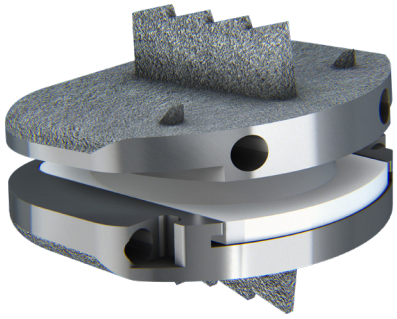
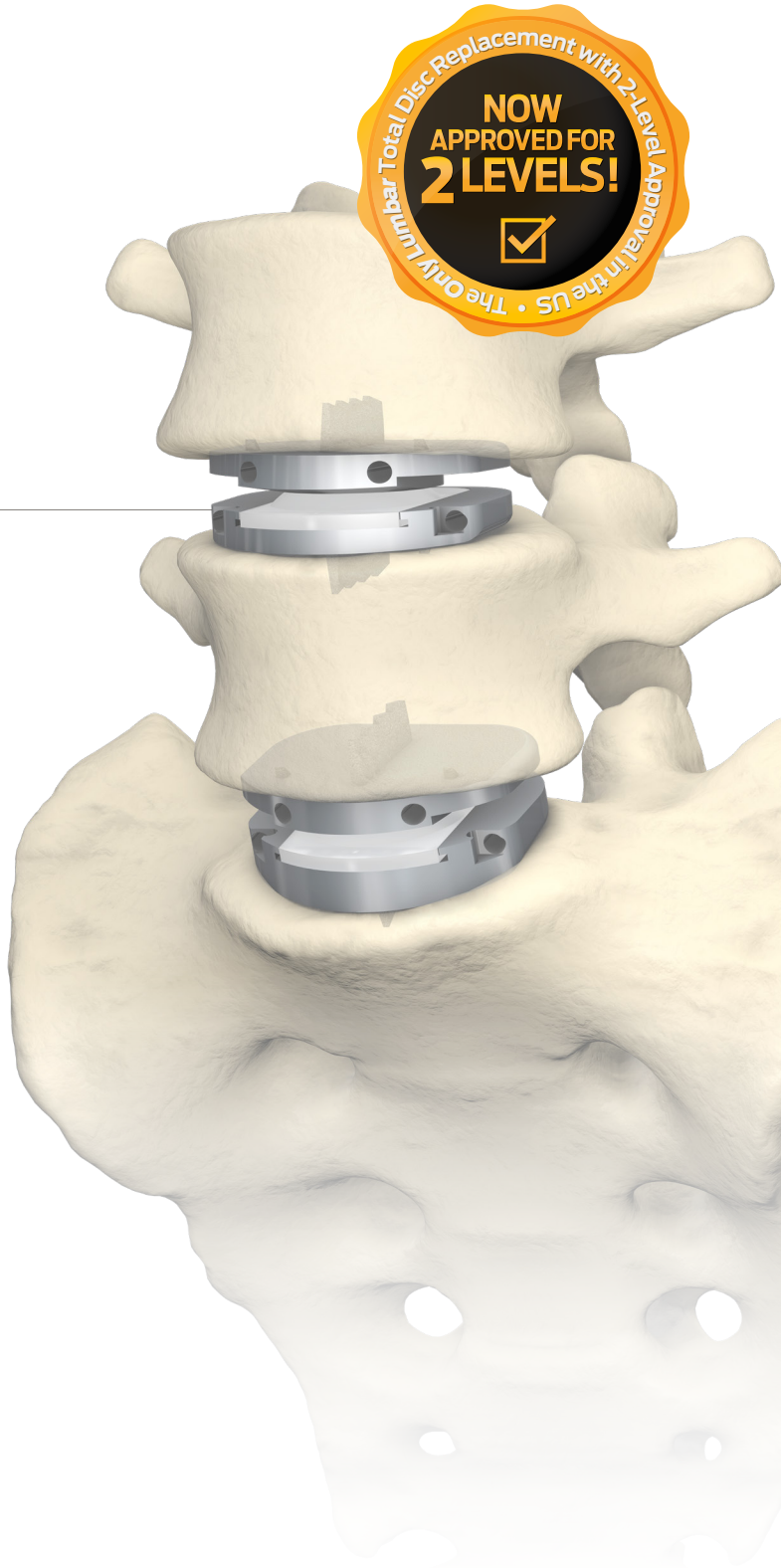
CENTINEL SPINE®

prodisc® L

Lumbar Total Disc Replacement System

SURGICAL TECHNIQUE GUIDE





prodisc® L

Lumbar Total Disc Replacement System

TABLE OF CONTENTS

NOTE *This guide alone does not provide sufficient background for direct use of Centinel Spine products. Instruction by a surgeon experienced in handling these products is mandatory.*

CENTINEL SPINE®

The leading global spine company focused exclusively on cervical and lumbar total disc replacement

ABOUT CENTINEL SPINE, LLC

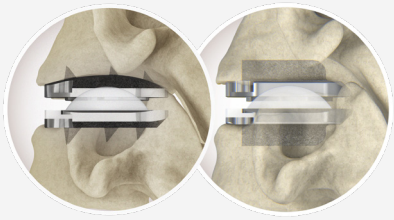
SINCE 1990 · 30+ YEARS OF CLINICAL SUCCESS

Centinel Spine®, LLC is the leading global medical device company exclusively focused on addressing cervical and lumbar spinal disease with prodisc®, the most complete and proven total disc replacement (TDR) technology platform in the world.

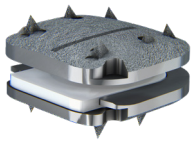
The Company's prodisc technology is the most studied and clinically-proven TDR system across the globe, validated by over 540 published papers[1] and more than 275,000 implantations[2]. Centinel Spine's prodisc is the only TDR technology with multiple motion-preserving anatomic solutions, allowing the surgeon to Match-the-Disc™ to each patient's anatomy for both cervical and lumbar total disc replacement.

prodisc® C
CERVICAL PORTFOLIO

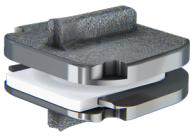
The Only Cervical Total Disc Replacement System that Allows **Matching the Disc** to the Needs of the Patient & Surgeon



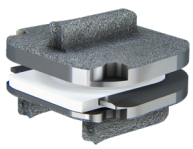
THE POWER OF 4 FDA-APPROVED cTDR DEVICES*



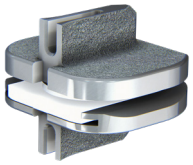
prodisc® C Vivo



prodisc® C SK



prodisc® C Nova

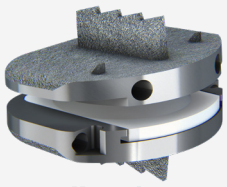


prodisc® C

* These devices are indicated & FDA-approved for 1 level.

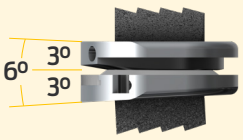
prodisc® L
ANATOMIC ENDPLATES™

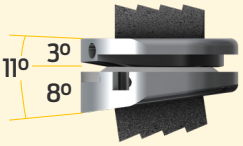
Designed to Better **Match Patient Anatomy**, Allowing a Customized Fit Throughout the Full Range of Indicated Levels (L3-S1)

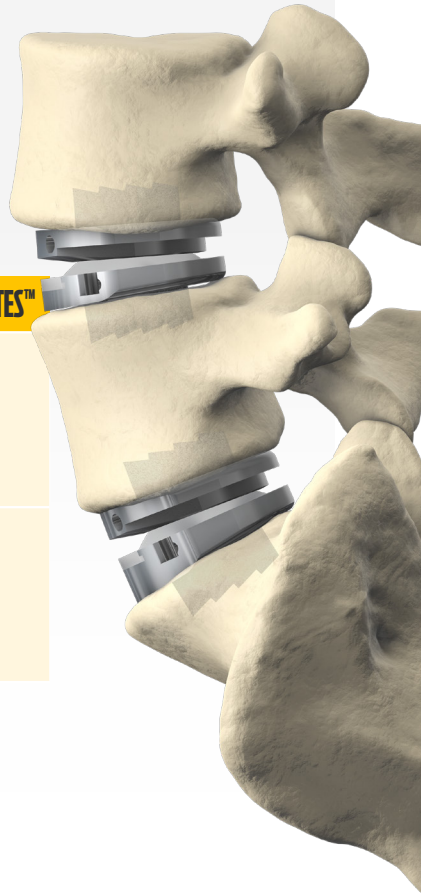


prodisc® L

NOW AVAILABLE: ANATOMIC ENDPLATES™







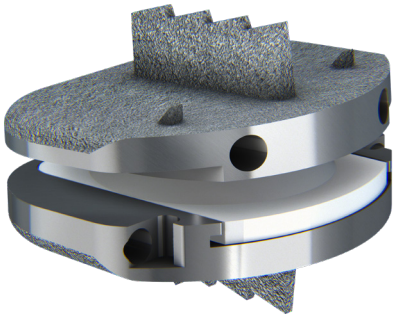
MATCH THE DISC™

LEARN MORE:
match.centinelspine.com

Introduction to prodisc® L

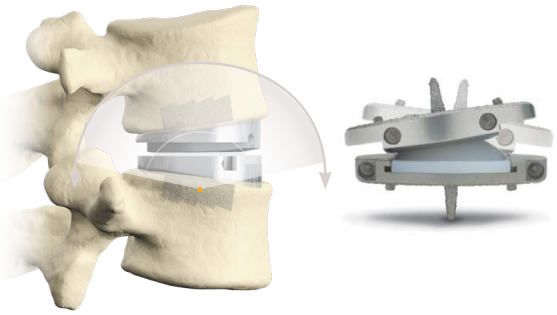
The prodisc L Total Disc Replacement is intended to replace a diseased and/or degenerated intervertebral disc of the lumbosacral region in patients with discogenic pain associated with degenerative disc disease (DDD) at one or two contiguous intervertebral levels between L3 and S1. Total disc replacement is intended to significantly reduce discogenic pain and improve patient function by allowing for the removal of the diseased disc while restoring the normal disc height.

The prodisc L Total Disc Replacement design is based on a ball and socket principle composed of three implant components—two cobalt chrome alloy (CoCrMo) endplates and an ultra-high-molecular-weight polyethylene (UHMWPE) inlay. The polyethylene inlay includes a radiopaque tantalum marker. The prodisc L Total Disc Replacement endplates have central keels and small spikes for initial fixation to the vertebral bodies and a plasma sprayed titanium coating on all bone-contacting surfaces to promote bony integration. The UHMWPE / CoCrMo coupling has historically been used in total joint replacement and has been used in spinal arthroplasty procedures for over two decades.



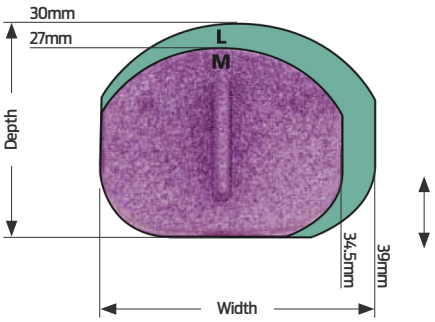
MRI Information

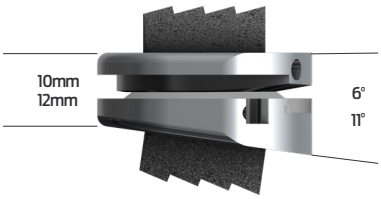
The prodisc L Total Disc Replacement is labeled MR Conditional, where it has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Please refer to page 7 for further information.



Ball and Socket Principle Provides a Fixed Center of Rotation

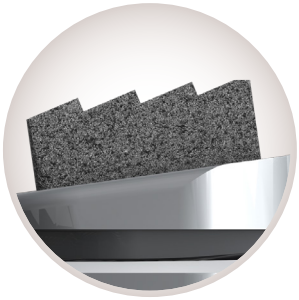
- Designed to allow controlled dynamic motion through the physiological range of motion
- Designed to prevent pure translational motion to theoretically protect the facets from excessive shear loading





Modular Design Accommodates Anatomical Needs of Individual Patients

- Medium and large footprints
- 10 and 12mm heights
- 6° and 11° lordotic angles
- 12 anatomical combinations



Central Keel Facilitates Midline Placement and Provides Secure Primary Fixation, and Titanium Plasma Sprayed Porous Coating Helps Foster Bony Integration

The prodisc L Total Disc Replacement provides the surgeon with a motion-preserving system for treating patients with degenerative disc disease. Successful application and clinical outcomes of this technology depend on a number of other critical factors:

- Completion of a company-sponsored training program on the use of prodisc L Total Disc Replacement and associated instrumentation
- Proper patient selection
- Safe and adequate surgical approach and exposure to the treated level
- Complete and meticulous discectomy, endplate preparation, and remobilization of the disc space
- Optimal implant footprint, height, lordosis selection, and placement

Indications for Use

The prodisc L Total Disc Replacement is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous intervertebral level(s) from L3 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than grade 1 spondylolisthesis at the involved level(s). Patients receiving the prodisc L Total Disc Replacement should have failed at least six months of conservative treatment prior to implantation of the prodisc L Total Disc Replacement.

Contraindications

The prodisc L Total Disc Replacement device should not be implanted in patients with the following conditions:

- Active systemic infection or infection localized to the site of implantation
- Osteopenia or osteoporosis defined as DEXA bone density measured T-score < -1.0
- Bony lumbar spinal stenosis
- Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium, tantalum)
- Isolated radicular compression syndromes, especially due to disc herniation
- Pars defect
- Involved vertebral endplate dimensionally smaller than
- 34.5 mm in the medial-lateral and/or 27 mm in the anterior-posterior directions
- Clinically compromised vertebral bodies at affected level due to current or past trauma
- Lytic spondylolisthesis or degenerative spondylolisthesis of grade > 1

Patient Exclusion Recommendations

Patient selection is extremely important. In selecting patients for a total disc replacement the following factors can be of extreme importance to the success of the procedure:

- The patient's occupation or activity level
- A condition of senility, mental illness, alcoholism, or drug abuse
- Certain degenerative diseases (e.g., degenerative scoliosis or ankylosing spondylitis) that may be so advanced at the time of implantation that the expected useful life of the device is substantially decreased

MRI Information

Centinel Spine prodisc L implants are labeled MR Conditional according to the terminology specified in ASTM F2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Nonclinical testing of the prodisc L demonstrated that the implant is MR Conditional. A patient with a prodisc L implant may be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla at Normal Operating Mode or First Level Controlled Mode
- Highest spatial gradient magnetic field of 900 Gauss/cm or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning

NOTE: ***In non-clinical testing, a Centinel Spine prodisc L implant of largest geometrical volume and mass was tested for heating and results showed a maximum observed heating of 1.8ºC for 1.5 T and a maximum observable heating of 1.7ºC for 3.0 T with a machine reported whole body averaged SAR of 2 W/kg as assessed by calorimetry.***

Patients may be safely scanned in the MRI chamber at the above conditions. Under such conditions, the maximal expected temperature rise is less than 2ºC. To minimize heating, the scan time should be as short as possible and the SAR as low as possible. Temperature rise values obtained were based upon a scan time of 15 minutes.

The above field conditions tested in a 1.5 T and a 3.0 T Philips Achieva (Philips Healthcare, Software release 2.6.3 SP4) MR scanner should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. Centinel Spine MR Conditional prodisc L implants may have the potential to cause artifact in the diagnostic imaging.

Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the prodisc L implant and it may be necessary to optimize MR imaging parameters in order to compensate for the presence of the implant.

A representative implant has been evaluated in the MRI chamber and worst case artifact information is provided below. Overall, artifacts created by prodisc L implants may present issues if the MR imaging area of interest is in or near the area where the implant is located.

- For FFE sequence: Scan duration: 3 min, TR 100 ms, TE 15 ms, flip angle 15º, worst case artifact will extend approximately 5.0 cm from the implant
- For SE sequence: Scan duration: 4 min, TR 500 ms, TE 20 ms, flip angle 70º, worst case artifact will extend approximately 4.0 cm from the implant

Preoperative Considerations

Perform a thorough review of patient history, physical exam and imaging studies to identify possible contraindications to total disc replacement or midline anterior lumbar approach and to verify that the lumbar disc in question is a clinically important pain generator. It is recommended that you use AP and lateral radiographs to preoperatively determine implant size and coordinate the surgical procedure with a spinal-access trained vascular or general surgeon.

NOTE: *In order to minimize the risk of atraumatic periprosthetic vertebral fractures, surgeons must consider all co-morbidities, past and present medications, previous treatments, etc. Upon reviewing all relevant information the surgeon must determine whether a bone density scan is prudent. A screening questionnaire for osteoporosis, SCORE (Simple Calculated Osteoporosis Risk Estimation)[3] may be used to screen patients to determine if a DEXA bone mineral density measurement is necessary. If DEXA is performed, exclusion from receiving the device should be considered if the DEXA bone density measured T-score is < -1.0, as the patient may be osteopenic.*

WARNINGS

Correct placement of the device is essential to optimal performance. Use of the prodisc L Total Disc Replacement should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics, has had experience with anterior approach spinal surgeries, and has had hands-on training in the use of this device.

In order to achieve proper prosthesis fit and fixation, patients with involved vertebral endplates dimensionally smaller than 34.5 mm in the medial-lateral and/or 27 mm in the anterior-posterior directions are not appropriate candidates for prodisc L surgery due to limitations in the prosthesis sizes available (Figure 1).

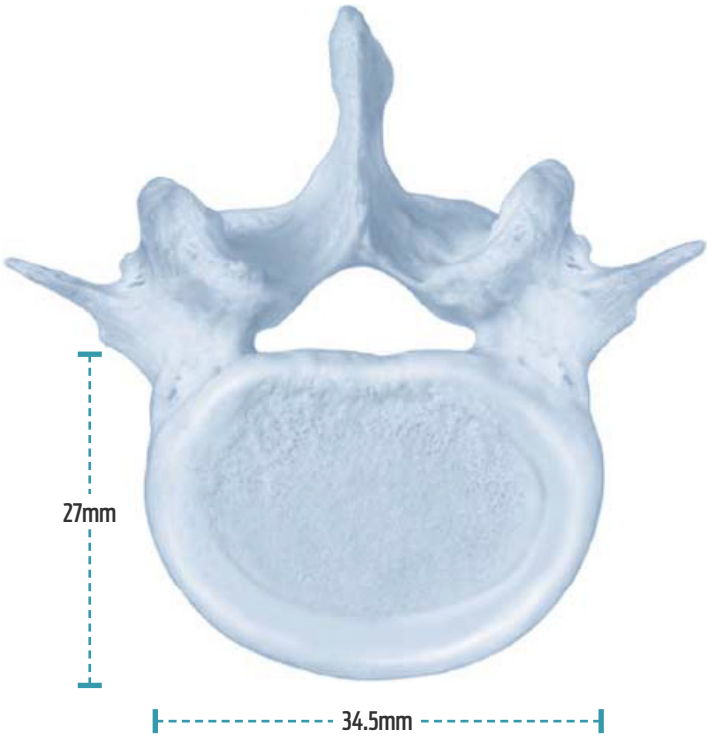


Figure 1.

SURGICAL TECHNIQUE

Patient Positioning

Insertion of the prodisc L implant is dependent on the use of AP and lateral fluoroscopy throughout the procedure. Patient positioning should allow for circumferential use of the C-arm at the operative levels with unobstructed movement in and out of the sterile field.

Position the patient in a supine, neutral position on a radiolucent operating table with arms abducted 90º. Alternatively, the arms may be adducted and crossed over the chest **(Figure 2)**.

Multi-level Considerations

Either the superior or inferior operative level may be addressed first, at the discretion of the operating surgeon. Multi-level prodisc L surgeries should be performed sequentially, level by level.

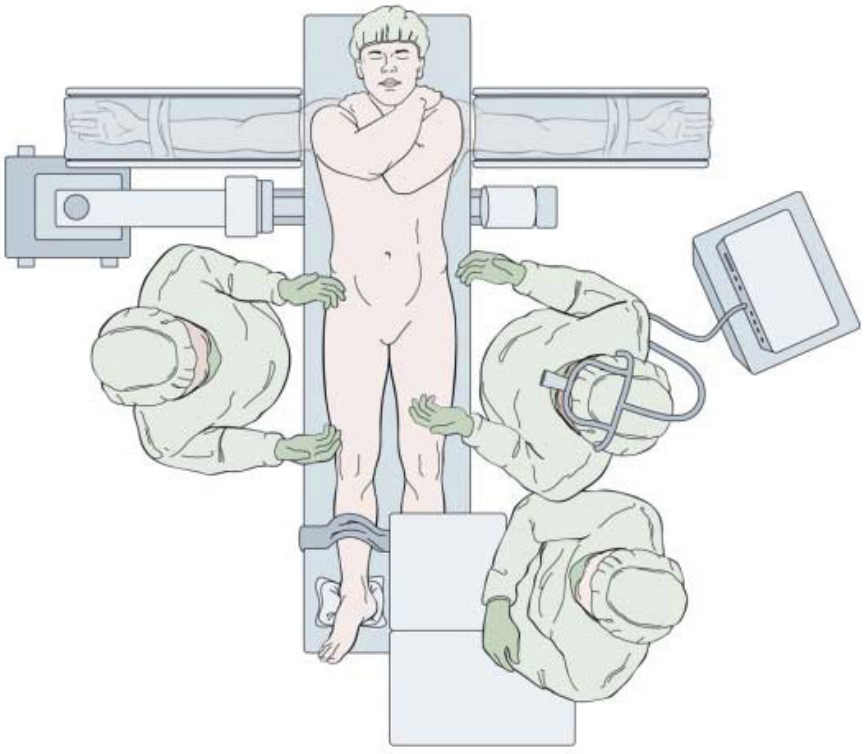


Figure 2.

Anterior Access & Approach

Locate the correct operative disc level and incision location by taking a lateral fluoroscopic view while holding a straight metal instrument at the side of the patient. This ensures that the incision and exposure will allow for direct visualization into the disc space **(Figure 3)**.

In multi-level cases, consider the best approach needed to best access both discs.

Expose the operative disc level through a standard mini-open retroperitoneal approach.

Perform a transverse skin incision, beginning at midline and continuing laterally 5–6 cm to the left. Incise the anterior rectus sheath along the same line, extending the dissection beyond the ends of the skin incision **(Figure 4)**. Elevate the anterior rectus sheath to allow for full mobilization of the rectus muscle **(Figure 5)**.

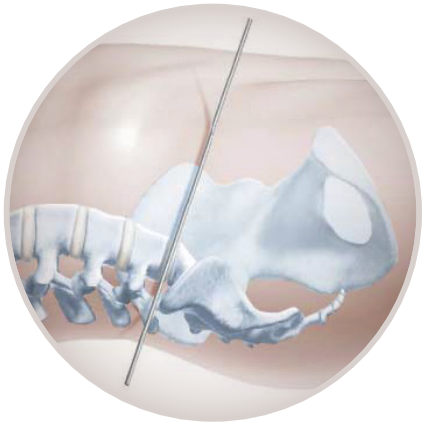


Figure 3.

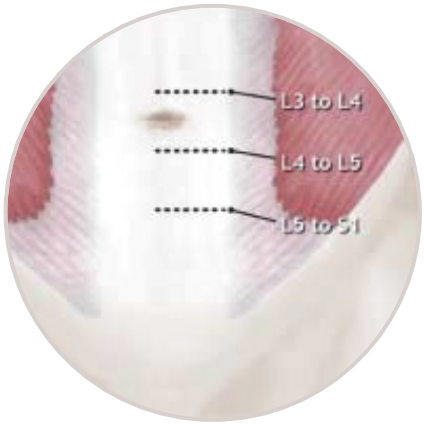


Figure 4.

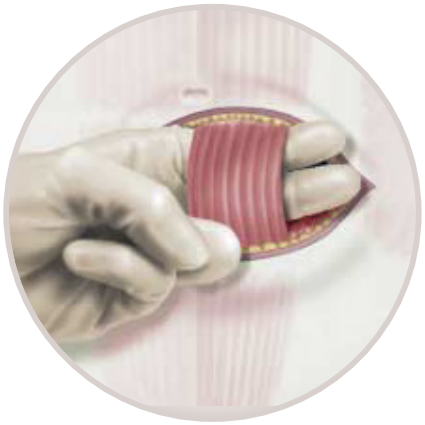


Figure 5.

Anterior Access & Approach
(Cont'd)

Retract the rectus muscle towards the midline, and incise the posterior sheath vertically to the peritoneum. Carefully push the peritoneum posteriorly at the edge of the fascial incision. Manually develop a plane between it and the abdominal wall, into the retroperitoneal space.

Bluntly elevate the peritoneum away from the psoas muscle. Identify the ureter and lift it away with the peritoneum. Palpate medially to feel for the disc, vertebral body and iliac artery. Elevate the peritoneum away in all directions to expose the disc space **(Figure 6)**.

NOTE: ***Avoid tearing the peritoneum when elevating it. Close any tears immediately before proceeding with the approach.***

L3-L4, L4-L5

The L3-L4 and L4-L5 disc spaces are typically located posterior to the aortic and vena cava bifurcation. Mobilize the left iliac artery, ligate and cut the iliolumbar vein(s), and then retract the artery and vein from left to right to provide adequate exposure of the disc space and vertebral bodies **(Figure 7)**.

NOTE: ***Care must be taken to ensure the left iliac vein and artery are mobile prior to retracting.***

L5-S1

The L5-S1 disc space is typically located below the aortic and vena cava bifurcation. Retract the left and right common iliac vessels laterally and superiorly to provide adequate exposure of the disc space and vertebral bodies. Take the middle sacral vessels to provide clear exposure of the disc space **(Figure 8)**.

NOTE: ***Use cautery cautiously to avoid injury to the superior hypogastric plexus.***

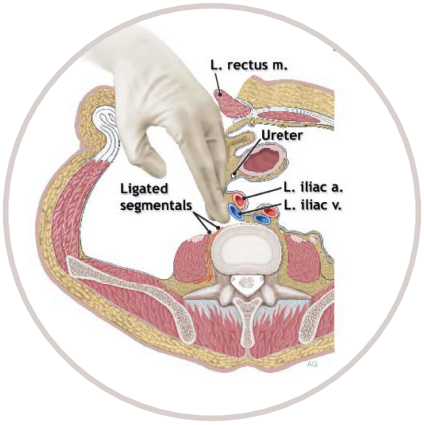


Figure 6.

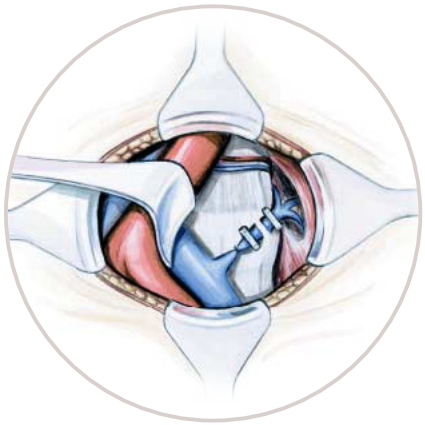


Figure 7.

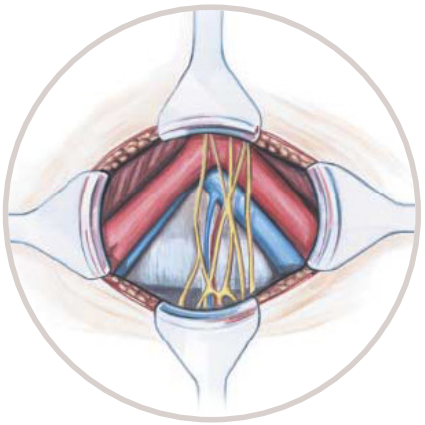


Figure 8.

Marking Midline

Instruments		
PDL118	Midline Indicator	
PDL120	Midline Marker, 8 mm width, 250 mm	

Use AP fluoroscopy to identify the midline of the operative level before the discectomy is initiated **(Figure 9)**. Mark the midline on the superior and inferior vertebral bodies adjacent to the operative level so the mark remains visible throughout the entire procedure. The Midline Indicator and Midline Marker may be used to facilitate this step.

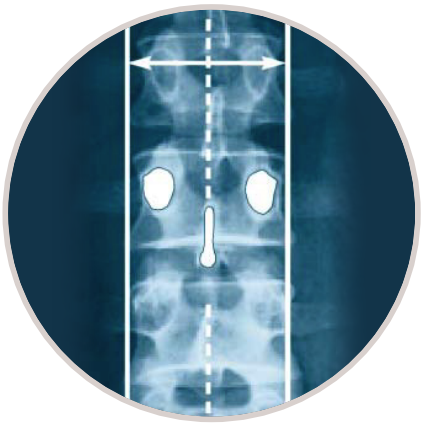
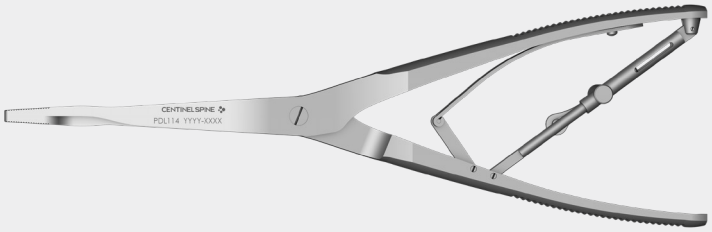


Figure 9.

Discectomy, Endplate Preparation & Remobilization

Instruments		
PDL114 or SFW650R	Vertebral Body Spreader, Angled	
PDL116 or SFW580R	Bone Elevator, 17 mm width, 337 mm	

The surgeon must remobilize the diseased segment, restore the disc height, and properly balance the soft tissues prior to implantation of the prodisc L Total Disc Replacement.

The prodisc L Total Disc Replacement may maintain motion, but it cannot create motion.

Create an annulotomy centered on midline and wide enough to accommodate the prodisc L implant **(Figure 10)**.

Perform a thorough discectomy using the Bone Elevator and standard rongeurs, Kerrisons, and curettes, ensuring the posterolateral corners are freed of disc material **(Figure 11)**.

Figure 10.

Figure 11.

Under fluoroscopy, insert the Vertebral Body Spreader to the posterior margin of the vertebral bodies to gradually remobilize the motion segment **(Figure 12)**.

Placement of the tips to the posterior margin will minimize the risk of endplate fracture. Place the spreader on one side to facilitate the discectomy on the contralateral side, and then repeat for the other side.

Remove the cartilaginous endplates to bleeding bone, taking care to not compromise the integrity of the bony endplates.

The posterior annulus should be completely exposed, and resected as necessary to expose the posterior longitudinal ligament (PLL) and to remobilize the segment.

If posterior remobilization cannot be achieved, the PLL may need to be released from the posterior vertebral body with a curved curette, transected, or completely resected.

Two Vertebral Body Spreaders can be used to obtain balanced remobilization.

NOTE: ***Ensure that a complete discectomy is performed and the integrity of the bony endplates is preserved to provide a firm base for mechanical stability and to reduce the potential for device subsidence. Fluoroscopy must be used to ensure the tips of the Vertebral Body Spreader are resting on the posterior margin prior to distracting, to minimize the risk of vertebral endplate fracture. Remodeling of the endplates is only recommended to remove significant posterior osteophytes that may interfere with prosthesis insertion. Remobilization and restoration of the disc height must be fully achieved prior to implantation of the*** prodisc L.

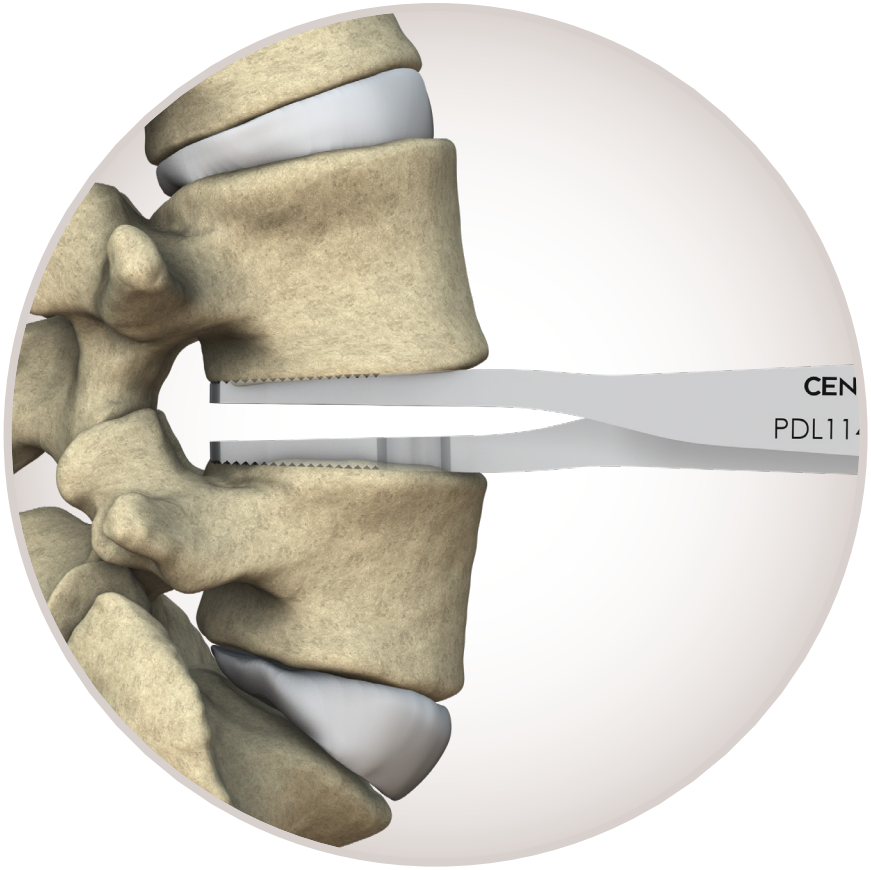


Figure 12.

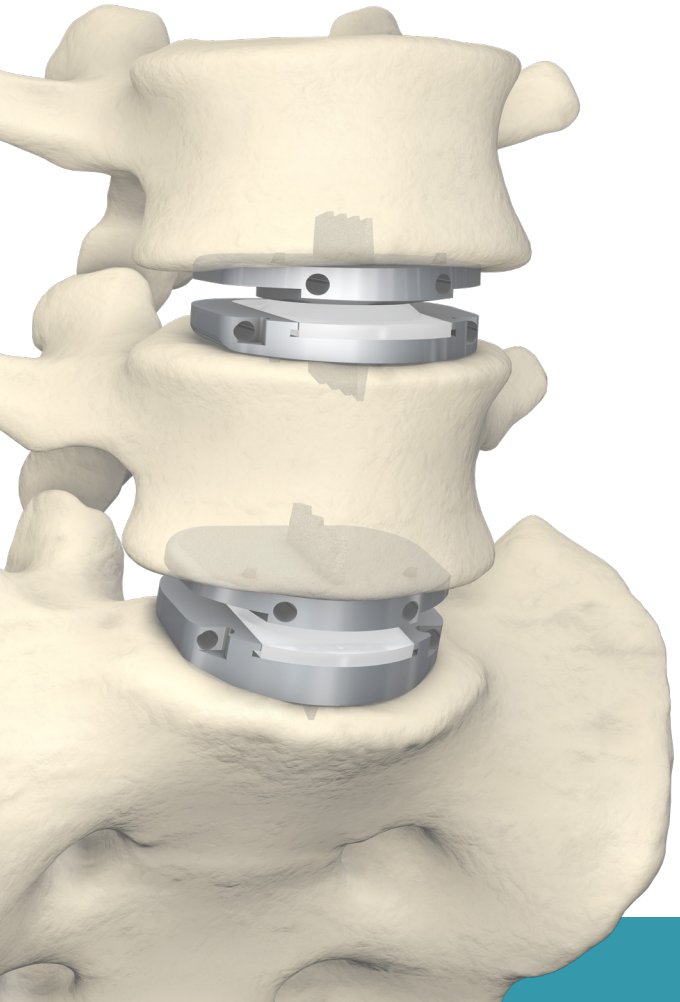
Implantation

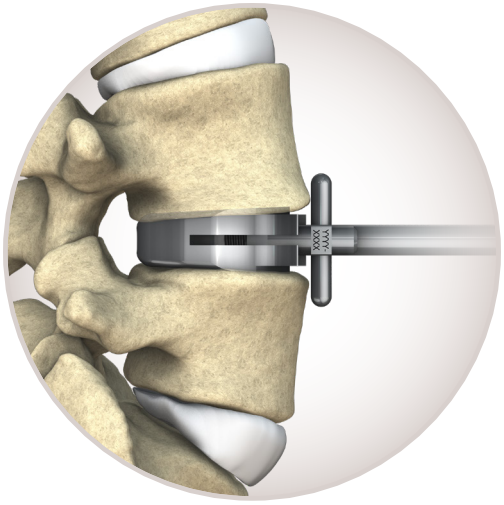
The prodisc L Total Disc Replacement contains 12 Trials that correspond to the 12 possible prodisc L Total Disc Replacement implant sizes. Trials are placed into the disc space intraoperatively to determine the appropriate implant footprint, lordotic angle and disc height.

The Trial is used as a jig to control the direction and depth of the chisel cuts in the vertebral bodies. The central keels on the prodisc L endplates will follow the path of the chisel cuts to its final position. Lastly, the endplates are distracted and the polyethylene inlay is inserted and locked into the inferior endplate.

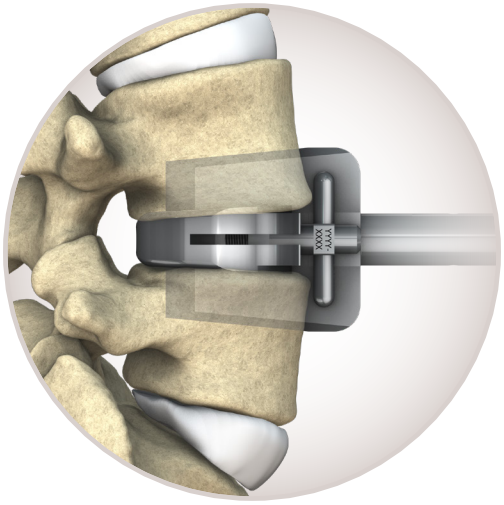
Implantation of the prodisc L implant is performed in three steps:

1. **Trial**
2. **Chisel**
3. **Insert Implant**

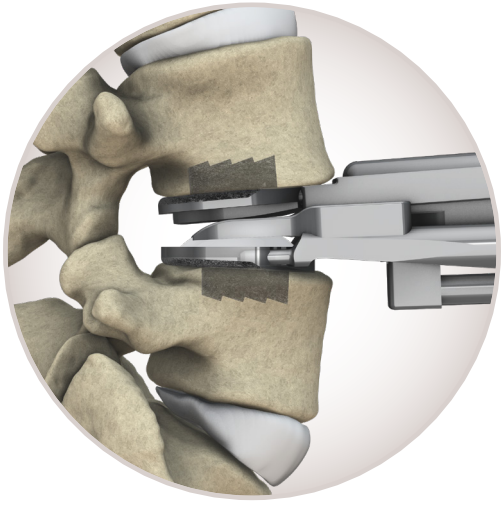




Trial



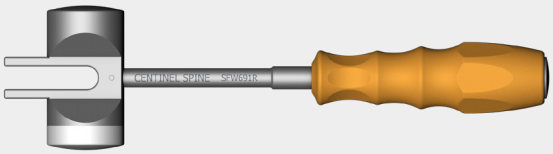
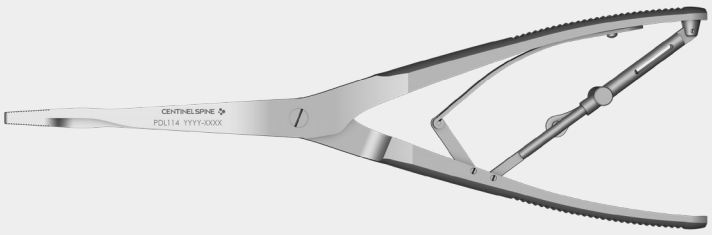
Chisel



Insert Implant

STEP 1: Trial

Instruments

PDL102 or SFW691R	Slotted Mallet					
PDL202	Handle, for Trial Implant					
PDL206 or SFW602R	Screwdriver, for Adjustable Stop					
PDL208 or SFW601R	Adjustable Stop, for Trial Implants					
PDL222 – PDL254	Trial Implants					
		Footprint	*Medium*	*Medium*	*Large*	*Large*
		Heights (mm)	*10 & 12*	*10 & 12*	*10 & 12*	*10 & 12*
		Lordotic Angle	*6°*	*11°*	*6°*	*11°*
IN1692	Strut					
PDL114 or SFW650R	Vertebral Body Spreader, Angled					

Implantation (Cont'd)

STEP 1: Trial (Cont'd)

Use the Screwdriver to assemble the Stop into the Trial. Ensure the Stop is fully seated in the Trial.

Connect the Handle to the shaft of the Trial by pulling back on the flange. The Handle locks onto the shaft of the Trial and can be oriented in one of four positions **(Figure 13)**.

Ensure proper connection of the Trial with the Handle **(Figure 14)**. Once properly connected, release the flange of the Handle.

Insert the Trial into the intervertebral disc space, centered on the midline mark and aligned with the sagittal plane of the vertebral body **(Figure 15)**.

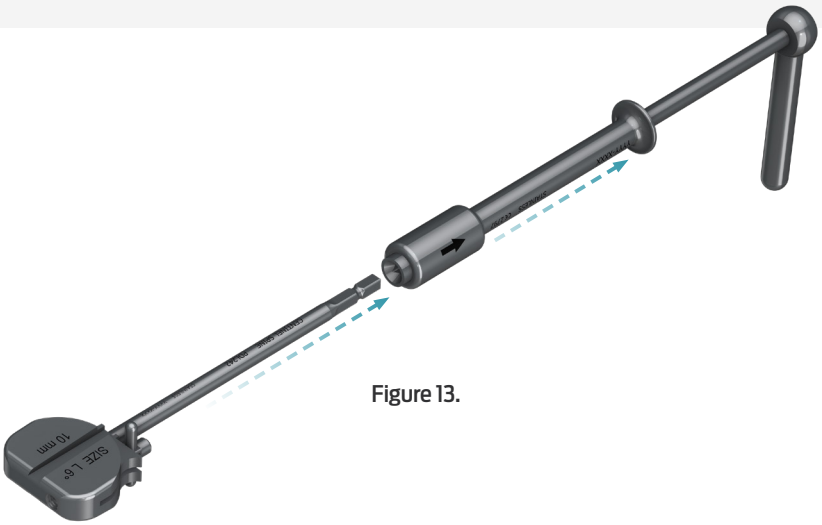


Figure 13.

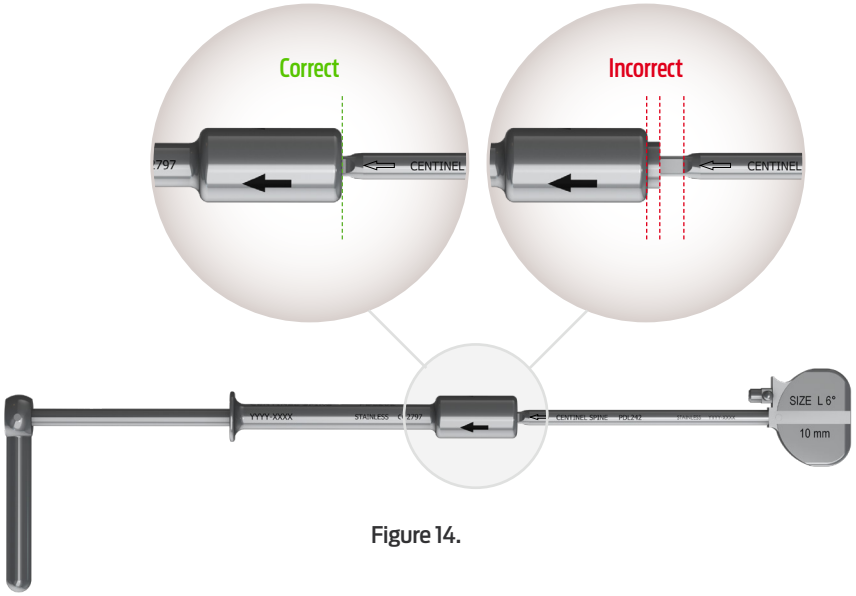


Figure 14.

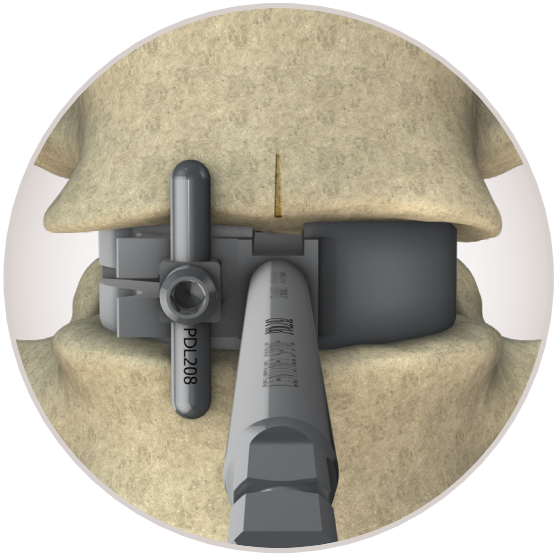


Figure 15.

If the intervertebral disc space collapses, inhibiting insertion of the trial, the Strut(s) may be used.

Under lateral fluoroscopy, distract the intervertebral disc space using the Vertebral Body Spreader and insert one or two Strut(s) along the lateral aspect of the intervertebral disc space **(Figure 16)**.

NOTE: ***The Strut is intended to temporarily maintain distraction to assist in inserting the Trial*** **(Figure 17)**. ***The Strut(s) should be removed once the Trial is inserted. The Strut is not intended to be rotated to create distraction or be impacted into the disc space. The Vertebral Body Spreader must be used to create distraction.***

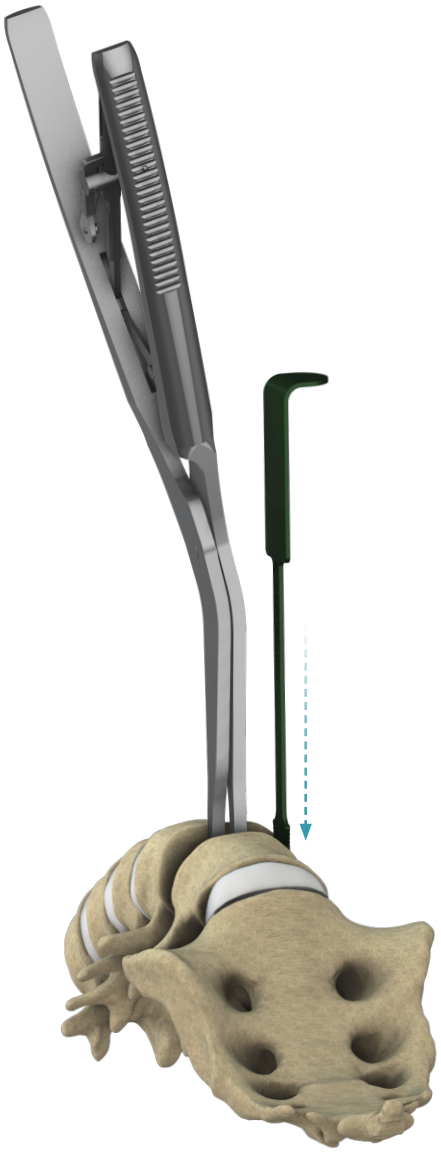


Figure 16.

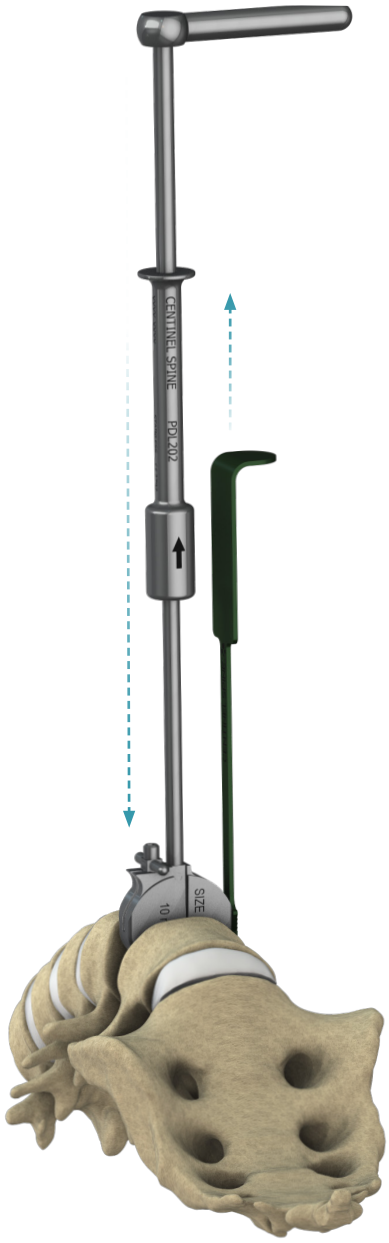


Figure 17.

Implantation (Cont'd)

STEP 1: Trial (Cont'd)

Under lateral fluoroscopy, advance the Trial to the posterior margin of the vertebral bodies with the Slotted Mallet **(Figure 18)**. The Stop can be backed out to allow the Trial to be positioned more posteriorly **(Figure 19)**. Each full counter-clockwise rotation of the Stop allows the Trial to be advanced 1 mm posterior.

Select the largest footprint to maximize coverage of the vertebral bodies, the disc height to match that of a normal adjacent disc space, and the lordosis angle that matches the anatomy.

NOTE: ***Ensure that the Stop is fully seated to the Trial body prior to inserting the Trial device. The optimal position of the Trial is at the posterior margin of the vertebral bodies, and centered on the midline. Ensure that the largest footprint is selected to minimize the potential for implant subsidence. Correct sizing, placement and lordotic angle are critical to ensure optimal performance.***

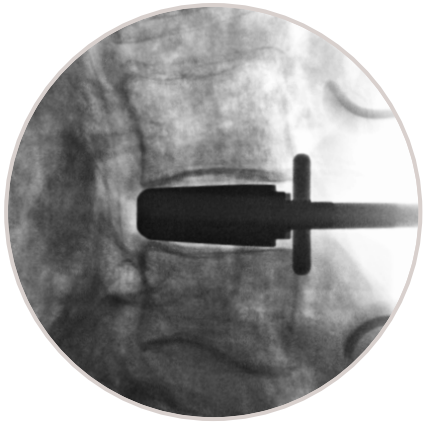


Figure 18.

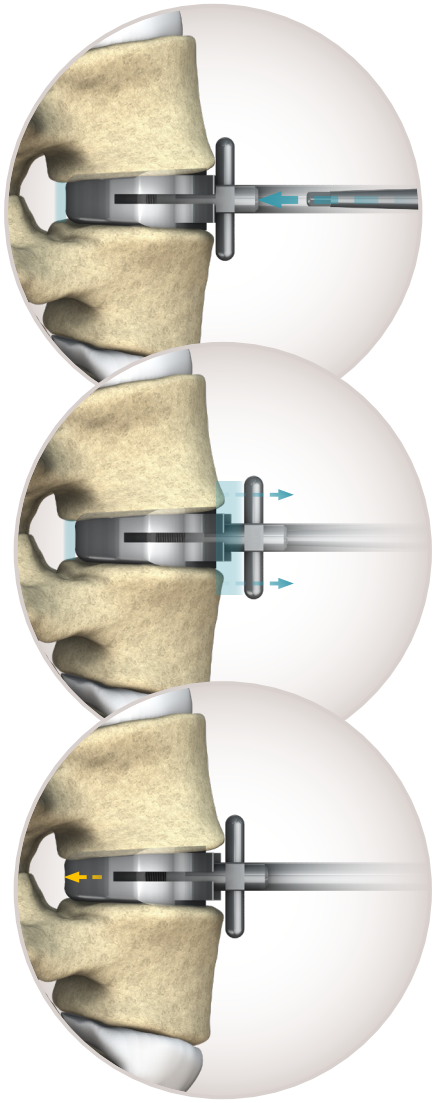
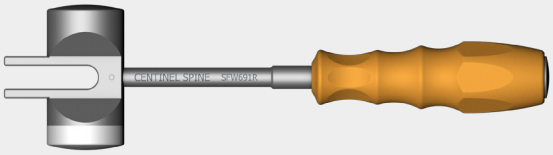


Figure 19.

Implantation (Cont'd)

STEP 2: Chisel

Instruments			
PDL102 or SFW691R	Slotted Mallet		
PDL322	Chisels	10mm	
PDL324		12mm	
IN1575	Hemi Chisel +3mm	10mm	
IN1576		12mm	

Remove the Handle from the Trial.

Slide the Chisel over the shaft of the Trial. Under lateral fluoroscopy, advance the Chisel into the vertebral bodies with the Slotted Mallet until the Chisel is fully seated on the Trial **(Figure 20)**.

Ensure that the Chisel depth is equal in both vertebral bodies.

The Chisel and Trial are left in place until the prodisc L implant is ready for insertion.

NOTE: ***Ensure that the Stop on the Trial is fully seated against the vertebral body prior to chiseling. Chiseling must be performed under lateral fluoroscopy. The depth of the chisel cuts within both vertebral bodies must be adequate prior to prodisc L implant insertion. The Chisel should be fully inserted on the Trial until the "Stop" on the Trial is reached; this will ensure that the Chisel depth is adequate.***

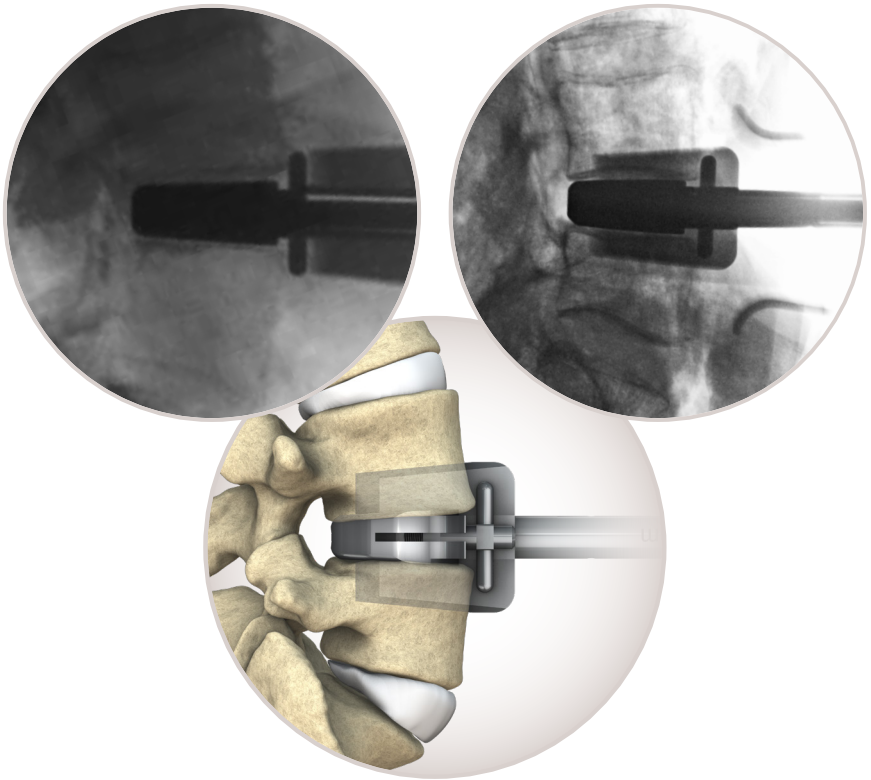


Figure 20.

Implantation (Cont'd)

STEP 2: Chisel (Cont'd)

It may be necessary to perform two chisel cuts to ensure adequate chisel depth on each vertebral body. The first chisel cut should follow the angle of the inferior vertebral body, then, the Chisel should be cephalized so the second cut follows the angle of the superior vertebral body **(Figures 21a & 21b)**.

Alternatively, the Hemi Chisel may be used to perform the second chisel cut to extend the chisel cut up to 3mm **(Figure 22)**.

NOTE: ***Use of the Hemi Chisel is limited to the superior chisel cut.***

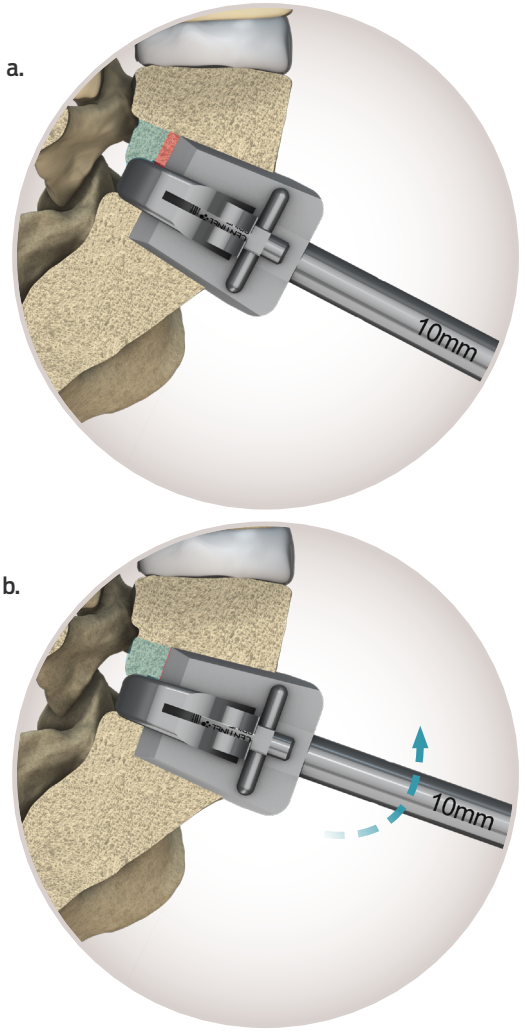


Figure 21.

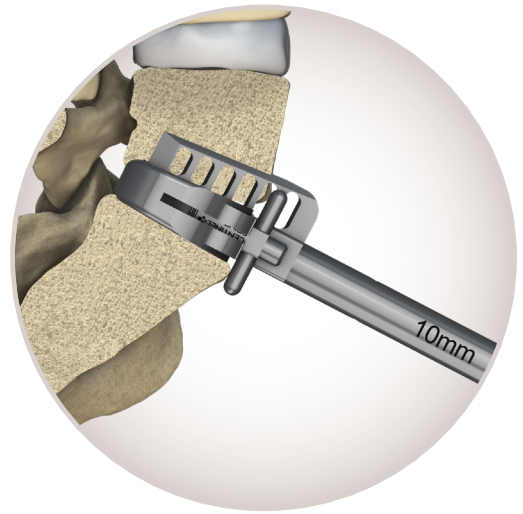
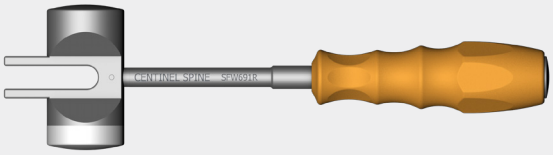
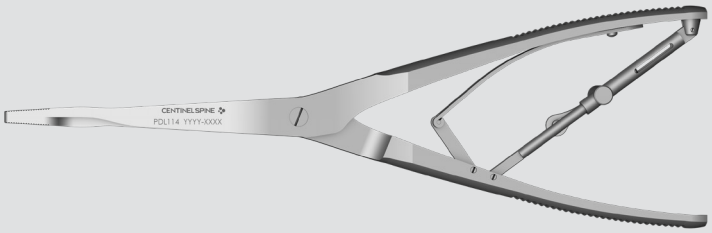


Figure 22.

Implantation (Cont'd)

STEP 3: Insert Implant

Instruments			
PDL102 or SFW691R	Slotted Mallet		
PDL402 or SFW672R	Inserters	Medium	
PDL404 or SFW673R		Large	
IN1692	Strut		
PDL114 or SFW650R	Vertebral Body Spreader, Angled		

The prodisc L implant endplates are inserted in a collapsed position and then distracted for polyethylene inlay insertion. This modular technique facilitates endplate insertion and provides efficient distraction for polyethylene inlay assembly.

Implantation (Cont'd)

STEP 3: Insert Implant (Cont'd)

ENDPLATE INSERTION

Press the release button on the back of the Inserter and externally rotate the inferior arms. Assemble the inferior endplate onto the pins of the inferior arms **(Figure 23)**. Press the release button and internally rotate the arms to lock the inferior endplate onto the pins **(Figure 24)**.

Load the superior endplate onto the pins on the superior arm of the Inserter **(Figure 25)**.

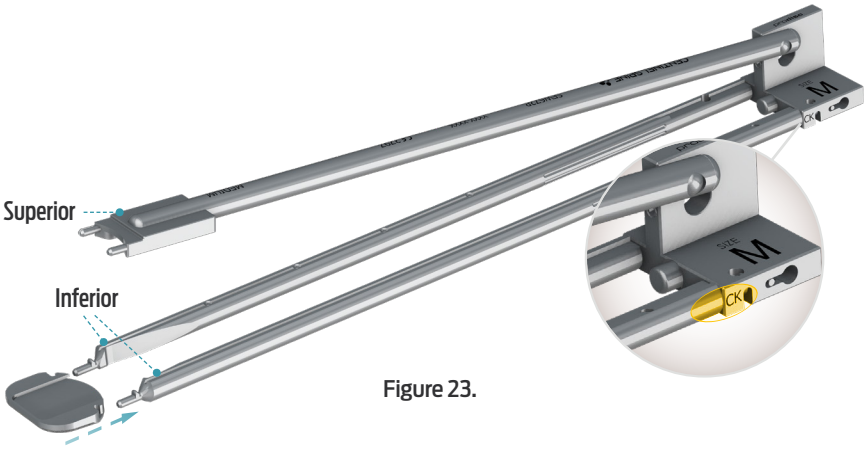


Figure 23.

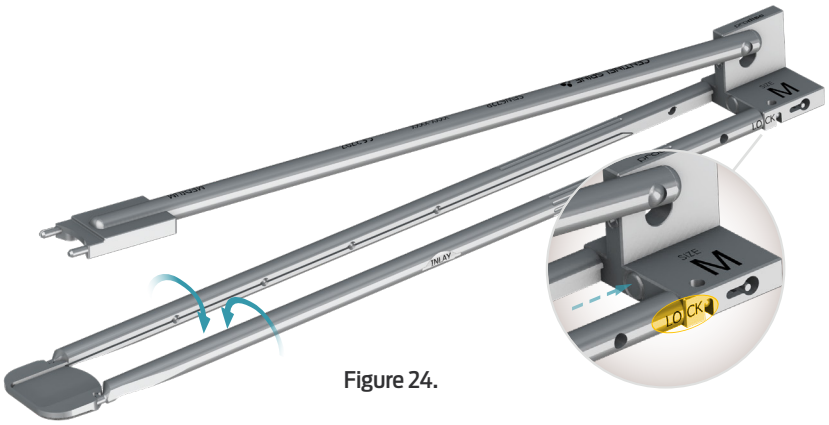


Figure 24.

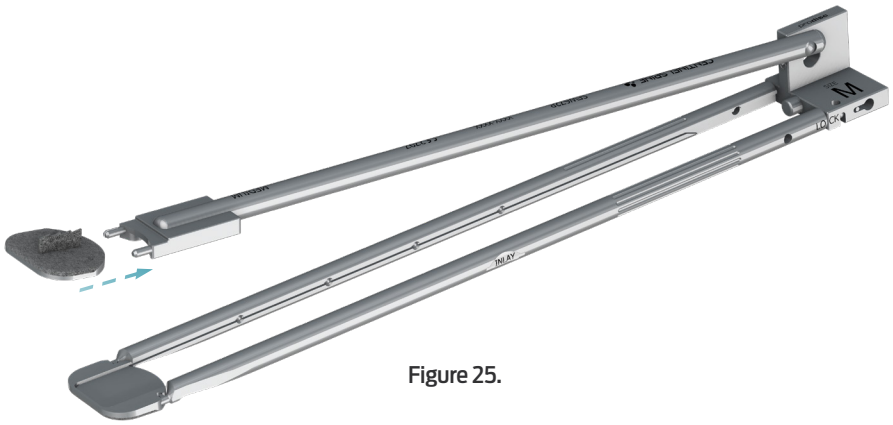


Figure 25.

Nest and hold the two endplates together by firmly gripping the Inserter arms **(Figure 26)**.

NOTE: ***Ensure inferior arms of Inserter are correctly locked prior to endplate insertion.***

Remove the Chisel and Trial. Ensure the disc space is clear of any disc or bony debris.

Align the keels of the implant with the chisel cuts. Under fluoroscopy, use the Slotted Mallet to insert the implant endplates to the posterior margin of the vertebral bodies **(Figure 27)**.

NOTE: ***Visually confirm that the anterior edge of the prosthesis is within the anterior edge of the vertebral body.***

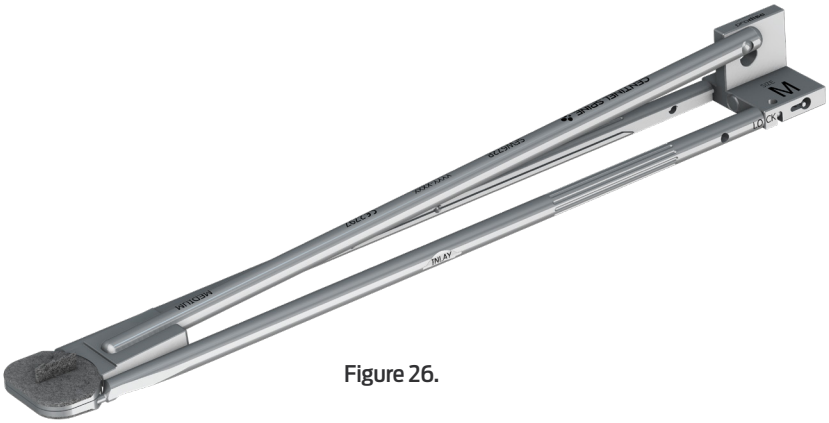


Figure 26.

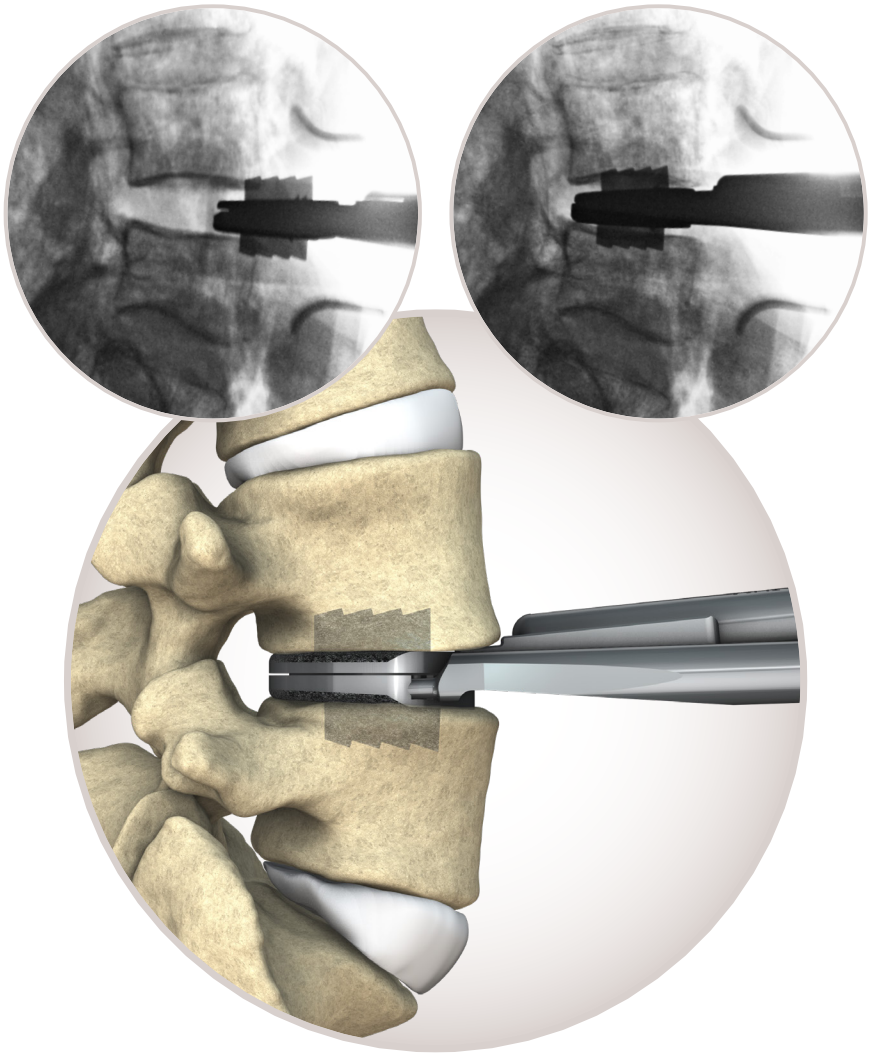


Figure 27.

Implantation (Cont'd)

STEP 3: Insert Implant (Cont'd)

If the intervertebral disc space collapses, inhibiting insertion of the implant, the Strut(s) may be used.

Under lateral fluoroscopy, distract the intervertebral disc space using the Vertebral Body Spreader and insert one or two Strut(s) along the lateral aspect of the intervertebral disc space **(Figure 28)**.

NOTE: ***The Strut is intended to temporarily maintain distraction to assist in inserting the implant. The Strut(s) should be removed once the implant is inserted*** **(Figure 29)**. ***The Strut is not intended to be rotated to create distraction or be impacted into the disc space. The Vertebral Body Spreader must be used to create distraction.***

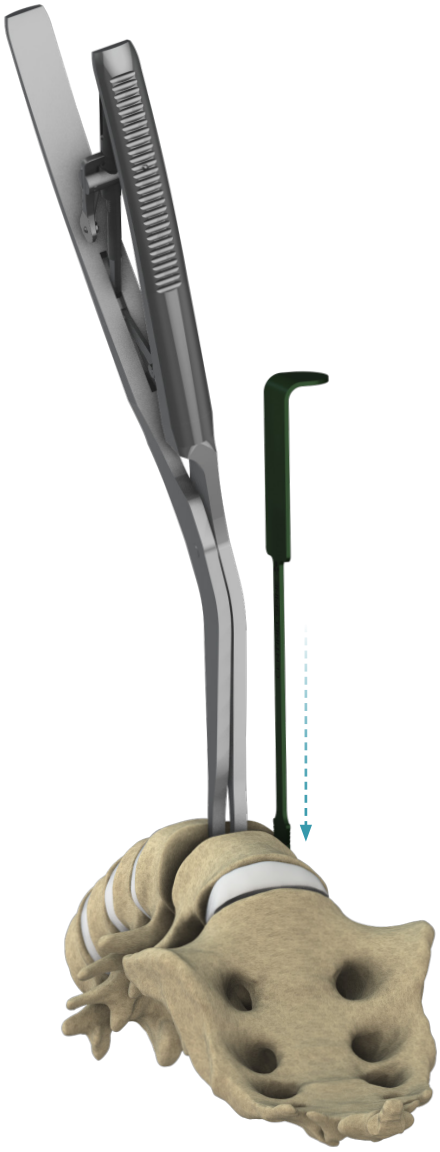


Figure 28.

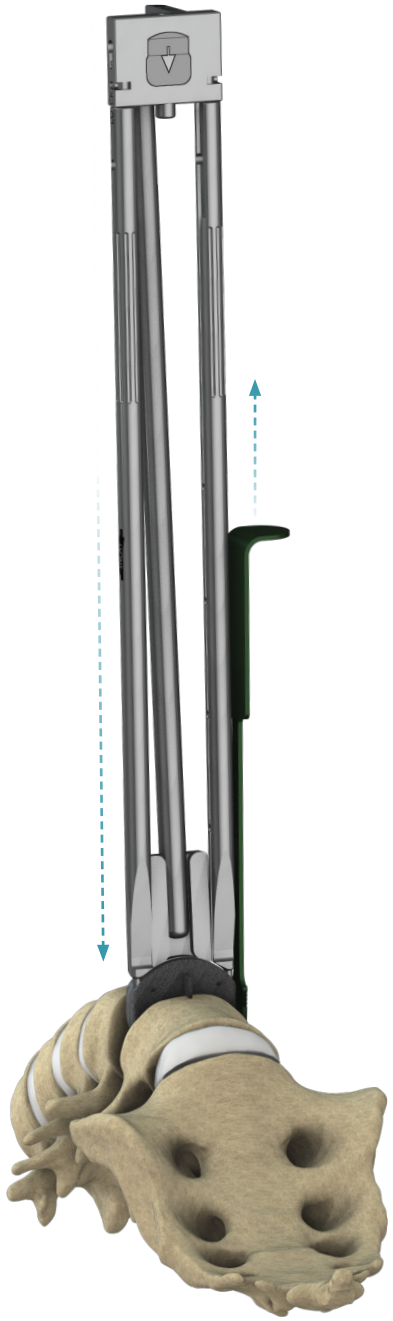


Figure 29.

Implantation (Cont'd)

STEP 3: Insert Implant (Cont'd)

Instruments			
PDL422 or SFW874R	Distractors	10mm	
PDL424 or SFW875R		12mm	

POLYETHYLENE INLAY INSERTION

Insert the polyethylene inlay into the grooves in the inferior arms of Inserter with the "Dome Up and Dome Up" **(Figure 30)**.

NOTE: ***Ensure that the polyethylene inlay is placed in the proper direction by confirming that the rounded profile is facing anterior.***

Advance the polyethylene inlay to the first ball detent **(Figure 31)**.

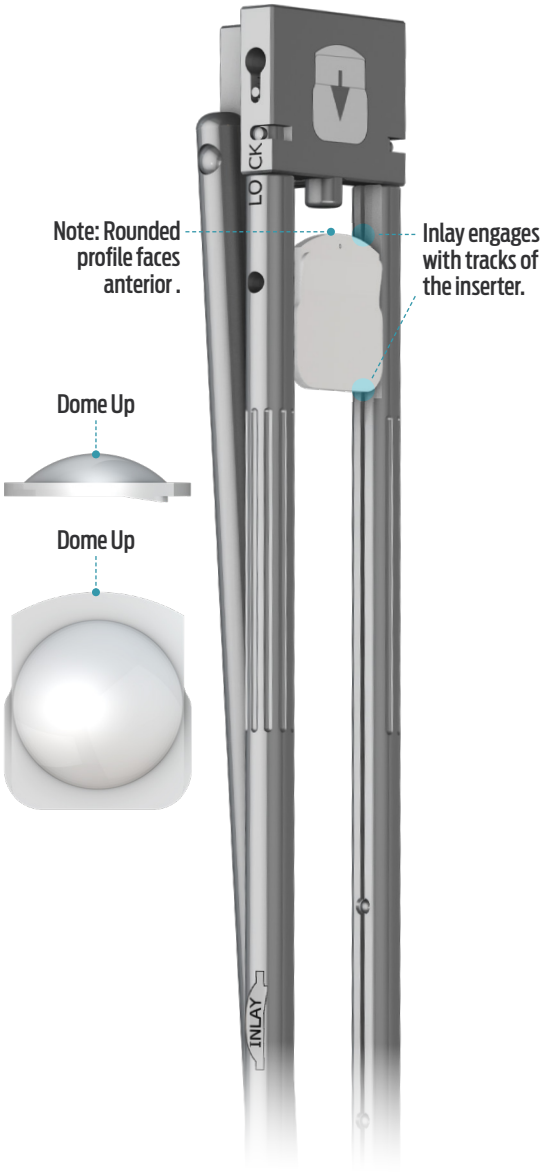


Figure 30.

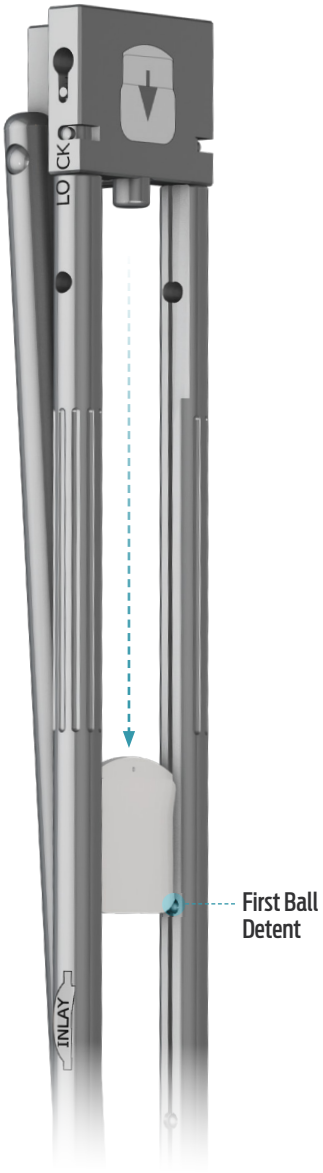


Figure 31.

Implantation (Cont'd)

STEP 3: Insert Implant (Cont'd)

Assemble the Distractor to the Inserter **(Figure 32)**. Under fluoroscopy, use the thumbscrew to fully advance the Distractor **(Figure 33)**. Verify that the posterior edge of the endplates have separated from each other **(Figure 34)**; this ensures adequate clearance for the insertion of the polyethylene inlay.

NOTE: ***Do not attempt to force and lock the polyethylene inlay if the endplates have not separated. Additional discectomy and remobilization may be required if the endplates do not separate.***

Figure 32.

Figure 33.

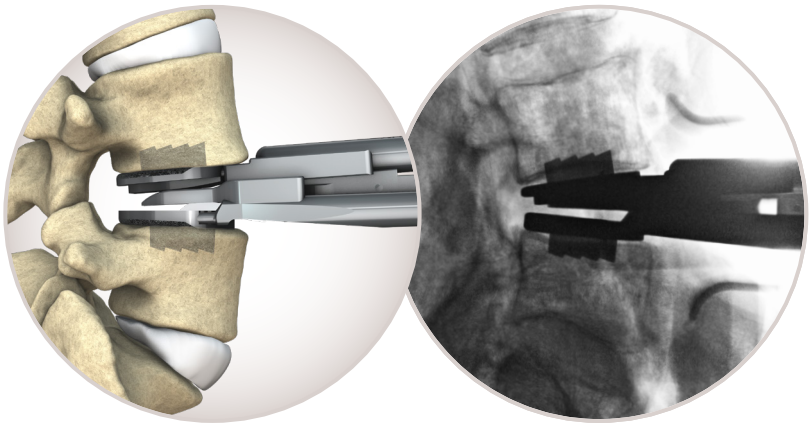


Figure 34.

Implantation (Cont'd)

STEP 3: Insert Implant (Cont'd)

Instruments			
PDL432 or SFW577R	Inlay Pusher	Medium	
PDL434 or SFW578R		Large	
IN1570	Superior Impactor	Medium	
IN1571		Large	

Insert the Inlay Pusher into the same grooves as the polyethylene inlay in the inferior arms. Manually push and lock the polyethylene inlay into the inferior endplate **(Figure 35)**. Remove the Inlay Pusher.

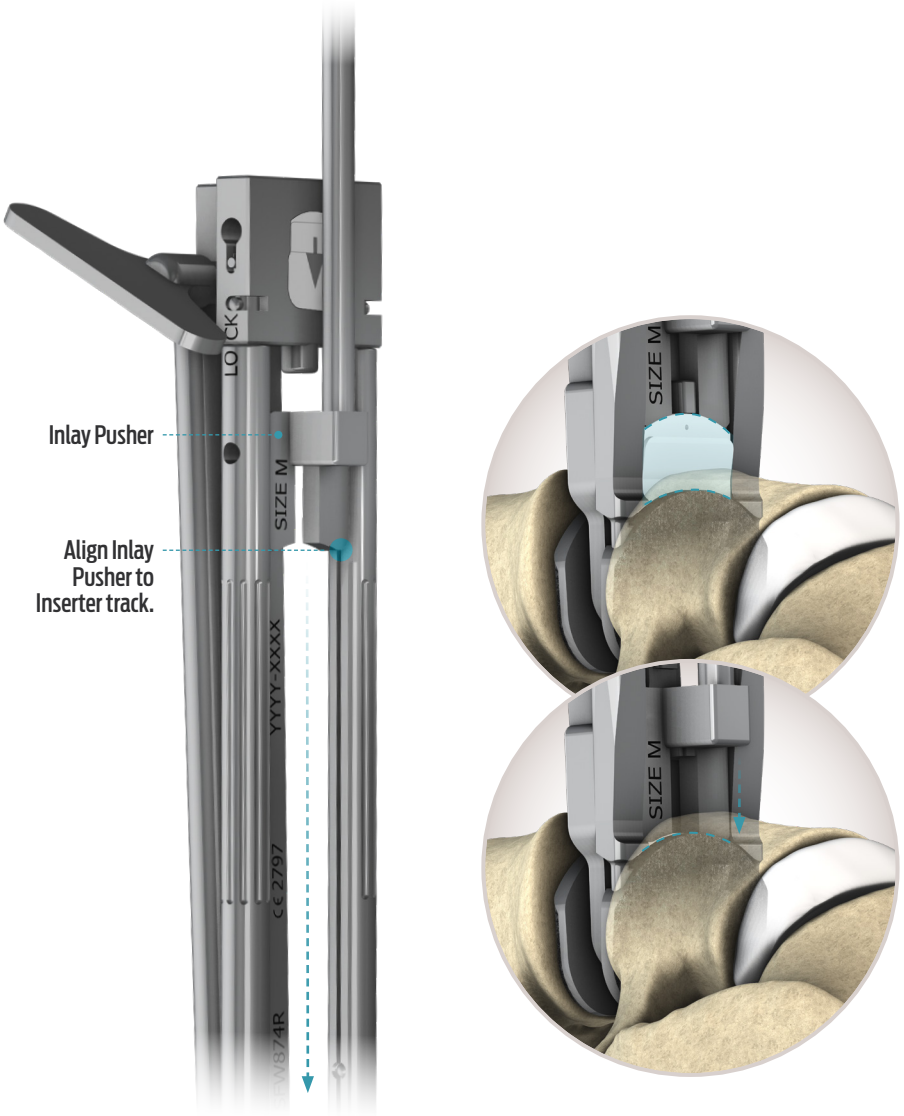


Figure 35.

Implantation (Cont'd)

STEP 3: Insert Implant (Cont'd)

Visually confirm the polyethylene inlay is locked into the inferior endplate. A nerve hook may be used to verify that NO STEP and NO GAP are present **(Figure 36)**.

Remove the Distractor from the Inserter.

NOTE: ***Ensure that the polyethylene inlay is securely locked within the inferior plate component. If the polyethylene inlay is not securely locked, anterior displacement of the polyethylene inlay will occur.***

Visually confirm the polyethylene inlay is locked into the inferior endplate by using a nerve hook to verify that NO STEP and NO GAP are present at the anterior edge of the endplate **(Figure 32).**

The tantalum marker does not ensure whether or not the inlay is fully seated in the inferior plate. It is still necessary to check visually and manually (e.g. "NO STEP" and "NO GAP") the seating of the inlay.

Press the release button of the Inserter and externally rotate the inferior arms to unlock the Inserter. Gently remove the Inserter from the prodisc L implant.

If needed, the Superior Impactor **(Figure 37)** may be used to advance the superior implant endplate posteriorly.

NOTE: ***Use of the Superior Impactor is limited to the superior implant endplate. Use caution when impacting the superior implant endplate as to not damage the polyethylene inlay.***

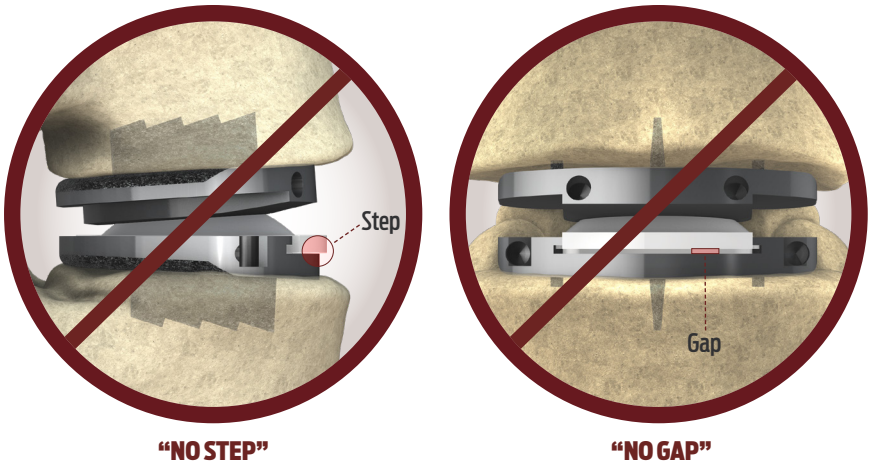


Figure 36.

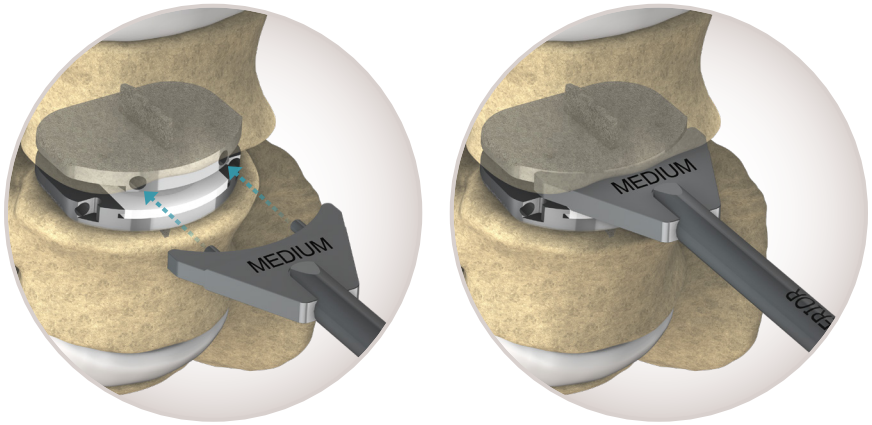


Figure 37.

FINAL IMPLANT VERIFICATION

Verify final implant position with lateral and AP imaging **(Figures 38 & 39)**.

The surgical wound is closed in routine fashion appropriate for the surgical exposure utilized.

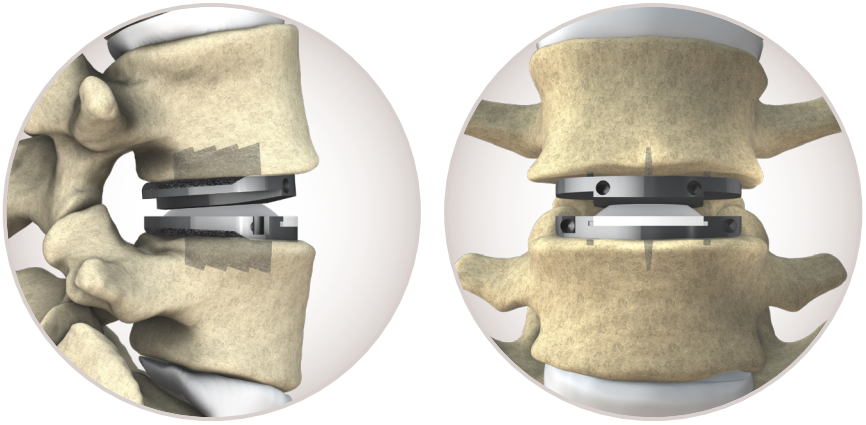


Figure 38.

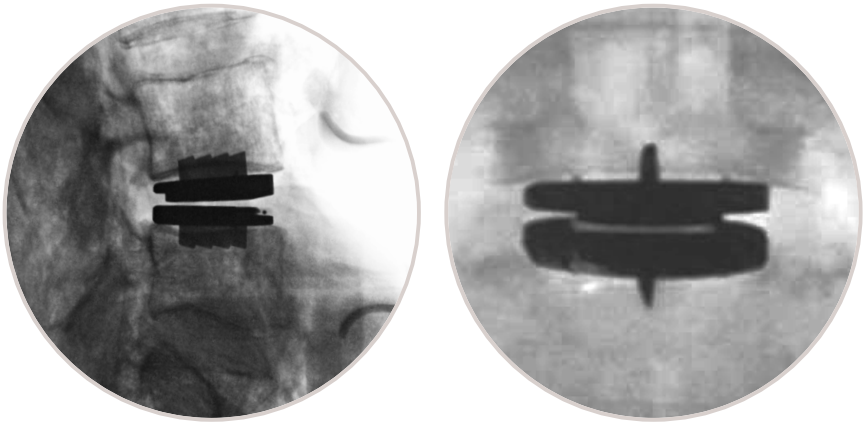


Figure 39.

Post-Operative Care

Following surgery, patients can begin ambulating on postoperative days 1 – 3 with supervised use of a walker and a simple corset when out of bed. Isometric leg exercises are recommended for the first two weeks postoperatively, with the subsequent initiation of out- patient physical therapy.

Patients should be instructed to avoid excessive bending or lifting for the first two weeks postoperatively, and can begin driving, light bending, and lifting from 2 to 6 weeks postoperatively, gradually resuming normal activities beginning at 6 weeks postoperatively.

Post-Operative Removal Procedure

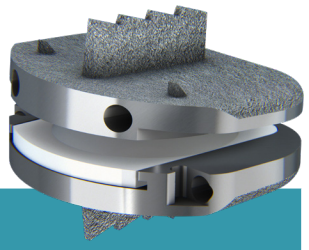
Should it be necessary to remove a prodisc L, please contact Centinel Spine to receive instructions regarding data collection. All explanted devices must be returned to Centinel Spine for analysis.

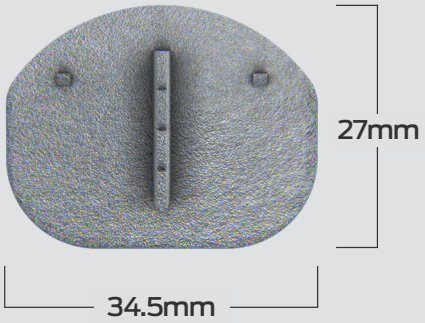
Please note that the prodisc L implant should be removed as carefully as possible in order to keep the implant and surrounding tissue intact. Also, please provide descriptive information about the gross appearance of the device in situ, as well as descriptions of the removal methods, i.e., intact or in pieces.

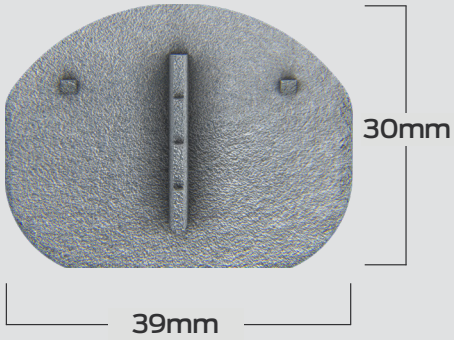
NOTE: *All implant removals must be reported immediately to Centinel Spine by emailing* **explant@centinelspine.com.**

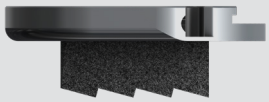
Implants

prodisc L Total Disc Replacement Implant Components, Sterile





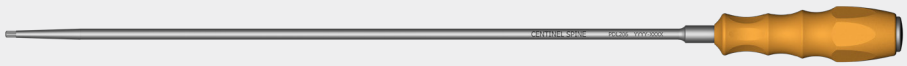


Components		Part Numbers	
		Medium	Large
Superior Endplates 	3º	PDL-M-SP03S	PDL-L-SP03S
	6º	PDL-M-SP06S	PDL-L-SP06S
	11º	PDL-M-SP11S	PDL-L-SP11S
Polyethylene Inlays 	10mm	PDL-M-PT10S	PDL-L-PT10S
	12mm	PDL-M-PT12S	PDL-L-PT12S
Inferior Endplates 	0º	PDL-M-IP00S	PDL-L-IP00S
	3º	PDL-M-IP03S	PDL-L-IP03S
	8º	PDL-M-IP08S	PDL-L-IP08S

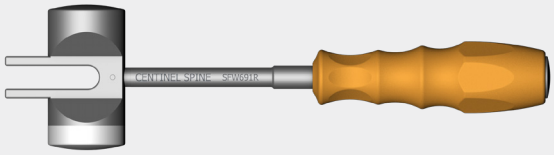
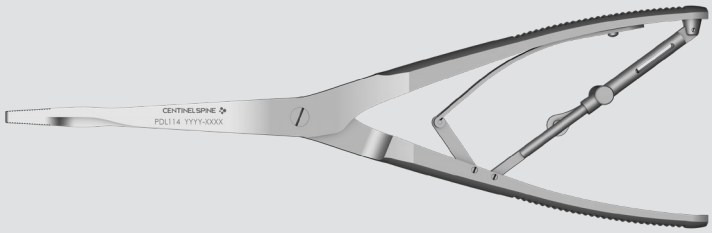
Instruments

CASE 1 | TOP TRAY | Instruments

	prodisc L Trial Implants		
PDL222	Medium, 6°	10mm	
PDL224		12mm	
PDL232	Medium, 11°	10mm	
PDL234		12mm	
PDL242	Large, 6°	10mm	
PDL244		12mm	
PDL252	Large, 11°	10mm	
PDL254		12mm	

PDL206 or SFW602R	Screwdriver, for Adjustable Stop	
PDL202	Handle, for Trial Implant	
PDL208 or SFW601R	Adjustable Stop, for Trial Implants	

CASE 1 | BOTTOM TRAY | Instruments

PDL120	Midline Marker, 8 mm width, 250 mm	
PDL116 or SFW580R	Bone Elevator, 17 mm width, 337 mm	
PDL102 or SFW691R	Slotted Mallet	
PDL114 or SFW650R	Vertebral Body Spreader, angled	
PDL118	Midline Indicator	

CASE 2 | TOP TRAY | Instruments

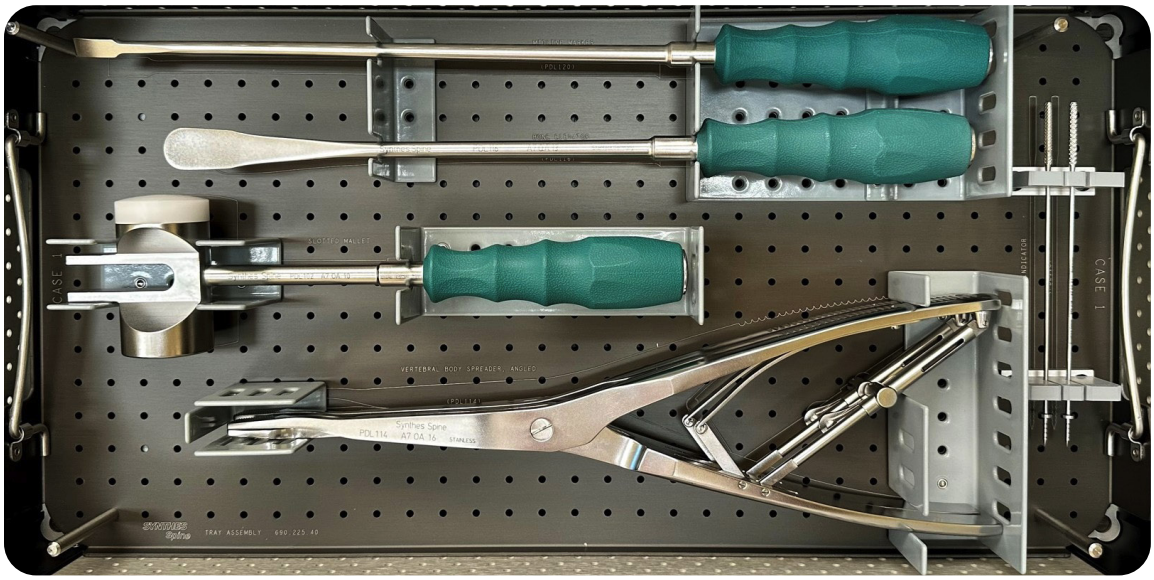
PDL322	Chisel	10mm	
PDL324		12mm	
PDL422 or SFW874R	Distractor	10mm	
PDL424 or SFW875R		12mm	
IN1570	Superior Impactor	Medium	
IN1571		Large	
IN1575	Hemi Chisel +3mm	10mm	
IN1576		12mm	
IN1692	Strut		

CASE 2 | BOTTOM TRAY | Instruments

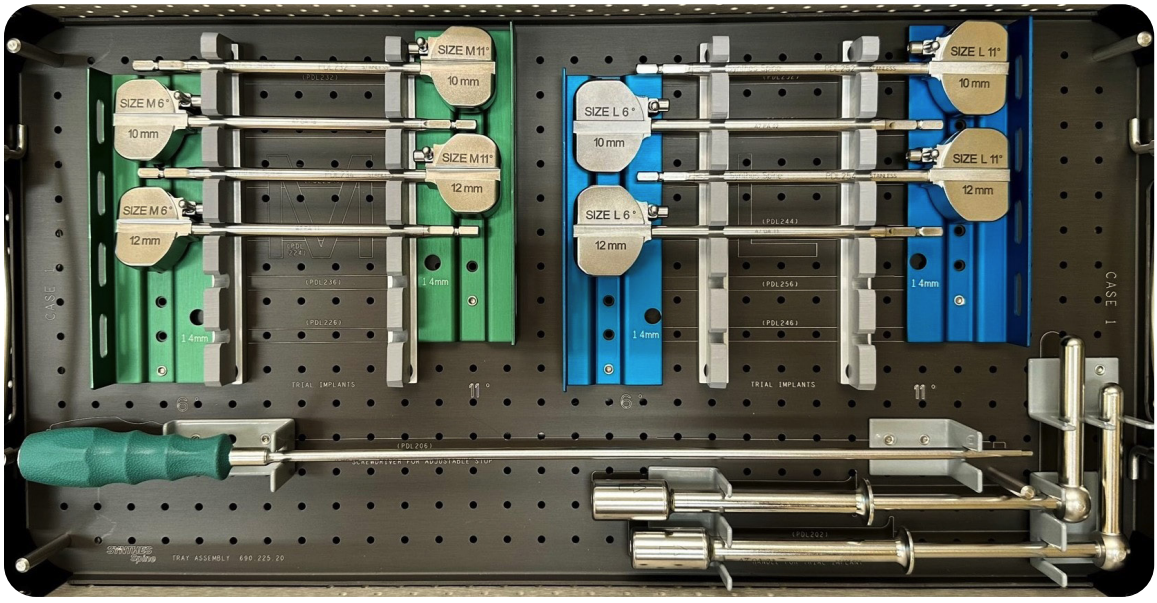
PDL402 or SFW672R	Inserter	Medium	
PDL404 or SFW673R		Large	
PDL432 or SFW577R	Inlay Pusher	Medium	
PDL434 or SFW578R		Large	
PDL442 or SFW582R	Lever		

Instrument Set

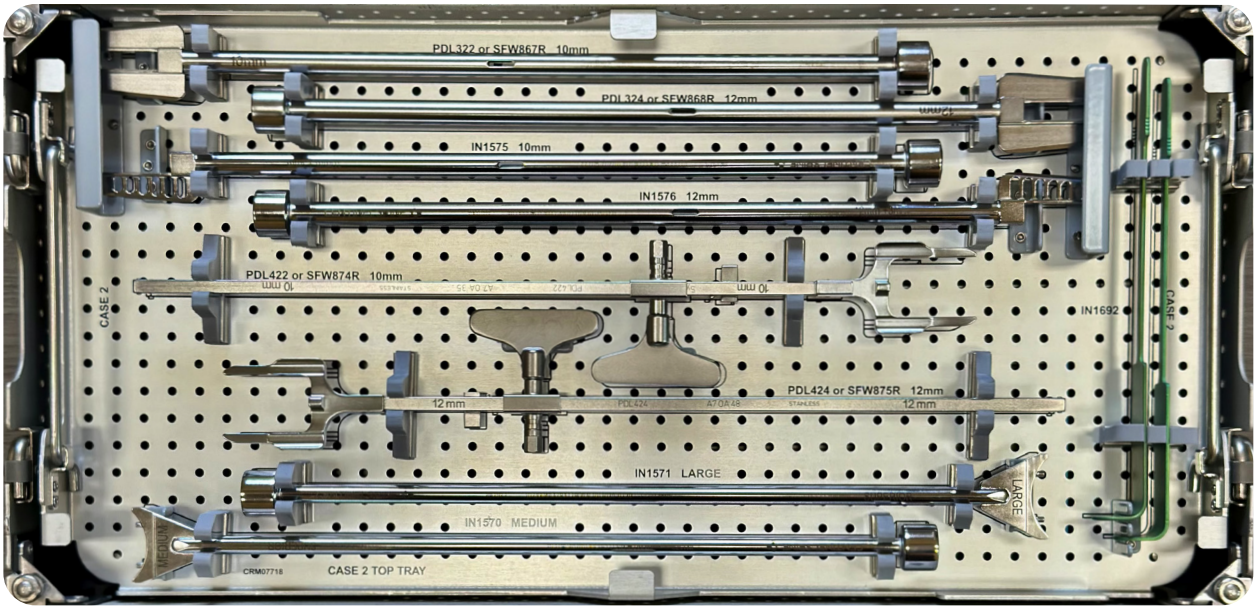
CASE 1 | TOP TRAY | Instrument Set Configuration



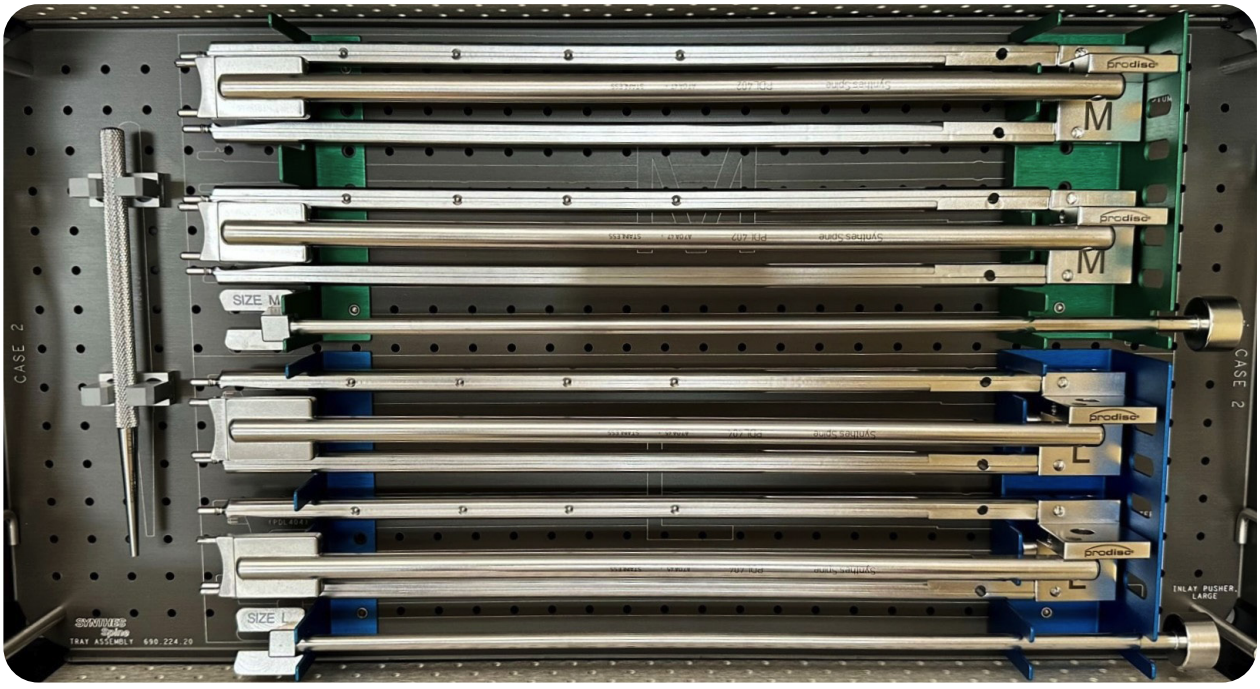
CASE 1 | BOTTOM TRAY | Instrument Set Configuration



CASE 2 | TOP TRAY | Instrument Set Configuration



CASE 2 | BOTTOM TRAY | Instrument Set Configuration



Processing, Reprocessing, Care & Maintenance

For additional information, please refer to package insert.

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://prodiscguides.centinelspine.com

For general information about reprocessing, care, and maintenance of Centinel Spine reusable devices, instrument trays, and cases, please refer to:

http://prodiscguides.centinelspine.com

For detailed cleaning and sterilization instructions, please refer to:

http://prodiscguides.centinelspine.com

References

[1] Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2024.

[2] Data on file at Centinel Spine.

[3] Lydick E, Cook K, Turpin J, et al. "Development and validation of a simple questionnaire to facilitate identification of women likely to have low bone density." Am J Man Care 1998; 4:37 – 48

CENTINEL SPINE

US Headquarters: 900 Airport Rd, Ste. 3B, West Chester, PA 19380 USA
Email (US): info@centinelspine.com
Web: www.centinelspine.com