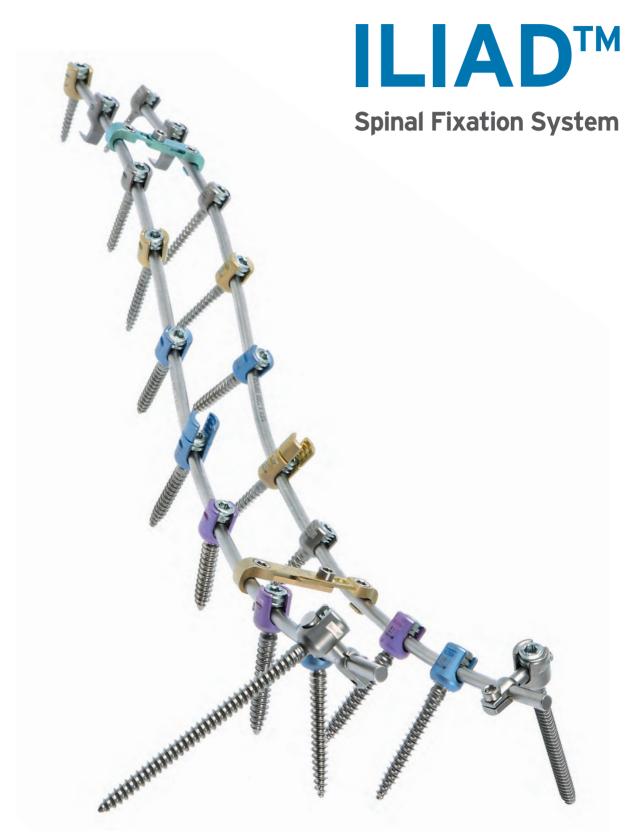


Surgical Technique











Surgical Technique

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INTRODUCTION

ILIAD™ Spinal Fixation System provides simple and comprehensive stabilization solutions for spinal fixation.

The Patented Reverse DOVETAIL Locking System with LINEAR **SLOT** is a foundation of the ILIAD™ system. This unique thread design practically eliminates cross threading, prevents splaying of the screw head and increase the holding moment up to 30Nm.

- Outside Head Diameter: 13.80mm
- Reverse Dove Tail Thread
- Linear Slot in the middle of Set Screw
- Top-Loading, Top-Tightening, Self-Tapping Screws
- Oscillation Angle up to 60°
- Anodized Color-coding of Polyaxial Pedicle Screws by Diameter
- Accomodate Both 6.0 and 6.35 Rods.
- Material: Ti6Al-4V ELI per ASTM F136



ILIAD™ Spinal Fixation System is used for lumbar and lumbosacral degenerative pathologies for which segmental spondylodesis is indicated.

- Degenerative Disc Diseases and Instabilities
- Degenerative Spondylolisthesis
- Isthmic Spondylolisthesis
- Pseudoarthrosis or Failed Spondylodesis

Contraindications

- Severe Osteoporosis
- Unstable Burst Fractures and Compression Fractures
- Destructive Tumors
- Acute Infections

Extensive Peridural Scarring





STEP 1 PATIENT POSITIONING

The patient is positioned on the operating table in the 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. Intra-abdominal pressure must be minimized to avoid venous congestion and excess intra-operative bleeding, while allowing adequate ventilation of the anesthetized patient. The patient of the should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral junction.



STEP 2 INCISION AND 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 to an additional level. The spinal column is then exposed in routine fashion by the surgeon and decompression is carried out as needed.

Note:

Decortication and placement of bone grafts are usually done after pedicle screw preparation just prior to insertion of the pedicle screw. Meticulous fusion techniques are critical for success of the procedure.





PEDICLE PREPARATION STEP 3 ENTRY POINT, DECORTICATION AND AWL

The pedicle entry point is intersected by the vertical line that connects the lateral edges of bony crest extension of the pars inter-articularis, 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. There differences should be considered carefully and noted on the pre-operative xrays. A small rounger or a burr may be used to decorticate the pedicle entry point. The awl is used to make an entry hole through the cortex at the pedicle entry point.

STEP 4 PEDICLE PREPARATION - PROBE

After confirmation of the position of the guide pins relative to the pedicle canal, the probe is inserted through the entry hole and gently pressed through 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. The probe can be measured at 10mm intervals (30, 40, 50mm) and the Curved Probe is also available.

AWL



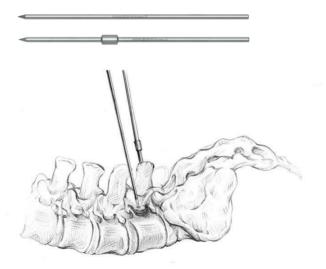
CURVED PEDICLE PROBE



STEP 5 PEDICLE SCREW PREPARATION - GUIDE PIN

After making the pedicle entry point through the cortex of the pedicle, guide pins are inserted into the pedicle canal. Ensure all liked shaped guide pins are inserted on the same side of the spinal column for identification purposes on the x-ray. After all guide pins have been inserted, intra-operative x-rays should be taken to verify the position of the guide pins relative to the pedicle canal. The different shaped pins can distinguish the right and the left.

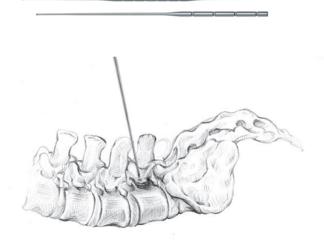
GUIDE PINS



STEP 6 PEDICLE PREPARATION - TESTER

After use of the probe and guide pins, the Tester is used to confirm continuity of the cortical walls of the pedicle. The Tester can also be used to palpate the inner surface of the pedicle canal to check for defects or punctures in the cortical walls.

BALL TIP PROBE (TESTER)

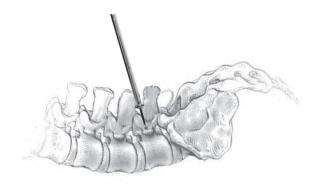


STEP 7 PEDICLE SCREW PREPARATION - TAP

After the step 6 is fully verified, a Tap (size collates to the size of screw to be used) is used to thread thepedicle canal so that the pedicle screw can be easily driven into the pedicle canal. 11 different sizes of Taps can be used for this step which corresponds to the outside diameter of the pedicle screw to be used.

FIXED TAP





STEP 8 PEDICLE PREPARATION SCREW DRIVER ASSEMBLY

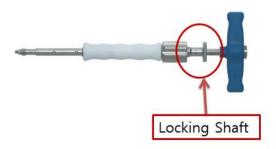
After all of the pedicle screw preparation steps (step 3 ~ step 7) are completed, the ILIAD pedicle screws are inserted via the ILIADO screw driver. The screw drivers and screw can be assembled together by taking screw head into the Screw Driver tip and then turning the Screw Driver Nut closed, in the clockwise direction, to attach the screw securely. The pedicle screws should be inserted into the vertebral body until to the desired height. The screw driver is disengaged from the ILIAD housing by turning the screw driver shaft counterclockwise while stabilizing the ILIAD housing with the screw driver sleeve. The pedicle screw should parallel the endplates and extend 50% to 80% into the vertebral body when fully seated.

POLYAXIAL SCREWDRIVER





* The Locking Shaft of the Screw Driver must be securely locked after assembly of pedicle screw before inserting the screw into the vertebral body.



STEP9 PEDICLE SCREW IMPLANTATION SCREW PLACEMENT

After the step 8, the screw is inserted and driven into the pedicle canal in the clockwise direction to the determined depth. After the screw is securely fastened inside the vertebral body, remove the screw driver by turning the Screwdriver shaft in the Counter-clockwise direction.



*Unlock the Locking Shaft to remove Screw Driver from the Pedicle Screw head. Simply pull out upward the shaft to unlock.



ILIAD™ Pedicle Screws

- 1. Available Screw Diameter 4.0 / 4.5 / 5.0 / 5.5 / 6.0 / 6.5 / 7.0 / 7.5 / 8.0 / 8.5mm
- Available Screw Type
 Mono & Poly Axial
 Reduction Mono & Poly Axial
 Cannulated Mono & Poly Axial
- 3. Oscillation Angle up to 60°
- 4. Accomodate both 6.0 and 6.35 Rods.

STEP 10 ROD SELECTION AND INSERTION

After the pedicle screws have been placed in the pedicles, the correct length of rod is selected. The rods are provided pre-cut in lengths ranging from 40mm to 500mm. The rod should extend approximately 5 millimeters beyond the superior and inferior pedicle screws. After the appropriate length of rod has been selected, lordosis may be bent into the rod via the rod bender. The polyaxial adjustability of the system eliminates the need for precision bending of the rod. A simple lordodic bend is sufficient and the amount of lordosis is based on the patient of sanatomy and the amount of reduction to be achieved; the rod is then loaded onto the pedicle screw heads with the Rod Holder.



ILIAD™ Rods

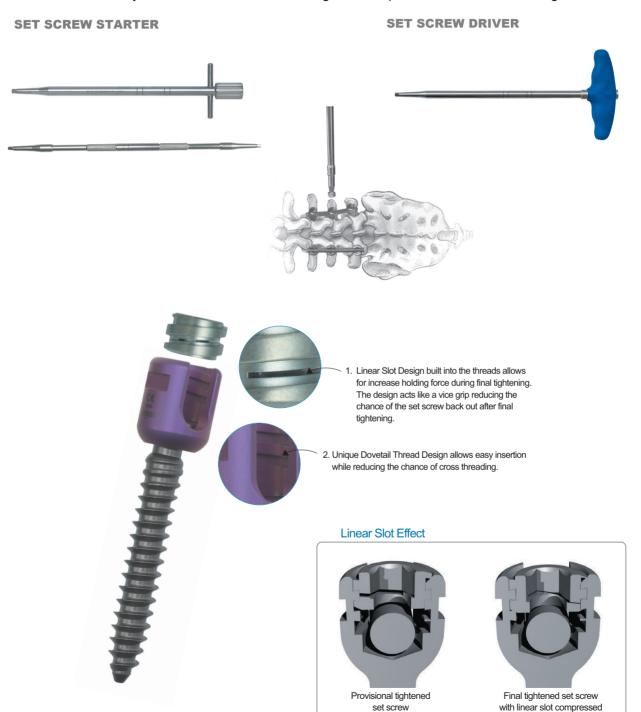
- 1. Titanium Alloy Rods / CoCr Rods Available
- 2. 6.0mm & 6.35mm Rod Diameter
- 3. Available in Pre-contoured and Straight Rod Configuration
- 4. Longest Available Size 500mm





STEP 11 SET SCREW INSERTION AND PLACEMENT

The set screw are loaded onto the Set Screw Starter and inserted onto each Iliad Screw housing. The Set Screw Starter is only used to position the set screw onto the housing. It must not used to tightened. The Set Screw Driver is used to tighten the set screw only as tight as to allow rod movement. The rod should be Loose at this point in order for the derotation of the rod can be accomplished. The screw Housing Holder and the Rod Pusher may be used to stabilize the housing and manipulate the rod while inserting the set screw.



STEP 12 DEROTATION, COMPRESSION, AND DISTRACTION

After all of the set screw assemblies have been loosely inserted onto the ILIAD screw housing, the derotator is used to rotate the contoured rod into lordosis. The proper position of the rod is confirmed by ensuring that the centerline laser marked on the rod is visible from the top and parallel to the floor. While the rod is held into place with the derotator, the setscrew of the of the most superior ILIAD housing is provisionally tightened via the T-Wrench. The remaining ILIAD set screws are left loose so compression and distraction can be accomplished. After the construct has been properly assembled, segmental compression and distraction is accomplished as needed to adjust frontal or sagital plane deformities. Compression is accomplished via the compressor. The compressor fits onto the rod on the outside of the provisionally-tightened ILIAD set screw assembly and the ILIAD screw to be compressed. As the compressor handle is closed, the loose ILIAD screw is drawn toward the provisionally-tightened ILIAD set screw/housing assembly accomplishing compression of the desired segment. When the desired amount of compression has been achieved, the setscrew of the loose set screw is tightened via the set-screw T-Wrench while being held into place with the compressor.

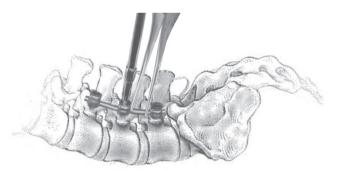
Note:

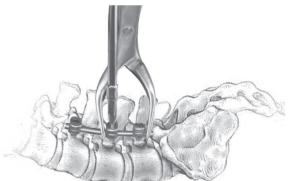
Caution should be taken not to over tighten the setscrew without use of the Power Holder as loosening or the pedicle screws may result. Distraction is accomplished via the spreader. The spreader fits onto the rod on the inside of the provisionally-tightened ILIAD set screw/housing assembly and the ILIAD screw to be distracted. As the spreader handle is closed, the loose ILIAD screw is pushed away from the provisionally-tightened ILIAD set screw/housing assembly accomplishing distraction of the desired segment. When the desired amount of distraction has been achieved, the setscrew of the loose set screw is tightened via the set-screw T-Wrench while being held into place with the spreader.

Note:

Caution should be taken not to over tighten the setscrew without use of the Power Holder as loosening or the pedicle screws may result.

DISTRACTION COMPRESSION





STEP13 FINAL LOCKING

After compression and distraction has been accomplished and the set-screws are provisionally tightened, the power holder is used to stabilize the assemblied construct durring final tightening the ILIAD set screw/housing assembly. The Torque Wrench is inserted into the cannulated hole of the power holder and engaged into the ILIAD set-screw. The power holder is then inserted over the ILIAD screw housing and engaged onto the rod. A window has been cut into one side of the anti-torque holder in case the ILIAD screws are too close together to fully insert the power holder over the ILIAD screw housing. Each ILIAD set screw/housing assembly is sequentially tightened using the torque wrench while being stabilized via the power holder.



ANTI-TORQUE WRENCH

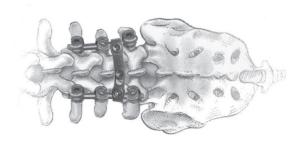


* Secure locking as picture below.



STEP 14 TRANSVERSE LINK SELECTION AND INSERTION

After final tightening of the ILIAD set screw/housing assembly, the transverse link is installed, if desired. The transverse link assembly consists of two transverse bar and two transverse hooks. Once the desired location of the transverse link has been determined, the appropriate transverse link size is selected. The transverse is placed over the rods via the transverse hook. The second transverse hook is then placed into position on the opposite rod. The compressor may be used to adjust and position the transverse link on the rods. The cross-link screw driver is used to tighten each transverse hook onto the rods as well as the tightening the center screw to determine the final length of the transverse link. The power holder should be used to secure the construct during the tightening

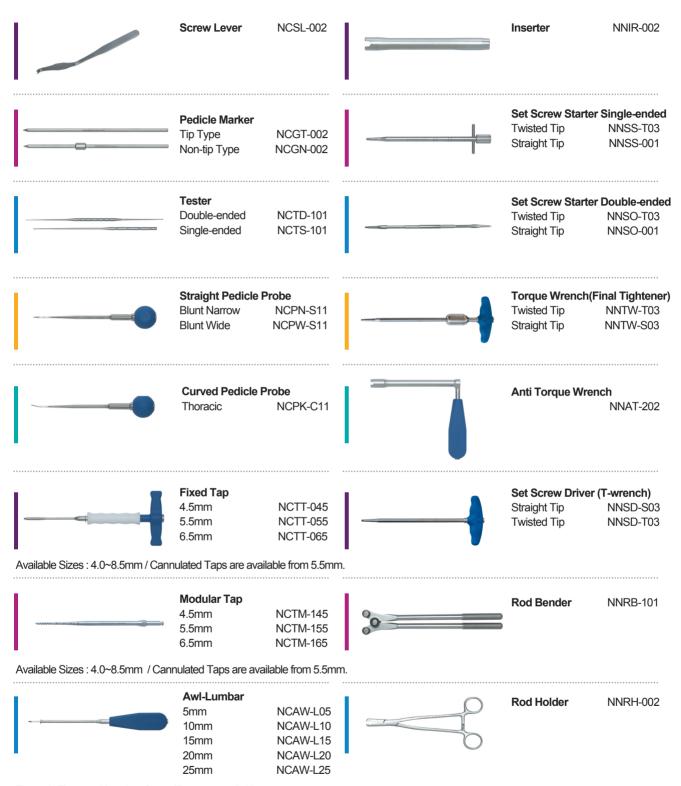


ILIAD™ Cross Links

- 1. ILIAD™ has 6 different sizes of Cross Links.
- 2. Available Cross Link Size 41 / 46 / 51 / 56 / 61 / 66mm
- 3. Cross Links are designed to accommodate either 6.0mm or 6.35mm rods in order to stablize a spinal construct.
- 4. One step tightening with a single instrument.

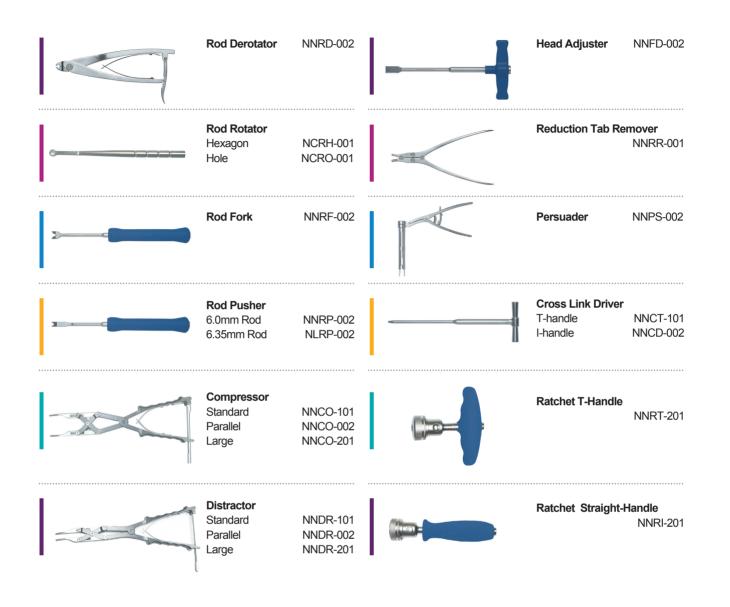


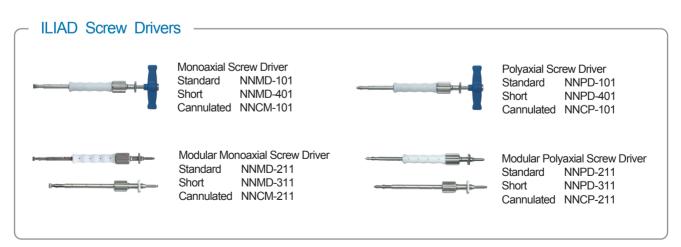
ILIAD™ Instrument List













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