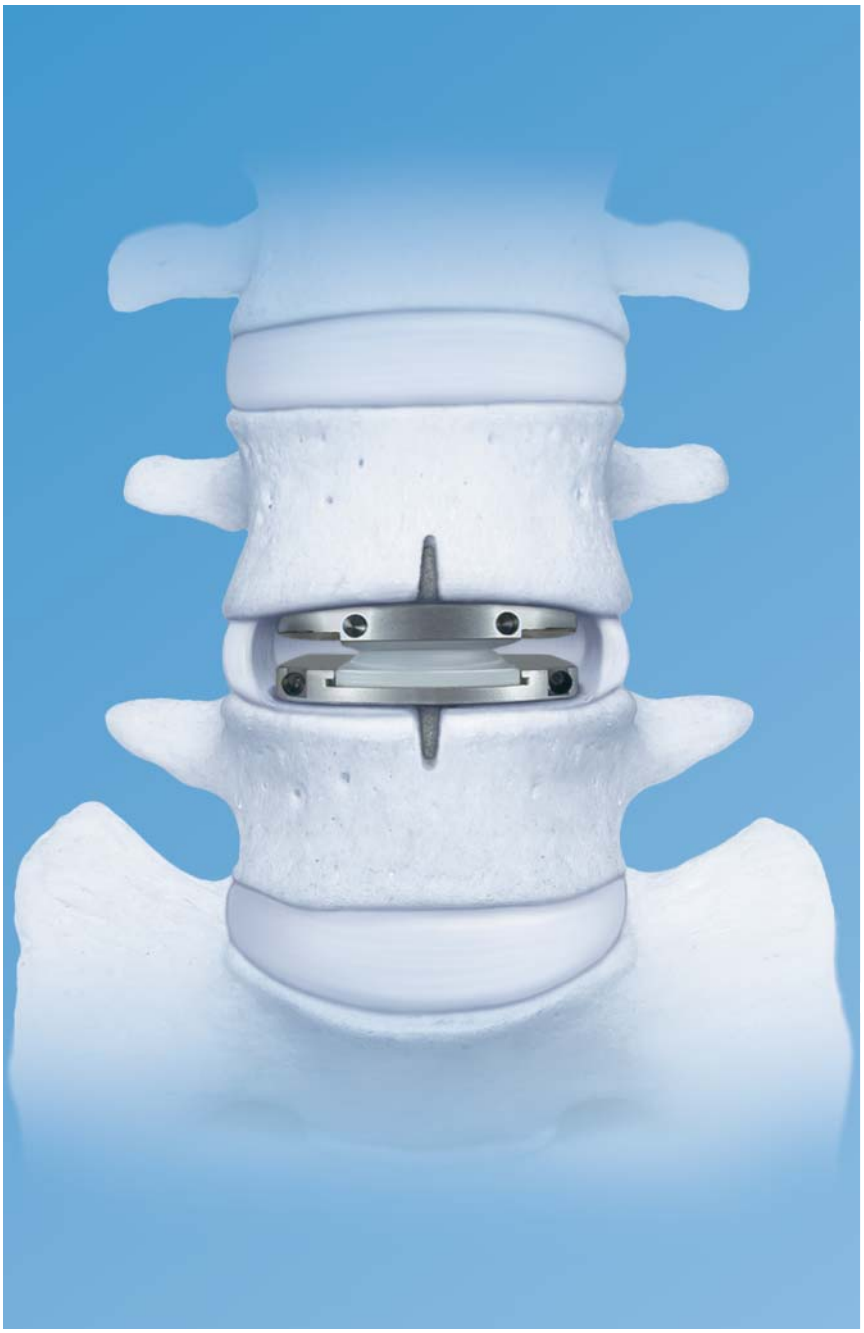
ProDisc-L Total Disc Replacement.

For replacement of a diseased and/or degenerated intervertebral disc of the lumbosacral region.

Technique Guide



SYNTHES® Spine

Instruments and implants approved by the AO Foundation

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Image intensifier control

Introduction

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 lumbar spinal segment level 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) end plates and an ultra-high-molecular-weight polyethylene (UHMWPE) inlay. The polyethylene inlay includes a radiopaque tantalum marker. The ProDisc-L Total Disc Replacement end plates 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 (Figure 1). The UHMWPE/CoCrMo coupling has historically been used in total joint replacement and has been used in spinal arthroplasty procedures for two decades.

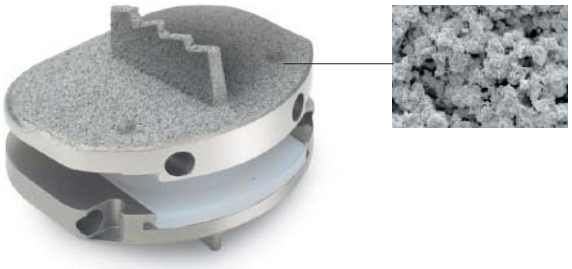


Figure 1

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 4 for further information.

Features

Ball and socket principle provides a fixed center of rotation (Figure 2)
- 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

Figure 2

Modular design accommodates anatomical needs of individual patients (Figures 3 and 4)
- Medium and large footprints
- 10, 12 and 14 mm heights
- 6° and 11° lordotic angles*
- 12 anatomical combinations

Figure 3

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, end plate preparation, and remobilization of the disc space
- Optimal implant footprint, height, lordosis selection, and placement

Figure 4

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 level 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. 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 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 end plate 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
Synthes 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 3.0 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 nonclinical testing, a Synthes ProDisc-L implant of largest geometrical volume and mass was tested for heating and results showed a maximum observed heating of 1.8°C for 1.5 T and a maximum observable heating of 1.7°C 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 2°C. 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. Synthes 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 15°, 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 70°, 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 significant 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)[1] 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 end plates 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 5).

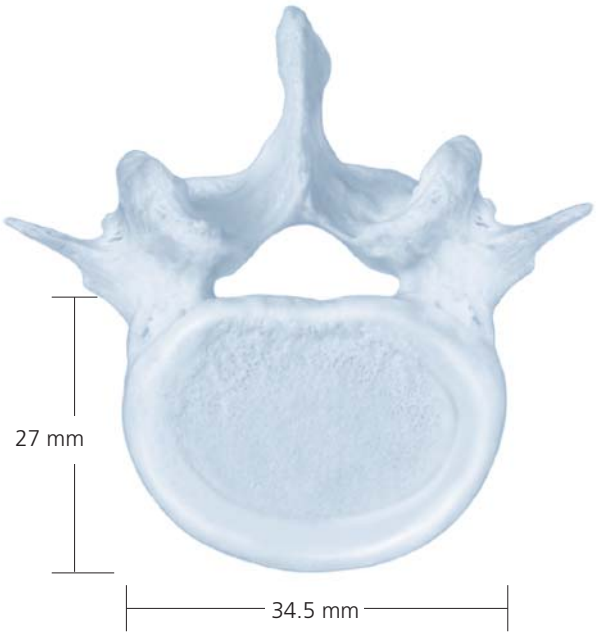


Figure 5

1 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.

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 90°. Alternatively, the arms may be adducted and crossed over the chest (Figure 6).

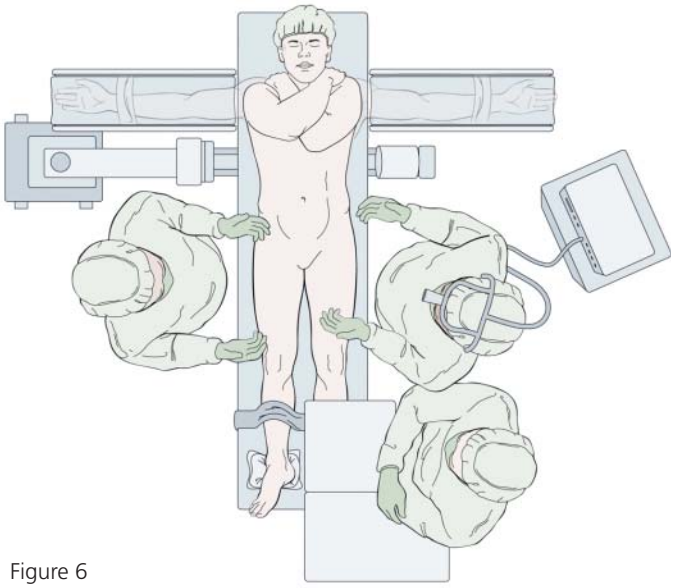


Figure 6

Anterior access and 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 7).

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 8). Elevate the anterior rectus sheath to allow for full mobilization of the rectus muscle (Figure 9).

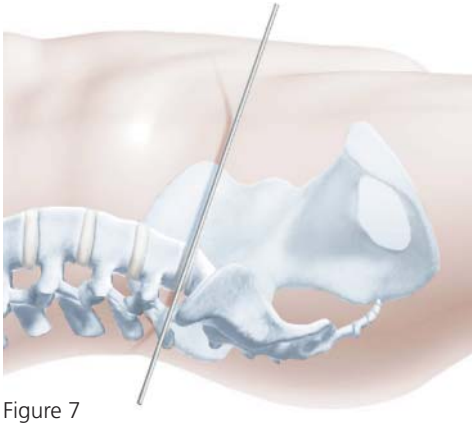


Figure 7

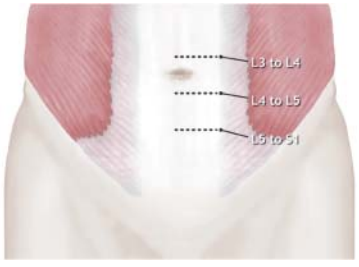


Figure 8

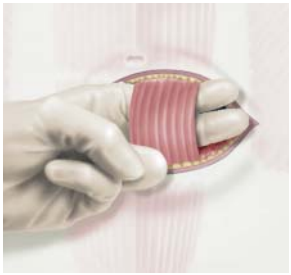


Figure 9

Anterior access and approach continued

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 10).

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 11).

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 12).

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

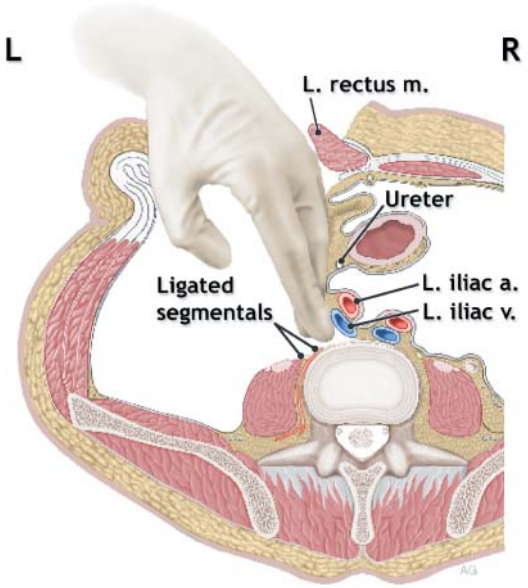


Figure 10

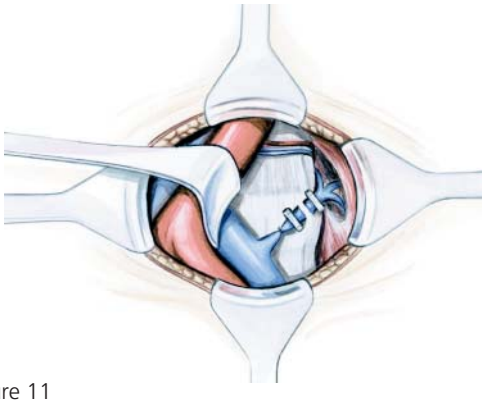


Figure 11

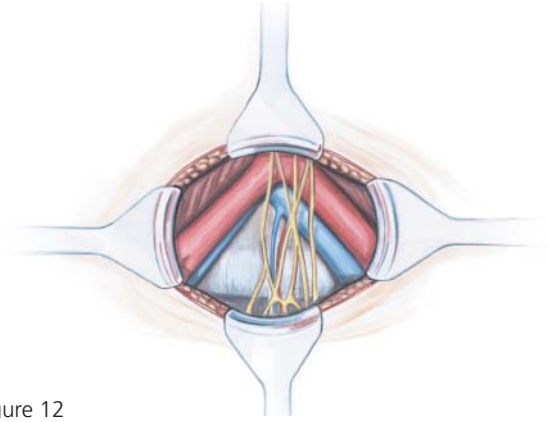


Figure 12

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 13). 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.

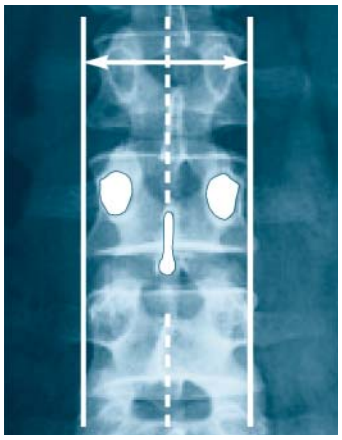


Figure 13

Discectomy, end plate preparation, and remobilization

Instruments	
PDL114	Vertebral Body Spreader, angled
PDL116	Bone Elevator, 17 mm width, 337 mm

Note: Performing a complete and meticulous discectomy and remobilization of the disc space is critical to the success of the surgery.

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 Total Disc Replacement implant (Figure 14).

Perform a thorough discectomy using the bone elevator and standard rongeurs, Kerrisons, and curettes, ensuring the posterolateral corners are freed of disc material (Figure 15).

Figure 14

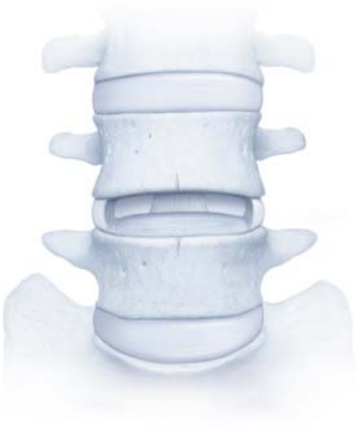


Figure 15

Discectomy, end plate preparation, and remobilization

continued

Under fluoroscopic control, insert the vertebral body spreader to the posterior margin of the vertebral bodies to gradually remobilize the motion segment (Figure 16). Placement of the tips to the posterior margin will minimize the risk of end plate fracture. Place the spreader on one side to facilitate the discectomy on the contralateral side, and then repeat for the other side.

Vertebral body spreader

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

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 (Figure 17).

Two vertebral body spreaders can be used to obtain balanced remobilization.

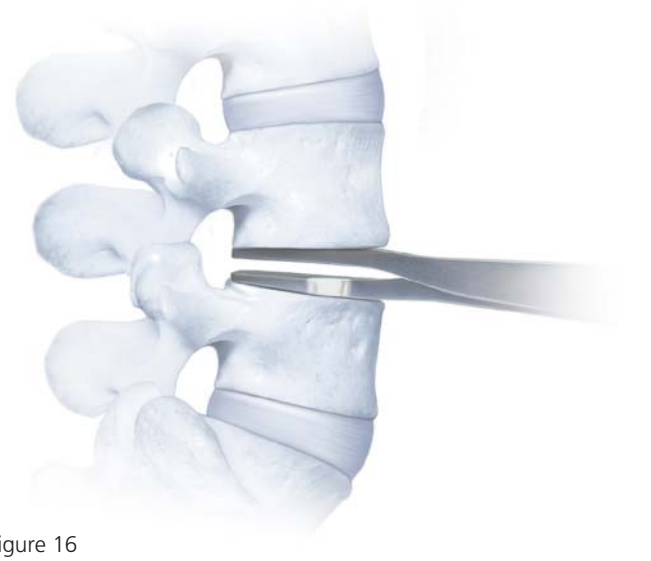


Figure 16

Note: Ensure that a complete discectomy is performed and the integrity of the bony end plates 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 end plate fracture. Remodeling of the end plates 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 Total Disc Replacement. Parallel distraction is critical for restoration of disc height.

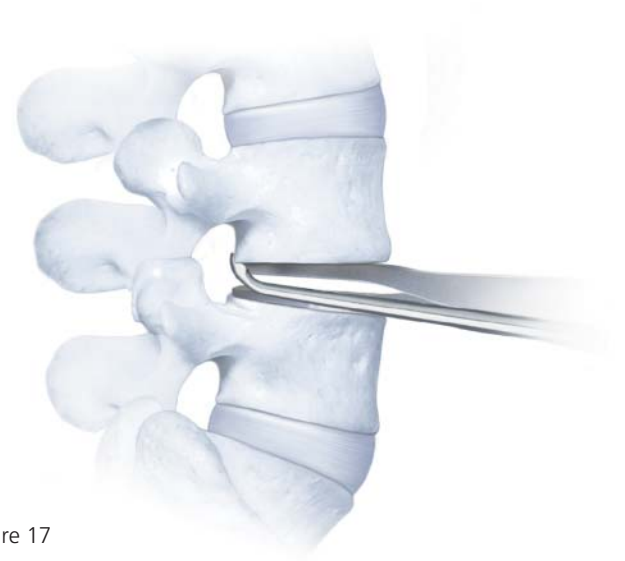
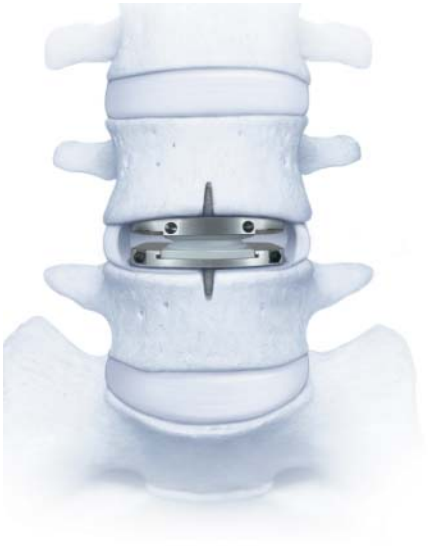


Figure 17

Implantation

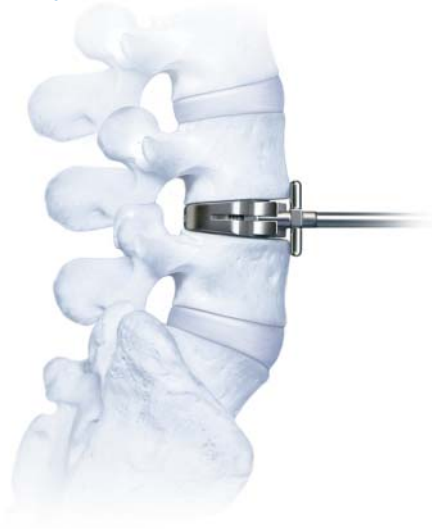
The ProDisc-L Total Disc Replacement contains 12 trials that correspond to the 12 possible ProDisc-L Total Disc Replacement implant sizes. Trials are placed into the disc space intraoperatively to determine the appropriate implant footprint, lordotic angle and disc height.

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 Total Disc Replacement end plates will follow the path of the chisel cuts to its final position. Lastly, the end plates are distracted and the polyethylene inlay is inserted and locked into the inferior end plate.

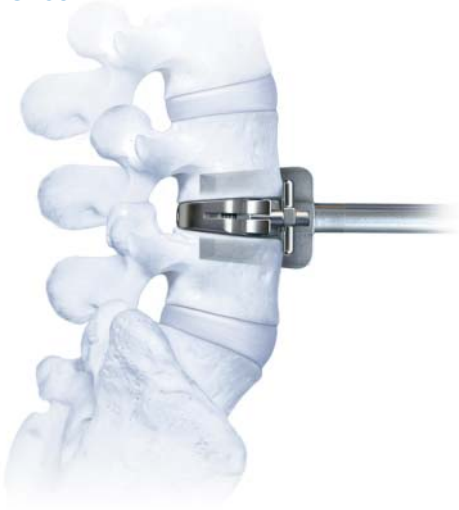


Implantation of the ProDisc-L Total Disc Replacement implant is performed in three steps:

1
Trial



2
Chisel



3
Insert implant

1
Trial

Instruments	
PDL102	Slotted Mallet
PDL202	Handle, for Trial Implant
PDL206	Screwdriver, for Adjustable Stop
PDL208	Adjustable Stop, for Trial Implants
PDL222 – PDL256	Trial Implants

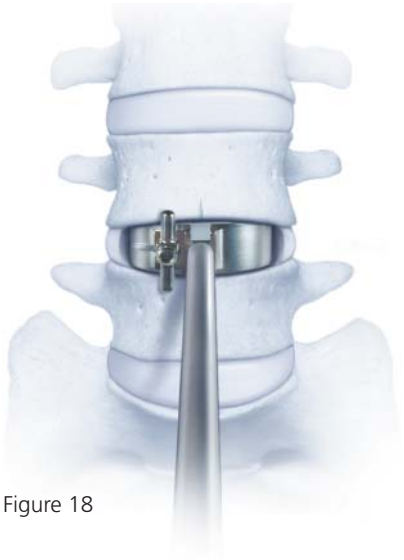


Figure 18

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 implant and can be oriented in one of four positions.

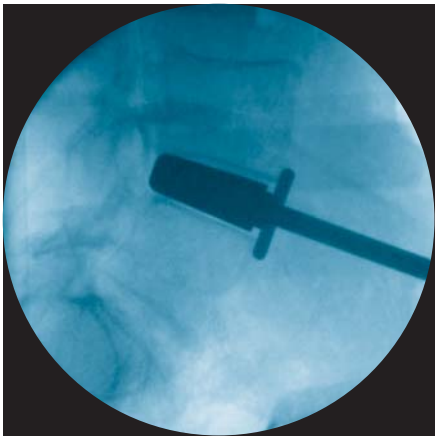
Insert the trial into the intervertebral disc space, centered on the midline mark and aligned with the sagittal plane of the vertebral body (Figure 18).

Trial Handle

Under lateral fluoroscopic control, advance the trial to the posterior margin of the vertebral bodies with the slotted mallet. The stop can be backed out to allow the trial to be positioned more posteriorly (Figure 19). Each full counterclockwise 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 adjustable stop instrument 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.



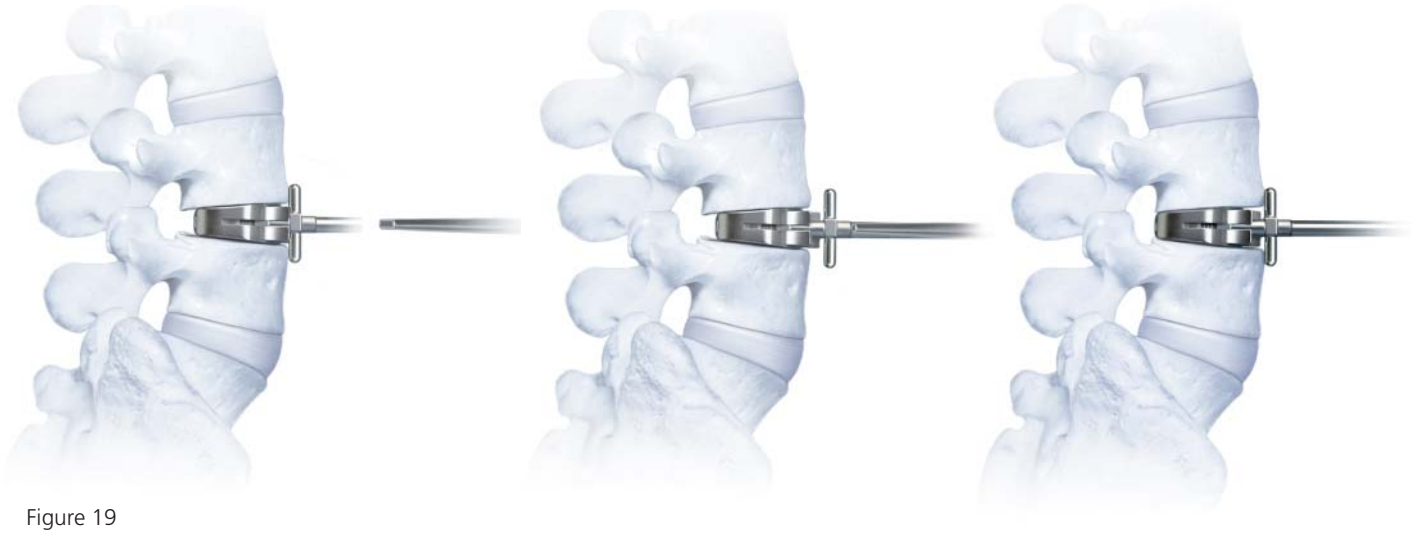


Figure 19

2
Chisel

Instruments	
PDL102	Slotted Mallet
PDL322–PDL326	Chisels

Remove the handle from the trial.

Slide the chisel onto the shaft of the trial. Under lateral fluoroscopic control, advance the chisel into the vertebral bodies with the slotted mallet until the chisel is fully seated on the trial (Figure 20).

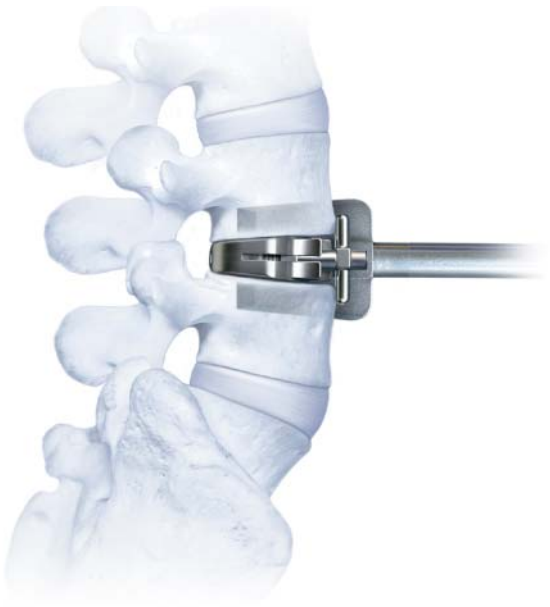


Figure 20

The chisel should be fully seated on the trial; this will ensure that the chisel depth is adequate.

The chisel and trial are left in place until the ProDisc-L Total Disc Replacement 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 fluoroscopic control. The depth of the chisel cuts within both vertebral bodies must be adequate prior to ProDisc-L Total Disc Replacement 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.

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 (Figure 21).

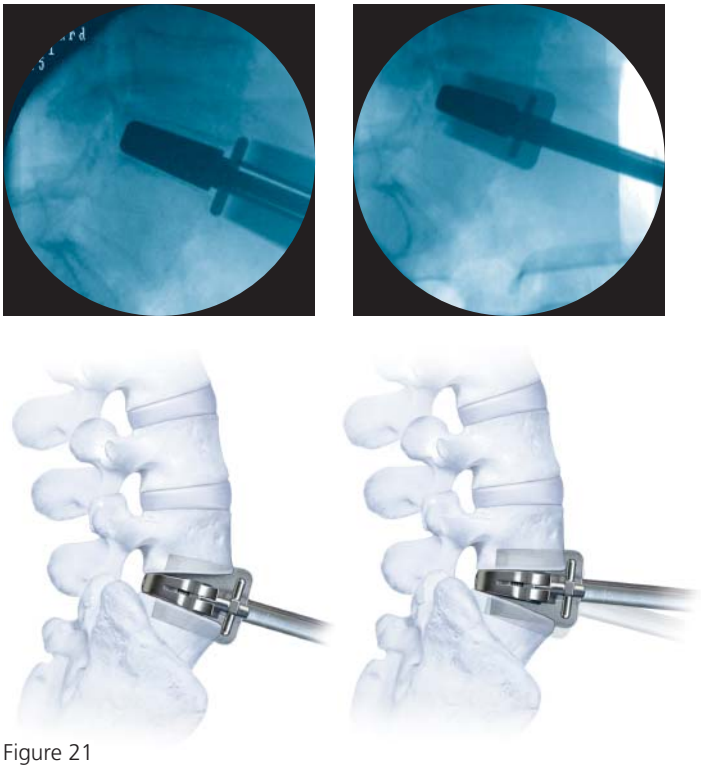


Figure 21

3
Insert implant

Instrument	
PDL102	Slotted Mallet
PDL402–PDL404	Inserters

Inserter

The ProDisc-L Total Disc Replacement implant end plates are inserted in a collapsed position and then distracted for polyethylene inlay insertion. This modular technique facilitates end plate insertion and provides efficient distraction for polyethylene inlay assembly.

End plate insertion
Press the release button on the back of the inserter and rotate the inferior arms outward. Assemble the inferior end plate onto the pins of the inferior arms. Press the release button and rotate the arms inward to lock the inferior end plate onto the pins (Figure 22).

Figure 22

Load the superior end plate onto the pins on the superior arms of the inserter (Figure 23).

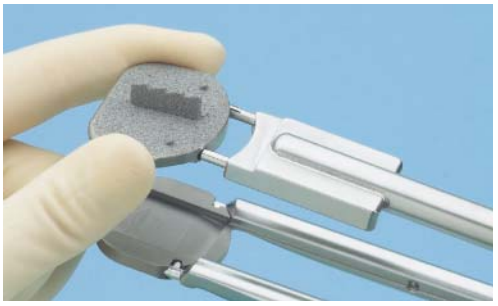


Figure 23

Nest and hold the two end plates together by firmly gripping the inserter arms (Figure 24).

Note: Ensure inferior arms of inserter are correctly locked prior to end plate insertion.

Figure 24

3

Insert implant continued

Remove the chisel and trial. Ensure the disc space is clear of any disc or bony debris.

Align the keels of the ProDisc-L Total Disc Replacement implant with the chisel cuts. Under fluoroscopic control, use the slotted mallet to insert the ProDisc-L Total Disc Replacement end plates to the posterior margin of the vertebral bodies (Figure 25).

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

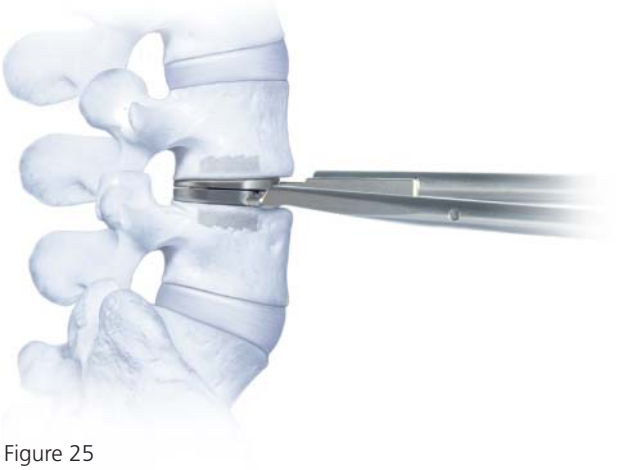


Figure 25

Polyethylene inlay insertion

Instrument	
PDL422– PDL426	Distractors

Distractor

Insert the polyethylene inlay into the grooves in the inferior arms of inserter with the "Dome Up and Dome Up" (Figure 26).

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 27).

Figure 26

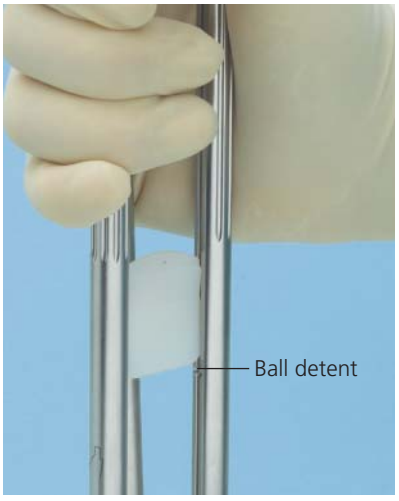


Figure 27

Polyethylene inlay insertion continued

Assemble the distractor to the inserter (Figure 28). Under fluoroscopic control, use the thumbscrew to fully advance the distractor (Figure 29). Verify that the posterior edge of the end plates have separated from each other (Figure 30); this ensures adequate clearance for the insertion of the polyethylene inlay.

Note: Do not attempt to force and lock the polyethylene inlay if the end plates have not separated. Additional discectomy and remobilization may be required if the end plates do not separate.

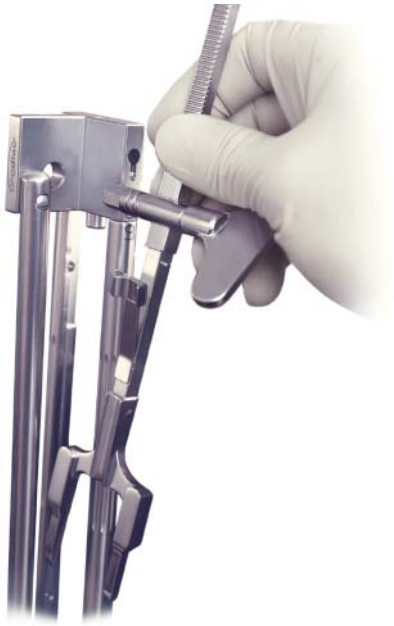


Figure 28

Figure 29

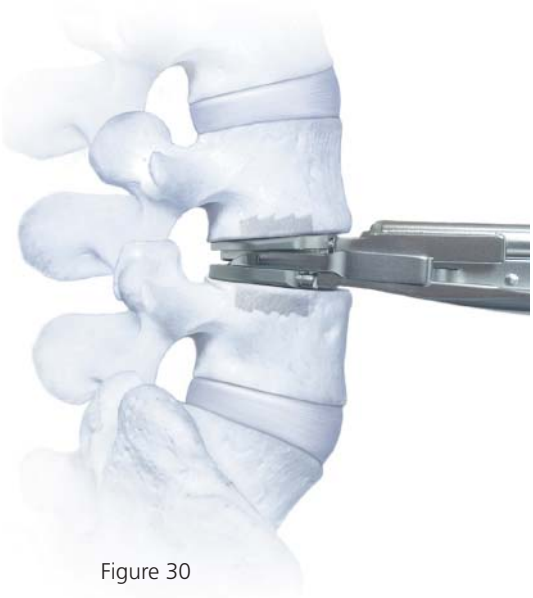
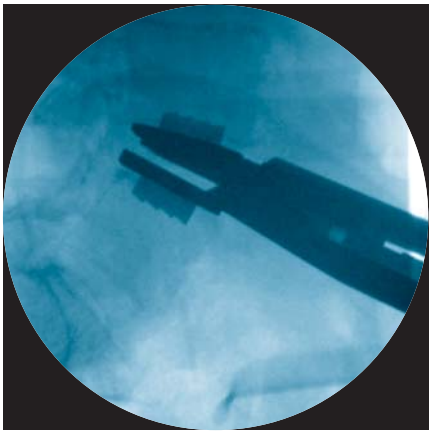


Figure 30



Instrument	
PDL432– PDL434	Inlay Pushers

Insert the inlay pusher into the same grooves in the inferior arms. Manually push and lock the polyethylene inlay into the inferior end plate (Figure 31). Remove the inlay pusher.

Visually confirm the polyethylene inlay is locked into the inferior end plate (Figure 32). A nerve hook may be used to verify that NO STEP and NO GAP are present.

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 end plate by using a nerve hook to verify that NO STEP and NO GAP are present at the anterior edge of the end plate (Figure 33).

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 rotate the inferior arms outward to unlock the inserter. Gently remove the inserter from the ProDisc-L Total Disc Replacement implant.

Inlay pusher

Figure 31

"NO STEP" "NO GAP"

Figure 32

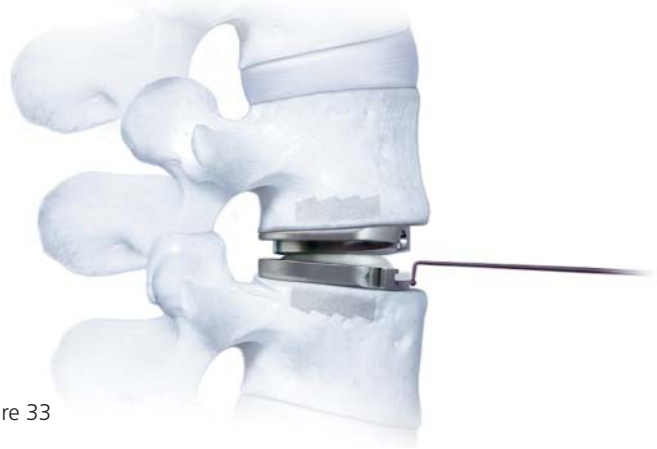


Figure 33

Final implant verification

Verify final implant position with lateral and AP imaging (Figure 34).

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

Postoperative 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 outpatient 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.

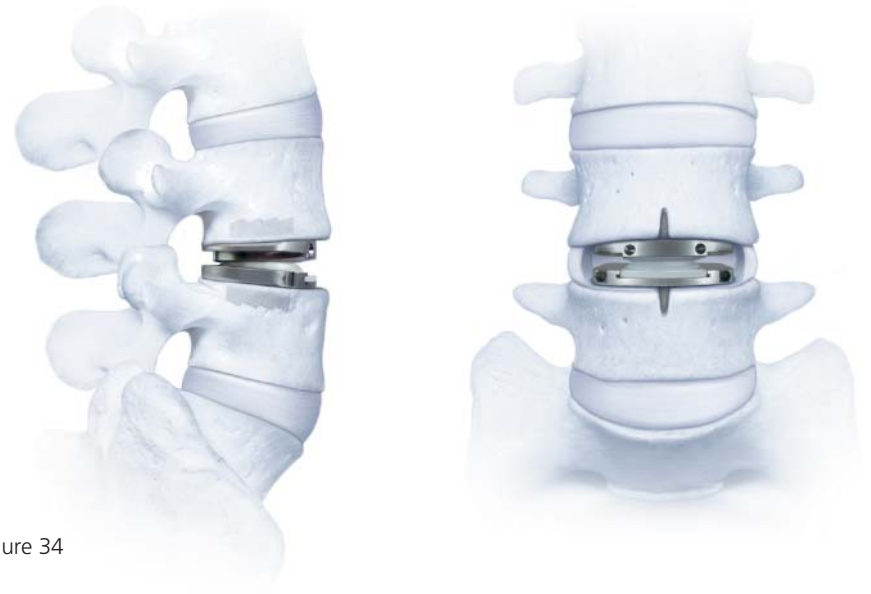
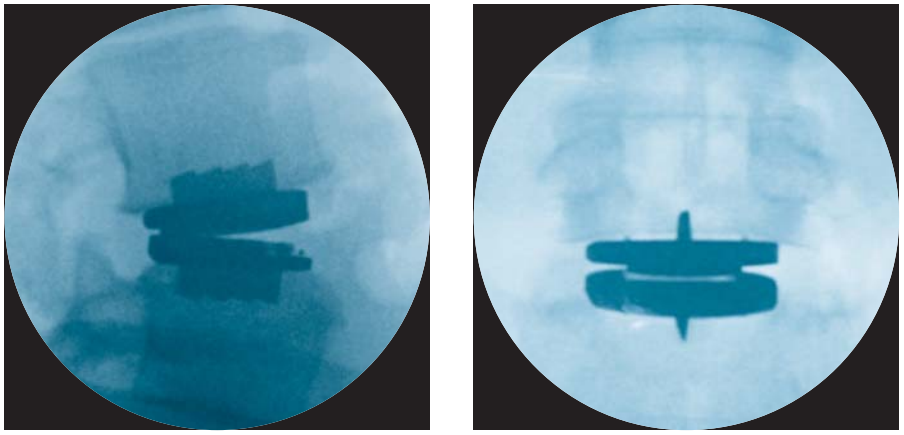


Figure 34



Implants

ProDisc-L Implant Components sold separately

Superior Endplates, sterile

PDL-M-SP06S Medium, 6°
PDL-M-SP11S Medium, 11°
PDL-L-SP06S Large, 6°
PDL-L-SP11S Large, 11°

Inferior Endplates, sterile

PDL-M-IP00S Medium
PDL-L-IP00S Large

Polyethylene Inlays with Tantalum Marker, sterile

PDL-M-PT10S Medium, 10 mm
PDL-M-PT12S Medium, 12 mm
PDL-M-PT14S Medium, 14 mm
PDL-L-PT10S Large, 10 mm
PDL-L-PT12S Large, 12 mm
PDL-L-PT14S Large, 14 mm

ProDisc-L Implant Component Reference Table

		Medium	Large
Superior Endplates 	6°	PDL-M-SP06S	PDL-L-SP06S
	11°	PDL-M-SP11S	PDL-L-SP11S
Polyethylene Inlays 	10 mm	PDL-M-PT10S	PDL-L-PT10S
	I2 mm	PDL-M-PT12S	PDL-L-PT12S
	I4 mm	PDL-M-PT14S	PDL-L-PT14S
Inferior Endplates 		PDL-M-IP00S	PDL-L-IP00S

Instruments

PDL102	Slotted Mallet	
PDL114	Vertebral Body Spreader, angled	
PDL116	Bone Elevator, 17 mm width, 337 mm	
PDL118	Midline Indicator	
PDL120	Midline Marker, 8 mm width, 250 mm	
PDL202	Handle, for Trial Implant	
PDL206	Screwdriver, for Adjustable Stop	

PDL222	Trial Implant, medium, 6°, 10 mm
PDL224	Trial Implant, medium, 6°, 12 mm
PDL226	Trial Implant, medium, 6°, 14 mm

PDL232	Trial Implant, medium, 11°, 10 mm
PDL234	Trial Implant, medium, 11°, 12 mm
PDL236	Trial Implant, medium, 11°, 14 mm

PDL242	Trial Implant, large, 6°, 10 mm
PDL244	Trial Implant, large, 6°, 12 mm
PDL246	Trial Implant, large, 6°, 14 mm

PDL252	Trial Implant, large, 11°, 10 mm
PDL254	Trial Implant, large, 11°, 12 mm
PDL256	Trial Implant, large, 11°, 14 mm

PDL208	Adjustable Stop, for Trial Implants

PDL322	Chisel, 10 mm
PDL324	Chisel, 12 mm
PDL326	Chisel, 14 mm

PDL402	Inserter, medium
PDL404	Inserter, large

PDL422	Distractor, 10 mm
PDL424	Distractor, 12 mm
PDL426	Distractor, 14 mm

PDL432	Inlay Pusher, medium
PDL434	Inlay Pusher, large

PDL442	Lever

ProDisc-L Instrument Set (PDL1000)

Graphic Cases

690.225	Graphic Case, for ProDisc-L Instruments (1)
690.224	Graphic Case, for ProDisc-L Instruments (2)

Instruments

PDL102	Slotted Mallet
PDL114	Vertebral Body Spreader, angled, 2 ea.
PDL116	Bone Elevator, 17 mm width, 337 mm
PDL118	Midline Indicator, 2 ea.
PDL120	Midline Marker, 8 mm width, 250 mm
PDL202	Handle, for Trial Implant, 2 ea.
PDL206	Screwdriver, for Adjustable Stop
PDL208	Adjustable Stop, for Trial Implants, 12 ea.
PDL322	Chisel, 10 mm
PDL324	Chisel, 12 mm
PDL326	Chisel, 14 mm
PDL402	Inserter, medium, 2 ea.
PDL404	Inserter, large, 2 ea.
PDL422	Distractor, 10 mm
PDL424	Distractor, 12 mm
PDL426	Distractor, 14 mm
PDL432	Inlay Pusher, medium
PDL434	Inlay Pusher, large
PDL442	Lever

690.225

690.224

Note: For additional information, please refer to package insert.
For detailed cleaning and sterilization instructions, please refer to
http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm
or to the below listed inserts, which will be included in the shipping container:
– Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305

Trial Implants

	Trial Implants
PDL222	Trial Implant, Medium, 6°, 10 mm
PDL224	Trial Implant, Medium, 6°, 12 mm
PDL226	Trial Implant, Medium, 6°, 14 mm
PDL232	Trial Implant, Medium, 11°, 10 mm
PDL234	Trial Implant, Medium, 11°, 12 mm
PDL236	Trial Implant, Medium, 11°, 14 mm
PDL242	Trial Implant, Large, 6°, 10 mm
PDL244	Trial Implant, Large, 6°, 12 mm
PDL246	Trial Implant, Large, 6°, 14 mm
PDL252	Trial Implant, Large, 11°, 10 mm
PDL254	Trial Implant, Large, 11°, 12 mm
PDL256	Trial Implant, Large, 11°, 14 mm

Synthes Spine
1302 Wrights Lane East
West Chester, PA 19380
Telephone: (610) 719-5000
To order: (800) 523-0322
Fax: (610) 251-9056

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