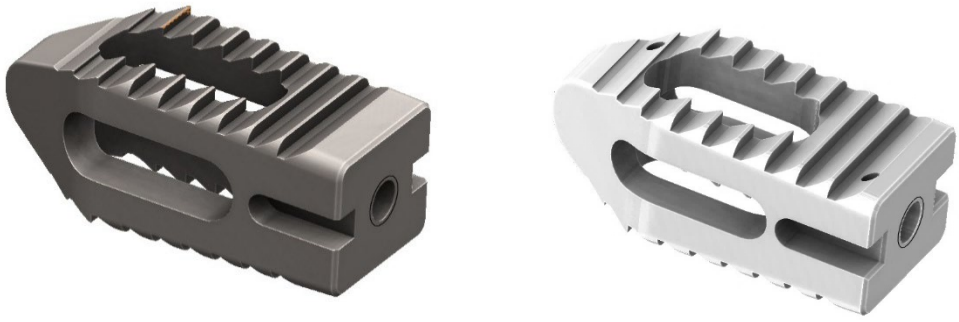
Kentrospine

PLIF Lumbar Interbody Fusion Cage

Surgical Technique



Contents

Product Overview

Introduction

Posterior Lumbar Interbody Fusion (PLIF) is a widely used surgical procedure designed to treat various lumbar spine conditions, such as degenerative disc disease, spondylolisthesis, and spinal instability. The primary goal of PLIF is to stabilize the spine and promote fusion between the affected vertebrae by removing the degenerated disc and inserting an interbody fusion cage. This technique involves accessing the spine through a posterior (back) approach, allowing the surgeon to directly address the disc space between two vertebrae.

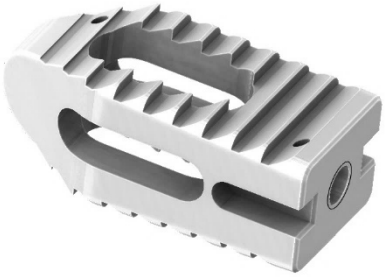
A critical component of the success of PLIF surgery is proper patient positioning. The position of the patient directly impacts the surgeon's ability to access the lumbar spine, visualize the surgical site clearly, and perform the procedure effectively. By carefully positioning the patient in a prone position on a specialized operating table, the surgical team ensures optimal alignment of the spine and reduces risks of complications such as nerve injury or pressure sores. Additionally, maintaining the spine's natural curvature, particularly lumbar lordosis, is crucial for providing the necessary access and restoring stability.

In this procedure, the surgeon utilizes intraoperative imaging (such as fluoroscopy) to ensure the precise level of surgery and to guide instrumentation and implant placement. The overall aim is to achieve spinal fusion, relieve pain, and restore proper function to the affected vertebral segment, leading to enhanced stability and improved quality of life for the patient.

Features

Kentrospine PLIF/TLIF Bullet Lumbar Interbody Fusion Cage

Kentrospine PLIF Ti



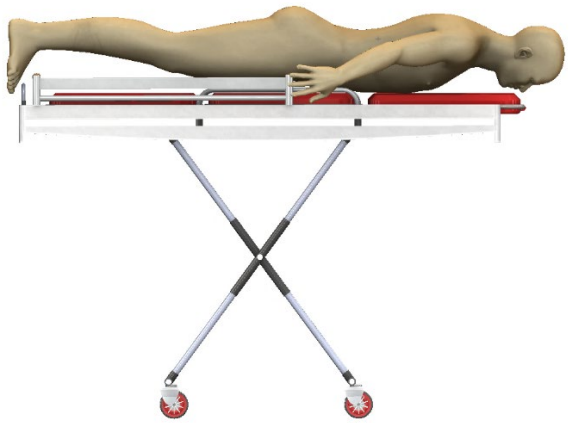
Kentrospine PLIF PEEK

- **Bullet Nose**: Bullet Nose/ Tapered entry – Facilitates ease of insertion.
- **Anatomic Shapes**: For precise & secure implantation.
- **Wide Graft Window**: Optimizes the contact between the graft and vertebral endplates, which enhances the quality of fusion.
- **Anterior & Posterior Window**: Enables graft Vascularization.
- **Groves**: For additional stability and may minimize the potential for expulsion
- **Lordosis Angle**: 5° Lordotic angle of the implant to restore the natural spine lordotic curve and makes a sagittal balance.
- **Titanium Alloy cage**: For better fracture resistance and for its biocompatibility feature
- **Multiple Heights (8 mm-14 mm)**: Adapts to patient anatomy for more secure construct

Surgical Technique

Step 1

Positioning the Patient:



- **Prone Position**: The patient is positioned prone (on their stomach) on a specialized operating table or frame. This allows access to the posterior aspect of the lumbar spine.
- **Spinal Frame or Prone Positioning Device**: The patient is placed on a spinal frame, or Jackson table, designed to allow free hanging of the abdomen. The frame or table is also equipped with supports for the chest, pelvis, and legs, which help maintain proper spinal alignment.
- **Free Hanging Abdomen**: The key feature of this positioning is that the abdomen is allowed to hang freely, creating more space in the lumbar region and reducing pressure on the abdominal organs. This helps to:
- Relieve pressure on the spinal column.
- Reduce venous congestion in the lower extremities.
- Improve access to the surgical site.
- **Protecting Pressure Points**: Care must be taken to protect the patient's pressure points, particularly the eyes, chest, knees, and genitals. This is done by ensuring appropriate padding (e.g., foam pads, gel cushions) is placed at these sites to prevent pressure sores or nerve damage during the procedure.
- The face is usually placed in a headrest or face cradle.
- Pillows or foam pads are placed under the chest and pelvis to relieve pressure on sensitive areas.
- **Restoring Lumbar Lordosis**: In PLIF, proper spinal alignment is essential, particularly to restore the natural lumbar lordosis (curvature) of the spine. The chest and hips must be positioned in such a way as to:
- Maintain or restore lordosis by positioning the patient in a way that allows the spine to have its natural curve.

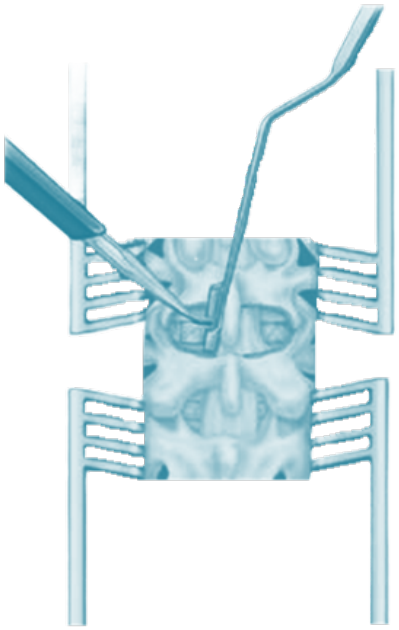
- Positioning of the chest should be such that the upper body does not sag too much, helping prevent excessive thoracic kyphosis.
- The hips may need slight flexion to help achieve a more neutral alignment of the lumbar spine.
- Padding or foam wedges are used under the hips or chest.
- Adjusting the height of the table or the use of a specialized prone support frame helps achieve the desired angle of the spine for optimal surgical access.
- Fine-tuning the position of the patient's head, chest, abdomen, and hips ensures the lumbar spine maintains a neutral to slightly lordotic position, which improves surgical visibility and minimizes the risk of injury.
- **Localizing X-ray/Fluoroscopy**: Before prepping and draping, intraoperative X-ray or fluoroscopy is used to confirm the exact location of the lumbar spine. This step ensures that the surgeon has the correct spinal level to perform the surgery.
- **Spinal Level Confirmation**: Fluoroscopy (real-time X-ray) allows the surgical team to verify that the correct vertebral level is exposed and will be used for the PLIF procedure.
- A radiolucent positioning frame or devices are used to facilitate imaging without interference.
- The X-ray or fluoroscopy helps ensure that any anatomical variations or alignment issues are addressed, ensuring accurate surgical navigation.

Step 2

Laminotomy and Facectomy

Incision of the Annulus

- A 15-blade scalpel is used to make a precise incision in the annulus fibrosus (the outer ring of the intervertebral disc), typically on the lateral side of the dural sac (the protective covering around the spinal cord).
- This incision is made bilaterally (on both sides of the disc space) to allow access to the disc space and facilitate the removal of disc material.
- Care must be taken to avoid damaging the dural sac or nerve roots during this step.



Removal of Disc Material

- Once the annulus is incised, the soft disc fragments or extruded disc material are removed from the intradiscal space (the area within the disc) or extruded fragments (material that has herniated beyond the normal disc space) using disc rongeurs.
- Disc rongeurs are surgical instruments with a sharp-edged grasping mechanism, designed to remove soft or fragmented tissue from the disc space.
- The goal is to remove all disc fragments that may be compressing the neural elements (such as nerve roots) and to clear space for the next steps of the procedure.

Decompression of Neural Elements

- A primary goal of the discectomy is to decompress the neural elements meaning the removal of any disc material that may be pressing on the nerve roots or the spinal cord, which can cause pain, weakness, or neurological deficits.
- The procedure must be done with minimal or no nerve root retraction, as excessive retraction could result in nerve injury or irritation.

Disc Space Distraction (if necessary)

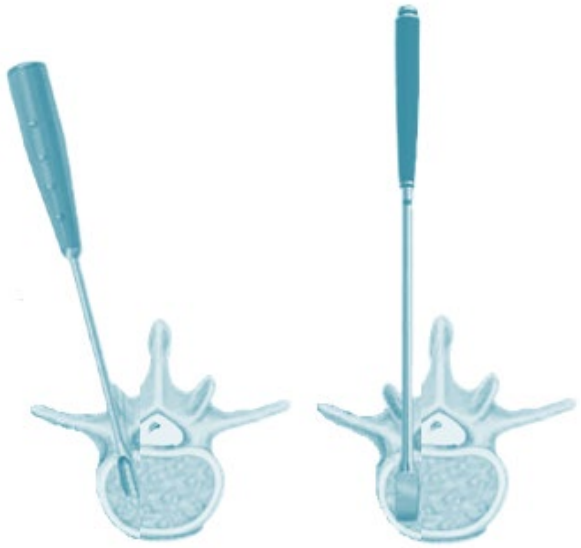
- If there is significant disc space collapse (where the space between the vertebrae has been narrowed due to disc degeneration), disc space distraction is typically performed. This step involves gently distracting (or separating) the vertebral bodies to restore the natural disc height.
- Distraction is often necessary before performing a complete discectomy, as it helps create more space for safely removing the remaining disc material.
- Special instruments, such as distractors or spinal spreaders, are used to achieve the desired distraction, restoring normal disc height and opening the space for the insertion of the interbody fusion cage.

Step 3

Disc Space Preparation

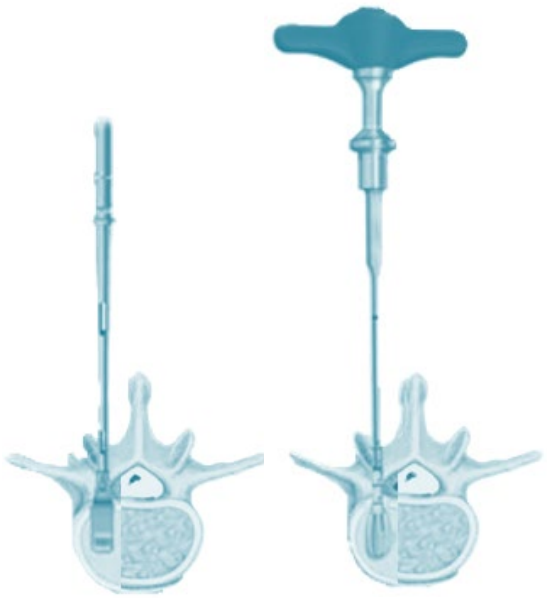
Securing the Distractor/Trial in the Disc Space

- After the initial discectomy (removal of the degenerated disc material), the next step is to secure a distractor or trial device into the disc space.
- Disc distractors are instruments designed to gently separate the vertebrae and restore the natural height of the disc space. This helps to create the proper environment for the fusion cage and enables better visualization of the disc space.
- Trial instruments may also be used to assess the appropriate size and fit of the fusion cage before it is implanted.



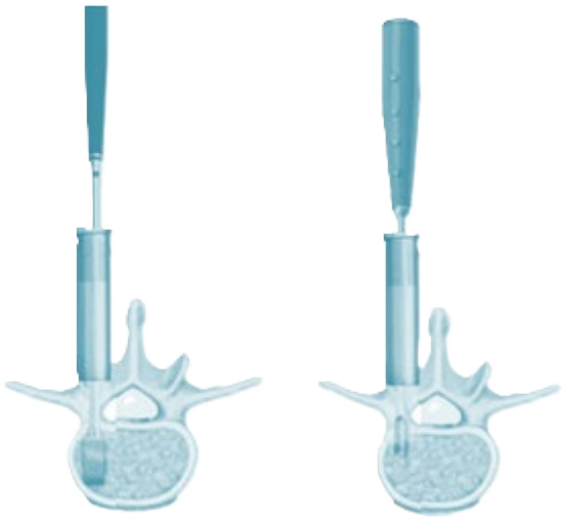
Removing the Remaining Disc Material

- Once the distractor or trial is in place, the remaining disc material (particularly from the endplates of the vertebrae) needs to be removed to provide a clean and roughened surface for optimal fusion.
- This is typically done using Rotate Cutters and Shavers,
- which are specialized instruments designed to clear the disc space.
- Rotate Cutters: These are rotating instruments with a cutting edge that help remove any remaining disc tissue from the endplates. They allow for precise removal of tissue without causing damage to the bone or surrounding structures.
- Shavers: These are another type of instrument used to smooth and refine the surface of the vertebral endplates, making them more conducive to bone graft integration and fusion.



Blunt-Tipped and Side-Cutting Instruments for Safety

- The Rotate Cutters and Shavers used in this step are typically blunt-tipped and side-cutting, which enhances safety during the procedure.
- Blunt tips prevent unintentional injury to surrounding structures, such as the nerve roots, dural sac, or the vertebral body.
- Side-cutting action allows for controlled tissue removal without risking damage to the endplates or other critical anatomical structures.

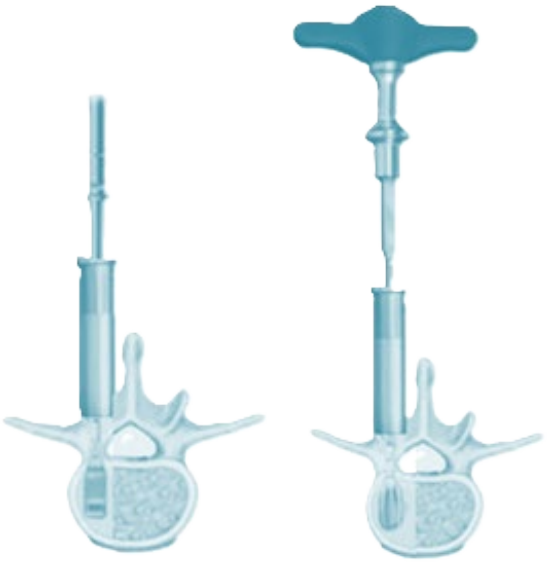


Preparing the Endplates

- The primary goal of this preparation step is to roughen and debride the vertebral endplates. This is essential because:
- The roughened surface of the endplates enhances the biological fusion process, allowing better integration of the bone graft or fusion cage.
- It provides a solid foundation for the interbody fusion cage, ensuring the cage will remain stable and support the vertebrae during the fusion process.

Assessing the Disc Space

- After the distraction, removal of disc material, and preparation of the endplates, the surgeon will assess the size and alignment of the disc space.
- This step may include additional imaging or fluoroscopy to ensure proper alignment before inserting the interbody fusion cage.
- Trial cages may be inserted and removed to verify the correct size and fit before final implantation.

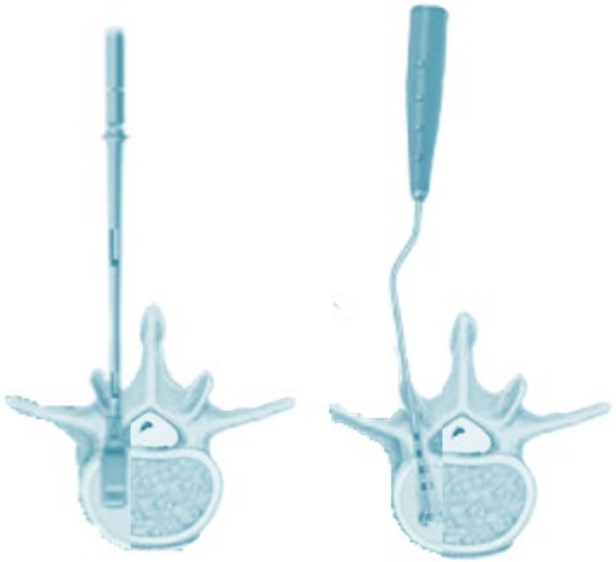


Step 4

End Plate Preparation

Removing Soft Tissue or Cartilage:

- After the intervertebral disc is removed, the surgeon must clear the vertebral endplates (the top and bottom surfaces of the vertebrae that face the disc space).
- Soft tissue or cartilage that remains on the endplates can hinder the fusion process, so it must be thoroughly removed.
- This is accomplished through vigorous scraping or curettage, using specialized instruments like curettes or scrapers. These tools allow the surgeon to carefully and effectively scrape away any remaining tissue from the surface of the vertebrae.

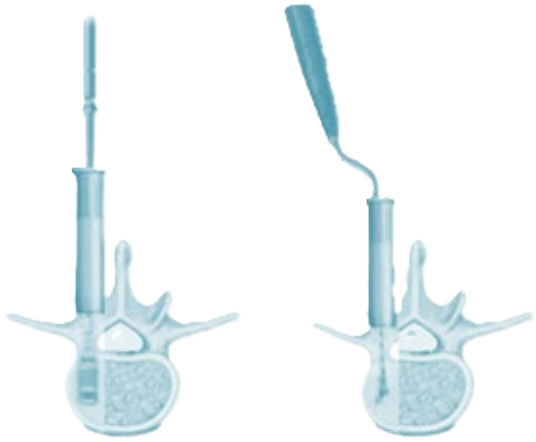


Scraping Technique:

- The surgeon starts by scraping medially (toward the middle or center) under the midline of the endplate. This ensures that the central part of the endplate is cleared first.
- The process is gradual and systematic, with the surgeon working from the center to the lateral (outer) edges of the endplate.
- A sweeping motion is often used to ensure that the scraping covers the entire surface of both the caudal (bottom) and cephalad (top) vertebral endplates.
- The goal is to achieve a clean, roughened surface that is conducive to bone graft incorporation.

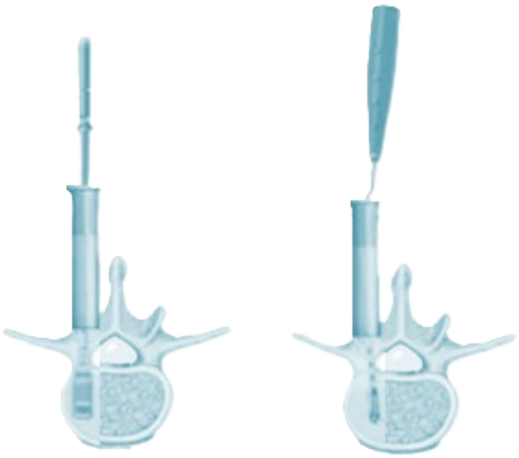
Ensuring Complete Endplate Clearance:

- The scraping continues until both the caudal (lower) and cephalad (upper) vertebral endplates are completely free of soft tissue or cartilage.
- The cleaned surface provides a solid base for the bone graft or interbody spacer to make direct contact with the vertebrae, which is necessary for successful bone fusion.
- A roughened surface is preferred because it enhances the bone-to-bone contact and facilitates the incorporation of the graft over time.



Facilitating Graft Incorporation:

- Removing the soft tissue from the endplates creates an ideal surface for the bone graft or interbody spacer to integrate into the vertebral bone. The graft serves as a scaffold for new bone growth, and over time, it will help fuse the vertebrae together.
- The better the endplates are prepared, the higher the chances of successful fusion, as the bone graft will be able to grow into the vertebrae more effectively.



Step 5

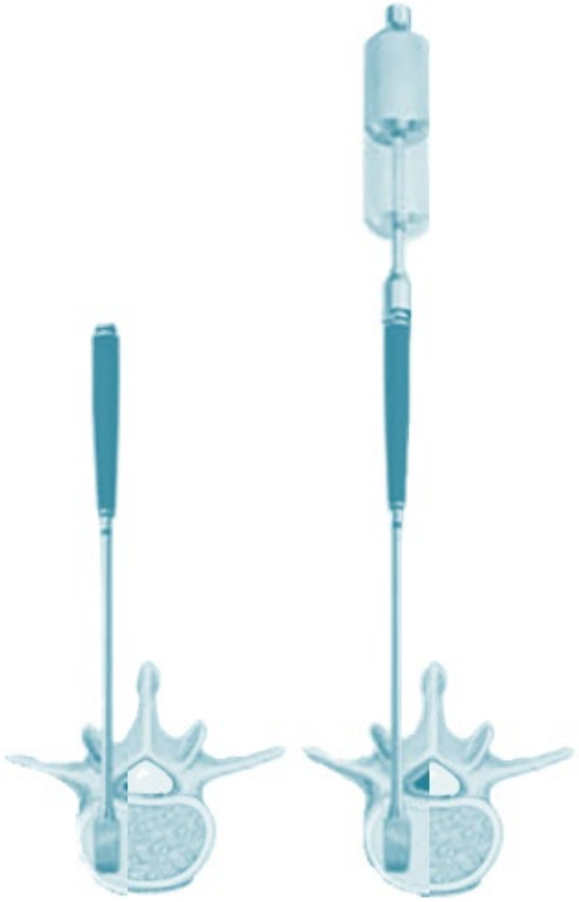
Trial Inserter

Inserting the Trial Devices:

- After the disc space has been distracted (opened), and the endplates have been prepared, the surgeon inserts the trial implant (or trial spacer) into the disc space.
- Multiple trial sizes may be used to find the ideal fit for the patient. The trial spacer should fit snugly in the space between the vertebrae, providing the right amount of support and restoring the proper disc height.
- The surgeon will insert the trials progressively, checking the fit each time, and adjust the height by gradually increasing the size of the trial spacer until the desired disc height is achieved. This is crucial to ensure proper alignment and adequate nerve decompression.

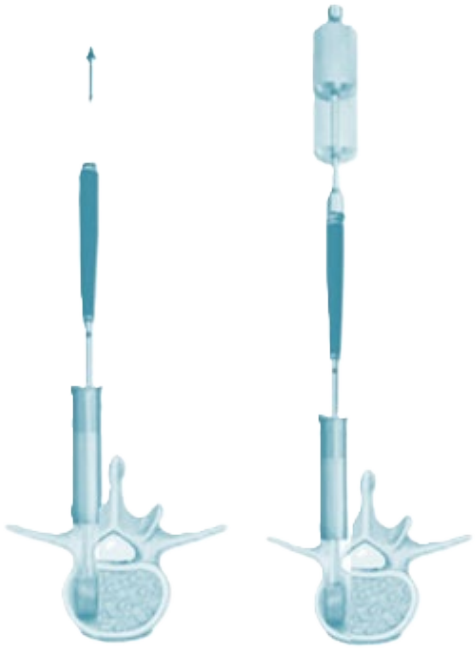
Confirming the Desired Disc Space Height:

- The goal is to restore the original disc height (the space between the vertebrae) as closely as possible. This also helps restore foraminal height to ensure that the nerve roots are not compressed.
- The surgeon assesses the trial spacer's placement in terms of height, fit, and stability. Correct disc height is crucial for maintaining spinal alignment and function, as well as for the success of the fusion.



Slap Hammer for Trial Removal:

- Once the appropriate trial spacer has been selected and the disc space height is confirmed, the surgeon will proceed with the final implant. However, if adjustments or changes are needed during the trial process, a Slap Hammer is used for removing the trial devices.
- A Slap Hammer is a tool with a percussive mechanism. The surgeon uses it to strike the trial inserter or trial spacer gently but firmly to help remove the trial device from the disc space. This tool provides a controlled force to avoid damaging the surrounding vertebrae or tissue during the removal process.
- he Slap Hammer allows for the safe and effective removal of the trial device, enabling the surgeon to switch to a different size or make adjustments as necessary.

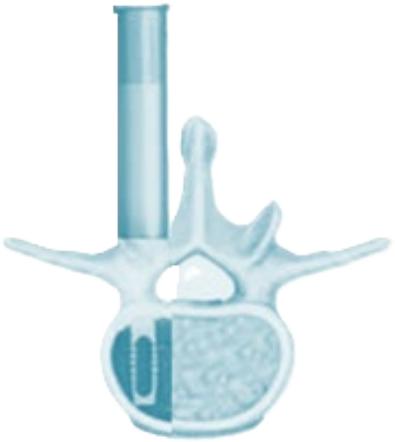


Step 6

Interbody Spacer Insertion

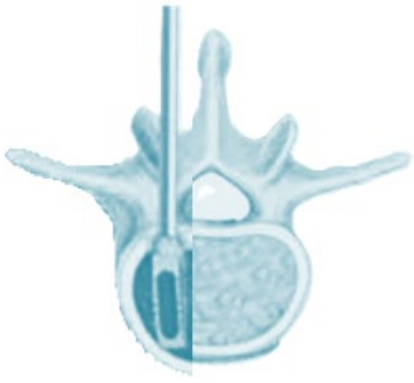
Choosing the Appropriately Sized Interbody Spacer:

- During the trial phase, the surgeon uses trial spacers to test different sizes and determine the appropriate fit for the patient's disc space.
- Once the correct size is identified, the interbody spacer (which can be made of materials like titanium, PEEK, or a combination of both) is chosen based on the trial's outcome. The final spacer should fit snugly within the disc space and restore the proper height between the vertebrae.



Attaching the Spacer to the Inserter:

- The interbody spacer is carefully attached to the spacer inserter tool. The inserter allows for controlled placement of the spacer into the disc space with minimal risk of damage to surrounding structures.
- The inserter is designed to hold the spacer securely while also providing the surgeon with precise control over the insertion process.



Placing Autograft Anteriorly:

- Autograft (bone taken from the patient's own body, typically from the iliac crest or another area) is often placed in the disc space anteriorly (toward the front).
- The bone graft is used to promote fusion between the vertebrae. The autograft is placed before the interbody spacer insertion, filling the space and aiding in the healing and eventual fusion of the vertebrae.

Inserting the Interbody Spacer:

- The interbody spacer is then carefully inserted into the prepared disc space using the inserter. The surgeon gently drives the spacer into place, making sure to apply controlled force.
- The spacer is typically inserted until it is positioned 3mm to 4mm below the posterior margin of the annulus (the outer ring of the disc). This positioning is crucial to ensure the spacer does not impinge on the surrounding structures, such as the spinal cord or nerve roots.

Alignment and Impacting the Spacer:

- It is essential that the interbody spacer is aligned properly within the disc space. This means ensuring that the spacer fits uniformly between the vertebrae, restoring proper disc height and alignment.
- Once the spacer is aligned, the surgeon will gently impact it into place. Impacting refers to carefully tapping or striking the inserter to fully seat the spacer in the disc space, ensuring that it is snugly positioned.
- The surgeon should be cautious during this process to avoid over-impacting, as it could damage the surrounding structures or cause excessive compression.

Confirming Spacer Positioning:

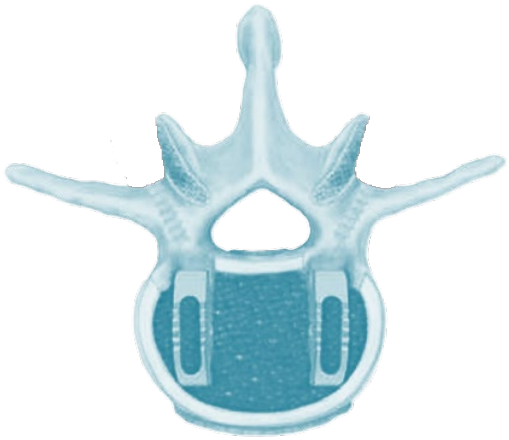
- After insertion, the surgeon checks the final position of the interbody spacer. The goal is to ensure that the spacer is correctly aligned, maintains the desired disc height, and provides a stable base for fusion.
- The interbody spacer should restore the disc space height and prevent collapse or instability in the spine.

Step 7

Final Placement

Probing the Extradural Space and Foraminal Decompression:

- Once the interbody spacer is securely inserted, the surgeon will carefully probe the extradural space and the foramina. This step is done to confirm that there is adequate decompression of the neural elements, particularly the nerve roots.
- Foraminal decompression refers to ensuring that the foramina (the small openings between vertebrae through which nerve roots exit the spinal column) are not narrowed, which could cause pressure on the nerve roots. Restoring the correct disc height and alignment with the interbody spacer should naturally alleviate compression on the nerve roots, but probing is necessary to verify this.
- The surgeon may use specialized instruments to check the space around the nerve roots, ensuring that there is no residual compression, which could lead to post-operative pain or neurological deficits (such as weakness, numbness, or pain radiating down the legs).



Ensuring Adequate Decompression:

- The neural elements including the spinal cord and nerve roots—must be protected and adequately decompressed to avoid any post-surgical complications.
- The surgeon will gently probe the area to verify that no part of the interbody spacer is impinging on the nerve roots or the spinal cord. If any compression is detected, the surgeon may adjust the spacer or perform additional decompression procedures.

Segmental Fixation for Immobilization:

- After confirming that the neural elements are decompressed, the next step is to immobilize the grafted interspace to promote successful spinal fusion. This is done using segmental fixation.
- Segmental fixation typically involves the use of screws, rods, and/or plates to stabilize the vertebrae and interbody spacer while the fusion process takes place. This step is crucial because the spine needs to remain immobile during the healing process to ensure that the graft or spacer fuses successfully with the vertebrae.

Standard techniques for segmental fixation include:

- Pedicle screws: These are inserted into the pedicles of the vertebrae and connected by rods or plates.
- Rods or plates: These are attached to the screws and act as a rigid frame to hold the vertebrae in place.
- The fixation system is designed to provide the necessary stability during the fusion process, allowing the bone graft (or spacer) to gradually heal and form a solid bond between the vertebrae.

Application of Fixation:

- The surgeon will use specialized tools to insert pedicle screws into the vertebral bodies and connect them with rods or plates. These instruments help to lock the spine into the correct position while fusion occurs.
- Fixation must be done with great care to ensure that the hardware is securely placed, without causing any additional stress or movement at the fusion site.

Post-Surgery Considerations:

- The segmental fixation provides immediate stability, but the fusion process may take several months to fully complete. The interbody spacer and autograft will eventually promote the formation of new bone tissue, which fuses the vertebrae together.
- The surgeon will monitor the patient post-operatively for any complications, ensuring that the graft is incorporating and that the neural elements remain decompressed.

Instruments

RVPLIF003 - LIF – Impacter

RVPLIF004 - LIF - T Handle

RVPLIF005 - LIF – Rasp

RVPLIF006 - LIF – Scraper

RVPLIF007 - LIF -
Serrated Cup Curette-L.

RVPLIF008 - LIF - Serrated
Cup Curette-R.

RVPLIF010TH - LIF - Shaver - 07mm to
RVPLIF017TH - LIF - Shaver - 14mm.

RVPLIF018P - LIF - PLIF Sizer - 07mm to
RVPLIF025P - LIF - PLIF Sizer - 14mm.

RVPLIF039 - LIF - Funnel.

RVPLIF040 - LIF - Impactor for Funnel

Implants

Kentrospine PLIF PEEK 10 X 20 - 07mm	ROPLIF102007P
Kentrospine PLIF PEEK 10 X 20 - 08mm	ROPLIF102008P
Kentrospine PLIF PEEK 10 X 20 - 09mm	ROPLIF102009P
Kentrospine PLIF PEEK 10 X 20 - 10mm	ROPLIF102010P
Kentrospine PLIF PEEK 10 X 20 - 11mm	ROPLIF102011P
Kentrospine PLIF PEEK 10 X 20 - 12mm	ROPLIF102012P
Kentrospine PLIF PEEK 10 X 20 - 13mm	ROPLIF102013P
Kentrospine PLIF PEEK 10 X 20 - 14mm	ROPLIF102014P
Kentrospine PLIF PEEK 10 X 22 - 07mm	ROPLIF102207P
Kentrospine PLIF PEEK 10 X 22 - 08mm	ROPLIF102208P
Kentrospine PLIF PEEK 10 X 22 - 09mm	ROPLIF102209P
Kentrospine PLIF PEEK 10 X 22 - 10mm	ROPLIF102210P
Kentrospine PLIF PEEK 10 X 22 - 11mm	ROPLIF102211P
Kentrospine PLIF PEEK 10 X 22 - 12mm	ROPLIF102212P
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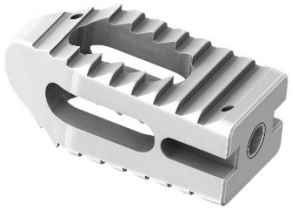
Kentrospine PLIF PEEK 10 X 22 - 14mm	ROPLIF102214P
Kentrospine PLIF PEEK 10 X 22 - 15mm	ROPLIF102215P
Kentrospine PLIF PEEK 10 X 22 - 16mm	ROPLIF102216P



Kentrospine PLIF Ti 10 X 20 - 07mm	ROPLIF102007T
Kentrospine PLIF Ti 10 X 20 - 08mm	ROPLIF102008T
Kentrospine PLIF Ti 10 X 20 - 09mm	ROPLIF102009T
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Kentrospine PLIF Ti 10 X 24 - 15mm	ROPLIF102415T
Kentrospine PLIF Ti 10 X 24 - 16mm	ROPLIF102416T

Indications and Contraindications

Indications, contraindications and possible adverse events:

Indications for use:
Kentrospine Lumbar interbody fusion cage is indicated for use in posterior lumbar interbody fusion in patients with degenerative Disc Diseases (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels.
DDD is defined as disco genic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Additionally, the lumbar cage is indicated to assist in the setting of spinal deformity as a supplement to pedicle screw fixation in patents diagnosed with degenerative scoliosis.
The Kentrospine PLIF implants are designed for **posterior lumbar approach.** These are available in both PEEK and titanium material.

Contraindications:
This device is not intended for cervical spine use. Contraindications include, but are not limited to:

- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any other condition which 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, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing a fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock, bone quality, or anatomic definition.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.
- Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:
- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

Potential adverse events:

- Adverse effects may occur when the device is used either with or without associated instrumentation. The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include, but are not limited to:
- Implant migration.
- Breakage of the device(s).
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis).
- Loss of neurological function, appearance of radiculopathy, dural tears, and development of pain, numbness, neroma, tingling sensation, sensory loss, and/or spasms.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone including the sacrum, pedicles, and vertebral body, and bone graft or bone graft harvest site at, above, or below the level of surgery.
- Retro pulsed graft.
- Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury.
- Cerebral spinal fluid leakage.
- Hemorrhage of blood vessels and hematomas.
- Discitis, arachnoiditis, and or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and pulmonary embolus.
- Bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening or movement of the device(s).
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and vertebral body) and bone graft or bone graft harvest site at, above, or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Change in mental status.
- Cessation of any potential growth of the operated portion of the spine.
- Death.

Warning and precautions:

Preoperative:
Information about the risks associated with reusing, reprocessing, or resterilising implants, emphasizing the importance of maintaining their structural integrity to prevent patient harm.

- Considerations regarding patient selection criteria, such as the impact of smoking, obesity, malnutrition, alcohol/drug abuse, poor bone quality, and nerve paralysis on surgical outcomes.
- Guidance on the necessity of using autogenous or allogenic bone grafts for successful fusion outcomes and the potential consequences if fusion does not occur.
- Focuses on device handling precautions, patient selection criteria, and the importance of using appropriate bone graft materials for successful outcomes.

Intraoperative:

- Instructions and considerations during surgery, particularly in deformity procedures, regarding the correct sizing and placement of implants to ensure adequate endplate engagement and to prevent implant migration or expulsion.
- Emphasis on surgical techniques, including good reduction practices, and the importance of correct selection and placement of implants to optimize surgical outcomes.
- Centers on surgical technique, implant sizing, placement, and the importance of maintaining implant integrity during surgery to avoid complications.

Postoperative:

- There is no explicit postoperative information provided in the excerpt. Generally, postoperative considerations would involve monitoring the patient's recovery, assessing fusion progress, managing pain, and addressing any complications that may arise.
- While not explicitly mentioned, postoperative care typically involves monitoring recovery, assessing fusion progress, and managing any complications that may arise after surgery.

PRECAUTION:
"The implantation of Kentrospine PLIF 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.