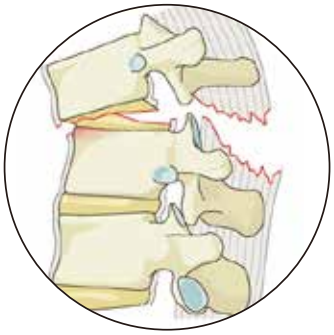
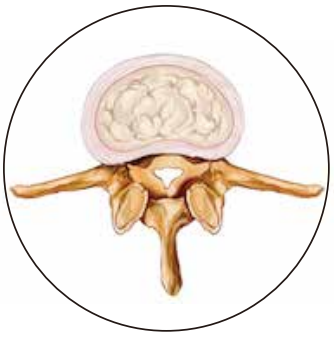
INDICATION

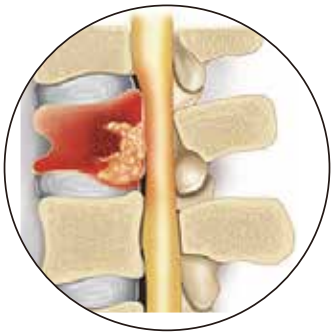


Fracture or dislocation



Spinal stenosis

Degenerative disc disease



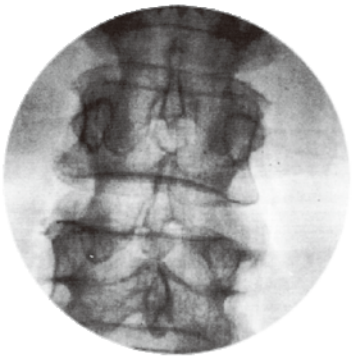
Tumor, tuberculosis

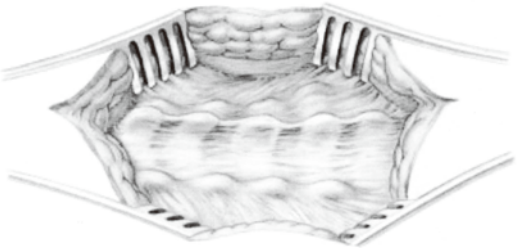
SURGICAL TECHNIQUE

Step1 Preliminary

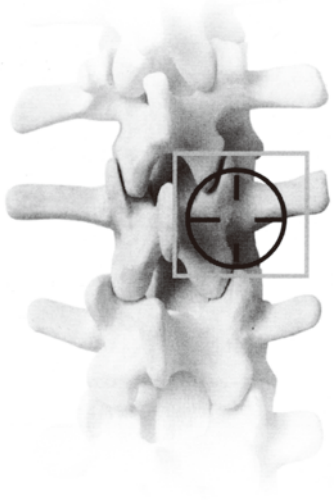
• The patient is placed on the operating table in the prone position. A spine surgery frame should be used which will avoid any pressure on the abdomen, there by avoiding vena caval compression.

• The surgical approach is carried out through a standard midline incision to the spinal column over the spinous processes. The incision should be long enough to ensure expose expected. The supraspinous and interspinous ligaments should be preserved. Meticulous subperiosteal exposure of the posterior elements is performed. The paraspinal musculature is detached to the outer margins of transverse processes. When indicated, soft tissue and bony decompression are performed to relieve neurological compression.





Step2 Insert pedicle screw



Step2.1 Identification of the pedicles

The dorsal entry point to the medullary canal of the lumbar pedicle is located at the convergent point of three distinct anatomic structures.

- Middle of the transverse process
- The superior facet
- The pars interarticularis

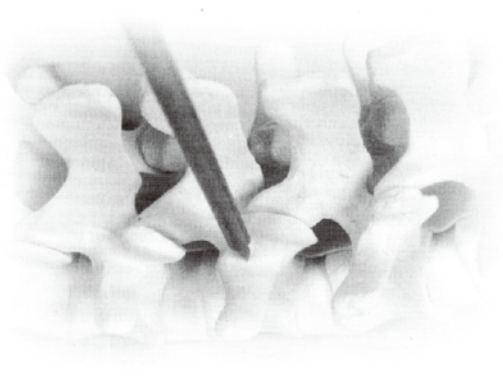
The starting point can also be identified at the intersection of two lines drawn through the middle of the transverse process and the lateral border of the superior articular facet.

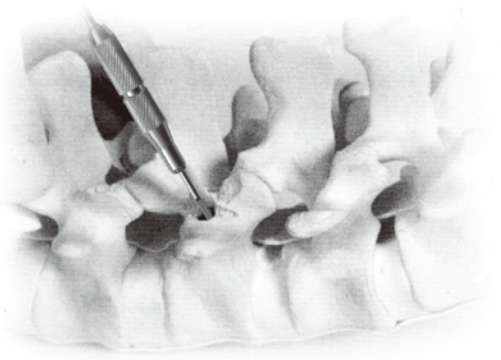
A burr or ronquer may be used to clear away the hard cortical bone at the junction of the facet and transverse process, thereby exposing the cancellous portion of the pedicle.

The starting point in the sacral pedicles is significantly different due to the lack of transverse processes and the presence of the sacral ala. The size and configuration of the S1 pedicle allow the surgeon more flexibility in positioning the bone bolt within the sacrum. The entrance point to the S1 pedicle is caudal and slightly lateral to the superior articular process. The entry point should be in the most caudal portion of the pedicle.

Step2.2 Preparation of the pedicle canal

An Awl or burr can be used establish an opening to the pedicle at this site. A Straight Awl is bored through the pedicle and into the vertebral body 50%~80%• The anteror cortex of the vertebral body should be violated with great caution. The scale on the Straight Awl can tip the drilling depth, and also can determine the depth of the pedicle screw.

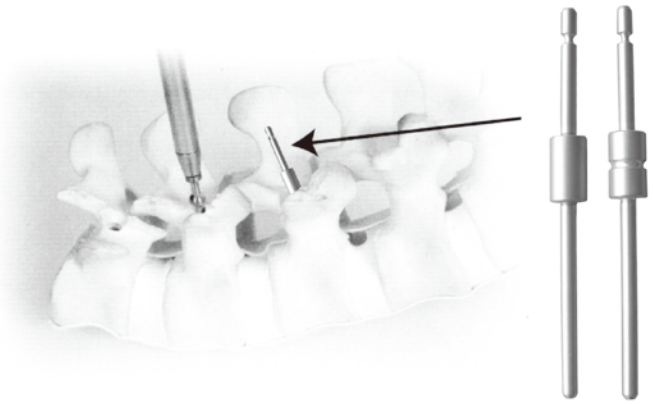




Step2.3 Determining screw length

Having opened the channel of the pedicle, all four walls of the pedicle can be palpated with a Probe to ensure that the walls of the pedicle have not been violatd. A Probe calibrated at 10mm intervals can then be inserted into the vertebral body and the length of the pedicle and vertebral body measured to determine appropriate screw length.

A radiographic Marker is placed through the pedicle and into the vertebral body, and its position within the confines of the pedicle is confirmed with plain radiographs or fluoroscopy. The appropriate length of the screw can also be confirmed on lateral radiographs by referring to the Marker.



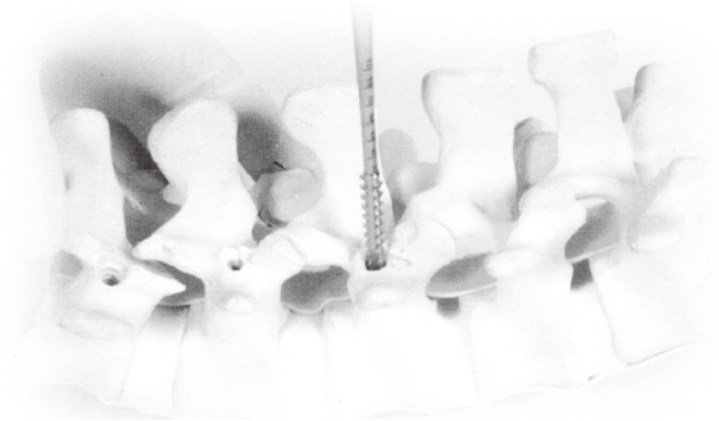
Step2.4 Tapping the pedicles

M9 instumentation offers two taps (4.5mm, 5.5mm) which correspond to the bone screw diameters.

The apropriate diameter tap is inserted through the pedicle and into the vertebral body.

Following this final preparation of the pedicle; a probe can be used to follow the tap threads through the cancellous bone and palpate for any perforations in the pedicle walls.

Note: Tops for reference only.

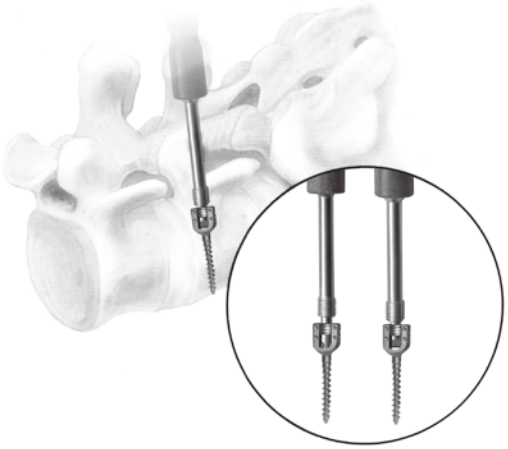


Step2.5 Screw insertion

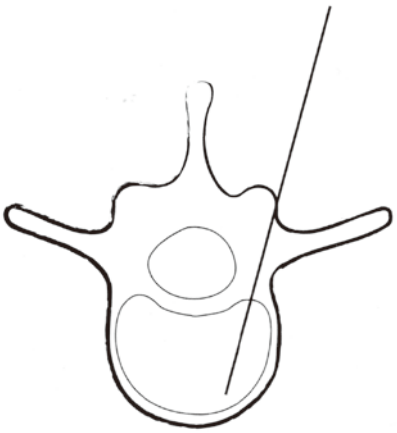
The pedicle screws are sequentially inserted using the Monoaxial/ Mutiaxial Screwdriver. Insert the pedicle screw into the Monoaxial/ Multiaxial Screwdriver and drive into the pedicles by following the previously tapped canal. The pedicle screws should be inserted until the tip of the wrench abuts the bony surface.

Multiaxial Screwdriver Application: The Multiaxial Screwdriver head is three-jaw, place the head of the Multiaxial Screwdriver into The head of the screw slot. Slide the Screwdriver sleeve down into the head of the screw, tightening the thread.

Note: Tightening after the three-jaw head fully inserted into the screw head, otherwise the three-jaw head will be deformation and the operation can not be well performed.



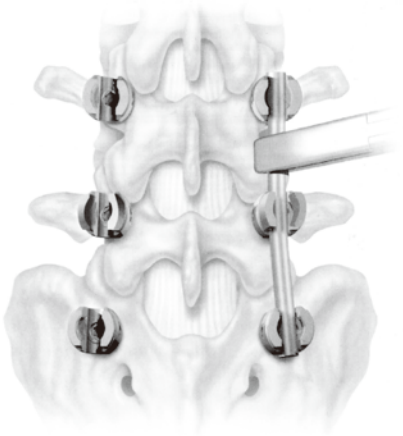
Note: Screw insertion should follow the angle of the pedicle canal.



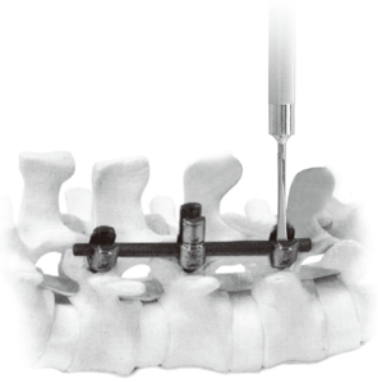
Step 3 Rod insertion

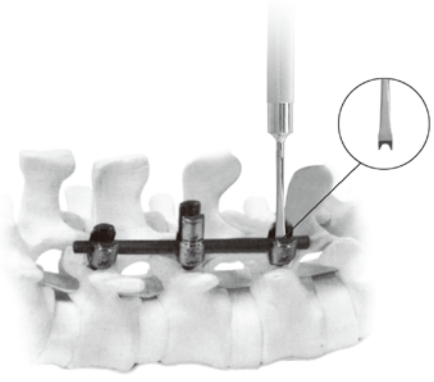
Due to differences in pedicle angles, as measured from the midline (spinous processes), screw position as viewed posteriorly may be malaligned. The Multi Axial Screw may be angled up to 25° medial and lateral to facilitate in the placement of the rod with minimal bending/ contouring.

There are a various length of the rod in M9 System so that the operationg of cutting rods is not necessary. A Rod Template may be used to determine the rod contour needed for construct assembly. The rod may be bent into lordosis using the Rod Bender. The rod does not have to be precisely bent for attachment to the pedicle screws, especially for a single-level fusion. However, bending the rod to an appropriate lordotic curvature lowers the profile of the implants and improves the biomechanics of the construct by reducing the bending moment and thus reducing the stresses on the pedicle screws. A lordotic bend in the rod also allows an element of medial or lateral adjustment on a multi-level construct.



Rod pusher is used to push the rod on the top of the pedicle screw head, the nut is then inserted through the quick screw driver into the head of the pedicle screw.

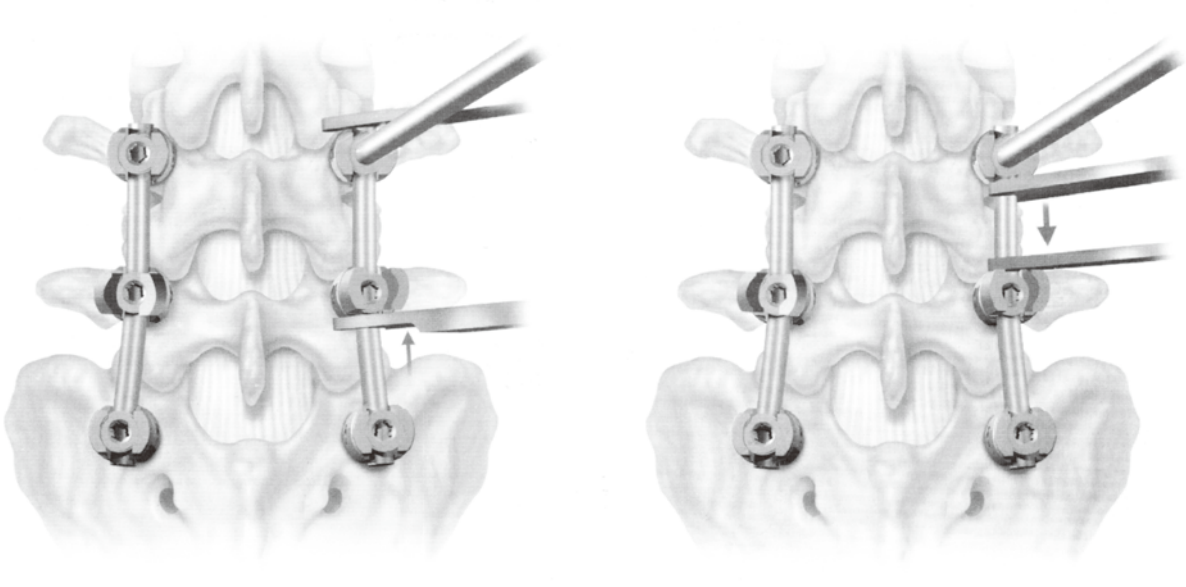




Step4 Compression / Distraction

If either compression or distraction is needed, it should be performed at this time. In either maneuver, the nut on one side of the motion segment should be provisionally tightened, with the nut loose in the implant to be compressed or distracted. Compression or distraction will occur against the provisionally tightened implant. Once satisfactory compression or distraction has been achieved, final tightening may be performed.

If it is determined there is inadequate anterior column support, suplemental means to reinforce the anterior column (PLIF) may be performed prior to final tightening of the nuts.



Note: Distraction is seldom indicated other than while performing a PLIF because of the increased risk of implant failure, pseudoarthrosis an creating segmental kyphosis.

Step5 Developing the fusion bed

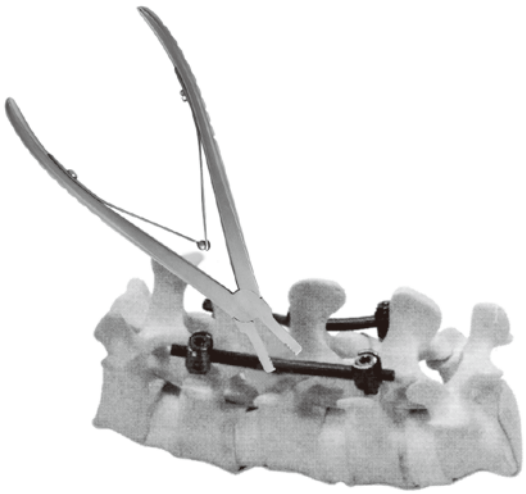
Meticulous development of the fusion bed enhances the potential for achieving solid fusion. First, the facet joint nutsules are removed. The articular carti;age of the facet joints is removed and cabcellous bone is exposed a high-speed burr. Cancellous bone graft is packed into each facet joint. The transverse processes; sacral alae and the lateral walls of the facet joints are decorticated.

Note: The reduced profile of the screw posts allows the surgeon to adequately visualize and decorticate the bony elements in the lateral gutter with the screws in place.

Step6 Final tightening

When all implants are securely in place, final tightening and break off the head of the Reduction Screws is done.

While the Nuts Screwdriver is inserted through the cannulation of the Counter Torque. The T-handle provides adequate leverage for tightening the cap. The handle of the Counter Torque device should be held firmly to prevent torquing of the construct while the cap is secured and sheared off.



Step7 Bone grafting, crosslink system and closure

Decortication and bone grafting can now take place. CROSSLINK may also be added at this time.

Wound closure is then performed in the customary manner.