Solutions by the people of Zimmer Spine.
zimmerspine.com
Versatile solutions
From the people of Zimmer Spine.

At Zimmer Spine we appreciate the fact that no two surgeons are alike. Which is why we create versatile spinal solutions that embrace a range of surgeon preferences. We want you to feel comfortable and confident in your surgical procedures with solutions such as the TITLE 2 Polyaxial Spinal System. It features simple, intuitive instrumentation and facilitates either an open or an MIS approach. All so you can deliver real patient results on your terms. It’s another solution that supports you in your quest to provide the absolute best in spinal care, brought to you by the people of Zimmer Spine.
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications/Contraindications</td>
<td>1</td>
</tr>
<tr>
<td>TITLE 2 Implants</td>
<td>3</td>
</tr>
<tr>
<td>TITLE 2 Instruments</td>
<td>5</td>
</tr>
<tr>
<td>Surgical Technique</td>
<td>11</td>
</tr>
<tr>
<td>Kit Contents</td>
<td>27</td>
</tr>
<tr>
<td>Warnings and Precautions</td>
<td>31</td>
</tr>
</tbody>
</table>
Indications/Contraindications

Indications

The TITLE 2 Polyaxial Spinal System is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the Thoracic, Lumbar and Sacral spine.

The TITLE 2 Polyaxial Spinal System is a Pedicle Screw System intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The TITLE 2 Polyaxial Spinal System is also indicated for pedicle screw fixation for severe spondylolisthesis (grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

In addition, TITLE 2 Polyaxial Spinal System, when not used with pedicle screws, is indicated for hook, wire, and/or sacral screw fixation from T1 to the ilium sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease, (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis, and kyphosis), tumor, fracture, and previous failed fusion surgery.

The TITLE 2 Poly Axial Spinal System can also be linked to the Minit® Posterior Cervical and Upper Thoracic Fixation System.
Contraindications

Contraindications include but are not limited to:

- History of recent infection, systemic, spinal, or localized
- Morbid obesity
- Mental illness
- Alcoholism or drug abuse
- Fever or Leukocytes
- Pregnancy
- Metal sensitivity / allergies to implant materials
- Severe Osteopenia
- Presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which may prevent secure implant screw fixation and/or decrease the useful life of the device
- Any condition where the device will interfere with anatomical structures or physiological performance, including inadequate tissue coverage over the operational site
- For pedicle screw cases, missing or congenitally deformed pedicles of the fifth lumbar vertebrae
- Patients unwilling or unable to follow post-operative care instructions
- Any circumstances not described under the heading, INDICATIONS
TiTLE 2 Implants

T-Link, GoldenGate® Cross Connector
(30 - 80mm)
161-3030 to 161-3080

Straight Rod
(5.5mm x 40mm - 5.5mm x 200mm)
500-5040 to 500-5200

Curved Rod
(5.5mm x 20mm - 5.5mm x 80mm)
535-5020 to 535-5080

Hex-End Straight Rod
(5.5mm x 250mm - 5.5mm x 450mm)
500-5250 to 500-5450

Cap Screw
800-0000

TiTLE 2 Axial Rod-to-Rod Connector
(5.5mm to 5.5mm)
502-5555

Minit Axial Rod-to-Rod Connector
(3.25mm to 5.5mm)
502-3255

Note: Rod-to-rod connectors have not been validated for use through the FlexPosure portal.
GoldenGate Cross Connectors are not designed to be used through the FlexPosure portal.
**Title 2** Offset Rod-to-Rod Connector
(5.5mm - 5.5mm)
501-5555

**Minit Offset Rod-to-Rod Connector**
(3.25mm - 5.5mm)
501-3255

---

**Pedicle Screw**
(5.5mm x 30mm - 7.5mm x 55mm)
800-5530 to 800-7555

**Polyaxial Screw**
(4.5mm x 25mm - 4.5mm x 45mm)
800-4525 to 800-4545

---

**Title 2 Cannulated Pedicle Screw**
5.5, 6.5, 7.5mm
810-5535 to 810-7535

---

**Title 2 Pedicle Screws**

<table>
<thead>
<tr>
<th>PART #</th>
<th>DIAMETER</th>
<th>COLOR</th>
<th>LENGTH</th>
<th>INCREMENT</th>
<th>TRAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>800-5560 to 800-7570</td>
<td>4.5mm</td>
<td>Magenta</td>
<td>25 - 45mm</td>
<td>5mm</td>
<td>4.5mm Implant Kit</td>
</tr>
<tr>
<td></td>
<td>5.5mm</td>
<td>Green</td>
<td>30 - 55mm</td>
<td>5mm</td>
<td>Standard Kit</td>
</tr>
<tr>
<td></td>
<td>6.5mm</td>
<td>Yellow</td>
<td>30 - 55mm</td>
<td>5mm</td>
<td>Standard Kit</td>
</tr>
<tr>
<td></td>
<td>7.5mm</td>
<td>Blue</td>
<td>30 - 55mm</td>
<td>5mm</td>
<td>Standard Kit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PART #</th>
<th>DIAMETER</th>
<th>COLOR</th>
<th>LENGTH</th>
<th>INCREMENT</th>
<th>TRAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>800-5530 to 800-7555</td>
<td>5.5mm</td>
<td>Green</td>
<td>60 - 70mm</td>
<td>5mm</td>
<td>Long Length Screw Kit</td>
</tr>
<tr>
<td></td>
<td>6.5mm</td>
<td>Yellow</td>
<td>60 - 70mm</td>
<td>5mm</td>
<td>Long Length Screw Kit</td>
</tr>
<tr>
<td></td>
<td>7.5mm</td>
<td>Blue</td>
<td>60 - 70mm</td>
<td>5mm</td>
<td>Long Length Screw Kit</td>
</tr>
</tbody>
</table>

*Refer to surgical technique L1519 for use with guidewire.
TiTLE 2 Instruments

Awl
ET1006-01
Marks the pedicle entry point.

Straight Pedicle Probe
ET1004-01
Creates a path through the pedicle and into the vertebral body.

Curved Pedicle Probe
ET1005-01
Creates a path through the pedicle and into the vertebral body.

Endo Pedicle Marker Driver
ET1076-01
Drives pedicle markers.

Endo Pedicle Marker Left
ET1074-01
Placed in the pedicle canal to identify appropriate screw trajectory fluoroscopically. Double-band design indicates placement on the left pedicle.

Endo Pedicle Marker Right
ET1075-01
Placed in the pedicle canal to identify appropriate screw trajectory fluoroscopically. Single-band design indicates placement on the right pedicle.
**Sounding Probe Straight**  
ET1002-01

**Sounding Probe Curved**  
ET1003-01

Checks pedicle integrity prior to tapping and screw insertion.

---

**Solid Awl-in-One (4.5mm - 7.5mm)**  
ET1120-45 to ET1120-75

Provides awl and tap in a single tool. An alternative to the standard Bone Awl.

---

**Solid Tap (4.5 - 7.5mm)**  
ET1088-45 to ET1088-75

*Cannulated Tap (5.5 - 7.5mm)*  
ET1090-55 to ET1090-75

Taps pedicle to prepare for polyaxial screw placement.

---

**Solid Sharp Tap (4.5 - 7.5mm)**  
ET1121-45 to ET1121-75

*Cannulated Sharp Tap (5.5 - 7.5mm)*  
ET1121-55C to ET1121-75C

Taps pedicle to prepare for polyaxial screw placement; sharper tip alternative.

---

**Locking Screwdriver, Solid, 3.5mm**  
ET1091-01

Drives and adjusts polyaxial pedicle screws; includes locking threads to provide tight connection between driver and screw. Can be used with Locking Screwdriver Sleeve.

*Refer to surgical technique L1519 for use with guidewire.*
**Captive Hex Screwdriver (3.5mm, 4.0mm)**
ET1051-01 (3.5mm), ET1052-01 (4.0mm)
Drives and adjusts polyaxial pedicle screws.

**Head Positioner**
ET1134-01
Aligns polyaxial screw heads for rod placement.

**Rod Holder**
ET1011-01
Holds rod for placement in the TITLE 2 construct.

**Endoscopic Rod Holder**
ET1062-01
Holds rod for placement in the TITLE 2 construct; allows rod to be held in both horizontal and vertical orientation.

**French Bender**
ET1036-01
Contour rods as necessary to conform to the construct.

**Cap Screw Extractor Tip**
ET1081-01, ET1082-01
*Note: Single use disposable instrument*
**Rod Rotation Wrench**  
ET1025-01  
Provides de-rotation and anatomical correction to rods.

---

**In Situ Bender (Right, Left)**  
ET1113-01, ET1113-02  
Provides sagittal plane adjustment and may be used in combination.

---

**4.0mm Ball Tip Screwdriver**  
ET1119-01  
Provides option to place cap screw when delivering from angle that is not collinear with polyaxial screw.  
*Note: Not to be used for Final Tightening.*

---

**Cap Screw Extractor Ext**  
ET1080-01  
Provides option for removal of cap screws. Used with Cap Screw Extractor Tip.

---

**Compressor**  
ET1008-01  
Compresses implants axially along the rod.

---

**Distractor**  
ET1009-01  
Distracts implants axially along the rod.

---

**Two-Piece Compressor**  
ET1130-01  
Provides alternative option for axial compression along the rod. Used with Compressor / Distractor Screwdriver.

---

**Two-Piece Distractor**  
ET1131-01  
Provides alternative option for axial distraction along the rod. Used with Compressor / Distractor Screwdriver.
Counter Torque
ET1132-01
Serves as counter torque wrench.

Marksman® Counter Torque Guide
ET1054-01
Eases initiation of closure tops into screws and functions as a traditional counter torque wrench.

Compressor/Distractor Screwdriver
ET1133-01
Used with 2-Piece Compressor and 2-Piece Distractor.
Note: For use with longer counter torque.

MIS Compressor/Distractor
ET1096-01
Provides axial compression and/or distraction along the rod.

Reducer
ET1095-01
Used with Reducer Driver as an alternative for spondylolisthesis reduction and rod approximation.

Rod Manipulator
ET1117-01
Achieve spondylolisthesis reduction and rod approximation.
**Reducer Driver**  
ET1094-01  
Used with Reducer as an alternative for spondylolisthesis reduction and rod approximation.

**Bone Screw Remover**  
ET1093-01  
Alternative to remove pedicle screws.

**Straight Ratcheting Handle**  
ET1001-01  
Attaches to Screw Driver for initial screw placement. Also utilized for the removal or revision of system constructs.

**T-Ratcheting Handle**  
ET1049-01  
Attaches to Screw Driver for initial screw placement. Also utilized for the removal or revision of system constructs.

**Torque Limiting Handle (50 in-lbs)**  
ET1020-01  
Optimally locks and limits input torque to 50 in-lbs. Used with the 3.5mm Captive Hex driver to lock GoldenGate Transverse Connectors.

**Torque Limiting T-Handle (90 in-lbs)**  
ET1098-01  
Optimally locks and limits input torque to 90 in-lbs. Used with 4.0mm Driver to lock cap screw.
Surgical Technique

Pedicle Preparation

Step 1

Pedicle Entry
Identify the correct anatomical landmarks for creating an entry point for the pedicle screw pilot hole.

Drawing a horizontal line through the middle of the transverse process and a vertical line through the superior facet of the vertebral level being addressed will give you an approximate entry point to the pedicle.

Once the entry point is identified, use the sharp tip of the Awl to penetrate the cortical bone and create a pilot hole.

Note: The optional Awl-In-One may be used in place of a Standard Bone Awl. Its trocar tip, integrated with a sharp threaded tap, reduces the number of steps required to prepare the pedicle.

Step 2

Pedicle Probe
After the pilot hole is created, insert the Straight or Curved Pedicle Probe and use it to create a channel for the pedicle screw.

It is important that the appropriate cephalad/caudad and converging angles are observed when engaging the Pedicle Probe.

Apply slight downward pressure while rotating back and forth to advance the Pedicle Probe into the pedicle and down into the anterior column.

To help determine depth, the Pedicle Probe is laser-marked with lines beginning at approximately 30mm and continuing in 10mm increments.

Note: Pedicle Probe markings are approximate measurements.
**Step 3**

**Pedicle Verification**

Use the Straight or Curved Sounding Probe to palpate the channel, verifying the integrity of the pedicle wall and confirming that the anterior cortex of the vertebral body has not been penetrated.

**Step 4**

**Tapping (if necessary)**

TITLE 2 screws are fully threaded and have a self-tapping feature designed to eliminate the need to tap the pedicle canal.

In many situations where patient bone quality is compromised or where there is a dense cortical layer, it may be necessary to utilize one of the size-specific taps in the TITLE 2 system.

If necessary, choose the appropriate diameter tap based on the diameter of the screw to be implanted.

Attach the tap to either the Straight Ratcheting or T-Ratcheting Handle. Shift the handle into the forward position and advance clockwise into the pedicle canal. Laser-marked lines on the tap begin at 30mm and continue in increments of 10mm.

Advance to the desired depth, shift the ratcheting handle in reverse and remove the tap in a counter-clockwise direction.
Screw Placement

The *TITLE 2* system offers two options for implanting pedicle screws.

**Step 5 Option 1**

Assemble 3.5mm Captive Hex Screwdriver
Choose the appropriate diameter and length of the *TITLE 2* polyaxial pedicle screw.

Attach either the Straight or T-Ratcheting Handle to the 3.5mm Captive Hex Screwdriver. Insert the hex end of the driver into the hex feature on the center of the screw shank.

**Step 5 Option 2**

Assemble 3.5mm Locking Screwdriver
Choose the appropriate diameter and length of the *TITLE 2* polyaxial pedicle screw.

Attach either the Straight or T-Ratcheting Handle to the 3.5mm Locking Screwdriver. Insert the hex end of the driver into the hex feature on the center of the screw shank.

Confirm that the shank of the screw is straight, and advance the sleeve into the threads in the polybody until tight.
**Step 6**

Polyaxial Screw Insertion

Insert the polyaxial screw into the prepared pedicle. Advance it to a depth where full angulation of the polyaxial head is maintained. Repeat the process until all screws are placed.

*Note:* Further advancement limits the angulation of the polyaxial screw.

**Step 7**

Screwdriver Removal

Remove the 3.5mm Captive Hex Screwdriver by pulling it straight out of the internal hex on the screw. Alternatively, remove the 3.5mm Locking Screwdriver by turning the sleeve counterclockwise to disengage from the head of the screw, then pull straight out of the internal hex on the screw.

*Note:* If the driver sticks in the head of the screw, remove the ratcheting handle and apply a small back and forth motion to the proximal end of the screwdriver to disengage from the hex in the head of the screw.
Step 8

Head Positioning
Use the Head Positioner instrument to align all the polyaxial screw heads.

The friction head feature on the TITLE 2 polyaxial screws will ensure their position is maintained once aligned.

Screw Placement

Step 9

Rod Selection
Select the desired rod. The TITLE 2 system offers a wide range of pre-cut and pre-contoured 5.5mm rods.

Use the Rod Template to assist in determining the length of the rod and the appropriate amount of contouring required to achieve the desired sagittal profile. It is recommended that 3–5mm of the rod extend beyond the head of the screw on the superior and inferior ends of the construct.

Table Top Rod Cutters may be used in situations where one of the pre-cut rod lengths is not ideal.

Rod bending may be necessary to ensure that the rod is fully seated within the head of the screw. The radius of the bend can be varied by pulling out and rotating the central button of the French Rod Bender.

Set the radius to the desired point, insert the rod into the French Rod Bender and close the handles to apply the bending force to rod.
Step 10

Rod Placement through Standard Incision
Use the Rod Holder to insert the rod into the heads of the polyaxial screws.

Step 11

Provisional Tightening
Attach a cap screw to the 4.0mm Captive Hex Driver. Insert all cap screws so they are provisionally tight.

Note: The 4.0mm Ball Tip Hex Driver can be used to help engage the cap screw when a direct angle to the cap screw cannot be achieved.
Reduction Option

There are four instrument options in the TITLE 2 system designed to assist with engaging the set screw when the position of the rod is proud of the polyaxial screw.

**Step 12 Option 1**

**Head Positioner (if necessary)**

The Head Positioner can also be utilized as a rod pusher. To push the rod, place the rod cutout on the rod and apply controlled downward pressure until the rod seats within the head of the polyaxial screw.

Once the rod is within the head of the polyaxial screw, use the 4.0mm Captive Hex Driver to place the cap screw.

**Step 12 Option 2**

**Marksman Counter Torque Guide (if necessary)**

The Marksman Counter Torque Guide can be used to drive the rod into the head of the screw.

Once the rod is within the head of the polyaxial screw, use the 4.0mm Captive Hex Driver to place the cap screw.

*Note: The Marksman Counter Torque Guide can also be used as an alignment guide for starting cap screws.*
Rod Manipulator (if necessary)
If the rod requires additional manipulation, the Rod Manipulator can be used. The Rod Manipulator attaches to the sides of the screw interfacing with the round recesses in the sides of the polyaxial screw head.

Clamp the Rod Manipulator down onto the sides of the screw and position the instrument so that the forceps’ handle is at a 45° angle relative to the rod.

Turn the adjustment knob on the Rod Manipulator clockwise until the rod is fully seated within the screw housing. Use the 4.0mm Captive Hex Driver to place the cap screw.

Spondy Reduction Instrument Assembly (if necessary)
To assemble, pass the Reduction Driver through the cannulation in the Reduction Instrument. Thread the driver until the hex end is extended past the distal end of the Reduction Instrument.

Attach the cap screw. Once the cap screw is on the Reduction Driver, turn the driver counterclockwise to back it up until the cap screw is at the proximal end of the opening.
**Step 12 Option 4b**

**Spondy Reduction Instrument (if necessary)**
Attach the Spondy Reduction Instrument to the head of the polyaxial screw to be reduced.

Advance the Spondy Driver in a clockwise motion; this will drive the rod into the head of the polyaxial screw.

As the rod is forced into the head of the polyaxial screw, the cap screw will engage the threads on the head of the polyaxial screw.

When the cap screw is provisionally tight, release the Reduction Instrument from the head of the screw and turn it counterclockwise to disengage from the sides of the screw.

Once disengaged from the screw, remove by pulling straight up on the Reduction Instrument and driver.

Standard final tightening technique should be followed.

---

**Compression Option**

The *TITLE 2* system offers two options for compression in an open surgery.

---

**Step 13 Option 1**

**Standard Open Compression (if necessary)**
Fully tighten the cap screw on one side of the segment being translated, while leaving the cap screw loose on the adjacent screw(s). Perform compression against the fully tightened screw.

After achieving desired amount of compression, tighten cap screw. Final cap screw tightening steps should be followed to fully lock construct.
**Step 13 Option 2**

**Lever-Style Open Compression (if necessary)**

Four instruments are required for this assembly: Counter Torque, 4.0mm Driver, Compressor, 90 in-lb Torque-Limiting Handle.

Place counter torque instrument through Level Compressor. Place the Counter Torque over the screw to be compressed with the 4.0mm Driver and 90 in-lb Torque-Limiting Handle (black) assembly engaged in the cap screw. Place the Compressor around the adjacent screw to (off of which to compress).

Squeeze the Counter Torque and Compressor together to compress the segment. Once desired compression is achieved, tighten cap screw on compressed screw.

---

**Distraction Option**

The *TITLE 2* system offers two options for distraction in an open surgery.

**Step 14 Option 1**

**Standard Open Distraction (if necessary)**

Fully tighten the cap screw on one side of the segment being translated, while leaving the set screw loose on the adjacent screw(s). Perform distraction against the fully tightened screw.

After achieving the desired amount of distraction, tighten the cap screw. Final cap screw tightening steps should be followed to fully lock the construct.
Lever-Style Open Distraction (if necessary)

Four instruments are required for this assembly: Counter Torque, 4.0mm Driver, Distractor, 90 in-lb Torque-Limiting Handle.

Place the Counter Torque over the screw to be distracted with the driver and 90 in-lb Torque-Limiting Handle (black) assembly engaged in the cap screw. Place the Distractor against the screw to distract from. Squeeze Counter Torque and Distractor together to distract the segment. Once desired distraction is achieved, tighten the cap screw on the distracted screw.

Final Tightening

Final Tightening

Once all correction procedures have been completed, the construct is ready for final tightening. Final tightening requires the Marksman Counter Torque, 4.0mm Captive Hex Screwdriver and 90 in-lb Torque-Limiting Handle (black).

Attach the Torque-Limiting Handle to the 4.0mm Captive Hex Screwdriver. Pass the driver assembly through the cannulated Marksman Counter Torque. Visually confirm that the hex on the driver fully engages the hex on the cap screw prior to positioning the Marksman Counter Torque over the screw head.
**Step 15b**

**Final Tightening**

While providing the appropriate Counter Torque, turn the Torque-Limiting Handle (black) clockwise to advance the cap screw.

The Torque-Limiting Handle will break over / click at 90 in-lbs. Repeat process until all remaining screws are fully tightened.

---

**Rod-to-Rod Connectors Option**

---

**Option 1: 5.5 to 5.5mm Connectors (if necessary)**

The set screws for the 5.5mm to 5.5mm connectors have a torque requirement of 50 in-lbs. When final tightening the set screws, utilize the *TITLE 2* Torque-Limiting Handle (gray) and the *TITLE 2* 3.5mm Hex Driver. Both of these items are found in the *TITLE 2* Spinal Instrumentation System. This is the same gray handle that is used to fully tighten the transverse connectors and the same 3.5mm Hex Driver used to implant *TITLE 2* pedicle screws.

---

**Option 2: 5.5mm to 3.25mm Connectors (if necessary)**

The set screws for the 5.5mm to 3.25mm connectors have torque recommendations of 30 in-lbs. When final tightening the set screws utilize the *Minit* Torque-Limiting Handle and the *TITLE 2* 3.5 mm Captive Hex Driver.

---

*Note: Rod to rod connectors have not been validated for use through the FlexPosure portal.*

---
Transverse Connector Preparation (if necessary)
Attach the 50 in-lb Torque-Limiting Handle (gray) to the 3.5mm Captive Hex Screwdriver.
Confirm that all set screws on the Transverse Connector are loose and will allow for free movement.

Transverse Connector Selection (if necessary)
Transverse Connectors are used to connect parallel rod segments. Use the Transverse Connector Template to determine the appropriate length Transverse Connector.
Transverse Connector Placement
(if necessary)
Using the Rod Holder, position the selected Transverse Connector over the rods.

Tighten the outer set screws on the Transverse Connector first. Turn the driver assembly clockwise until the 50 in-lb Torque-Limiting Handle breaks over / clicks.

Tighten center set screw. Turn the driver assembly clockwise until the 50 in-lb Torque-Limiting Handle breaks over / clicks.

Construct Removal Option

Removal and Revision
(if necessary)
The TITLE 2 system provides instrumentation specifically designed for removal. If the center hex in screw head can be accessed, utilize either the 3.5mm Captive Hex Screwdriver or the 3.5mm Locking Screwdriver to remove the screw. If the center hex feature on the screw cannot be accessed, the Bone Screw Remover should be used.

Remove all cap screws from the screw. Remove the rod from the screw heads.

Attach Ratcheting Handle to Bone Screw Remover. Turn the Racheting Handle counterclockwise to remove the screw.
# TITLE 2 Kit Contents

Module Number ET4000-42

## TITLE 2 Instruments

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Standard Kit Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>ET1008-01</td>
<td>Compressor</td>
<td>1</td>
</tr>
<tr>
<td>ET1009-01</td>
<td>Distractor</td>
<td>1</td>
</tr>
<tr>
<td>ET1010-01</td>
<td>Rod Template</td>
<td>1</td>
</tr>
<tr>
<td>ET1011-01</td>
<td>Rod Holder</td>
<td>1</td>
</tr>
<tr>
<td>ET1025-01</td>
<td>Rod Rotation Wrench</td>
<td>1</td>
</tr>
<tr>
<td>ET1036-01</td>
<td>French Bender</td>
<td>1</td>
</tr>
<tr>
<td>ET1043-01</td>
<td>T-Link Template, Packaging</td>
<td>1</td>
</tr>
<tr>
<td>ET1049-01</td>
<td>Ratcheting T-Handle, Grey</td>
<td>1</td>
</tr>
<tr>
<td>ET1052-01</td>
<td>Captive Hex Screwdriver, 4.0mm</td>
<td>2</td>
</tr>
<tr>
<td>ET1054-01</td>
<td>Marksman Countertorque Guide</td>
<td>1</td>
</tr>
<tr>
<td>ET1062-01</td>
<td>Endoscopic Rod Holder</td>
<td>1</td>
</tr>
<tr>
<td>ET1093-01</td>
<td>TITLE 2 Bone Screw Remover</td>
<td>1</td>
</tr>
<tr>
<td>ET1094-01</td>
<td>TITLE 2 Reducer Driver</td>
<td>1</td>
</tr>
<tr>
<td>ET1095-01</td>
<td>TITLE 2 Reducer</td>
<td>1</td>
</tr>
<tr>
<td>ET1096-01</td>
<td>MIS Compressor/Distractor</td>
<td>1</td>
</tr>
<tr>
<td>ET1097-01</td>
<td>MIS Compressor/Distractor Driver</td>
<td>1</td>
</tr>
<tr>
<td>ET1020-01</td>
<td>Torque Limiting Handle</td>
<td>1</td>
</tr>
<tr>
<td>ET1098-01</td>
<td>Torque Limiting T-Handle</td>
<td>1</td>
</tr>
</tbody>
</table>
## TITLE 2 Instrument/Implant Set

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Standard Kit Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>ET1001-01</td>
<td>Ratchet Handle</td>
<td>2</td>
</tr>
<tr>
<td>ET1002-01</td>
<td>Sounding Probe Straight</td>
<td>1</td>
</tr>
<tr>
<td>ET1003-01</td>
<td>Sounding Probe Canned</td>
<td>1</td>
</tr>
<tr>
<td>ET1004-01</td>
<td>Straight Pedicle Probe</td>
<td>1</td>
</tr>
<tr>
<td>ET1005-01</td>
<td>Curved Pedicle Probe</td>
<td>1</td>
</tr>
<tr>
<td>ET1006-01</td>
<td>Awl</td>
<td>1</td>
</tr>
<tr>
<td>ET1049-01</td>
<td>Ratcheting T-Handle</td>
<td>1</td>
</tr>
<tr>
<td>ET1051-01</td>
<td>3.5mm Captive Hex Screwdriver</td>
<td>2</td>
</tr>
<tr>
<td>ET1074-01</td>
<td>Endo Pedicle Marker Left</td>
<td>3</td>
</tr>
<tr>
<td>ET1075-01</td>
<td>Endo Pedicle Marker Right</td>
<td>3</td>
</tr>
<tr>
<td>ET1076-01</td>
<td>Endo Pedicle Marker Driver</td>
<td>1</td>
</tr>
<tr>
<td>ET1080-01</td>
<td>TITLE 2, Cap Screw Extractor Ext</td>
<td>1</td>
</tr>
<tr>
<td>ET1081-01</td>
<td>TITLE 2, Cap Screw Extractor Tip/#1</td>
<td>1</td>
</tr>
<tr>
<td>ET1082-01</td>
<td>TITLE 2, Cap Screw Extractor Tip/#2</td>
<td>1</td>
</tr>
<tr>
<td>ET1088-55</td>
<td>Solid Tap, 5.5mm</td>
<td>1</td>
</tr>
<tr>
<td>ET1088-65</td>
<td>Solid Tap, 6.5mm</td>
<td>1</td>
</tr>
<tr>
<td>ET1088-75</td>
<td>Solid Tap, 7.5mm</td>
<td>1</td>
</tr>
<tr>
<td>ET1091-01</td>
<td>TITLE 2 Lock Screwdriver, Solid</td>
<td>2</td>
</tr>
</tbody>
</table>

## Accessory Instrument Set

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Standard Kit Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>ET1113-01</td>
<td>In-Situ Bender for 5.5mm</td>
<td>1</td>
</tr>
<tr>
<td>ET1117-01</td>
<td>T2 Rod Manipulator Assy</td>
<td>1</td>
</tr>
<tr>
<td>ET1118-01</td>
<td>Sleeve, Locking Screwdriver</td>
<td>2</td>
</tr>
<tr>
<td>ET1119-01</td>
<td>4.0mm Ball Tap Hex Screwdriver</td>
<td>2</td>
</tr>
<tr>
<td>ET1130-01</td>
<td>2 Piece Compressor</td>
<td>1</td>
</tr>
<tr>
<td>ET1131-01</td>
<td>2 Piece Distractor</td>
<td>1</td>
</tr>
<tr>
<td>ET1132-01</td>
<td>Countertorque Assembly</td>
<td>1</td>
</tr>
<tr>
<td>ET1133-01</td>
<td>4.0mm Driver Shaft Assembly</td>
<td>1</td>
</tr>
<tr>
<td>ET1134-01</td>
<td>T2 Head Positioner</td>
<td>1</td>
</tr>
<tr>
<td>ET1113-02</td>
<td>In-Situ Bender for 5.5mm</td>
<td>1</td>
</tr>
<tr>
<td>ET1121-45</td>
<td>S/S/INS, Sharp Tap, Solid, 4.5mm</td>
<td>1</td>
</tr>
<tr>
<td>Part Number</td>
<td>Description</td>
<td>Standard Kit Quantity</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>161-3030</td>
<td>T-Link, <em>GoldenGate</em>, 30mm</td>
<td>2</td>
</tr>
<tr>
<td>161-3040</td>
<td>T-Link, <em>GoldenGate</em>, 40mm</td>
<td>2</td>
</tr>
<tr>
<td>161-3050</td>
<td>T-Link, <em>GoldenGate</em>, 50mm</td>
<td>2</td>
</tr>
<tr>
<td>161-3060</td>
<td>T-Link, <em>GoldenGate</em>, 60mm</td>
<td>2</td>
</tr>
<tr>
<td>161-3070</td>
<td>T-Link, <em>GoldenGate</em>, 70mm</td>
<td>1</td>
</tr>
<tr>
<td>161-3080</td>
<td>T-Link, <em>GoldenGate</em>, 80mm</td>
<td>1</td>
</tr>
<tr>
<td>500-5040</td>
<td>Straight Rod, 5.5mm X 40mm</td>
<td>2</td>
</tr>
<tr>
<td>500-5060</td>
<td>Straight Rod, 5.5mm X 60mm</td>
<td>2</td>
</tr>
<tr>
<td>500-5080</td>
<td>Straight Rod, 5.5mm X 80mm</td>
<td>2</td>
</tr>
<tr>
<td>500-5100</td>
<td>Straight Rod, 5.5mm X 100mm</td>
<td>2</td>
</tr>
<tr>
<td>500-5120</td>
<td>Straight Rod, 5.5mm X 120mm</td>
<td>2</td>
</tr>
<tr>
<td>500-5200</td>
<td>Straight Rod, 5.5mm X 200mm</td>
<td>2</td>
</tr>
<tr>
<td>535-5020</td>
<td>Curved Rod, 3.5R 5.5mm X 20mm</td>
<td>2</td>
</tr>
<tr>
<td>535-5030</td>
<td>Curved Rod, 3.5R 5.5mm X 30mm</td>
<td>4</td>
</tr>
<tr>
<td>535-5040</td>
<td>Curved Rod, 3.5R 5.5mm X 40mm</td>
<td>4</td>
</tr>
<tr>
<td>535-5050</td>
<td>Curved Rod, 3.5R 5.5mm X 50mm</td>
<td>4</td>
</tr>
<tr>
<td>535-5060</td>
<td>Curved Rod, 3.5R 5.5mm X 60mm</td>
<td>4</td>
</tr>
<tr>
<td>535-5070</td>
<td>Curved Rod, 3.5R 5.5mm X 70mm</td>
<td>4</td>
</tr>
<tr>
<td>535-5080</td>
<td>Curved Rod, 3.5R 5.5mm X 80mm</td>
<td>4</td>
</tr>
<tr>
<td>800-0000</td>
<td>TITLE 2 Cap Screw</td>
<td>20</td>
</tr>
<tr>
<td>800-5530</td>
<td>TITLE 2 Pa Ped. Screw, 5.5X30mm</td>
<td>4</td>
</tr>
<tr>
<td>800-5535</td>
<td>TITLE 2 Pa Ped. Screw, 5.5X35mm</td>
<td>4</td>
</tr>
<tr>
<td>800-5540</td>
<td>TITLE 2 Pa Ped. Screw, 5.5X40mm</td>
<td>6</td>
</tr>
<tr>
<td>800-5545</td>
<td>TITLE 2 Pa Ped. Screw, 5.5X45mm</td>
<td>6</td>
</tr>
<tr>
<td>800-5550</td>
<td>TITLE 2 Pa Ped. Screw, 5.5X50mm</td>
<td>6</td>
</tr>
<tr>
<td>800-6530</td>
<td>TITLE 2 Pa Ped. Screw, 6.5X30mm</td>
<td>4</td>
</tr>
<tr>
<td>800-6535</td>
<td>TITLE 2 Pa Ped. Screw, 6.5X35mm</td>
<td>6</td>
</tr>
<tr>
<td>800-6540</td>
<td>TITLE 2 Pa Ped. Screw, 6.5X40mm</td>
<td>6</td>
</tr>
<tr>
<td>800-6545</td>
<td>TITLE 2 Pa Ped. Screw, 6.5X45mm</td>
<td>6</td>
</tr>
<tr>
<td>800-6550</td>
<td>TITLE 2 Pa Ped. Screw, 6.5X50mm</td>
<td>6</td>
</tr>
<tr>
<td>800-6555</td>
<td>TITLE 2 Pa Ped. Screw, 6.5X55mm</td>
<td>6</td>
</tr>
<tr>
<td>800-7530</td>
<td>TITLE 2 Pa Ped. Screw, 7.5X30mm</td>
<td>4</td>
</tr>
<tr>
<td>800-7535</td>
<td>TITLE 2 Pa Ped. Screw, 7.5X35mm</td>
<td>6</td>
</tr>
<tr>
<td>800-7540</td>
<td>TITLE 2 Pa Ped. Screw, 7.5X40mm</td>
<td>6</td>
</tr>
<tr>
<td>800-7545</td>
<td>TITLE 2 Pa Ped. Screw, 7.5X45mm</td>
<td>6</td>
</tr>
<tr>
<td>800-7550</td>
<td>TITLE 2 Pa Ped. Screw, 7.5X50mm</td>
<td>6</td>
</tr>
<tr>
<td>800-7555</td>
<td>TITLE 2 Pa Ped. Screw, 7.5X55mm</td>
<td>6</td>
</tr>
</tbody>
</table>
### 4.5mm Tap Instrument Set

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Standard Kit Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>ET1088-45</td>
<td>Solid Tap, 4.5mm</td>
<td>1</td>
</tr>
<tr>
<td>ET1120-45</td>
<td>S/S/INS, Awl-In-One, Solid, 4.5mm</td>
<td>1</td>
</tr>
</tbody>
</table>

### 4.5mm Implant Kit

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Standard Kit Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>800-4525</td>
<td>TITLE 2 PA Pedicle Screw, 4.5X25mm</td>
<td>8</td>
</tr>
<tr>
<td>800-4530</td>
<td>TITLE 2 PA Pedicle Screw, 4.5X30mm</td>
<td>8</td>
</tr>
<tr>
<td>800-4535</td>
<td>TITLE 2 PA Pedicle Screw, 4.5X35mm</td>
<td>8</td>
</tr>
<tr>
<td>800-4540</td>
<td>TITLE 2 PA Pedicle Screw, 4.5X40mm</td>
<td>8</td>
</tr>
<tr>
<td>800-4545</td>
<td>TITLE 2 PA Pedicle Screw, 4.5X45mm</td>
<td>8</td>
</tr>
<tr>
<td>501-5555</td>
<td>5.5mm/5.5mm Axial Rod Connector</td>
<td>2</td>
</tr>
<tr>
<td>502-5555</td>
<td>5.5mm/5.5mm Dual Rod Connector</td>
<td>2</td>
</tr>
<tr>
<td>501-3255</td>
<td>3.25mm/5.5mm Axial Rod Connector</td>
<td>2</td>
</tr>
<tr>
<td>502-3255</td>
<td>3.25mm/5.5mm Dual Rod Connector</td>
<td>2</td>
</tr>
</tbody>
</table>

### TiTITLE 2 Long Length Screw Kit

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Standard Kit Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>800-5560</td>
<td>T2 Screw, 5.5mm X 60mm</td>
<td>4</td>
</tr>
<tr>
<td>800-5565</td>
<td>T2 Screw, 5.5mm X 65mm</td>
<td>4</td>
</tr>
<tr>
<td>800-5570</td>
<td>T2 Screw, 5.5mm X 70mm</td>
<td>4</td>
</tr>
<tr>
<td>800-6560</td>
<td>T2 Screw, 6.5mm X 60mm</td>
<td>4</td>
</tr>
<tr>
<td>800-6565</td>
<td>T2 Screw, 6.5mm X 65mm</td>
<td>4</td>
</tr>
<tr>
<td>800-6570</td>
<td>T2 Screw, 6.5mm X 70mm</td>
<td>4</td>
</tr>
<tr>
<td>800-7560</td>
<td>T2 Screw, 7.5mm X 60mm</td>
<td>4</td>
</tr>
<tr>
<td>800-7565</td>
<td>T2 Screw, 7.5mm X 65mm</td>
<td>4</td>
</tr>
<tr>
<td>800-7570</td>
<td>T2 Screw, 7.5mm X 70mm</td>
<td>4</td>
</tr>
</tbody>
</table>
Warnings and Precautions

Warnings

• The FDA has placed labeling limitations on this device.

• The safety and effectiveness of pedicle screw spinal systems have been established only 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 degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, hypnosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition is unknown.

• When used as a Pedicle Screw System, this system is intended for Grade 3 or 4 spondylolisthesis at the fifth lumbar/first sacral joint.

• The benefit of spinal fusions utilizing any pedicle screw fixation has not been adequately established in patients with stable spines.

• Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and vascular or visceral injury.
Precautions

• The implantation of Pedicle Screw System should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

• This device system is not intended to be the sole means of support. Its use without bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending loosening or fracture of the implant will eventually occur.

• Mixing of dissimilar metals can accelerate the corrosion process. Stainless Steel and Titanium components must NOT be used together in building a construct.

• No components of the TiTITLE2 Poly Axial Spinal System should be used with components from any other system or manufacturer, unless otherwise noted in the INDICATIONS section.

• The Delivery Instrumentation should be used to implant and connect the devices. The use of any other drivers, taps, or other instrumentation may compromise the integrity of the construct.

• As with all orthopedic implants, none of the TiTITLE2 Poly Axial Spinal System implants should ever be reused under any circumstances.

• Instruments designated for single use must not be reused and must be properly disposed of.

• All implants and some instruments are intended for single use only; refer to the product label to determine if the instrument is intended for single use only. Single use devices should not be re-used. Possible risks associated with re-use of single use devices include:
  o Mechanical malfunction
  o Transmission of infectious agents

• Using bent or damaged Guidewires can adversely affect Cannulated Pedicle Screw placement.

• Torque limiting instrument adjustment screws or caps with set screws should not be manipulated during the cleaning process. Manipulation or disassembly of the instrument will affect the calibration of the instrument and it will require re-calibration prior to use.

• Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, etc. which may impact the performance of the system.
  · The proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, poor muscle or bone quality, and nerve paralysis patients.
Solutions by the people of Zimmer Spine.

You are devoted to helping your patients reduce their pain and improve their lives. And the people of Zimmer Spine are devoted to you. We are dedicated to supporting you with best-in-class tools, instruments and implants. We are driven by the opportunity to share our unrivaled education and training. We are committed partners who will do everything in our power to assist you in your quest to provide the absolute best in spinal care. And we can be counted on always to act with integrity as ethical partners who are worthy of your trust. We are the people of Zimmer Spine.

This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. Please refer to the package inserts for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects.