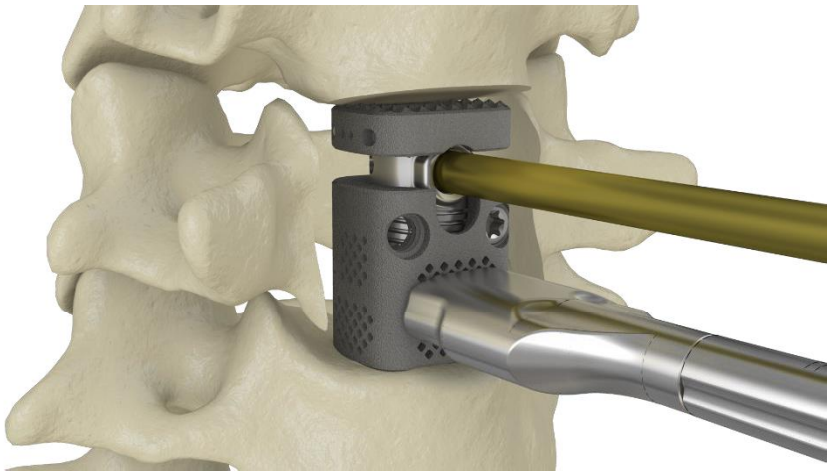
To expand the CAPRI Cervical 3D Expandable Corpectomy Cage, pass the Height/Angle Driver—connected to the grey 12 in-lbs Torque Limiting Handle—down the cannulated shaft of the Inserter. Turn the Driver clockwise to expand the height of the cage. If necessary, to collapse the height of the cage, turn the Height/Angle Driver counter-clockwise.



This product is intended for export and is not sold or offered for sale in the United States.

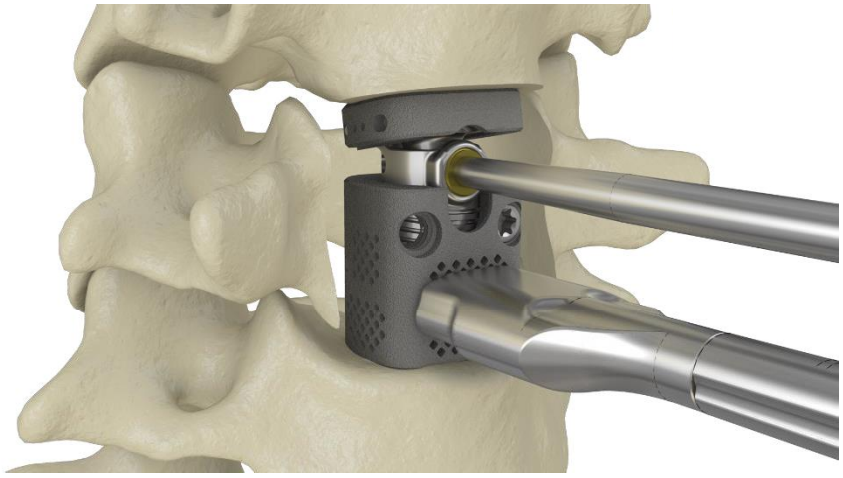
VI. ENDPLATE ANGULATION ADJUSTMENT

Once the cage has been expanded to the desired height, the Height/Angulation Driver can be used to adjust the angulation of the articulating endplate to match the desired lordosis of the adjacent vertebral body. Attach the Height/Angulation Driver to the gray 12 in-lbs Torque Limiting Handle and use it to engage the set of gears located just below the articulating endplate. By turning the Height/Angulation Driver clockwise, the anterior aspect of the cage will increase in height. By turning the Height/Angulation Driver counter-clockwise, the anterior aspect of the cage will decrease in height.



VII. FINAL LOCKING

With the desired height and angulation achieved, use the Size 10 Tapered Driver attached to the AO Spin Top Handle to insert the Angle Locking Screw over the gears and provisionally tighten into the implant. If desired, use the Angle Adjustment Guide when inserting the Angle Locking Set Screw. Remove the Driver and final tighten the angle locking screw using the Size 10 Non-Tapered Driver attached to the 12 in-lbs Torque Limiting Handle. The Torque Limiting Handle will emit an audible “click” once it reaches the necessary torque.

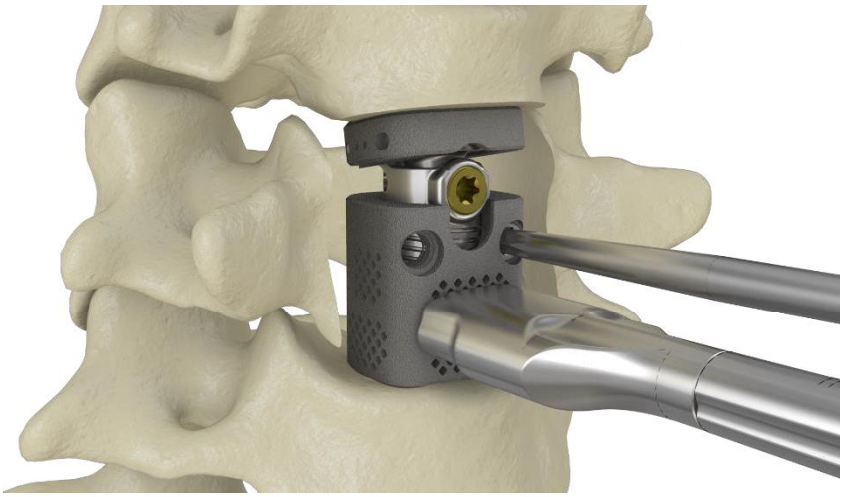


This product is intended for export and is not sold or offered for sale in the United States.

VII. FINAL LOCKING (CONT.)

Using the Size 10 Non-Tapered Driver attached to the 12 in-lbs Torque Limiting Handle, final lock the pre-assembled height locking set screw located in the anterior aspect of the cage. The Torque Limiting Handle will emit an audible “click” once it reaches the necessary torque.

NOTE: The angle locking screw and the pre-assembled height locking set screw must be final tightened to 12 in-lbs in order to finalize the construct.

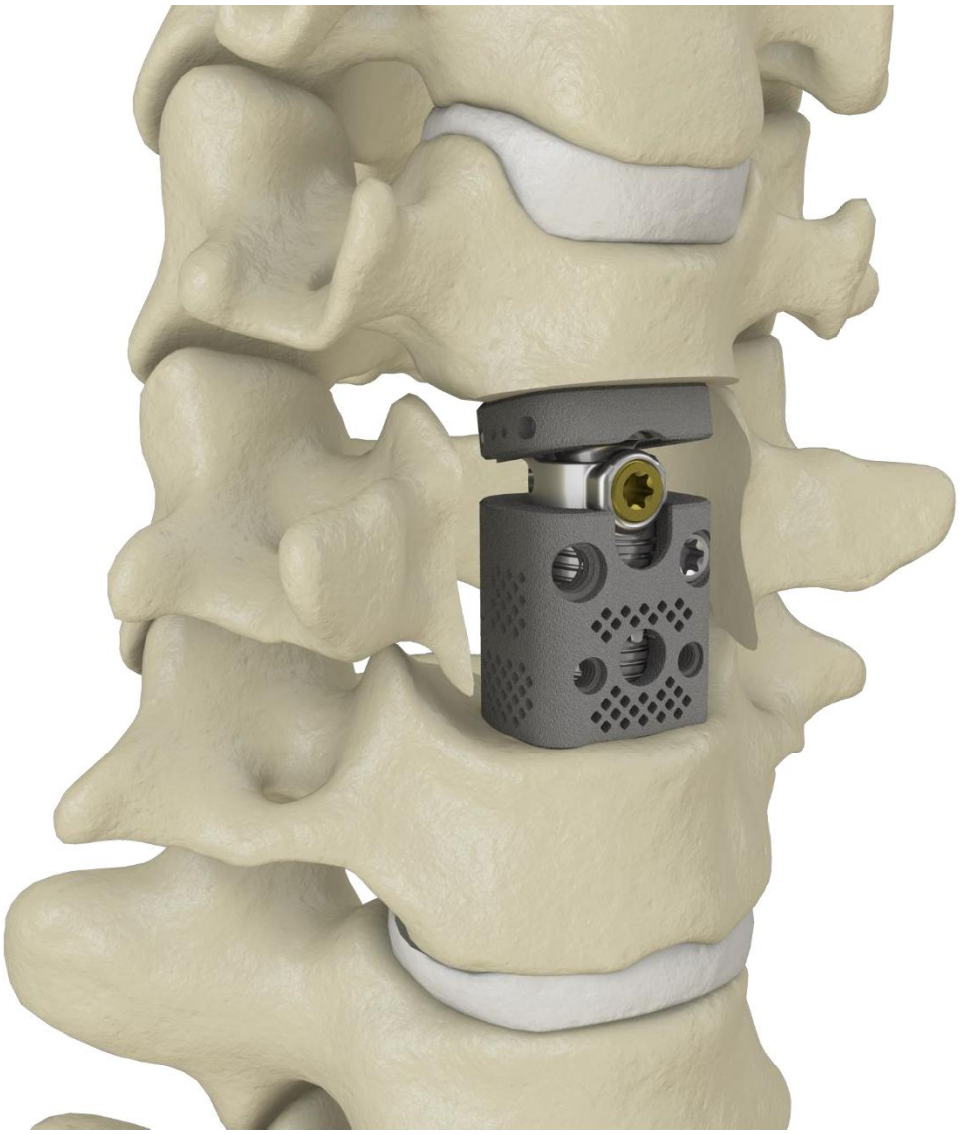


If removal of the implant is needed, re-attach the Inserter to the cage. Using the Size 10 Tapered Driver attached to the AO Spine Top Handle, unlock and remove the angle locking screw, and untighten the pre-assembled height locking set screw. If necessary, the Height/Angulation Driver can be used to decrease the angulation of the cage prior to removal by engaging the set of gears located just below the articulating endplate and turning the Height/Angulation Driver counter-clockwise. Collapse the height of the cage by inserting the Height/Angulation Driver into the Inserter and turning the Driver counter-clockwise. With the cage still attached to the Inserter, remove the cage from the corpectomy space.

This product is intended for export and is not sold or offered for sale in the United States.

STEP VIII: FINALIZING THE CONSTRUCT

Apply a supplemental internal fixation device appropriate for the implanted level, such as K2M Posterior Cervical Screw and Hook Systems, or K2M Anterior Cervical Plate Systems, to finalize the construct.



This product is intended for export and is not sold or offered for sale in the United States.

K2M
COMPLEX SPINE INNOVATIONS℠

CAPRI®
CERVICAL 3D EXPANDABLE

⚠ BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT

This booklet is designed to assist in using the CAPRI™ Corpectomy Cage Systems. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

DEVICE DESCRIPTION

The CAPRI Corpectomy System implants are vertebral body replacement devices that are designed in a variety of lengths, widths and heights to match the patient's anatomy. Solid (titanium) and adjustable (titanium and cobalt chrome) cages are available and can be implanted via posterior, anterior or lateral approaches.

INDICATIONS

When used as a thoracolumbar vertebral body replacement device, the CAPRI Corpectomy Cage System is intended for use in the thoracolumbar spine (T1 to L5) to replace collapsed, damaged, or unstable vertebral bodies due to tumor or trauma (i.e. fracture). The CAPRI Corpectomy Cage Systems is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The CAPRI device may be used with allograft or autograft.

When used as a cervical vertebral body replacement device, the CAPRI Corpectomy Cage System is intended for use in the cervical spine (C3-C7) in skeletally mature patients to replace diseased or damaged vertebral bodies due to tumor, trauma (i.e. fracture), or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The CAPRI device may be used with allograft or autograft.

For all the above indications the CAPRI implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

MATERIALS

The implants of the CAPRI Corpectomy Cage Systems are manufactured from Titanium (per ASTM F3001), Titanium Alloy (per F136), and Cobalt Chrome (per ASTM F1537).

CLEANING/ REPROCESSING OF K2M SURGICAL INSTRUMENTS

K2M surgical instruments are supplied non-sterile and must be thoroughly cleaned prior to sterilization. While it is recommended that the following steps are included in a decontamination/ reprocessing protocol the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for K2M implants or disposable surgical instruments.

Contaminated instruments should be wiped clean of visible soil at the point of use, to prevent drying of soil and contaminants in and on the device.

Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean K2M surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of 1 minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water. Automatic cleaning may be used in addition to manual cleaning. Do not ultrasonically clean torque limiting handles.

STERILIZATION

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The following steam autoclave cycles are recommended, however sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for assuring sterility..

	Autoclave Cycle	Temperature	Time	Drying Time
USA	Prevacuum	132°C (270°F)	4 minutes	30 minutes
Outside USA	Prevacuum	134°C (273°F)	3 minutes	30 minutes

Usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation is recommended.

Sterile Devices

Implant components labeled as STERILE are gamma irradiated.

CAUTION: Do not use if package is damaged. If the tamper proof seals or sterile packaging appear to be compromised or damaged, return the package and its contents to K2M.

CAUTION: The implants are intended for single use only. ⊗ Do not attempt to clean or resterilize the implants. Reprocessing of single use devices may introduce risks associated with guaranteeing sterility assurance.

STORAGE

Store sterile packages in a well-ventilated area that provides protection from dust, insects, moisture, and vermin.

Use caution during sterilization and storage. Do not allow contact with metal or other hard objects that could damage the finish or prevent proper use. (See Preoperative Warnings and Precautions).

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prion decontamination protocol. K2M recommends contacting the Centers for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

INSTRUCTIONS FOR USE 📖

(For complete instructions refer to the appropriate surgical technique provided by your local K2M sales representative.)

The CAPRI Corpectomy Cage Systems should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.

CONTRAINDICATIONS

1. The CAPRI Corpectomy Cage Systems is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, drug/ alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. This device is not recommended for patients who have received prior fusion at the level(s) to be treated. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. This device is not intended for use except as indicated.

POTENTIAL ADVERSE EVENTS

1. Potential adverse events include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
2. Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

WARNINGS AND PRECAUTIONS

1. The CAPRI Corpectomy Cage Systems is intended for use for the indications listed. Safety and effectiveness of the implants have not been established for other applications. The implants are for single use only and are not designed to be combined with devices from other manufacturers ⊗
2. For optimum results careful preoperative diagnosis and planning, meticulous surgical technique and extended postoperative care by experienced spinal surgeons are essential. Prior to use, the surgeon should be specifically trained in the use of this system and the associated instrumentation to facilitate correct selection and placement of the implants. The size and shape of bones and soft tissue place limitations on the size and strength of the implants and proper selection will reduce the risk of breakage or migration of the device.
3. Patient selection and compliance is extremely important. Spinal implant surgery on patients with conditions listed under Contraindications may not be candidates for this procedure. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a titanium implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
4. Potential risks identified with the use of this device system which may require additional surgery include device component failure, loss of fixation, non-union, fracture of the vertebra, and neurological, vascular or visceral injury.
5. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Especially avoid sharp or reverse bends and notches.
6. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
7. The CAPRI Corpectomy Cage Systems implants are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.
8. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating, migration or imaging artifacts in the MR environment.

PREOPERATIVE

1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
2. Preoperative planning should identify degree of correction possible without neurological damage using techniques similar to other Partial Vertebral Body replacement procedures.
3. Use care in handling and storage of the implants. Prior to surgery all components should be inspected and any evidence of damage or corrosion should be reported to your local K2M sales representative.
4. An adequate inventory of implant sizes should be available at the time of the surgery.
5. All components should be cleaned and sterilized before use.
6. Before the initial experience we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device.

OPERATIVE

1. The primary goal of this surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. The placement of the vertebral body replacement implants should be checked radiographically prior to final tightening of the construct.
3. Care should be taken when positioning the implants to avoid neurological damage.

POSTOPERATIVE

1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.
2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
3. Implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone, even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
4. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
5. Surgical implants must never be reused. An explanted titanium implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

PI062-2A11-00 Rev. 0

K2M, Inc.
600 Hope Parkway SE
Leesburg, VA
571.919.2000

Emergo Europe
Prinsessegracht 20
2514 AP
The Hague
The Netherlands

www.K2M.com
©2017 K2M, Inc. All rights reserved.
K2-75-7008-02 Rev. 0
Actual device color may vary. Consult product catalog for details. This product is intended for export and is not sold or offered for sale in the United States.

K2M, Inc.
Leesburg, Virginia 20175
USA
PH 1.866.526.4171 • 1.571.919.2000
FX 1.866.862.4144

EC REP
Emergo Europe
The Hague, The Netherlands
PH +31.70.345.8570
FX +31.70.346.7299

CE 0086