

BACK 2
BASICS
DIRECT



Dymaxeon[®] Spine System

Simple, Streamlined, Smart

Surgical Procedure

Dymaxeon® Spine System

Introduction

The Dymaxeon® pedicle screw system offers the spinal surgeon an outstanding system for stabilization of spinal deformity, reduction of spondylolisthesis, and enhanced fusion. This comprehensive system provides for lumbar stabilization through a top loading variable axis pedicle screw system. This system allows for a surgeon to tailor the spinal construct to meet the specific needs of the patient. The instrumentation is designed for patient safety and surgeon comfort. The trays are arranged in a systematic approach for greater OR efficiency.

Indications

The Dymaxeon® Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patient's as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral/iliac spine (T1 – S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Dymaxeon® Spine System is a non-cervical spinal fixation system, used as a Pedicle Spinal System utilized in conjunction with sacral/iliac screw fixation, or anterior-lateral spinal fixation intended to provide stabilization of the spine limited to skeletally mature patients and for use with autogenous graft material. The Dymaxeon® Spine System is to be utilized in acute and/or chronic instabilities, deformities, or conditions outlined below in the indications section for providing internal spinal stability.

Surgeons implanting this system are expected to be fully versed and trained in the techniques and methods utilized in placement of this spinal fixation system.

Patient Positioning

The patient should be positioned on the operating table in a prone position. There are numerous frames that can be used including, but not limited to The Wilson Frame, Chest Rolls, Relton Hall Frame, Hasting Frame, Heffington Frame and the Andrews Frame. Minimize intra-abdominal pressure to avoid venous congestion and excess intra-operative bleeding and allow adequate ventilation under anesthesia in the patient as well. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral junction.

Exposure

The surgical approach is carried out through a standard midline incision to the spinal column over the anatomic position of the spinous process. The exposure of the spinous process should extend one additional level. The spinal column is then exposed in routine fashion by the surgeon and decompression is carried out as needed.

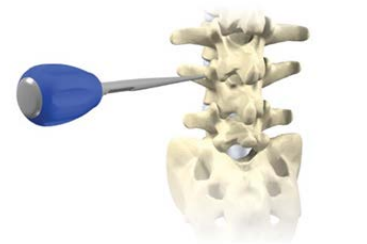
Dymaxeon® Spine System

Pedicle Entry Point



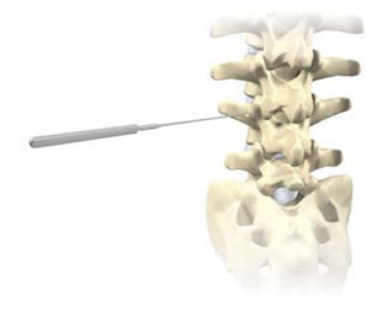
The pedicle entry point is intersected by the vertical line that connects the lateral edges of bony crest extension of the pars interarticularis, and the horizontal line that bisects the middle of the transverse process. Anatomical variation in individual patients may cause slight differences in the entry site. These differences should be considered carefully and noted on the pre-operative MRI, CT images and on the intra-operative x-rays. A small rongeur or a burr may be used to decorticate the pedicle entry point. **The Pedicle Starter Awl (09.0651)** is used to make an entry hole through the cortex at the pedicle entry point.

Pedicle Gear Shift Probe Insertion



The **Pedicle Gear Shift Probe (09.0652)** is inserted through the entry hole and gently pressed into the pedicle canal. The probe is passed through the pedicle canal until the anterior cortex of the vertebral body is reached. Caution should be taken not to violate the anterior wall of the vertebral body or cortical walls

Ball Tip Control Probe Insertion



Following the insertion of the probe, the **Ball Tip Control Probe, Standard (09.0653)** is inserted to confirm continuity of the cortical walls of the pedicle. It can also be used to palpate the inner surface of the pedicle canal to check for defects or perforations of the cortical walls

Dymaxeon® Spine System

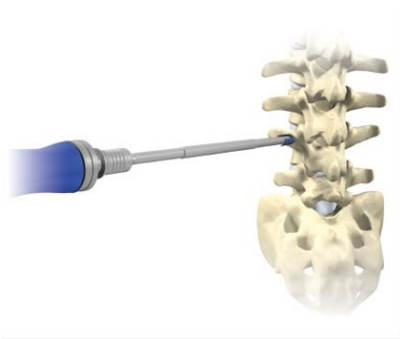
Screw Selection

Select the proper screw. The screws are self-tapping and range from 4.5 mm to 8.5 mm in diameter to fit all anatomic variations encountered during spinal stabilization procedures.

The screw is then placed on the driver and holds securely by interference fit. The driver may be ratcheted for clockwise or counter clockwise rotation or set in fixed position.



Screw Insertion



The pedicle screws are inserted using the ***Poliaxial & Monoaxial Screwdriver (with T- handle 09.0654 | 09.0655 | 09.0656 | 09.0657)***.

The screw is placed on the screwdriver. The screwdriver head is inserted into the Dymaxeon® Screw housing. The pedicle screw is inserted into the vertebral body to the desired depth. The pedicle screw should parallel the endplates and extend 50% to 80% into the vertebral body when fully seated. After screw insertion is complete, the poly screw driver is disengaged from the Dymaxeon® Screw housing by turning the poly screw driver shaft counterclockwise.

Rod Selection

The correct length of the rod is then selected. Both pre-bent and straight rods made of titanium alloy are available. Rods diameter is 5.5mm and 6.0mm with lengths ranging from 40mm to 400mm in 5mm increments. The rod should extend approximately 5 millimeters beyond the outer edges of the proximal screw bodies of the most superior and most inferior pedicle screws.



Dymaxeon® Spine System

Rod Bending



A standard feature of the Dymaxeon® system is pre-lordosed rods. In select circumstances requiring customized bends based on rod templating, the rod can be shaped utilizing the **Rod Bender (09.0664)**. The poliaxial adjustability of the system eliminates the need for precision bending of the rod. A simple lordotic bend is sufficient and the amount of curvature is based on the patient's anatomy and the amount of reduction to be achieved.

Rod Placement & Aligning

The rod is then placed into the Dymaxeon® Screw housing.

The screw allows up to 50° of angulation which should be sufficient to adjust to the position of the rod which can also be done by the **Rod Benders (09.0664)**. The **Vertebral Rod Aligner (09.0674)** and the **Rod Holders (09.0662)** can be used to stabilize the housing while inserting set screws



Rod Setting

Once all of the set screws have been loosely inserted into the Dymaxeon® Screw housing, the **Rod Holders (09.0662)** are used to rotate the contoured rod into lordosis. While the rod is held in place with the Rod Holder, the set screw of the superior Fusion screw housing is provisionally tightened using the **4mm T Screwdriver (09.0661)**. The remaining Dymaxeon® set screws are left loose so compression and distraction can be accomplished.

Compression & Distraction

Compression or Distraction may then be performed at the surgeon's discretion.

Compression is accomplished using the ***Vertebral Implant Compressor (09.0667)***. The compressor fits onto the rod on the outside of the provisionally-tightened Dymaxeon® screw and the Dymaxeon® screw to be compressed. As the compressor handle is closed, the loose Dymaxeon® screw is drawn toward the other provisionally - tightened Dymaxeon® screw accomplishing compression of the desired segment. When the desired amount of compression has been achieved, the set screw of the loose connector is tightened using the 4mm T Screwdriver while being held in place with the compressor.

Distraction is accomplished using the ***Vertebral Implant Spreader (09.0666)***. The spreader fits onto the rod on the inside of the provisionally tightened screw and the screw to be distracted. As the spreader handle is closed, the loose Fusion screw is pushed away from the other provisionally- tightened screw accomplishing distraction of the desired segment. When the desired amount of distraction has been achieved, the set screw of the loose screw is tightened using the 4mm driver while being held in place with the spreader.

Transverse Link Assembly (optional)



The **Transverse Link** assembly consists of one transverse bar and two transverse hooks. There are three sizes of transverse bars, small, medium and large. The length of each transverse bar is 80mm, 100mm and 120mm respectively. Once the desired location of the transverse link has been determined, the appropriate transverse bar size is selected. The bar is assembled with one transverse hook and the hook-bar assembly is placed over the rod with the **Adjustable Transverse Connector Driver (09.0675)**. The second transverse hook is then assembled on the transverse bar and placed into position on the opposite rod **Adjustable Transverse Connector Driver (09.0675)**. The compressor may be used to adjust and position the transverse link on the rods. And the 3mm driver is used to tighten each transverse hook set screw onto the rods.

Wound Closure

Wound closure is performed in the customary manner

Implantables

Ref. #	Description
06.1201B	SINGLE ROD CONNECTOR
06.1202B	DOUBLE ROD CONNECTOR
06.2100B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW CAP
06.2235B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5 x35mm
06.2240B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5 x40mm
06.2245B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5 x45mm
06.2250B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5 x50mm
06.2255B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5 x55mm
06.2260B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5 x60mm
06.2265B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5 x65mm
06.2270B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5 x70mm
06.2335B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5.5 x35mm
06.2340B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5.5 x40mm
06.2345B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5.5 x45mm
06.2350B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5.5 x50mm
06.2355B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5.5 x55mm
06.2360B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5.5 x60mm
06.2365B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5.5 x65mm
06.2370B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø5.5 x70mm
06.2435B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø6 x.35mm
06.2440B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø6 x.40mm
06.2445B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø6 x.45mm
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06.2470B	DYMAXEON® OPEN MONOAXIAL PEDICULAR SCREW Ø6 x.70mm
06.2535B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø4.5 x35mm
06.2540B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø4.5 x40mm
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06.2635B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø5 x35mm
06.2640B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø5 x40mm
06.2645B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø5 x45mm
06.2650B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø5 x50mm
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06.2755B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø5.5 x55mm

Dymaxeon® Spine System

Ref. #	Description
06.2760B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø5.5 x60mm
06.2765B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø5.5 x65mm
06.2770B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø5.5 x70mm
06.2835B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø6 x35mm
06.2840B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø6 x40mm
06.2845B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø6 x45mm
06.2850B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø6x50mm
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06.2970B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø6.5 x70mm
06.2980B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø6.5 x80mm
06.2990B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø6.5 x90mm
06.3040B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x40mm
06.3045B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x45mm
06.3050B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x50mm
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06.3080B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x80mm
06.3090B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x90mm
06.3399B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7.5 x35mm
06.3400B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7.5 x40mm
06.3445B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7.5 x45mm
06.3402B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7.5 x50mm
06.2650B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø5 x50mm
06.2655B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø5 x55mm
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Dymaxeon® Spine System

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06.2935B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø6.5 x35mm
06.2940B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø6.5 x40mm
06.2945B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø6.5 x45mm
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06.3050B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x50mm
06.3055B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x55mm
06.3060B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x60mm
06.3070B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x70mm
06.3080B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x80mm
06.3090B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7 x90mm
06.3399B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7.5 x35mm
06.3400B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7.5 x40mm
06.3445B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7.5 x45mm
06.3402B	DYMAXEON® OPEN POLYAXIAL PEDICULAR SCREW Ø7.5 x50mm
06.6345B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø4.5
06.6346B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø4.5
06.6347B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø4.5
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06.6352B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5 x35mm
06.6353B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5 x40mm
06.6354B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5 x45mm
06.6355B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5 x50mm
06.6356B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5 x55mm
06.6357B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5 x60mm
06.6358B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5 x65mm
06.6359B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5 x70mm
06.6362B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5.5
06.6363B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5.5
06.6364B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5.5
06.6365B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5.5
06.6366B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5.5
06.6367B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5.5
06.6368B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5.5
06.6369B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø5.5
06.6372B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6 x35mm
06.6373B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6 x40mm
06.6374B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6 x45mm
06.6375B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6 x50mm
06.6376B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6 x55mm
06.6377B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6 x60mm
06.6378B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6 x65mm
06.6379B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6 x70mm
06.6380B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6.5
06.6381B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6.5
06.6382B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6.5

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06.6383B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6.5
06.6384B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6.5
06.6385B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6.5
06.6386B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6.5
06.6387B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6.5
06.6388B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø6.5
06.6385B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø7 x40mm
06.6386B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø7 x45mm
06.6387B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø7 x50mm
06.6388B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø7 x55mm
06.6389B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø7 x60mm
06.6390B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø7 x70mm
06.6391B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø7 x80mm
06.6392B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø7 x90mm
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06.6400B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø7.5
06.6401B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø7.5
06.6402B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø8 x40mm
06.6403B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø8 x45mm
06.6404B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø8 x50mm
06.6405B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø8 x55mm
06.6406B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø8 x60mm
06.6407B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø8 x70mm
06.6408B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø8 x80mm
06.6409B	DYMAXEON® 5.5 OPEN POLYAXIAL PEDICULAR SCREW Ø8 x90mm
06.6416B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6417B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6418B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6419B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6420B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6419B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6420B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6421B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6422B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6423B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6424B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6425B	DYMAXEON® 5.5 POLYAXIAL SPONDYLOLISTHESIS SCREW
06.6422B	DYMAXEON® 5.5 Vertebral ROD Ø5.5X100mm (VIOLET)
06.6423B	DYMAXEON® 5.5 Vertebral ROD Ø5.5X150mm (VIOLET)
06.6424B	DYMAXEON® 5.5 Vertebral ROD Ø5.5X200mm (YELLOW)
06.6425B	DYMAXEON® 5.5 Vertebral ROD Ø5.5X250mm (YELLOW)
06.6426B	DYMAXEON® 5.5 Vertebral ROD Ø5.5X300mm (BLUE)
06.6427B	DYMAXEON® 5.5 Vertebral ROD Ø5.5X350mm (BLUE)
06.6428B	DYMAXEON® 5.5 Vertebral ROD Ø5.5X400mm (GREEN)
06.6429B	DYMAXEON® 5.5 CURVED ROD 35 mm (YELLOW)
06.6430B	DYMAXEON® 5.5 CURVED ROD 40 mm (YELLOW)
06.6431B	DYMAXEON® 5.5 CURVED ROD 45 mm (YELLOW)

Dymaxeon® Spine System

Ref. #	Description
06.6432B	DYMAXEON® 5.5 CURVED ROD 50 mm (YELLOW)
06.6433B	DYMAXEON® 5.5 CURVED ROD 55 mm (YELLOW)
06.6434B	DYMAXEON® 5.5 CURVED ROD 60 mm (YELLOW)
06.6435B	DYMAXEON® 5.5 CURVED ROD 65 mm (YELLOW)
06.6436B	DYMAXEON® 5.5 CURVED ROD 70 mm (YELLOW)
06.6437B	DYMAXEON® 5.5 CURVED ROD 75 mm (YELLOW)
06.6438B	DYMAXEON® 5.5 CURVED ROD 80 mm (YELLOW)
06.6439B	DYMAXEON® 5.5 CURVED ROD 90 mm (YELLOW)
06.6440B	DYMAXEON® 5.5 CURVED ROD 100 mm (YELLOW)
06.6441B	DYMAXEON® 5.5 CURVED ROD 110 mm (YELLOW)
06.6442B	DYMAXEON® 5.5 CURVED ROD 120 mm (YELLOW)
06.6443B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 25mm (BLUE)
06.6444B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 30mm
06.6445B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 35mm (VIOLET)
06.6446B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 40mm (GREEN)
06.6447B	DYMAXEON® 5.5 MULTI-AXIAL TRANSVERSE CONNECTOR 40-
06.6448B	DYMAXEON® 5.5 MULTI-AXIAL TRANSVERSE CONNECTOR 50-
06.6449B	DYMAXEON® 5.5 MULTI-AXIAL TRANSVERSE CONNECTOR 60-
06.6454B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 5mm
06.6455B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 7mm
06.6456B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 9mm
06.6457B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 13mm
06.6458B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 5mm
06.6459B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 7mm
06.6460B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 9mm
06.6461B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 13mm
06.6462B	DYMAXEON® 5.5 OPEN LAMINAR HIGH NECK HOOK
06.6463B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 5mm
06.6464B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 5mm
06.6465B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 7mm
06.6466B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 7mm
06.6467B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 9mm
06.6468B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 9mm
06.6469B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 13mm
06.6470B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 13mm
06.6471B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK LEFT 5mm
06.6472B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK RIGHT 5mm
06.6473B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK LEFT 7mm
06.6474B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK RIGHT 7mm
06.6475B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK LEFT 9mm
06.6476B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK RIGHT 9mm
06.6431B	DYMAXEON® 5.5 CURVED ROD 45 mm (YELLOW)
06.6432B	DYMAXEON® 5.5 CURVED ROD 50 mm (YELLOW)
06.6433B	DYMAXEON® 5.5 CURVED ROD 55 mm (YELLOW)
06.6434B	DYMAXEON® 5.5 CURVED ROD 60 mm (YELLOW)
06.6435B	DYMAXEON® 5.5 CURVED ROD 65 mm (YELLOW)
06.6436B	DYMAXEON® 5.5 CURVED ROD 70 mm (YELLOW)
06.6437B	DYMAXEON® 5.5 CURVED ROD 75 mm (YELLOW)
06.6438B	DYMAXEON® 5.5 CURVED ROD 80 mm (YELLOW)
06.6439B	DYMAXEON® 5.5 CURVED ROD 90 mm (YELLOW)
06.6440B	DYMAXEON® 5.5 CURVED ROD 100 mm (YELLOW)
06.6441B	DYMAXEON® 5.5 CURVED ROD 110 mm (YELLOW)
06.6442B	DYMAXEON® 5.5 CURVED ROD 120 mm (YELLOW)

Dymaxeon® Spine System

Ref. #	Description
06.6443B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 25mm (BLUE)
06.6444B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 30mm
06.6445B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 35mm (VIOLET)
06.6446B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 40mm (GREEN)
06.6447B	DYMAXEON® 5.5 MULTI-AXIAL TRANSVERSE CONNECTOR 40-
06.6448B	DYMAXEON® 5.5 MULTI-AXIAL TRANSVERSE CONNECTOR 50-
06.6449B	DYMAXEON® 5.5 MULTI-AXIAL TRANSVERSE CONNECTOR 60-
06.6454B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 5mm
06.6455B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 7mm
06.6456B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 9mm
06.6457B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 13mm
06.6458B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 5mm
06.6459B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 7mm
06.6460B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 9mm
06.6461B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 13mm
06.6462B	DYMAXEON® 5.5 OPEN LAMINAR HIGH NECK HOOK
06.6463B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 5mm
06.6464B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 5mm
06.6465B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 7mm
06.6466B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 7mm
06.6467B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 9mm
06.6468B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 9mm
06.6469B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 13mm
06.6470B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 13mm
06.6471B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK LEFT 5mm
06.6472B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK RIGHT 5mm
06.6473B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK LEFT 7mm
06.6474B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK RIGHT 7mm
06.6475B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK LEFT 9mm
06.6476B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK RIGHT 9mm
06.6431B	DYMAXEON® 5.5 CURVED ROD 45 mm (YELLOW)
06.6432B	DYMAXEON® 5.5 CURVED ROD 50 mm (YELLOW)
06.6433B	DYMAXEON® 5.5 CURVED ROD 55 mm (YELLOW)
06.6434B	DYMAXEON® 5.5 CURVED ROD 60 mm (YELLOW)
06.6435B	DYMAXEON® 5.5 CURVED ROD 65 mm (YELLOW)
06.6436B	DYMAXEON® 5.5 CURVED ROD 70 mm (YELLOW)
06.6437B	DYMAXEON® 5.5 CURVED ROD 75 mm (YELLOW)
06.6438B	DYMAXEON® 5.5 CURVED ROD 80 mm (YELLOW)
06.6439B	DYMAXEON® 5.5 CURVED ROD 90 mm (YELLOW)
06.6440B	DYMAXEON® 5.5 CURVED ROD 100 mm (YELLOW)
06.6441B	DYMAXEON® 5.5 CURVED ROD 110 mm (YELLOW)
06.6442B	DYMAXEON® 5.5 CURVED ROD 120 mm (YELLOW)
06.6443B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 25mm (BLUE)
06.6444B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 30mm
06.6445B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 35mm (VIOLET)
06.6446B	DYMAXEON® 5.5 FIXED TRANSVERSE CONNECTOR 40mm (GREEN)
06.6447B	DYMAXEON® 5.5 MULTI-AXIAL TRANSVERSE CONNECTOR 40-
06.6448B	DYMAXEON® 5.5 MULTI-AXIAL TRANSVERSE CONNECTOR 50-
06.6449B	DYMAXEON® 5.5 MULTI-AXIAL TRANSVERSE CONNECTOR 60-
06.6454B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 5mm
06.6455B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 7mm
06.6456B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 9mm
06.6457B	DYMAXEON® 5.5 OPEN PEDICULAR HOOK 13mm

Dymaxeon® Spine System

Ref. #	Description
06.6458B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 5mm
06.6459B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 7mm
06.6460B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 9mm
06.6461B	DYMAXEON® 5.5 OPEN LAMINAR HOOK 13mm
06.6462B	DYMAXEON® 5.5 OPEN LAMINAR HIGH NECK HOOK
06.6463B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 5mm
06.6464B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 5mm
06.6465B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 7mm
06.6466B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 7mm
06.6467B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 9mm
06.6468B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 9mm
06.6469B	DYMAXEON® 5.5 THORACIC OFFSET HOOK LEFT 13mm
06.6470B	DYMAXEON® 5.5 THORACIC OFFSET HOOK RIGHT 13mm
06.6471B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK LEFT 5mm
06.6472B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK RIGHT 5mm
06.6473B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK LEFT 7mm
06.6474B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK RIGHT 7mm
06.6475B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK LEFT 9mm
06.6476B	DYMAXEON® 5.5 LUMBAR OFFSET HOOK RIGHT 9mm

B2B Spinal Instruments

Ref. #	Description
77.1851	SPINE LOW BACK INSTRUMENT CASE
77.2045	STRIKE PROBES
77.2046	CURVE PROBES
77.2048	ROD ROTATION FORCEPS
77.2049	VERTEBRAL ROD ALIGNER
77.2050	PERSUADER
77.2051	TORQUE WRENCH
77.2069	BLOCKER SCREWDRIVER
77.2065	TAP & DRILL HANDLE QUICK COUPLING
77.1852	SPINE LOW BACK INSTRUMENT TRAY 1
77.2056	SPINE LOW BACK INSTRUMENT TRAY 2
77.2068	POLYAXIAL SCREWDRIVER
77.2067	POLYAXIAL SPONDYLOLISTHESIS SCREWDRIVER
77.2044	ROD FORK SHORT
77.2052	ROD FORK LONG
77.1897	SET SCREW INSERTER
09.0650	B2B SUPPLEMENTAL SPINE INSTRUMENT CASE 1
09.0651	AWL- LIMITED DEPTH
09.0654	OPEN POLYAXIAL SCREWDRIVER
09.0655	RATCHET WRENCH
09.0656	OPEN MONOAXIAL SPONDYLOLISTHESIS DRIVER
09.0658	OPEN POLYAXIAL SPONDYLOLISTHESIS SCREWDRIVER
09.0659	OPEN MONOAXIAL & POLYAXIAL SET SCREW
09.0660	IN-SITU ROD BENDER
09.0661	T-SCREWDRIVER 4mm
09.0671	TRANSVERSE CONNECTOR SET SCREWDRIVER 3MM
09.0672	SPINE INSTRUMENT TRAY
09.0673	SUPPLEMENTAL SPINE INSTRUMENT CASE 2
09.0681	RING DRIVER
09.0682	T-PROBE
09.0683	SPONDYLOLISTHESIS SCREW MANIPULATOR
09.0685	SCREWDRIVER
09.0722	ADJUSTMENT FORK, LONG
09.0723	ADJUSTMENT FORK, SHORT
09.0727	PEDICLE THIN PROBE
77.1851	SPINE LOW BACK INSTRUMENT CASE
77.2045	STRIKE PROBES
77.2046	CURVE PROBES
77.2048	ROD ROTATION FORCEPS

Dymaxeon® Spine System

Ref. #	Description
77.2049	VERTEBRAL ROD ALIGNER
77.2050	PERSUADER
77.2051	TORQUE WRENCH
77.2069	BLOCKER SCREWDRIVER
77.2065	TAP & DRILL HANDLE QUICK COUPLING
77.1852	SPINE LOW BACK INSTRUMENT TRAY 1
77.2056	SPINE LOW BACK INSTRUMENT TRAY 2
77.2068	POLYAXIAL SCREWDRIVER
77.2067	POLYAXIAL SPONDYLOLISTHESIS SCREWDRIVER
77.2044	ROD FORK SHORT
77.2052	ROD FORK LONG
77.1897	SET SCREW INSERTER
09.0650	B2B SUPPLEMENTAL SPINE INSTRUMENT CASE 1
09.0651	AWL- LIMITED DEPTH
09.0654	OPEN POLYAXIAL SCREWDRIVER
09.0655	RATCHET WRENCH
09.0656	OPEN MONOAXIAL SPONDYLOLISTHESIS DRIVER
09.0658	OPEN POLYAXIAL SPONDYLOLISTHESIS SCREWDRIVER
09.0659	OPEN MONOAXIAL & POLYAXIAL SET SCREW
09.0660	IN-SITU ROD BENDER
09.0661	T-SCREWDRIVER 4mm
09.0671	TRANSVERSE CONNECTOR SET SCREWDRIVER 3MM
09.0672	SPINE INSTRUMENT TRAY
09.0673	SUPPLEMENTAL SPINE INSTRUMENT CASE 2
09.0681	RING DRIVER
09.0682	T-PROBE
09.0683	SPONDYLOLISTHESIS SCREW MANIPULATOR
09.0685	SCREWDRIVER
09.0722	Adjustment Rocker (Fork), Long
09.0723	Adjustment Rocker (Fork), Short
09.0727	PEDICLE THIN PROBE
09.0728	Curette
09.0729	BLUNT PROBE
09.0730	AWL/SHORT AWL
09.0731	COLLARED PROBE/PROBE-FINDER
09.0732	B2B ROD ROTATION WRENCH/ROD ROTATION KEY
08.9039	SPINE SET
09.0643	TAP & DRILL T HANDLE QUICK COUPLING
09.0652	PROBE
09.0662	ROD HOLDER
09.0666	DISTRACTOR

Dymaxeon® Spine System

Ref. #	Description
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09.0667	COMPRESSOR
09.0674	VERTEBRAL ROD ALIGNER
09.0675	ADJUSTABLE TRANSVERSE CONNECTOR DRIVER
09.0678	MARKER
09.0679	ROD POSITIONER, SHORT
09.0680	ROD POSITIONER LONG
09.0684	DEPTH GAUGE FOR SPINE
09.0687	DESKTOP ROD CUTTER
09.0688	PERSUADER
09.0707	SPONDYLOLISTHESIS TIP BREAKER
09.0708	SCREW TAP 4.5-5MM FOR QUICK COUPLING
09.0709	SCREW TAP 5,5-6-6,5 MM FOR QUICK COUPLING
09.0714	SPINE INSTRUMENTS CASE 3
09.0715	SPINE IMPLANT CASE
09.0716	SPINE IMPLANT TRAY
09.0733	POLYDRIVER
09.0734	SCREW TAP 7MM FOR QUICK COUPLING
09.0735	SCREW TAP 8MM FOR QUICK COUPLING
09.0745	FLAT BENDER
09.0746	SQUARE MARKER
09.0749	IMPLANT BOX
09.0799	MOULDABLE ROD TEMPLATE

Important Information

Warnings

The warnings discussed within this manual do not include all possible adverse surgical events, but are inherent to metallic internal fixation devices of the spine. The surgeon is instructed to thoroughly explain the general surgical risks to the patient before surgical treatment is initiated.

The safety and effectiveness of pedicle screw spinal systems have been established for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis or nonunion.). The effectiveness of these devices for any other conditions are unknown.

Based on laboratory fatigue testing results, when utilizing the Dymaxeon® Spinal System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of this system when implanted.

Cautions

Only experienced spinal surgeons with specific training in the use of the Dymaxeon® Pedicle Screw System should implant this system for lumbar fusion procedures. Spinal instrumentation using the Dymaxeon® Spinal Surgical System is a technically demanding procedure with potential risks of serious injury to the patient if not properly utilized.

1. Surgical implants and may never be reused. Small defects and internal stress patterns may be present with previously re-used implants and may lead to early breakage even though the device may appear undamaged.
2. Correct implant handling is of vital importance. Avoidance of any metallic notching, scratching, or reverse bending of the devices is imperative! Alterations will produce defects in surface finish in internal stresses that may become a focal point for eventual implant breakage. Do not use the implant if damage is suspected. Proper contouring of metallic implants with proper equipment is essential.

3. Bending the construct. Titanium alloy component should never be bent sharply or reverse bending applied. If a construct is over contoured 1 please select a new construct for proper contouring rather than reverse bending or over contouring of the implant.
4. Implant removal after healing is recommended. Any number of complications can occur if the device is not removed after its intended use has been fulfilled
 - a. Corrosion with localized tissue reaction or pain.
 - b. Implant migration resulting in injury.
 - c. Risk of additional injury from postoperative injury or trauma.
 - d. Loosening, bending or breakage, which could make implant removal impractical or significantly difficult.
 - e. Local pain, discomfort, or abnormal sensation due to device presence.
 - f. Possible increased risk of infection.
 - g. Bone loss due to stress shielding. The surgeon must carefully weigh the risks versus benefits, when deciding whether to remove the implant and at what point in time implant removal should occur.
 - h. Implant removal should be followed by adequate postoperative management to avoid re-fracture or deformity such as bracing. If the patient is older and has a low activity level, the surgeon may choose avoid implant removal thus eliminating the risks involved with secondary surgery.
5. Patient instruction is imperative following surgery. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful spinal fusion and bone healing. The patient should be informed about their procedure and implant limitations, strict limitation of physical activity, especially lifting and twisting during healing phases, as well as participation in any active sports during the healing phase. The patient should be instructed that the metallic implant is not as strong as normal healthy bone and could loosen, bend, or fail if excessive demands are placed on it, especially in the absence of complete bony healing. Active, debilitated, or psychology impaired patients who are not able to follow instructions or those who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation following spinal fusion.

Failure to follow proper instructions and activity restrictions may lead to implant migration, damage to nerves, or blood vessels in addition to loss of bone fixation.