

Eisertech, LLC Spinal System

Surgical Technique

Notes

- This technique manual assumes that the surgeon is familiar with the techniques for performing spinal fixation using spinal systems as an adjunct to fusion.
- This manual is not intended to teach a surgeon how to perform a spinal fusion procedure.
- This manual provides instruction in how to appropriately use the equipment provided by Eisertech, LLC.

I. Expose the spine

- Expose the affected level(s) through a conventional muscle-splitting posterior approach to the spine.
- Either a unilateral or bilateral approach may be utilized.
- Anterior spinal fixation may require a lateral or anterolateral approach to the spine.

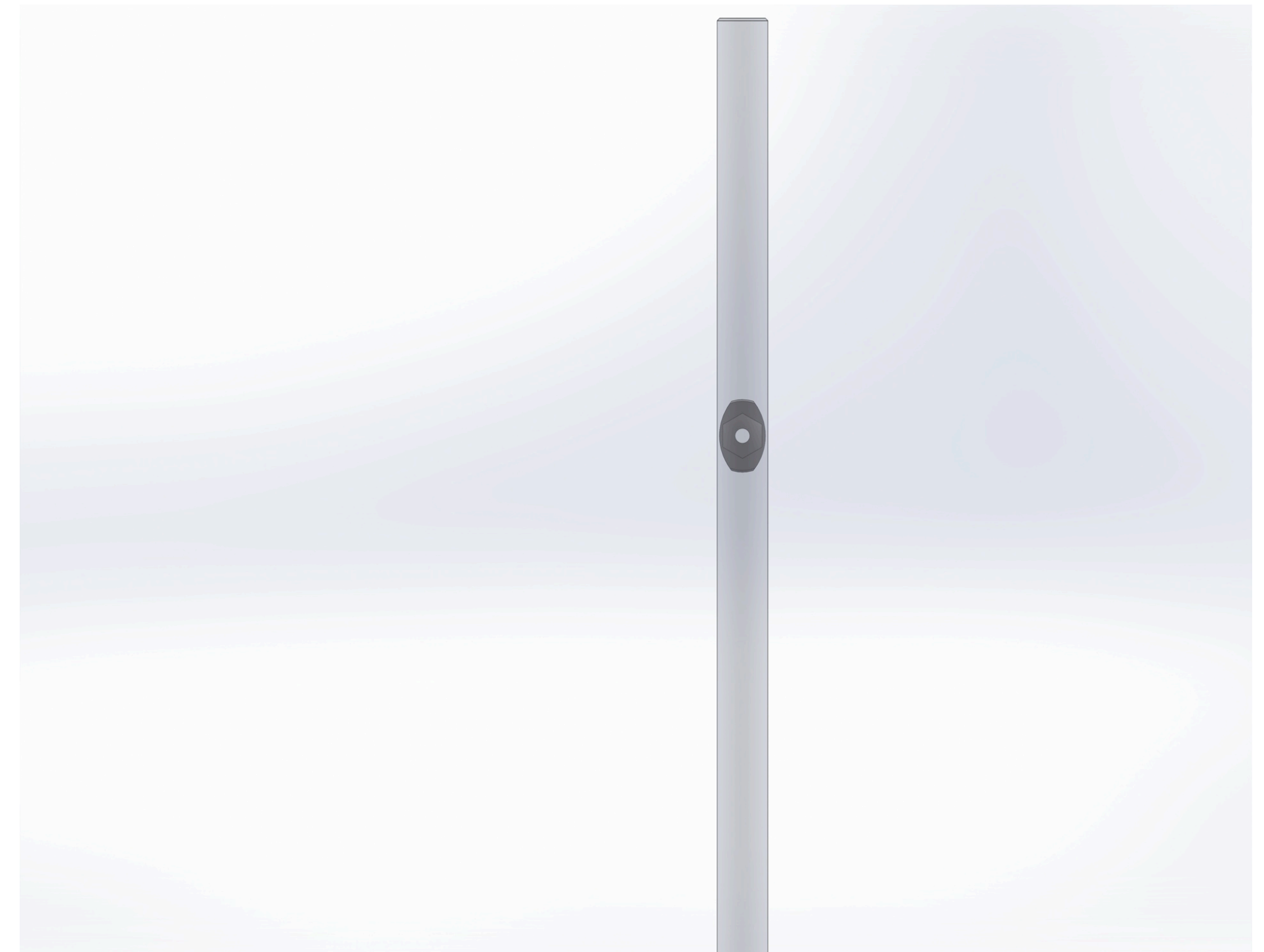


2. Prepare the bone

- An awl or drill may be used to create a hole in the bone for placing the screw.

3. Insert the screws and hooks

- Attach the screw to the screw driver by inserting the hex head of the screw into the hex recess of the driver and then tighten the tightening wheel.
- Drive the screw into the bone, leaving the “paddle” shape of the head lined up in the desired final rod orientation. The “paddle” portion of the screw head should be as closely aligned to the rod orientation as possible.
- Attach hooks to the spine as required by the surgical plan.



Perfect Alignment

4. Attach the tulip

- Select the desired tulip.
- Attach the tulip to the tulip driver.
- Attach the tulip to the screw by turning it 90 degrees from the intended final location, slipping it over the screw head, and turning it to its final position.
- Repeat for each screw.

5. Insert the rods

- Select the desired rod length.
- Insert the rods into the receiving channels in the tulips.

6. Tighten the set screws

- Insert the set screws into the tulips.
- Tighten set screws to lock the rod relative to the bone screw.

7. Add Wedding Band or End to End Connectors if Required

- Wedding Band Connectors (WBC) may be used to connect to rods side-by-side. To use the connectors, slip one rod into each rod hole, and tighten all four set screws.
- Different diameter rods may be connected this way, by selecting the WBC with the size corresponding to the rod diameter.
- End-to-End Connectors (EEC) may be used to connect two rods end to end. Like the WBC, the EEC can connect different diameter rods if required.

8. Close the incision

- Close the incision in the usual manner.

Revision

- Should it become necessary to remove the Spinal System, the implant may be retrieved by loosening the set screws, removing the rods, removing the tulips, and removing the bone screws or hooks from the bone.
- Sets screws may be loosened with any standard 5mm hex driver.
- Pedicle screws may be removed with the Eisertech screw driver, or alternately with a 4.25mm nut driver if Eisertech equipment is not available.
- An explanted Spinal System must never be re-used or re-implanted. Even though the device appears undamaged, it may have defects and internal stresses that may lead to early breakage.

Device Description:

The SPINAL SYSTEM consists of a variety of polyaxial screws, rods, hooks, locking nuts, and rod-to-rod connectors. Implant components can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient.

All components are made of titanium alloy, per ASTM F136.

INDICATIONS

When used as a pedicle screw fixation system, the Eisertech Spinal System is 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 posterior thoracic, lumbar, and sacral spine:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment
3. Fracture
4. Dislocation
5. Scoliosis
6. Kyphosis
7. Spinal tumor and/or
8. Failed previous fusion (pseudoarthrosis)

The Eisertech Spinal System is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic and lumbar spine, the Eisertech Spinal System is also intended for the following indications:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Spinal stenosis
3. Spondylolisthesis
4. Spinal deformities
5. Fracture
6. Pseudoarthrosis
7. Tumor resection and/or
8. Failed previous fusion

CONTRAINDICATIONS

The Spinal System should not be implanted in patients with active systemic infection or infection localized to the site of implantation.

Severe osteoporosis may prevent adequate fixation to the bone and those preclude the use of this or any other spinal instrumentation system.

WARNINGS

• Use as indicated. The safety and effectiveness when implanted in the spine for any other indications has not been established.

PRECAUTIONS

- Use of the Spinal System should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics; has had experience with spinal fusion procedures and spinal fixation; and has had hands-on training in the use of this device.
- One or two Spinal System screws should be implanted at each surgical level.
- The Spinal System should not be implanted in patients with severe osteoporosis or osteopenia.
- The surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- The Spinal System is supplied non-sterile. It must be sterilized before use.
- Implant components can break when subjected to the increased loading associated with delayed union or nonunion.
- Patients with previous spinal surgery at the level to be treated may have different outcomes compared to those without previous surgery.

The following potential adverse events (singly or in combination) could also result from the implantation of the Spinal System:

1. Bursitis.
2. Decrease in bone density due to stress shielding.
3. Degenerative changes or instability of segments adjacent to fused vertebral levels
4. Fracture of bony structures.
5. Implant material sensitivity, or allergic reaction to a foreign body.
6. Infection, early or late.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. Nonunion, delayed union.
9. Discomfort, or abnormal sensations due to the presence of the device.
10. Paralysis.
11. Spinal cord impingement or damage.
12. Vascular damage could result in catastrophic or fatal bleeding
13. Death.

Part Number	Description
100002-7530C	30mm x 7.5mm DIA Cannulated Screw
100002-7535C	35mm x 7.5mm DIA Cannulated Screw
100002-7540C	40mm x 7.5mm DIA Cannulated Screw
100002-7545C	45mm x 7.5mm DIA Cannulated Screw
100002-7550C	50mm x 7.5mm DIA Cannulated Screw
100002-7555C	55mm x 7.5mm DIA Cannulated Screw
100002-7560C	60mm x 7.5mm DIA Cannulated Screw
100002-6530C	30mm x 6.5mm DIA Cannulated Screw
100002-6535C	35mm x 6.5mm DIA Cannulated Screw
100002-6540C	40mm x 6.5mm DIA Cannulated Screw
100002-6545C	45mm x 6.5mm DIA Cannulated Screw
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100002-5545C	45mm x 5.5mm DIA Cannulated Screw
100002-5550C	50mm x 5.5mm DIA Cannulated Screw
100002-5555C	55mm x 5.5mm DIA Cannulated Screw
100002-5560C	60mm x 5.5mm DIA Cannulated Screw
100147-55C	5.5mm Top-Loading Tulip
100228-5520C	5.5mm Reduction Tulip
100003-0	Set Screw

Part Number	Description
100180-55030	030mm L x 5.5mm DIA Straight Rod
100180-55035	035mm L x 5.5mm DIA Straight Rod
100180-55040	040mm L x 5.5mm DIA Straight Rod
100180-55045	045mm L x 5.5mm DIA Straight Rod
100180-55050	050mm L x 5.5mm DIA Straight Rod
100180-55055	055mm L x 5.5mm DIA Straight Rod
100180-55060	060mm L x 5.5mm DIA Straight Rod
100180-55065	065mm L x 5.5mm DIA Straight Rod
100180-55070	070mm L x 5.5mm DIA Straight Rod
100180-55075	075mm L x 5.5mm DIA Straight Rod
100180-55080	080mm L x 5.5mm DIA Straight Rod
100180-55085	085mm L x 5.5mm DIA Straight Rod
100180-55090	090mm L x 5.5mm DIA Straight Rod
100180-55095	095mm L x 5.5mm DIA Straight Rod
100180-55100	100mm L x 5.5mm DIA Straight Rod
100180-55110	110mm L x 5.5mm DIA Straight Rod
100180-55120	120mm L x 5.5mm DIA Straight Rod
100180-55200	200mm L x 5.5mm DIA Straight Rod
100196-55030150	030mm L x 5.5mm DIA Curved Rod
100180-55035150	150mm L x 3.5mm DIA Straight Rod
100196-55040150	040mm L x 5.5mm DIA Curved Rod
100180-55045150	150mm L x 4.5mm DIA Straight Rod
100196-55050150	050mm L x 5.5mm DIA Curved Rod
100180-55055150	150mm L x 5.5mm DIA Straight Rod
100196-55060150	060mm L x 5.5mm DIA Curved Rod
100180-55065150	150mm L x 6.5mm DIA Straight Rod
100196-55070150	070mm L x 5.5mm DIA Curved Rod
100180-55075150	150mm L x 7.5mm DIA Straight Rod
100196-55080150	080mm L x 5.5mm DIA Curved Rod
100180-55085150	150mm L x 8.5mm DIA Straight Rod
100196-55090150	090mm L x 5.5mm DIA Curved Rod
100180-55095150	150mm L x 9.5mm DIA Straight Rod
100196-55100150	100mm L x 5.5mm DIA Curved Rod
100180-55110150	150mm L x 1.5mm DIA Straight Rod
100196-55120150	120mm L x 5.5mm DIA Curved Rod
100196-55200150	200mm L x 5.5mm DIA Curved Rod
100223-0	Screw Driver
100240-55C	5.5mm Cannulated Tap
100240-65C	6.5mm Cannulated Tap
100240-75C	7.5mm Cannulated Tap
100241-0	Tulip Inserter
100242-0	Retaining Sleeve
100243-0	Tulip Draw Rod
100244-11001656-00	MPS Implant Tray Assembly