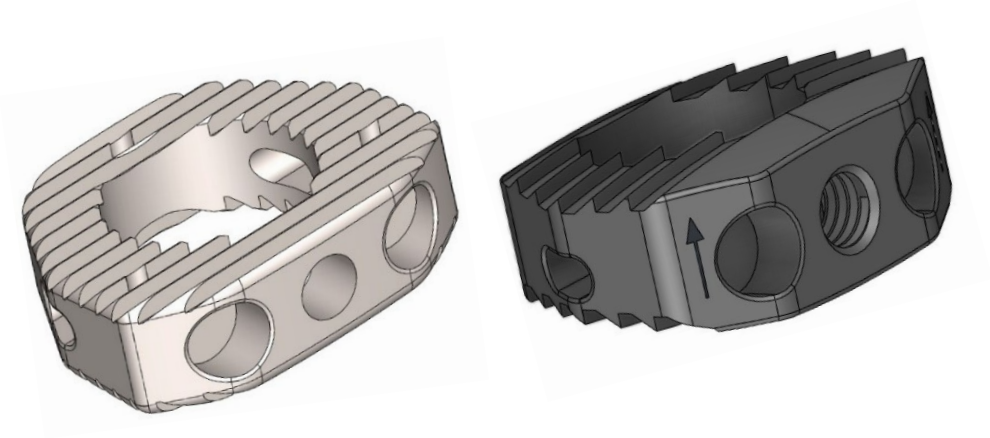
Kentrospine

ACC Anterior Cervical Cage System

Surgical Technique



Contents

Product Overview

Introduction

The Anterior Cervical Cage (ACC) is an essential device used in spinal implant surgery, particularly in the treatment of cervical spine disorders such as degenerative disc disease, herniated discs, and cervical spondylosis. The ACC is designed to provide stabilization to the spine following the removal of a damaged intervertebral disc and is typically used in anterior cervical discectomy and fusion (ACDF) procedures.

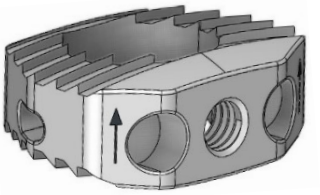
The ACC cage is typically inserted during an anterior cervical discectomy and fusion (ACDF) surgery. This procedure aims to relieve pressure on the spinal cord and nerves by removing damaged disc material and stabilizing the spine with the cage, which promotes fusion of the vertebrae. The cage is usually made from biocompatible materials such as titanium, PEEK (polyetheretherketone), or carbon fiber, designed to support the vertebral structure while facilitating bone growth across the disc space.

Advantages of the ACC Cage in Surgery

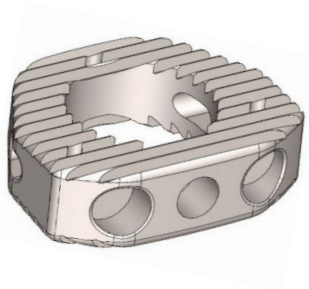
- Stability: Provides immediate stability to the cervical spine, crucial for healing and bone growth.
- Biomechanical Compatibility: ACC cages are designed to mimic the natural biomechanical properties of the spine.
- Promotes Fusion: The structure and materials of the ACC cage support bone growth across the intervertebral space, promoting long-term spinal fusion.
- Minimally Invasive: The anterior approach allows for a less invasive procedure with typically faster recovery times compared to posterior approaches. This technique has become a standard approach for many cervical spine pathologies, and its success hinges on the careful selection of materials, precise surgical technique, and proper postoperative care.

Features

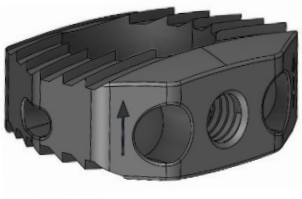
Kentrospine ACC Anterior Cervical Cage System



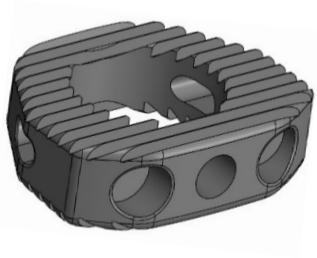
ACC PEEK (Curved)



ACC PEEK (Wedge)



ACC Ti (Curved)



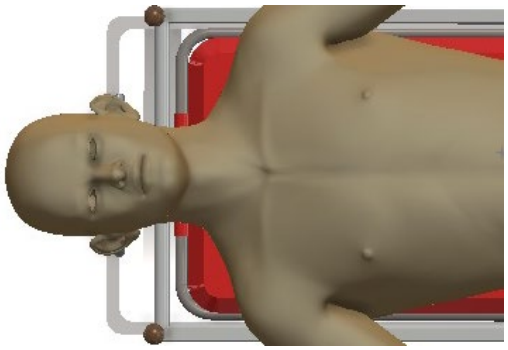
ACC Ti (Wedge)

- Available in multiple heights to accommodate various patient anatomies.
- **Better Graft Chamber**: Large graft chamber, which accommodates bone graft to promote fusion.
- **Solid Frame cage without sharp edge**: For biomechanical stability and smooth insertion into the disc space which minimize the risk of injury.
- **Cranial & Caudal Anchoring element**: Which is in the form of groves for a firm implant fit and high primary stability.
- **Groves**: Which provides better grip of implant on end plate.
- **Directional serrations**: Directional serrations to resist expulsion.
- **Threaded insertion feature**: Threaded insertion feature for exceptional implant control.
- **Tapered nose**: Tapered nose- for ease of insertion.
- **Lordotic Angle**: 7° of lordosis to closely approximate the curvature of the cervical spine.
- **Marking on Implant**: For the ease of identification for using placement instruments.

Surgical Technique

Step 1

Positioning the Patient:



- **Supine Positioning**: The patient is placed supine, meaning they lie flat on their back on the operating table. This position provides optimal access to the anterior cervical spine, which is necessary for the anterior cervical discectomy and fusion (ACDF) approach.
- **Use of a Radiolucent Operating Table**: A radiolucent
- table is used to allow for unobstructed X-ray imaging during the surgery. "Radiolucent" means the table doesn't block or interfere with X-ray or fluoroscopic imaging, which is important to verify proper alignment and positioning during the procedure.
- **Neutral Neck Positioning**: The patient's neck should be placed in a sagittally neutral position—this means the neck should not be excessively flexed or extended. Keeping the neck in a neutral alignment is important to avoid distorting the anatomical relationship between the cervical vertebrae and to facilitate a clear view on the X-ray. A supporting cushion is placed under the patient's neck to help maintain this position and support the natural curvature of the cervical spine.
- **Ensuring Access to the C6–C7 Region**: If the surgery is targeting the C6–C7 level (common in cervical spine procedures), it's crucial that the patient's shoulders do not obstruct the X-ray monitoring. The shoulders must be positioned so that they do not block the view of the C6–C7 vertebrae during the X-ray or fluoroscopy. This is especially important for real-time monitoring of surgical progression and to guide accurate placement of the ACC cage.

- **Vertebrae Visibility**: It's essential that both vertebrae (above and below the targeted disc space) are completely visible on radiographic imaging. This ensures that the surgeon can precisely monitor the entire surgical field, including the correct removal of the disc, preparation of the vertebral endplates, and insertion of the ACC cage. Full visibility on the X-ray provides guidance in placing the cage correctly and ensures optimal alignment for spinal fusion.

Step 2

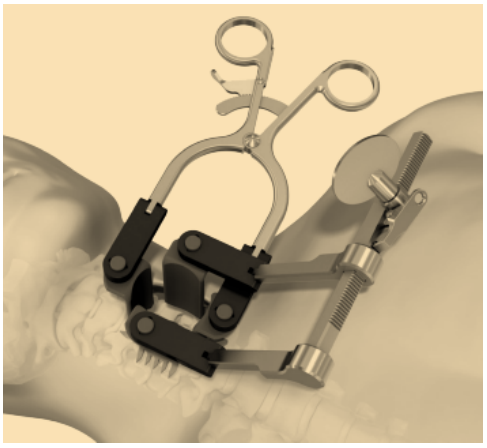
Exposure and Discectomy:

- **Access:**

Begin by locating the correct operative level using radiographic imaging (e.g., fluoroscopy or X-ray). This ensures precise identification of the targeted disc space, typically C5-C6 or C6-C7, based on the surgical plan.

Next, proceed to expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine. This approach involves making a small incision on the anterior neck, which allows access to the cervical spine.

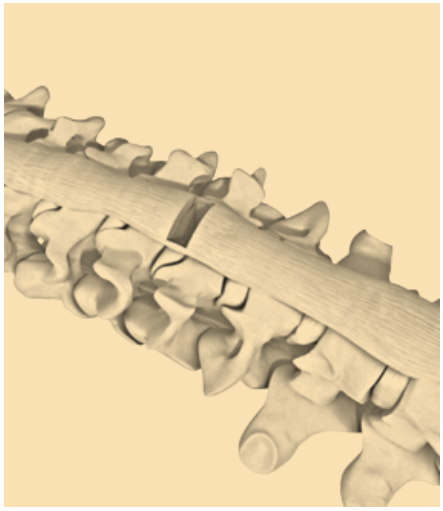
Precaution: When positioning the retractor, take extra care to avoid soft tissue damage, particularly to the oesophagus, trachea, and blood vessels. Proper retractor placement is crucial to prevent injury to these structures while ensuring adequate exposure of the spine.



- **Discectomy:**

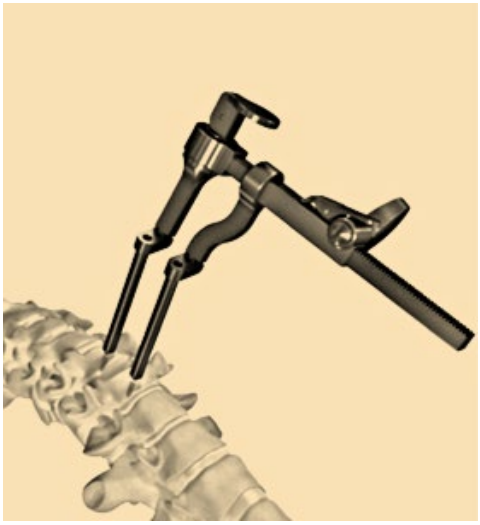
Once the disc space is adequately exposed, proceed with the discectomy. This involves the removal of the damaged intervertebral disc and any associated osteophytes (bone spurs), which are contributing to nerve compression or other spinal pathology.

Prepare the fusion site by carefully removing any remaining disc material and debris from the endplates of the vertebrae. Ensure the vertebral surfaces are adequately prepared to facilitate optimal fusion. The method of preparing the fusion site may vary depending on the clinical indication (e.g., using specialized tools to smooth the vertebral endplates and enhance graft placement).



Step 3

Segment Distraction and end plate preparation:



- Apply controlled segmental distraction by using a distraction instrument to separate the vertebrae at the targeted disc space. Begin by gently engaging the instrument on both vertebral bodies above and below the intervertebral disc.
- Gradually distract the segment to restore the natural disc height and decompress the spinal cord or nerve roots. This step is essential for providing adequate space in the intervertebral space for the insertion of the ACC cage.
- Ensure that the distraction force is applied gradually and evenly to avoid excessive movement or injury to the vertebral bodies or surrounding structures. The distraction should be sufficient to open the disc space without compromising vertebral stability.
- Maintain this distraction to provide optimal access to the disc space while preparing for the next step of endplate preparation. The vertebrae should now be adequately separated to allow for proper cleaning and preparation of the vertebral endplates for the upcoming fusion process. After the discectomy is complete, the next step is to prepare the vertebral endplates. Begin by using appropriate surgical instruments to remove the superficial cartilaginous layers of the endplates. This will expose bleeding bone, which is crucial for promoting bone healing and fusion.
- Adequate cleaning of the endplates is essential for ensuring the vascular supply to the autologous bone graft or bone graft substitute. This vascularity facilitates the fusion process by encouraging bone growth. However, be cautious not to over-clean the endplates, as excessive removal of bone beneath the cartilaginous layer can weaken the vertebral endplates, potentially compromising the structural integrity of the spine.

- Remove any osteophytes (bone spurs) or other bone fragments around the disc space to achieve complete decompression of the neural structures, such as the spinal cord and nerve roots. This step is critical for reducing the risk of residual compression after the ACC cage is inserted. Adequate decompression ensures that there is no pressure on the spinal cord or nerves, which is vital for the success of the procedure and for relieving symptoms like pain or numbness.

Step 4

Implant Size and Shape Determination

- **Choose the Trial Implant:**

Select the trial implant based on the height of the disc space and the specific anatomy of the patient. The height should match the distance between the vertebrae after segmental distraction, ensuring proper restoration of the intervertebral space.

Curved

The trial implant serves as a guide for selecting the appropriate implant size and confirming that the chosen cage will fit properly within the disc space.

- **Determine the Shape of the Trial Implant:**

Select the shape of the trial implant that best matches the geometry of the prepared endplates. This can either be curved or wedge-shaped, depending on the alignment and natural curvature of the cervical spine at the operative level.

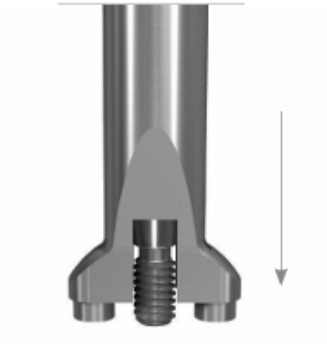
Wedge-shaped

The curved trial implant is typically used when the endplates have a natural, convex shape, while the wedge-shaped trial implant is selected for a more lordotic alignment to better match the vertebral anatomy and restore the normal cervical curvature.

Step 5

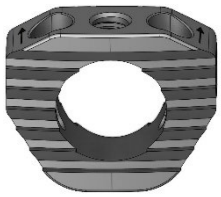
Connect trial implant to holder

- Once the appropriate trial implant has been selected based on size and shape, connect the trial implant to the holder for ease of placement and manipulation during the procedure.
- Ensure that the trial implant is securely engaged with the holder, taking care to align the cranial and caudal ends properly. The holders are typically etched with the labels "CRANIAL" and "CAUDAL" to assist in correctly orienting the implant. These markings ensure that the trial implant is positioned in the correct direction relative to the vertebral bodies.



Connecting curved trial implant

- When using a curved trial implant, it is important to ensure that the curved surface faces cranially (toward the head). The trial implants and final implants are usually marked with two arrows pointing cranially to indicate the correct orientation.



- Connect the trial implant to the holder by aligning the curved surface of the implant with the "CRANIAL" etching on the holder. This ensures that the implant is positioned correctly, with the cranial side of the implant matching the cranial surface of the vertebrae, maintaining proper anatomical alignment.

Connecting wedge shape trial implant

- For wedge-shaped trial implants, there is no dedicated cranial or caudal side, unlike curved implants. This means that the wedge-shaped implant can be attached to the holder with any surface facing cranially.
- Connect the trial implant to the holder ensuring that one of the flat surfaces of the wedge-shaped implant is aligned with the "CRANIAL" side of the holder. Because the wedge-shaped implant is symmetrical, you have flexibility in positioning it as long as the implant's proper orientation for the procedure is maintained.

Step 6

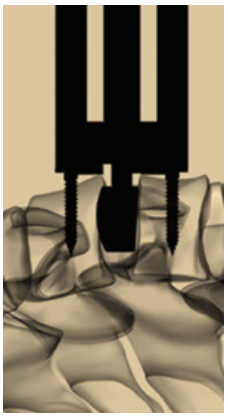
Attach depth limiter to holder

- The depth limiter can be attached to the side of the holder to assist with controlling the depth of implant insertion.
- Ensure that the depth limiter is securely attached to the holder. The depth limiter features a stop that will come into contact with the anterior edge of the vertebral body as the Kentrospine ACC implant is being inserted.
- The stop is designed to prevent over-insertion of the implant, ensuring that it is positioned approximately 2mm beyond the anterior edge of the vertebral body. This precise positioning is important for achieving optimal 2implant placement while maintaining the correct alignment of the spine and avoiding any injury to surrounding structures.

Step 7

Insert trial implant and check size

- Before inserting the trial implant, carefully confirm that all disc material and debris have been completely removed from the insertion path. This step is critical to prevent any remnants of disc material from being displaced into the spinal canal, which could potentially cause complications such as nerve compression or irritation.
- Once the path is cleared, proceed to insert the trial implant into the prepared disc space, ensuring that it fits properly. The implant should slide smoothly into place without resistance, confirming that the chosen size is appropriate for the disc space.
- Check the size of the trial implant to ensure it fits well within the prepared intervertebral space, providing proper alignment and restoration of disc height. The implant should match the curvature and anatomy of the vertebrae to ensure a stable foundation for the final implant. If necessary, adjust the implant size to ensure optimal fit before proceeding.
- Select the trial implant that corresponds to the estimated height of the intervertebral cage based on preoperative imaging or surgical judgment. Remember, the height of the trial implant will match the height of the final cage to ensure proper fitting.
- The trial implant is designed to mimic the final cage in terms of size and shape but is typically made of a softer material (such as titanium or PEEK) to prevent damage to the vertebral endplates during insertion.



- **Correct Cranial/Caudal Alignment of Holder:**
  Important: Orient the trial implant holder in the correct cranial/caudal alignment with the disc space. Ensure that the trial implant is positioned appropriately with respect to the vertebral bodies to maintain spinal alignment and avoid causing any improper positioning. The holder should be aligned in such a way that the trial implant will enter the disc space in a straight, controlled manner.

- **Insertion of the Trial Implant:**
  Carefully insert the trial implant into the disc space, ensuring that it moves smoothly along the insertion path without damaging the surrounding tissues or structures. Controlled and Light Hammering: If necessary, use a mallet for controlled and light tapping to advance the trial implant into the intervertebral disc space. Apply gentle force to avoid excessive impaction and prevent endplate damage.

Precautions:

- Avoid excessive impaction force during trial implant insertion. Applying too much force could cause endplate fractures or compromise the integrity of the vertebral bodies.
- Image Intensifier (Fluoroscopy): Use an image intensifier or fluoroscopy to monitor the position of the trial implant as it is advanced. This ensures the implant is correctly placed and prevents misalignment during insertion.

Assessment of Fit:

- Check the fit of the trial implant once it is inserted into the disc space. The implant should fit tightly between the vertebral endplates when the segment is fully distracted. This ensures that the implant is stable and will provide adequate support for the final fusion. If the trial implant appears to be too loose or too tight, it indicates the need for a different size.

- **Adjusting Size if Necessary:**

  If the fit is not optimal, select the next larger or smaller size trial implant and repeat the insertion process. It's often best to begin with smaller height trial implants to avoid overstretching the disc space. Once the correct fit is found with the smaller height, trial with a taller implant can be done if necessary. This approach helps reduce the risk of over-distracting the segment, which could cause instability or complications.

- **Confirming Correct Position:**

  After inserting the trial implant, confirm that it fits well between the vertebral endplates, and that there is no significant movement or loosening. The trial implant must not rock or shift when light pressure is applied. Ensure it provides the correct spinal alignment and the disc space height is restored appropriately.

- **Removal of Trial Implant:**

  Important Warning: Trial implants are not meant for final implantation. They must be removed before proceeding with the insertion of the permanent interbody cage. Once the correct size is determined, carefully remove the trial implant using the designated removal instruments. Take care to avoid damaging the disc space or surrounding structures.

Step 8

Determine Size:

- Based on the trial implant that has been tested for the correct fit, select the final interbody fusion cage that corresponds to the size of the trial implant.
- The cage height, width, and lordotic angle should align with the trial implant. The curved or wedge-shaped cage must match the trial implant's size and geometry, ensuring proper fit and spinal alignment.
- **Selecting the Curved or Wedge-Shaped Cage:**
- **Curved Cage**:
- A curved cage is typically selected if the desired goal is to restore or maintain the natural lordotic curve of the cervical spine.
- This cage type has a slight curve that mirrors the cervical spine's natural curvature and can help maintain proper alignment of the vertebrae during the healing process.
- Curved cages are ideal for preventing the segment from collapsing into kyphosis (forward bending) after surgery.


Curved

Wedge-Shaped Cage:

- A wedge-shaped cage may be used in cases where there is kyphosis (forward bending) or loss of lordosis that needs to be corrected.
- The wedge shape allows for a restoration of the normal disc height and helps to restore cervical lordosis by pushing the vertebral bodies into better alignment.
- It is especially useful in cases where the natural curvature is severely altered and needs to be corrected during the procedure.


Wedge-shaped

Ensure Compatibility:

- Compatibility with Trial Implant: Ensure that the chosen cage corresponds to the trial implant in terms of height, width, and lordotic angle. Double-check the size with imaging or by comparing the trial implant directly to the cage.
- Confirm that the final cage is fully compatible with the disc space, ensuring that it will not interfere with adjacent structures or cause instability.

- Excessive Impaction Force: Avoid excessive impaction with the cancellous bone impactor to prevent damaging the implant. Overly aggressive impaction can lead to implant deformation or compromise the integrity of the vertebral endplates.
- Use light, controlled force during insertion to ensure the implant is seated securely in place without causing any damage to the surrounding bone or the implant itself.

Step 9

Prepare the implant

Remove the Depth Limitator from the Holder:

- Remove the depth limitator from the holder if it is attached. The depth limitator is used to prevent over-insertion of the implant and can be detached to allow free placement of the implant into the disc space.

Connect the Selected Implant to the Holder:

Connecting the Curved Implant:

- Orientation of the Curved Implant: The curved surface of the implant must always face cranially (towards the head). The curved implant is typically marked with two arrows pointing cranially to indicate the direction.

Positioning the Implant on the Holder:

- Attach the curved implant to the holder, ensuring that the cranial implant surface (marked with the arrows) aligns with the side etched "CRANIAL" on the holder. This will ensure the implant is positioned correctly for insertion into the disc space.

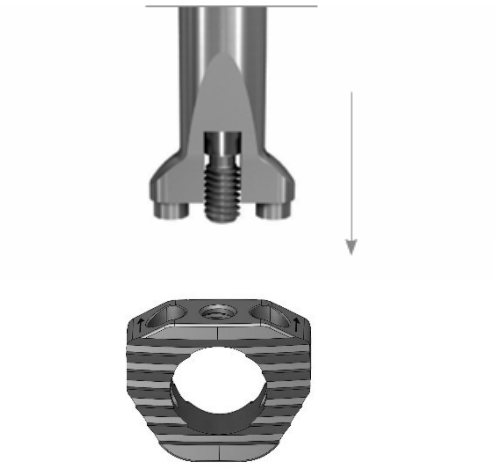
Double-check that the curved surface is facing upwards (cranially), maintaining the correct spinal alignment.

Connecting the Wedge-Shaped Implant:

- Orientation of the Wedge-Shaped Implant: Wedge-shaped implants do not have a specified cranial or caudal side, making them more flexible in terms of orientation.

Positioning the Wedge-Shaped Implant:

- The wedge-shaped trial implants and implants can be connected to the holder with either surface pointing cranially, as there is no specific cranial or caudal direction.
- However, it is important to align the wedge implant with the anatomical requirements of the patient (i.e., correcting kyphosis or maintaining lordosis).



Place the Kentrospine ACC Cage Implant into the Open Packing Block:

- Once the implant is securely attached to the holder, place the Kentrospine ACC cage implant into the open packing block. This packing block stabilizes the implant and ensures that it is in the correct position before insertion into the disc space.

Cranial Side Facing Up:

- Ensure that the cranial side of the implant faces upwards while placed in the packing block. This helps maintain the correct orientation during the next steps.

Precaution:

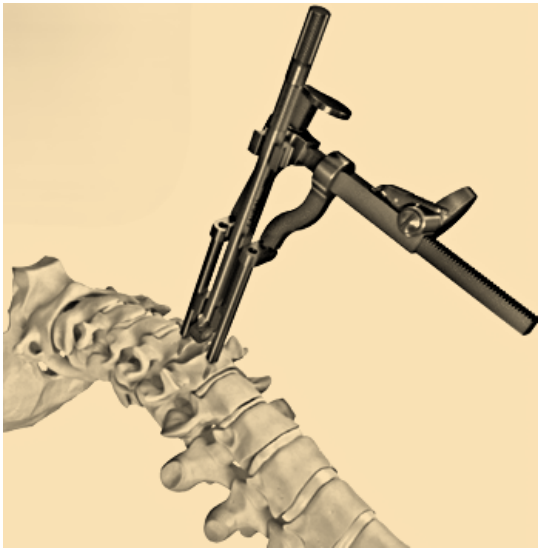
- Always confirm the orientation of the implant before proceeding to ensure it aligns with the desired spinal curvature.
- Handle the implant carefully during placement to avoid any unnecessary stress or damage to the implant, especially when placing it in the packing block.

Step 10

Implant Insertion

Attach the Depth Limitator to the Holder:

- If necessary, attach the depth limitator to the side of the holder. This tool helps limit how deep the implant is placed into the disc space, ensuring that it is seated at the proper depth without being over-inserted.
- This step is optional but may be beneficial in cases where precise depth control is required.



Orient the Implant and Holder in the Correct Cranial/Caudal Alignment:

- Ensure that the implant and holder are in the correct cranial/caudal alignment.
- For curved implants, ensure that the curved surface faces cranially.
- For wedge-shaped implants, orientation does not matter as they do not have a specified cranial or caudal side.
- Double-check the implant's orientation in the holder to prevent any incorrect placement.

Insert the Implant into the Distracted Segment:

- Carefully insert the implant into the distracted segment of the cervical spine.
- Distracted segment refers to the space created between the vertebral bodies after distraction, allowing room for the implant.

Positioning with Gentle Impaction:

- If necessary, use gentle impaction with a mallet on the holder to advance the implant into the disc space.
- Apply light, controlled force to avoid damaging the implant or causing excessive movement of the vertebrae.

Release the Distractor and Remove All Instruments:

- After the implant is positioned correctly, release the distractor to allow the vertebral bodies to return to their natural alignment.
- Once the distractor is released, carefully remove all instruments from the surgical field, including the holder and depth limitator (if used).

Position Check with Image Intensifier (Fluoroscopy):

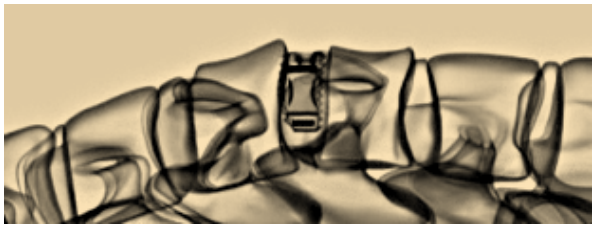
- **Precaution:** Use fluoroscopy or an image intensifier to verify the correct position of the implant during insertion. The implant should be flush with the vertebral endplates, properly aligned, and correctly positioned in the disc space.
  Continuous imaging will help confirm that the implant is placed securely and in the right alignment, reducing the risk of complications.

- **Warning:** Avoid Excessive Impaction**:**
  Excessive impaction can cause implant damage or result in the implant being inserted too deeply, which can lead to complications such as:
  Spinal cord compression
  Nerve root injury
  Implant failure
- Always use gentle, controlled impaction to ensure the implant is placed at the appropriate depth and position without risking damage.

Step 11

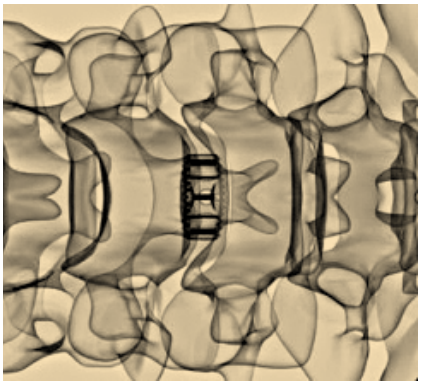
Verifying Cage Position

- The correct positioning of the Kentrospine ACC Cage Implant within the disc space is crucial for achieving optimal spinal alignment and successful fusion.
- The optimal position of the cage is centered within the periphery of the vertebral endplates. This means the cage should not extend beyond the anterior or posterior margins of the vertebral endplates.2
- The implant should be flush with the vertebral endplates, ensuring stability and reducing the risk of migration.



Using Intraoperative Imaging to Verify Position:

- **Anteroposterior (AP) View:** In the AP view, confirm that the cage is centered between the vertebral endplates, with no tilt or displacement.
- **Lateral View:** In the lateral view, ensure the implant is aligned with the natural lordosis of the cervical spine and that it is seated properly between the vertebral bodies.
- **X-ray Markers:** The Kentrospine ACC Cage is equipped with three x-ray markers to help assess implant position during surgery.



- The markers are located:
  - **2mm from the anterior edge** of the implant.
  - **1mm from the posterior edge** of the implant.
- These markers provide visual confirmation of the implant's position relative to the vertebral bodies in both the AP and lateral views.

Final Position Check:

- Ensure correct positioning using intraoperative imaging with the x-ray markers visible in the images.

- **Warning:** Verify the final implant position relative to the vertebral bodies in both the AP and lateral views to ensure it is correctly centered and appropriately seated.

Implant Removal (If required)

- In some cases, the implant may need to be removed before final implantation or if repositioning is required. Here's how to safely remove the Kentrospine ACC Cage Implant.

Implant Removal Technique:

- Attach the implant holder to the implant, ensuring it is aligned correctly in the cranial/caudal direction.
- Cranial/Caudal Alignment: Ensure that the implant is connected to the holder in the correct cranial/caudal orientation to avoid misalignment during removal.
- Carefully remove the implant from the disc space. Avoid sudden movements to prevent any damage to the vertebral structures or the implant.
- **Warning:** Do not push the implant towards the posterior elements (i.e., the spinal cord or nerve roots). This could cause injury to sensitive spinal structures.
- **Precaution:** Avoid excessive tilting of the insertion device to prevent the implant from separating from the holder or becoming damaged during the removal process.

Important Notes:

- Single-Use Implant: The Kentrospine ACC Cage Implant is single-use only. It should not be reused under any circumstances. Once removed, the implant should be discarded.
- Reusing implants could compromise their integrity and lead to an increased risk of complications.

Instruments

RVPACC01 - ACC - Cervical Depth Limiter.

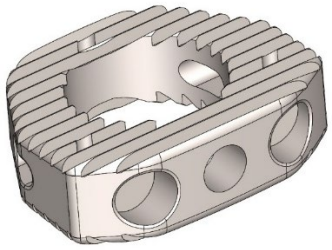
RVPACC02 - ACC - Cervical Implant Holder.

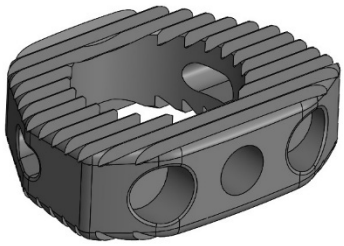
RVPACC03 - ACC - Impactor.

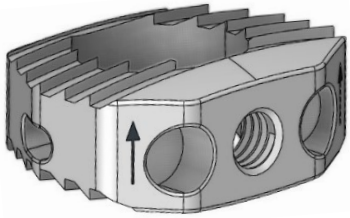
RVPACC04 - ACC - 05mm Curved Trial Implant
RVPACC09 - ACC - 10mm Curved Trial Implant
RVPACC10 - ACC - 05mm Wedge Trial Implant
RVPACC15 - ACC - 10mm Wedge Trial Implant

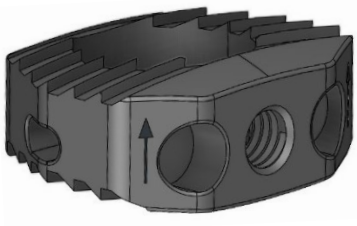
Implants

Kentrospine ACC PEEK (Wedge) 15 X 12.5 - 05mm	ROACC05WP
Kentrospine ACC PEEK (Wedge) 15 X 12.5 - 06mm	ROACC06WP
Kentrospine ACC PEEK (Wedge) 15 X 12.5 - 07mm	ROACC07WP
Kentrospine ACC PEEK (Wedge) 15 X 12.5 - 08mm	ROACC08WP
Kentrospine ACC PEEK (Wedge) 15 X 12.5 - 09mm	ROACC09WP
Kentrospine ACC PEEK (Wedge) 15 X 12.5 - 10mm	ROACC10WP
Kentrospine ACC Ti (Wedge) 15 X 12.5 - 05mm	ROACC05WP
Kentrospine ACC Ti (Wedge) 15 X 12.5 - 06mm	ROACC06WP
Kentrospine ACC Ti (Wedge) 15 X 12.5 - 07mm	ROACC07WP
Kentrospine ACC Ti (Wedge) 15 X 12.5 - 08mm	ROACC08WP
Kentrospine ACC Ti (Wedge) 15 X 12.5 - 09mm	ROACC09WP
Kentrospine ACC Ti (Wedge) 15 X 12.5 - 10mm	ROACC10WP
Kentrospine ACC PEEK(Curved) 15 X 12.5 - 05mm	ROACC05C
Kentrospine ACC PEEK(Curved) 15 X 12.5 - 06mm	ROACC06C
Kentrospine ACC PEEK(Curved) 15 X 12.5 - 07mm	ROACC07C
Kentrospine ACC PEEK(Curved) 15 X 12.5 - 08mm	ROACC08C
Kentrospine ACC PEEK(Curved) 15 X 12.5 - 09mm	ROACC09C
Kentrospine ACC PEEK(Curved) 15 X 12.5 - 10mm	ROACC10C
Kentrospine ACC Ti (Curved) 15 X 12.5 - 05mm	ROACC05C
Kentrospine ACC Ti (Curved) 15 X 12.5 - 06mm	ROACC06C
Kentrospine ACC Ti (Curved) 15 X 12.5 - 07mm	ROACC07C
Kentrospine ACC Ti (Curved) 15 X 12.5 - 08mm	ROACC08C
Kentrospine ACC Ti (Curved) 15 X 12.5 - 09mm	ROACC09C
Kentrospine ACC Ti (Curved) 15 X 12.5 - 10mm	ROACC10C









Indications and Contraindications

Indications, contraindications and possible adverse events:

Indications for use:
Kentrospine Anterior cervical interbody fusion cage implants are intended for use in anterior cervical as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2–C7). The Kentrospine ACC & Kentrospine SELF implants are designed for an anterior cervical approach.
These are available in both PEEK and Titanium material.
Kentrospine Anterior cervical interbody fusion cage implants are indicated for degenerative spine disease. For multisegmental fusions, additional stabilization with a plate is recommended.

Contraindications:
Use of these implants is contraindicated in patients with the following conditions:
1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Prior fusion at the level(s) to be treated.
3. Severe osteoporosis which may prevent adequate fixation.
4. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
5. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
6. Any patient not willing to cooperate with postoperative instructions.
7. Any condition not described in the indications for use.
8. Fever or leukocytosis.
9. Pregnancy.
10. Any other condition that 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, elevations of the white blood count (WBC), or a marked left shift in the WBC differential count.
11. Any case not needing a fusion.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
14. Any case where the implant components selected for used would be too large or too small to achieve a successful result.
15. Any case that requires the mixing of metals from two different components or systems.
16. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
17. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

Potential adverse events:
• Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:
• Loosening, bending or breakage of components
• Displacement/migration of device components
• Tissue sensitivity to implant material
• Potential for skin breakdown and/or wound complications
• Non-union or delayed union or mal-union
• Infection
• Nerve damage, including loss of neurological function (sensory and/or motor), paralysis, dysesthesia, hyperesthesia, paresthesia, radiculopathy, reflex deficit, cauda equina syndrome
• Dural tears, cerebral spinal fluid leakage
• Fracture of vertebrae
• Foreign body reaction (allergic) to components or debris
• Vascular or visceral injury
• Change in spinal curvature, loss of correction, height and/or reduction
• Urinary retention or loss of bladder control or other types of disorders of the urogenital system
• Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise
• Reproductive system compromise including impotence, sterility, loss of consortium and sexual dysfunction.
• Pain or discomfort
• Bursitis
• Decrease in bone density due to stress shielding
• Loss of bone or fracture of bone above or below the level of surgery
• Bone graft donor site pain, fracture, and/or delayed wound healing
• Restriction of activities
• Lack of effective treatment of symptoms for which surgery was intended
• Need for additional surgical intervention

Warning and precautions:

<u>Warnings: Preoperative:</u>

- It is strongly advised that the Kentrospine ACC implant is implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.
- Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- Information related to patient conditions affecting clinical outcomes like severe bone diseases, diabetes, immunosuppressive therapy, and poor bone quality.
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Intraoperative:

- Kentrospine ACC implants must always be applied by enosseal or subperiosteal implantation, i.e. by direct contact with the vital bone.
- Patient positioning, exposure, and discectomy.
- Careful positioning of the retractor is required to protect against soft tissue damage.
- Insert trial implant into the intervertebral disc space, ensuring disc material has been removed from the insertion path, using an image intensifier for position checking, and trialing with smaller height trial implants before taller ones.
- Insert implant into the intervertebral disc space, connecting to the holder, using image intensifier control, avoiding excessive impaction, and verifying final implant position with intraoperative imaging.

Postoperative:

- There is no explicit postoperative information provided in the text excerpt. Typically, postoperative care involves monitoring the patient's recovery in the immediate aftermath of surgery, managing pain, preventing complications, and planning for discharge

PRECAUTION:

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

"Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system".

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system 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 abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

Reprocessing Instructions:

Warnings and Precautions:

- Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices.
- Caution should be exercised when handling devices with sharp points or cutting edges.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Do not stack instruments or place heavy instruments on top of delicate devices.
- Dry, soiled surgical instruments are more difficult to clean. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids, bone and tissue debris, saline, or disinfectants to dry on used instruments.
- The cleaning and sterilization instructions provided below have been validated by Rivarp Medical as being capable of preparing a medical device for reuse. The processor remains responsible for ensuring that the processing, as actually performed using equipment, materials and personnel at the processing facility, achieves the desired result. This requires verification and/or validation and routine process monitoring.

Reprocessing Overview:
The sequence of steps required to prepare non-sterile instruments for use are summarized in the chart below. More detailed instructions for each step are given on the following pages.

Instruments disassemble & reassemble instructions for Cleaning:

Instruments disassemble & reassemble instructions for cleaning:

- Multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self-evident. More specific instructions are given below.
- Disassemble the instruments at point of use area.
- After thorough cleaning, reassemble the small components / parts of the instruments before sterilization and instruments which needs to assemble with other instruments for its desired functions, needs to be reassembled after sterilization by physicians and staff in operating centers prior to surgery.
- During disassembly and reassembly, visually inspect the device and components for wear and tear of components that cannot be assessed in the fully assembled configuration.
- **Note:** If damage or wear and tear (unacceptable deterioration such as corrosion, discoloration, and pitting, cracked seals) is noted that may compromise the function of the instrument, contact your Rivarp Medical Representative for a replacement.
- Mating devices should be checked for proper assembly. Instruments with moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) should be operated to ensure smooth operation throughout the intended range of motion.