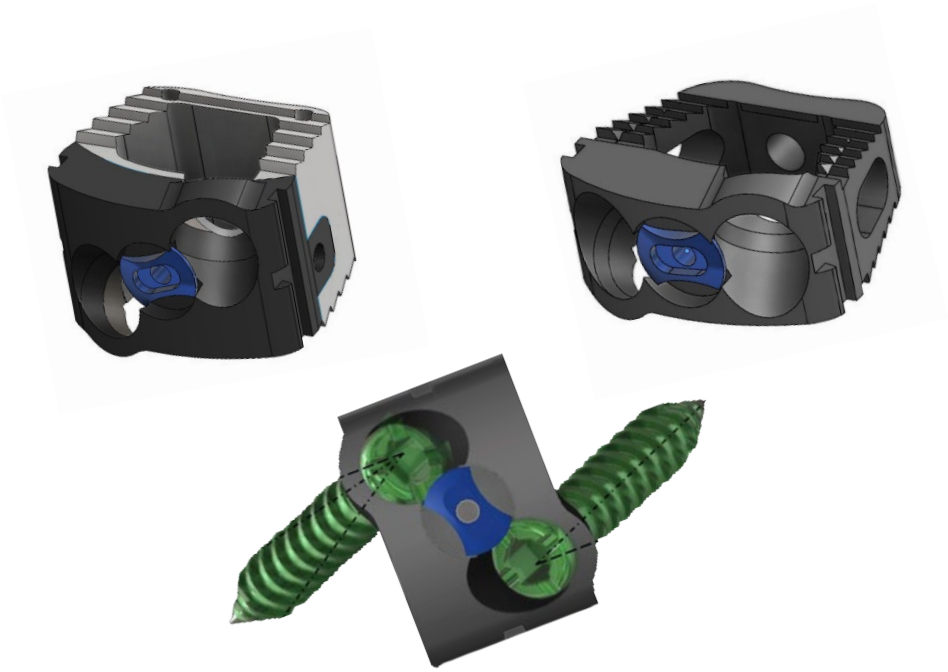
Rivarp MEDICAL

Kentrospine SELF
RVP/SLFSTM/002

Kentrospine

Self Standalone Anterior Cervical Cage

Surgical Technique



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Product Overview

Introduction

The Self-Standalone Anterior Cervical Cage is a cutting-edge implant used in the treatment of cervical spine disorders, such as degenerative disc disease, disc herniation, or cervical spondylosis. It is primarily employed during anterior cervical discectomy and fusion (ACDF) procedures, which involve the removal of a damaged or degenerated cervical disc and the subsequent stabilization of the spine.

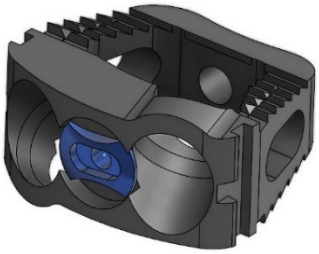
What sets the self-standalone cervical cage apart from traditional fusion devices is its self-locking mechanism, which eliminates the need for additional fixation hardware, such as screws, plates, or external stabilizers. The cage is designed to securely fit into the intervertebral disc space, providing immediate structural support and stabilization. This simplifies the surgical process, reduces operative time, and minimizes the potential for complications associated with more complex hardware.

Made from biocompatible materials like titanium or PEEK (Polyetheretherketone), the cage is typically filled with bone graft material to facilitate the natural fusion process. As the bone graft integrates into the vertebrae, the cervical spine becomes stable, relieving pressure on the spinal cord and nerve roots, which can lead to a reduction in pain and improved mobility.

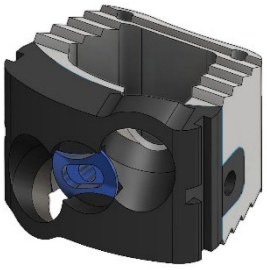
The self-standalone cage is ideal for patients who require a reliable and minimally invasive solution to cervical spine issues. By eliminating the need for additional fixation, this device allows for a more straightforward, efficient, and less invasive surgical approach, while still promoting a successful fusion and recovery.

Features

Kentrospine Self Standalone Anterior Cervical Cage System



Ti



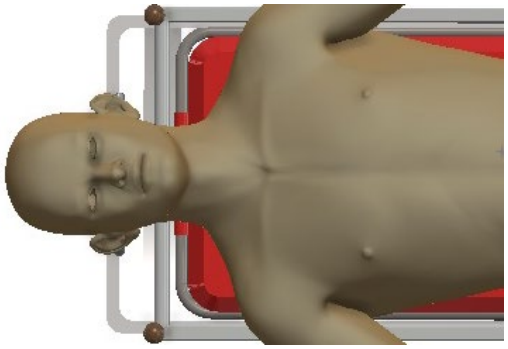
PEEK + Ti

- **Zero Anterior Profile**: It is beneficial in reducing the occurrence and severity of postoperative dysphagia.
- **Implant matches the natural anatomical profile**: Integrated plate and spacer is designed to preserve the anatomical profile of spine.
- **Lordotic Angle**: 6° of lordosis to closely approximate the curvature of the cervical spine.
- **Minimal Surgical Interventions**: It facilitates a less invasive approach through a small incision with less retraction.
- **Titanium Alloy Spacers**: For better fracture resistance and for its biocompatibility feature.
- **Groves on Implants**: which provides better grip of implant on end plates.
- **Camlock Locking Mechanism**: Provides a secure and rigid screw locking interface with cam-lock mechanism.
- **Stability**: Biomechanical testing has proved that the stability of standalone cage is comparable to traditional plates and spacer combination.
- **Available Sizes**: 5mm,6mm, 7mm, 8mm, 9mm,10mm.
- **Locking Screws**: Screws form a bone wedge with $40^0 \pm 5^0$ Cranial /caudal angle.
- One step locking screw.
- Self-tapping screws helps in easy initial engagement.

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 Self Standalone 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 Self Standalone cage. Full visibility on the X-ray provides guidance in placing the cage correctly and ensures optimal alignment for spinal fusion.

Step 2

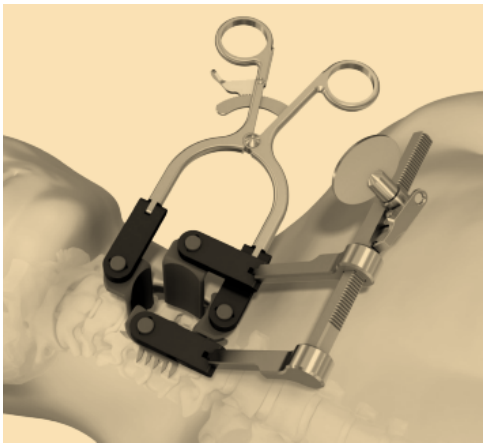
Exposure and Discectomy:

- **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.

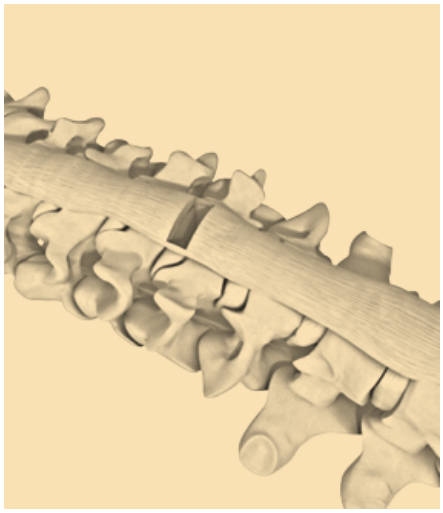
Precaution: When positioning the retractor, take extra care to avoid soft tissue damage, particularly to the oesophagus, trachea, and blood vessels. Proper retractor placement is crucial to prevent injury to these structures while ensuring adequate exposure of the spine.



- **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.

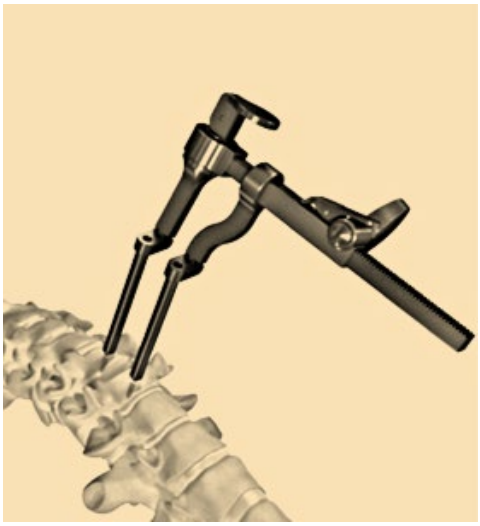
Prepare the fusion site by carefully removing any remaining disc material and debris from the endplates of the vertebrae. Ensure the vertebral surfaces are adequately prepared to facilitate optimal fusion. The method of preparing the fusion site may vary depending on the clinical indication (e.g., using 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 Self Standalone 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 Self Standalone 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:**

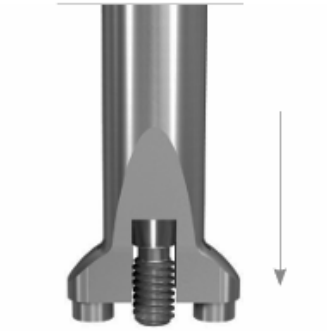
Select the trial implant based on the height of the disc space and the specific anatomy of the patient. The height should match the distance between the vertebrae after segmental distraction, ensuring proper restoration of the intervertebral space.

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.

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.



- For the trial implants, there is no dedicated cranial or caudal side. This means that the 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 implant is aligned with the "CRANIAL" side of the holder. Because the implant is symmetrical, you have flexibility in positioning it as long as the implant's proper orientation for the procedure is maintained.

Step 6

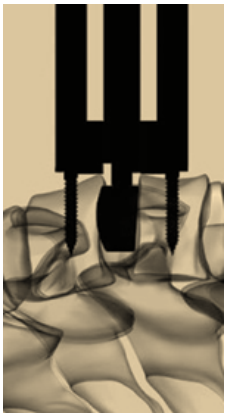
Attach depth limiter to holder

- 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 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 implant 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 cage must match the trial implant's size and geometry, ensuring proper fit and spinal alignment.
- The shape of the implant 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.
- 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

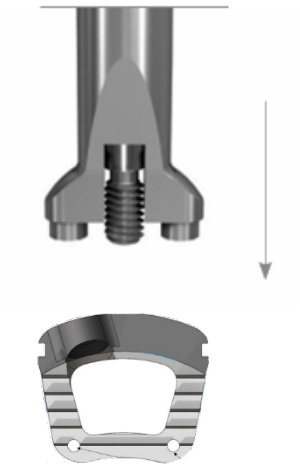
Prepare the implant

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:

- Orientation of the Implant: The implants do not have a specified cranial or caudal side, making them more flexible in terms of orientation.
- The 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 implant with the anatomical requirements of the patient (i.e., correcting kyphosis or maintaining lordosis).



Place the Kentrospine Self Standalone Cage Implant into the Open Packing Block:

- Once the implant is securely attached to the holder, place the Kentrospine Standalone 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:

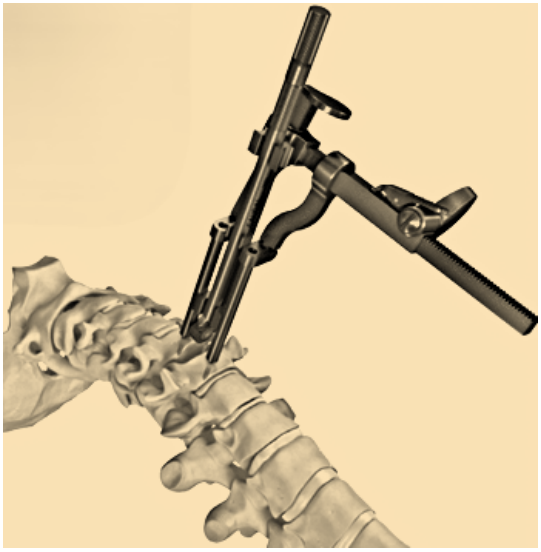
- Always confirm the orientation of the implant before proceeding to ensure it aligns with the desired spinal curvature.
- Handle the implant carefully during placement to avoid any unnecessary stress or damage to the implant, especially when placing it in the packing block.

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.
- 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):

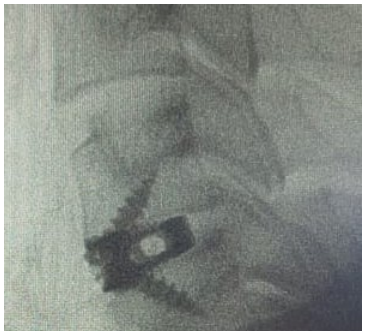
- **Precaution:** Use fluoroscopy or an image intensifier to verify the correct position of the implant during insertion. The implant should be flush with the vertebral endplates, properly aligned, and correctly positioned in the disc space.
  Continuous imaging will help confirm that the implant is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

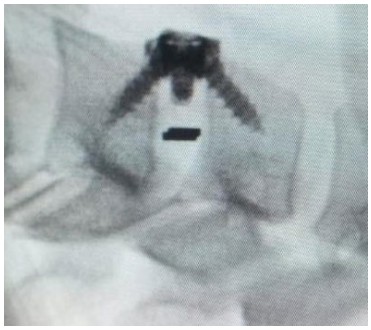
Verifying Cage Position

- The correct positioning of the Kentrospine Self Standalone 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.
- 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 Self Standalone Cage is equipped with the x-ray markers to help assess implant position during surgery.
- 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 Self Standalone 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 Standalone 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

RVPSELF001 - SELF - Awl with Sleeve

RVPSELF002 - SELF - Impactor

RVPSELF003 - SELF - Camlock Screw Driver

RVPSELF004 - SELF - Guide sleeve

RVPSELF005 - SELF - Cage Holder

RVPSELF006 - SELF - Quick Change Handle

RVPSELF008 - SELF - 2.5mm Drill Shaft

RVPSELF007 - SELF - Angled Screw Driver

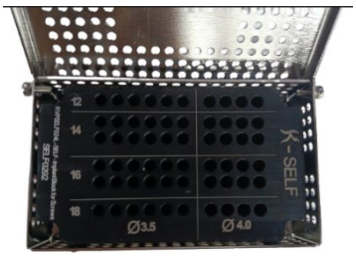
RVPSELF010 - SELF - Locking Screwdriver

RVPSELF011 - SELF - Hexagonal Bit, RVPSELF012 - SELF - Awl Bit, RVPSELF012 - SELF - Awl Bit

RVPSELF0(14,15,16) SELF - Rasp – 05,07,09 mm

RVPSELF0(17-22) SELF - Rasp – (05-10) mm

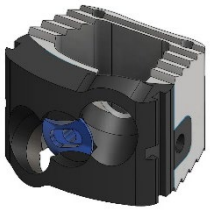
RVPSELF023L - SELF - Implant Layer for Cages

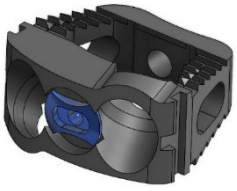


RVPSELF024 - SELF - Implant Box for Screws

Implants

Kentrospine SELF (Stand-alone Cervical Cages) PEEK+Ti - 05mm	ROSLF05CP
Kentrospine SELF (Stand-alone Cervical Cages) PEEK+Ti - 06mm	ROSLF06CP
Kentrospine SELF (Stand-alone Cervical Cages) PEEK+Ti - 07mm	ROSLF07CP
Kentrospine SELF (Stand-alone Cervical Cages) PEEK+Ti - 08mm	ROSLF08CP
Kentrospine SELF (Stand-alone Cervical Cages) PEEK+Ti - 09mm	ROSLF09CP
Kentrospine SELF (Stand-alone Cervical Cages) PEEK+Ti - 10mm	ROSLF10CP
Kentrospine SELF (Stand-alone Cervical Cages) Ti 14 X 12 - 05mm	ROSLF05C
Kentrospine SELF (Stand-alone Cervical Cages) Ti 14 X 12 - 06mm	ROSLF06C
Kentrospine SELF (Stand-alone Cervical Cages) Ti 14 X 12 - 07mm	ROSLF07C
Kentrospine SELF (Stand-alone Cervical Cages) Ti 14 X 12 - 08mm	ROSLF08C
Kentrospine SELF (Stand-alone Cervical Cages) Ti 14 X 12 - 09mm	ROSLF09C
Kentrospine SELF (Stand-alone Cervical Cages) Ti 14 X 12 - 10mm	ROSLF10C
Kentrospine SELF (Stand-alone Cervical Screw) - Ø3.5mm X 12mm	ROACCS3512
Kentrospine SELF (Stand-alone Cervical Screw) - Ø3.5mm X 14mm	ROACCS3514
Kentrospine SELF (Stand-alone Cervical Screw) - Ø3.5mm X 16mm	ROACCS3516
Kentrospine SELF (Stand-alone Cervical Screw) - Ø3.5mm X 18mm	ROACCS3518
Kentrospine SELF (Stand-alone Cervical Screw) - Ø4.0mm X 12mm	ROACCS4012
Kentrospine SELF (Stand-alone Cervical Screw) - Ø4.0mm X 14mm	ROACCS4014
Kentrospine SELF (Stand-alone Cervical Screw) - Ø4.0mm X 16mm	ROACCS4016
Kentrospine SELF (Stand-alone Cervical Screw) - Ø4.0mm X 18mm	ROACCS4018





Indications and Contraindications

Indications, contraindications and possible adverse events:

Indications for use:
Kentrospine SELF standalone 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 SELF implants are designed **for an anterior cervical approach**
Contraindications:

Contraindications include, but are not limited to:
- Any case needing to mix metals from different components.
- any case not described in the indications.
- any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WbC), or a marked left shift in the WbC differential count.
- any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- any patient unwilling to cooperate with postoperative instructions.
- Any condition not described in the indications for use.
- Fever or leukocytosis.
- infection local to the operative site.
- Mental illness.
- Morbid obesity.
- Pregnancy.
- Prior fusion at the level(s) to be treated.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- signs of local inflammation.
- suspected or documented metal allergy or intolerance.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth. Contraindications of this device are consistent with those of other spinal systems.

Potential adverse events:
- All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:
- bone loss or decrease in bone density, possibly caused by stress shielding.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
- Cessation of any potential growth of the operated portion of the spine.
- Change in mental status
- death.
- development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Disassembly, bending, and/or breakage of any or all of the components.
- Dural tears, pseudo meningocele, fistula, persistent CSF leakage, and/or meningitis.
- early or late loosening of the components and implant migration.
- Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation, and/or autoimmune disease.
- Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone of the autograft, or at the bone graft harvest site at, above, and/or below the level of surgery.
- gastrointestinal complications.
- Graft donor site complications including pain, fracture, infection, or wound healing problems.
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Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.
- Wound necrosis or wound dehiscence.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- infection.
- Loss of neurologial function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss, and/or spasms.
- non-union (or pseudarthrosis), delayed union, and mal-union.
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- scar formation possibly causing neurological compromise around nerves and/or pain.
- subsidence of the device into vertebral body(ies).
- Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
NOTE: additional surgery may be necessary to correct some of these anticipated adverse events.

Warning and precautions:

Preoperative:
- Before surgery, it is crucial to inform the patient about the potential risks associated with the implantation of the system.
- These risks include death, device component fracture, loss of fixation, non-union, vertebral fracture, neurological injury, and vascular or visceral injury.
- Patients with certain degenerative diseases (such as diabetes, rheumatoid arthritis, or osteoporosis) or who have undergone previous spinal surgery may have higher risks of complications like implant breakage or spinal fracture.
- It's important to ensure that the patient understands these risks and the limitations of the treatment methods specific to this system.

Intraoperative:
- During the surgery, the implantation of the components should strictly adhere to the recommended surgical technique to minimize risks.

- The components of the system are made from PEEK radiolucent polymer, titanium alloy.
- Mixing these components with stainless steel from other systems is not advisable due to metallurgical, mechanical, and functional reasons. Surgeons should be experienced in spinal surgery and familiar with the specific techniques required for this system to reduce the likelihood of complications related to incorrect implantation or inadequate asepsis.

- **Preoperative:**
- After surgery, patients should be monitored closely for signs of complications such as device failure (fracture, loss of fixation), non-union, neurological deficits, or vascular issues.
- Patients with previous spinal surgery may experience different clinical outcomes, which should be carefully managed postoperatively.
- The limitations and risks associated with the implantation should be communicated clearly to the patient, and they should be informed about the potential need for additional surgeries to address any complications that may arise.
- Additionally, general surgical risks should be discussed to manage patient expectations and ensure appropriate postoperative care.

PRECAUTION:

"The implantation of Kentrospine SELF Cage System Systems 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.