ProDisc-L Total Disc Replacement.
Product information.

Modular ball and socket implant

Reproducible surgical technique

Maintains motion

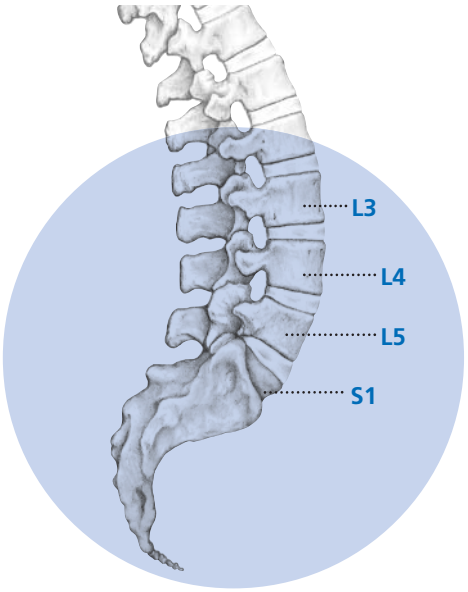
SYNTHES® Spine

Instruments and implants approved by the AO Foundation

ProDisc-L Total Disc Replacement

Indications

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.



ProDisc-L design

The ProDisc-L Total Disc Replacement is the first and only FDA-approved spinal arthroplasty device to utilize a semi-constrained ball and socket. The integration of the ball and socket, established arthroplasty materials, and refined instrumentation into the ProDisc-L system has resulted in a total disc replacement that is safe and effective, with a simple and reproducible surgical technique.

ProDisc-L motion

The ProDisc-L IDE clinical study is the first and only to assess range of motion in a spinal arthroplasty device as a primary endpoint of overall success. Ninety-four percent (94%) of all ProDisc-L patients demonstrated normal range of motion at 24 months. The ProDisc-L implant maintains motion at the implanted level and may help to restore spinal balance.

Design Philosophy

Ball and socket

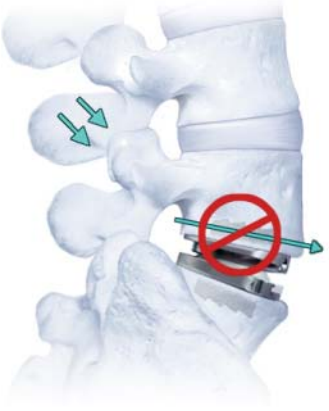
The ProDisc-L implant is composed of three components: two cobalt chromium alloy (CoCrMo) end plates and an ultra-high-molecular-weight polyethylene (UHMWPE) inlay. The polyethylene inlay includes a radiographic tantalum marker. The end plates are inserted into position and the polyethylene inlay is locked into the inferior end plate, creating the ball and socket joint.

Controlled and predictable motion

The locked polyethylene inlay creates a single articulation with the superior end plate, forming a ball and socket joint with a fixed center of rotation. Motion is controlled and predictable along the polyethylene inlay dome, regardless of loading conditions.

Controlled translation

The ProDisc-L Total Disc Replacement is a semi-constrained implant that restores the normal range of motion while controlling translation. The highly conforming surfaces of the superior end plate and polyethylene inlay prevent the end plates from translating independently.



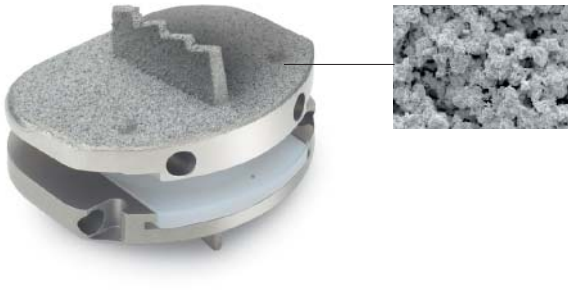
Patented keel fixation with porous plasma-sprayed titanium coating

Secure primary fixation

The patented central keel and lateral spikes on the ProDisc-L implant provide immediate and secure fixation to the vertebral bodies.

Long-term fixation and bony integration

A porous plasma-sprayed titanium coating covers all bone-contacting surfaces to promote bony integration for long-term fixation.



Established arthroplasty materials

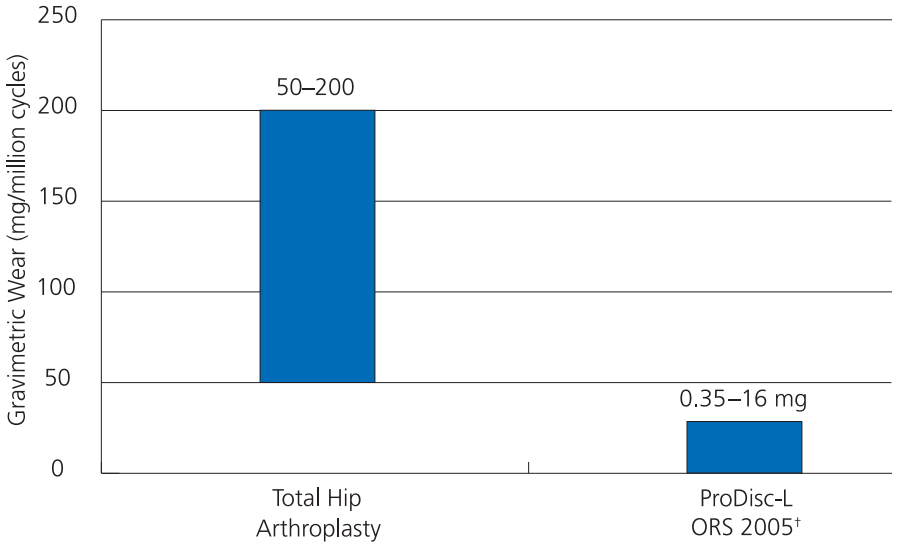
Nearly two decades of clinical use in the spine

CoCrMo/UHMWPE has been used clinically in spinal arthroplasty devices since 1987 and has been determined to be safe and effective in two total disc replacement IDE studies. The CoCrMo/UHMWPE articulation has the longest clinical history in spinal arthroplasty. ProDisc I was initially implanted in 1990, and over 30,000* ProDisc-L devices have been implanted worldwide since 1999.

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 product insert for further information.

Wear rates are significantly less than total joints



In vitro wear rates depend on numerous testing parameters such as load, range of motion, and motion patterns. ProDisc-L was tested under a variety of conditions.

Due to the lower loads and range of motion, clinical wear rates in the spine are significantly less than hips and knees.

† Reference: Nechtow, Orthopaedic Research Society, 2005.

Sizing

ProDisc-L sizing is simple and intuitive, with 12 anatomical implant combinations. The modular design allows the surgeon to select the appropriate footprint, height, and lordotic angle that best match patient anatomy.

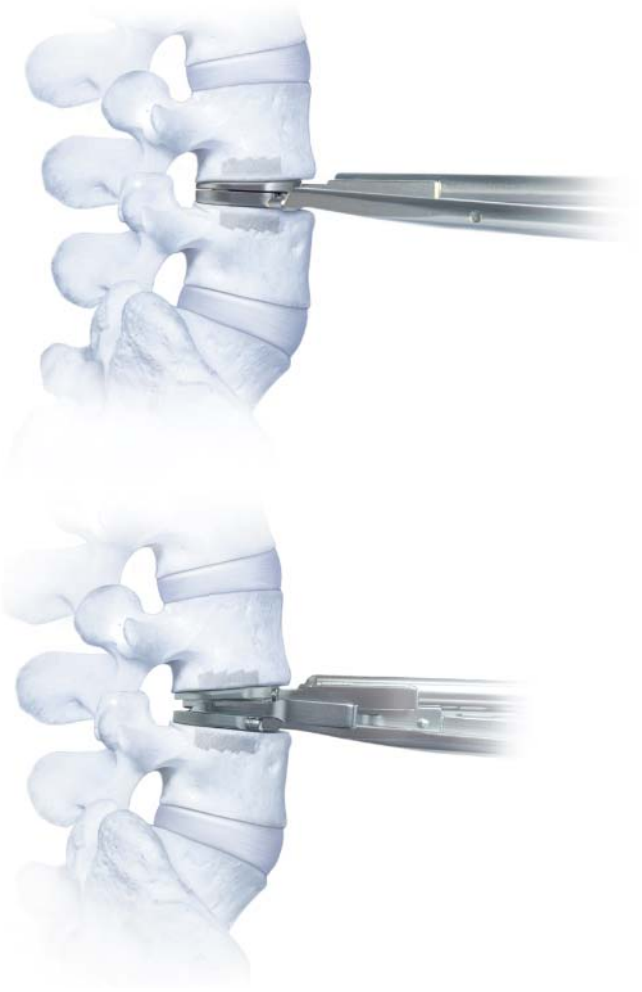
– 2 Footprints: medium and large
– 3 Heights: 10, 12 and 14 mm
– 2 Lordotic angles: 6° and 11°

*Through December, 2010.

Modular design

Facilitates implant insertion
The ProDisc-L end plates are nested together and inserted in a collapsed position. This unique nesting design facilitates placement into the disc space with minimal force.

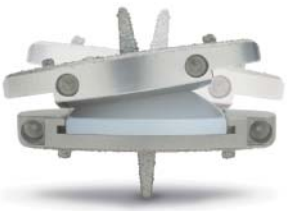
Controlled distraction
Once the end plates are in place, the polyethylene inlay is inserted under controlled distraction. This precise distraction technique minimizes forces in the spinal segment.



Normal range of motion

The ProDisc-L implant is designed to restore a normal range of motion† in flexion/extension, lateral bending, and axial rotation.

Patients in the IDE clinical study exhibited a mean range of motion of 7.7° at 24 months.

Flexion/Extension	Lateral Bending	Axial Rotation
		
13°/7°	10°/10°	Limited by anatomy

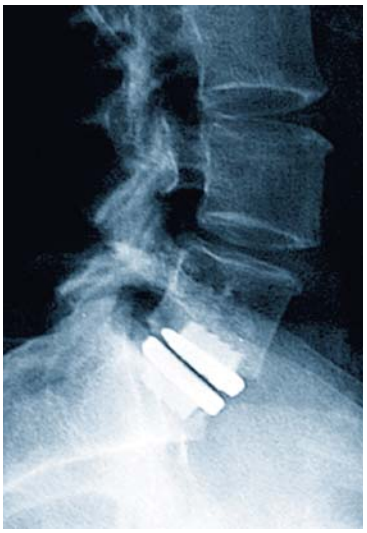
† References: White and Panjabi (1990), Hayes (1989), Pearcy (1984,1985), Dvorak (1989,1991), Louis (1982).

Clinical Results

Long-term clinical results

The ProDisc-L concept was developed in the late 1980s by Dr. Thierry Marnay, a French orthopaedic surgeon. From 1990 to 1993, Dr. Marnay and a surgeon colleague implanted a series of ProDisc I Total Disc Replacements. A total of 64 patients were implanted with 93 devices, and then followed to evaluate the performance of ProDisc I. A retrospective analysis of 55 of the original 64 patients showed the following results 7 to 11 years postoperatively:

– Patients reported a significant decrease in back and leg pain
– 91% of the patients were satisfied with the procedure
– All implants were intact
– There was no evidence of osteolysis



Lateral radiograph of ProDisc I

ProDisc I (1990) → **ProDisc-L (1999)**

Ball and socket kinematics	→	Clinically proven, no change
Keel fixation	→	Clinically proven, single keel facilitates midline placement
Ti/UHMWPE articulation	→	CoCrMo/UHMWPE articulation provides superior wear characteristics
Enbloc insertion	→	Modular insertion facilitates surgical technique

IDE clinical study

The ProDisc-L Total Disc Replacement was studied and approved using the most comprehensive overall success criteria for any FDA-approved spinal arthroplasty device. The prospective, randomized trial was conducted at 17 centers across the United States and studied 292 patients with degenerative disc disease (DDD) at a single level from L3 to S1. Patients were randomized 2:1 to receive either a ProDisc-L Total Disc Replacement or a circumferential spinal fusion. Each patient was required to demonstrate success in ten primary endpoints to be considered an overall success.

The IDE clinical study for the ProDisc-L Total Disc Replacement was not designed to demonstrate superiority; however, **there was a statistically significant difference in favor of the ProDisc-L group in the rate of overall success.***[1]

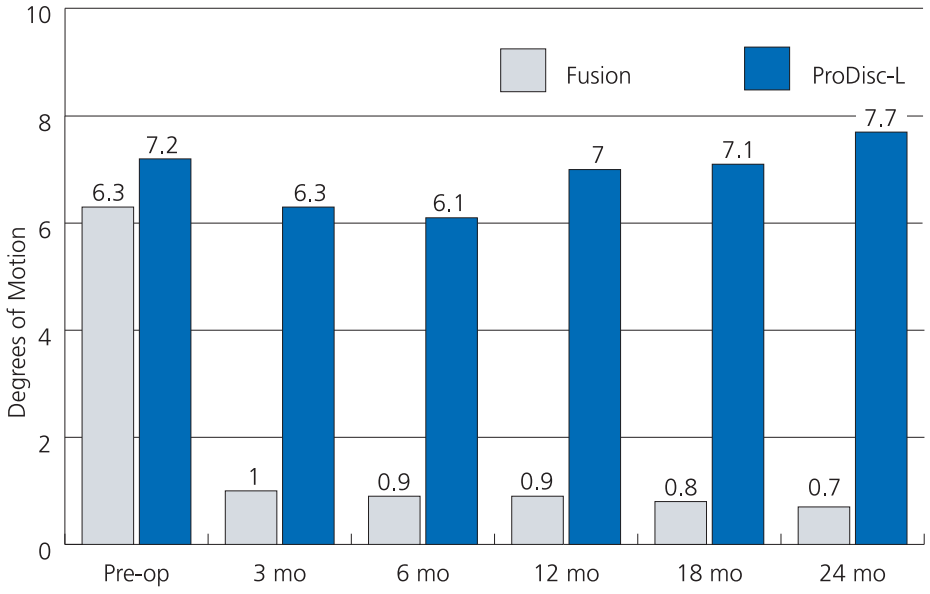
Maintains motion

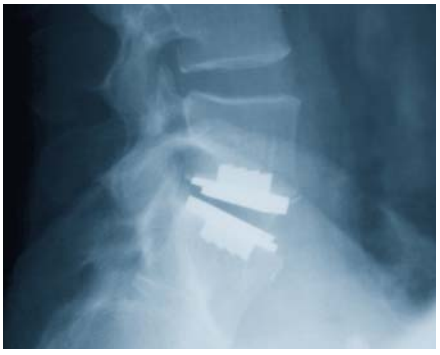
– 93.7% of ProDisc-L patients had normal motion† at 24 months.

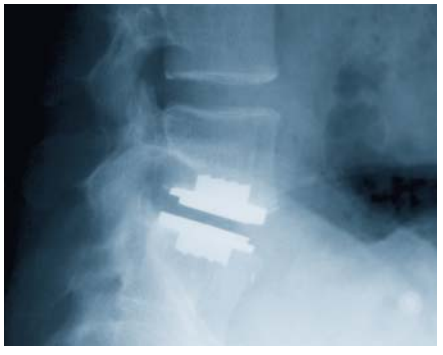
– ProDisc-L patients demonstrated a mean range of motion of 7.7° at 24 months.

† Normal motion defined as ≥ 6° (with ± 3° measurement error applied) to 20° at L3–L4 or L4–L5, and ≥ 5° (with ± 3° measurement error applied) to 20° at L5–S1.

Flexion/Extension ROM (mean values)







ProDisc-L flexion and extension radiograph series

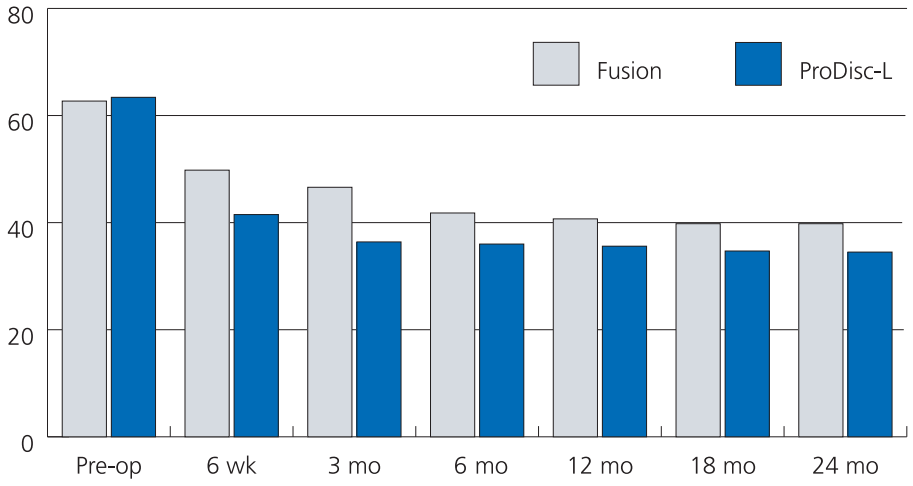
* $p < 0.05$, one-sided Fisher's Exact Test

1. *Summary of Safety and Effectiveness Data for the PRODISC-L Total Disc Replacement, Premarket Approval Application (PMA) Number: P050010.* Retrieved April 18, 2007, from http://www.fda.gov/cdrh/pdf5/p050010b.pdf

Significant decreases in ODI and VAS scores compared to fusion

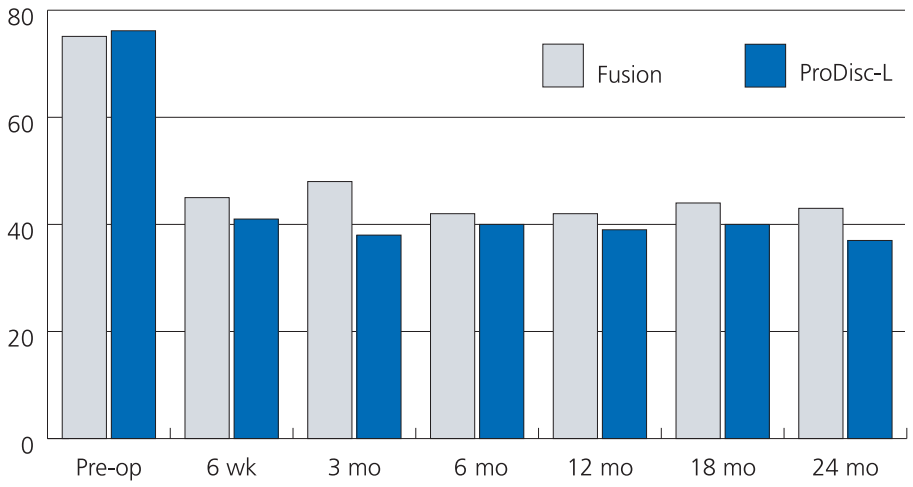
– ProDisc-L patients demonstrated a mean improvement in ODI scores of 46.1% from baseline to 24 months compared to 37.8% for fusion patients.

Mean ODI scores



– ProDisc-L patients demonstrated a mean decrease of 39 points from baseline to 24 months in VAS pain scores compared to 32 points for fusion patients.

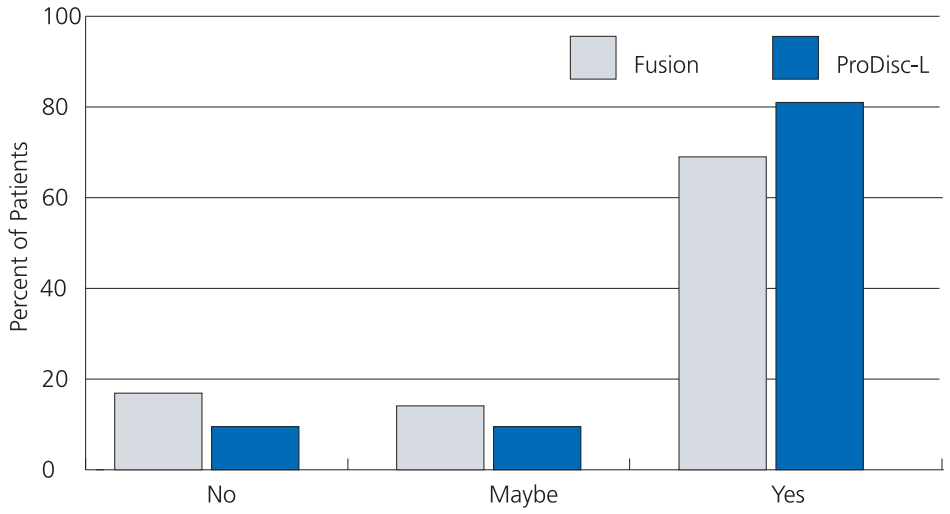
Mean VAS pain scores



High rate of patient satisfaction

– 81.0% of ProDisc-L patients would choose to have surgery again.

Would have surgery again?



Safe and reproducible surgical technique, with minimal learning curve

Each investigational site was required to enroll their first three ProDisc-L patients as non-randomized cases, with a total of 50 non-randomized, training patients treated.

– The ProDisc-L training patients demonstrated equivalent clinical results at 24 months compared to the ProDisc-L randomized patients.

Criteria	ProDisc-L Randomized	ProDisc-L Non-Randomized
ODI 15% improvement	77.2%	85.4%
Device success	96.3%	100.0%
Neurological success	91.2%	83.3%
SF-36	79.2%	89.6%
No migration	98.0%	97.8%
No subsidence	99.3%	97.8%
No radiolucency	100.0%	100.0%
No loss of disc height	100.0%	100.0%
Fusion success	100.0%	100.0%
ROM	93.7%	97.8%
Overall Success	**63.5%**	**66.7%**

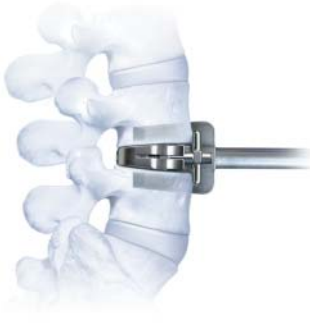
Technique and Instrumentation Overview

Safe and reproducible surgical technique

Synthes has worked with leading spine surgeons to refine the ProDisc-L surgical technique. The ProDisc-L implant and instrumentation function as a unified system, enabling simple and safe implantation of the ProDisc-L implant in three steps:

Trial

Chisel



Implant

Final position

Streamlined instrumentation

Precise implant placement

The ProDisc-L instrumentation has been engineered to allow precise implantation through a midline mini-open anterior retroperitoneal approach. The position and size of the trial and chisel within the disc space corresponds directly to final implant position and size, facilitating accurate implant selection and placement.

Minimal exposure and vascular retraction, maximum visualization

All features of the instruments are contained within the medial-lateral width of the implant, minimizing the size of the incision and amount of vascular retraction.

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
	12 mm	PDL-M-PT12S	PDL-L-PT12S
	14 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

ProDisc-L Instrument Set (PDL1000) continued

Trial Implants

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

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