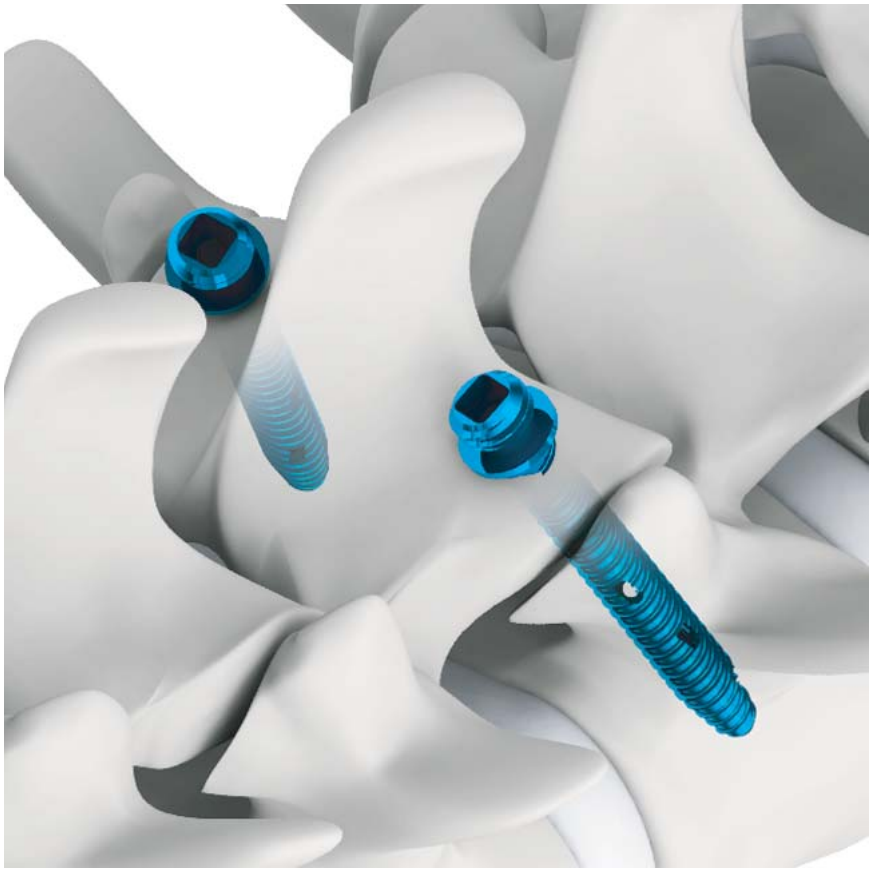
Zavation



Facet Screw System

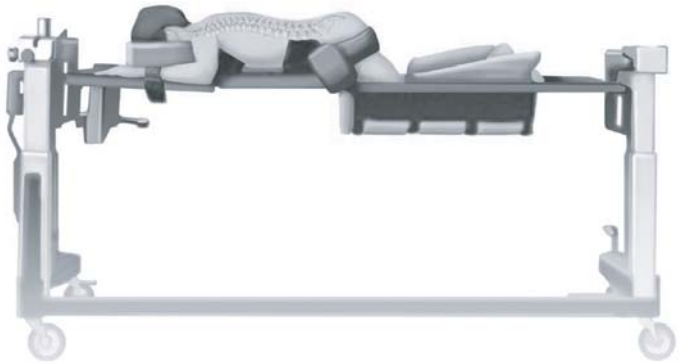
Surgical Technique Guide

Table of Contents

Refer to the Instructions for Use (package insert) for indications, contraindications, precautions and warnings.

Patient Positioning

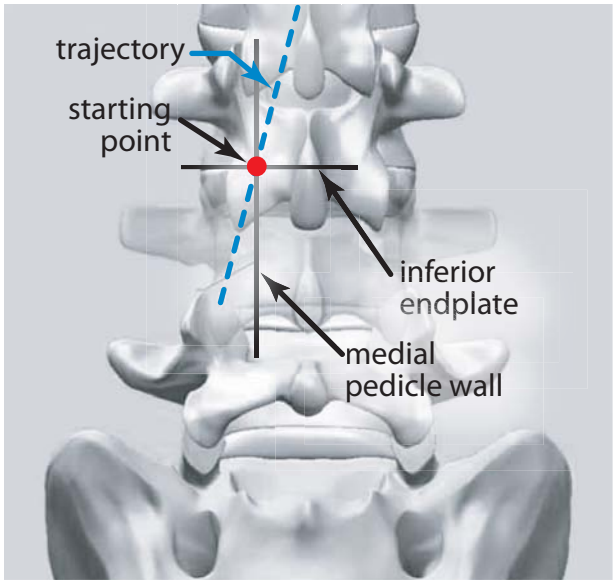
Place the patient prone on the operating table. Ideally, place the lumbar spine in anatomic lordosis and the thoracic spine in anatomic kyphosis. Prep and drape the spine in the standard sterile fashion.



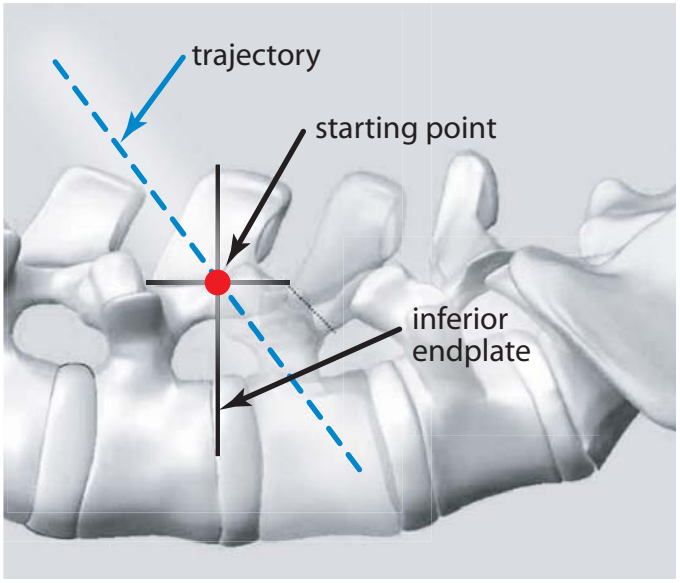
Evaluate the anatomy and assess its ability to accept the pre-operative construct strategy. Identify all system components required for the final construct.

Guide Pin Placement

Use A/P and lateral fluoroscopy to identify and target the appropriate anatomy.



Review AP fluoro to identity the AP starting point.



Review lateral fluoro to identify the lateral starting point and cephalocaudad trajectory.

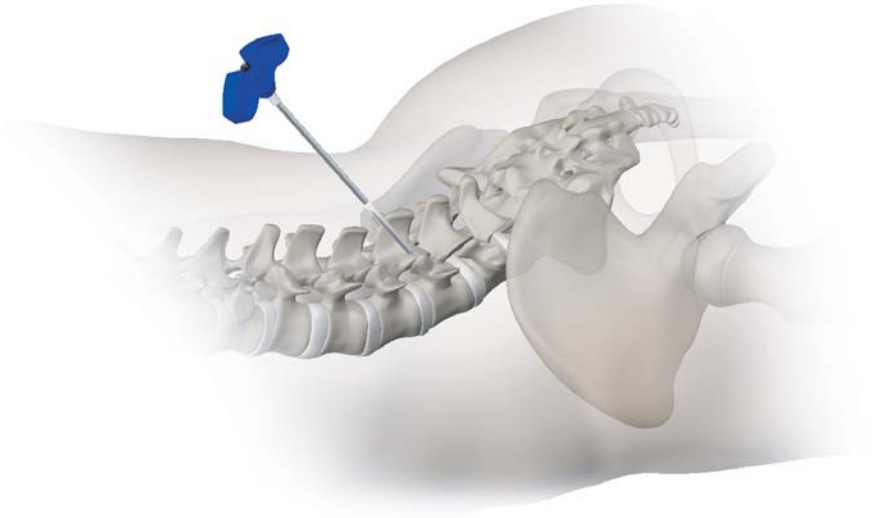
The AP starting point is just above the inferior endplate of the vertebral body above the pedicle in which the Facet Screw will be placed, and along a vertical line that intersects the medial border of the same pedicle. Measure the length of the line from starting point to the lateral vertebral wall to assess length of screw.

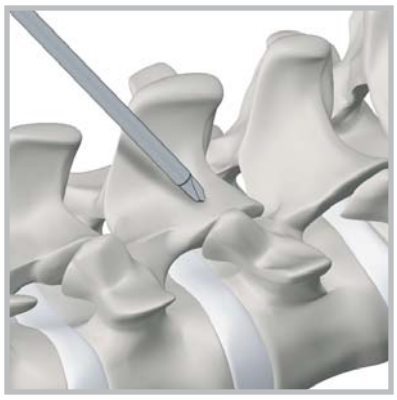
Step 1: Advance Jamshidi

Starting midline, advance the Jamshidi through the skin along one of the oblique lines until the Jamshidi has docked onto bone. Line up the Jamshidi just above inferior endplate of the vertebral body cephalad to the targeted pedicle and medial border of the pedicle wall.

Continue taking AP fluoroscopic views while moving the Jamshidi until the tip of the needle is docked on the appropriate spot on the lamina.

The starting point is cephalad to the peak of the facet around the base of the upslope. Line up the Jamshidi with the pedicle so that it is at an angle that will stay within the pedicle walls and proceed into the vertebral body. Verify correct trajectory with lateral fluoroscopic imaging. Gently mallet the Jamshidi until it has just penetrated the superior cortex of the facet. Stop when the Jamshidi can stand on its own.



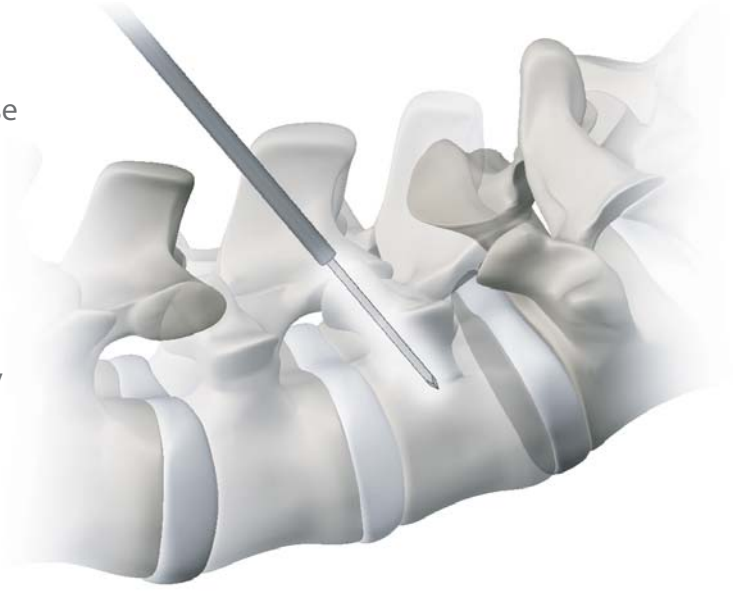


Jamshidi Detail

Step 2: Place Guidewire

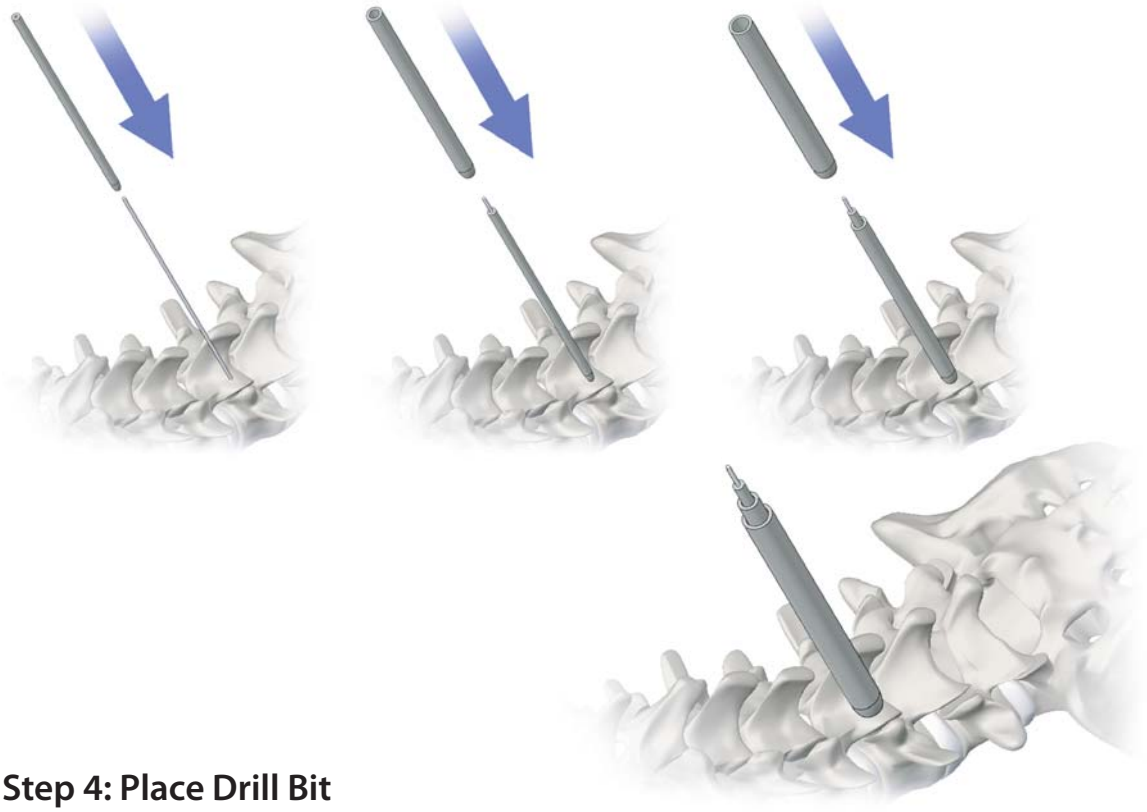
Remove the inner needle from the Jamshidi. Use the cannula of the Jamshidi as a drill guide and insert the guidewire by drilling along the trajectory into the vertebral body until the desired depth is reached. Check AP and lateral imaging during guidewire insertion.

Remove the Jamshidi outer sleeve, leaving only the guidewire in place.



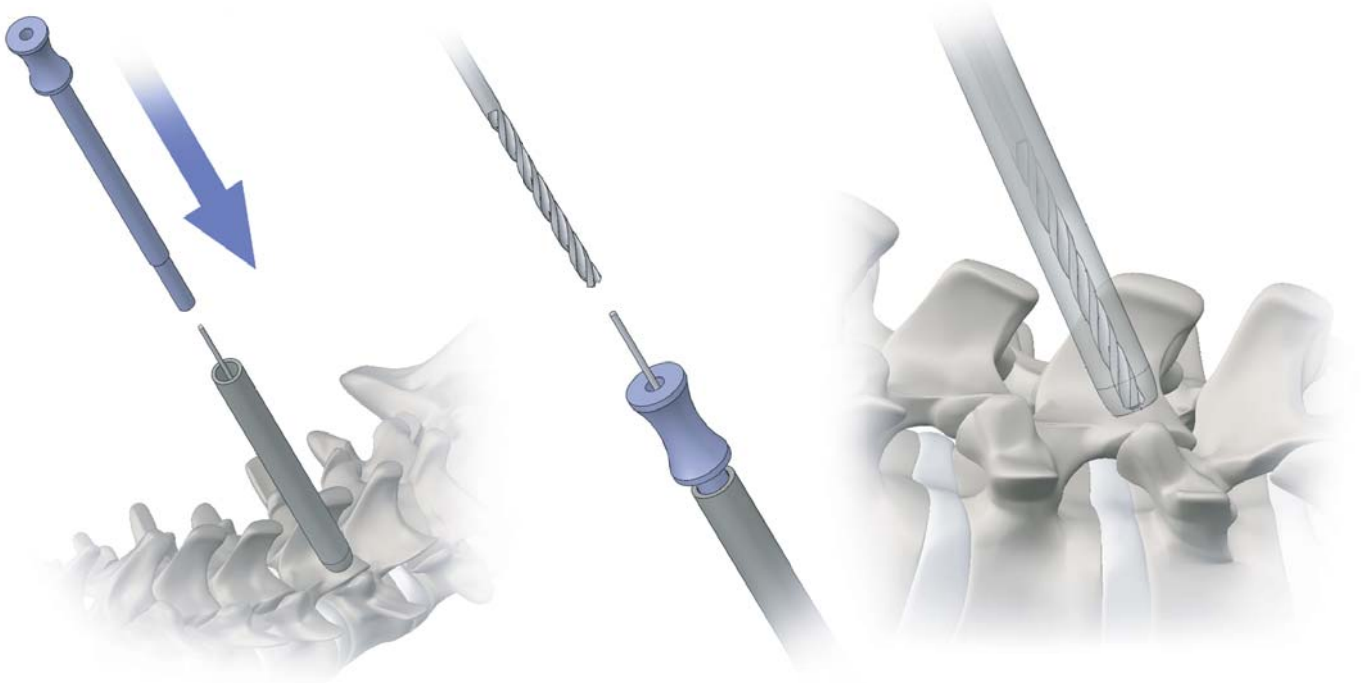
Step 3: Place Dilators

Sequentially place dilators over the guidewire until the appropriate diameter is achieved.



Step 4: Place Drill Bit

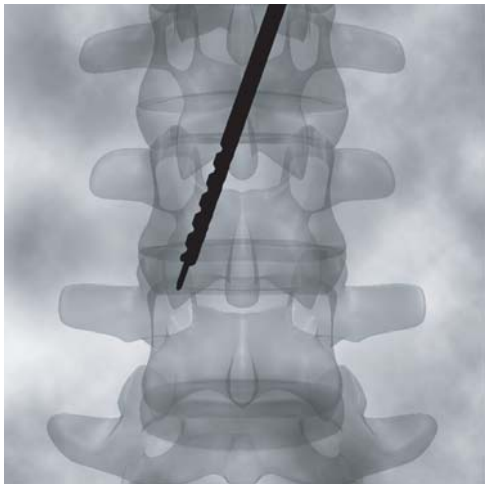
After insertion of the final dilator, remove the inner dilators and sequentially place the Drill Guide and Drill Bit over the guidewire until they contact the facet.

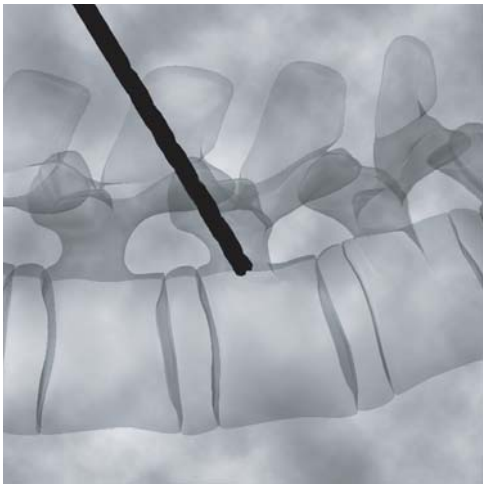


Step 5: Advance Drill Bit

Using AP fluoroscopic imaging, advance the Drill Bit until it is seen to just penetrate the superior cortical margin of the pedicle.

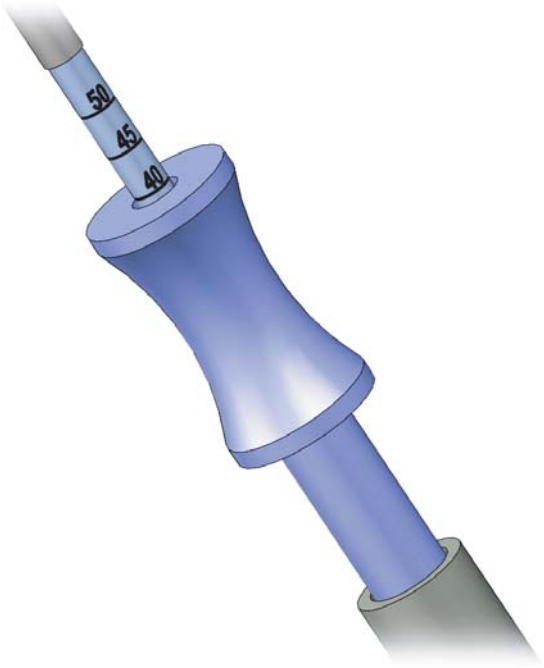
Revert to lateral imaging and continue advancing the Drill Bit until the tip nears the caudal cortical and/or anterior margin of the pedicle.





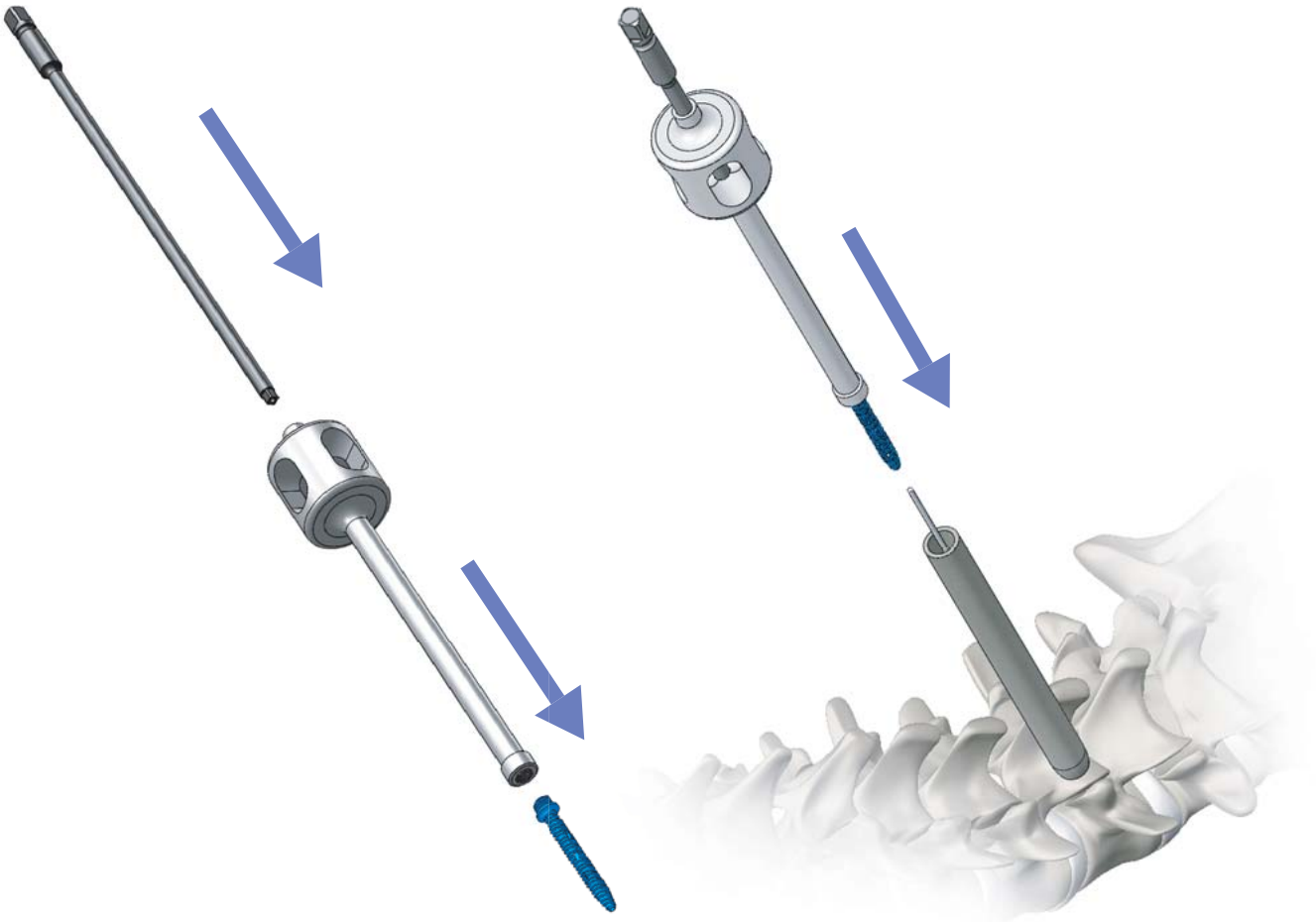
Step 6: Measure for Screw Length

Advance the depth gauge into the hole until resistance is felt. Select a screw length based on the depth gauge reading relative to the proximal surface of the Drill Guide.

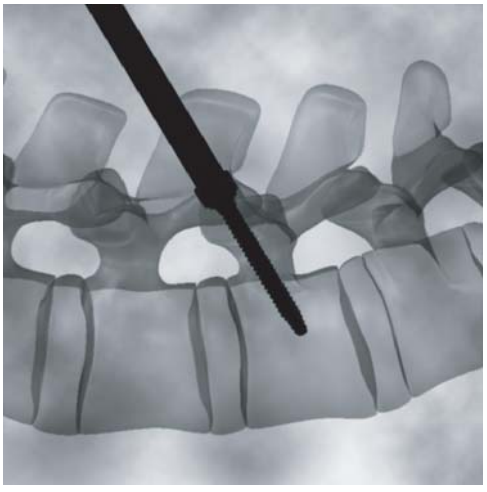


Step 7: Insert the Screw

Assemble the Screw to the threaded tip of the Driver Sleeve. Insert the Driver through the Sleeve and into the head of the Screw. Pass the Screw and Driver assembly over the guidewire. Apply gentle downward pressure and drive the Screw clockwise to advance. When AP imaging indicates that the tip of the Screw has entered the pedicle, remove the guidewire.

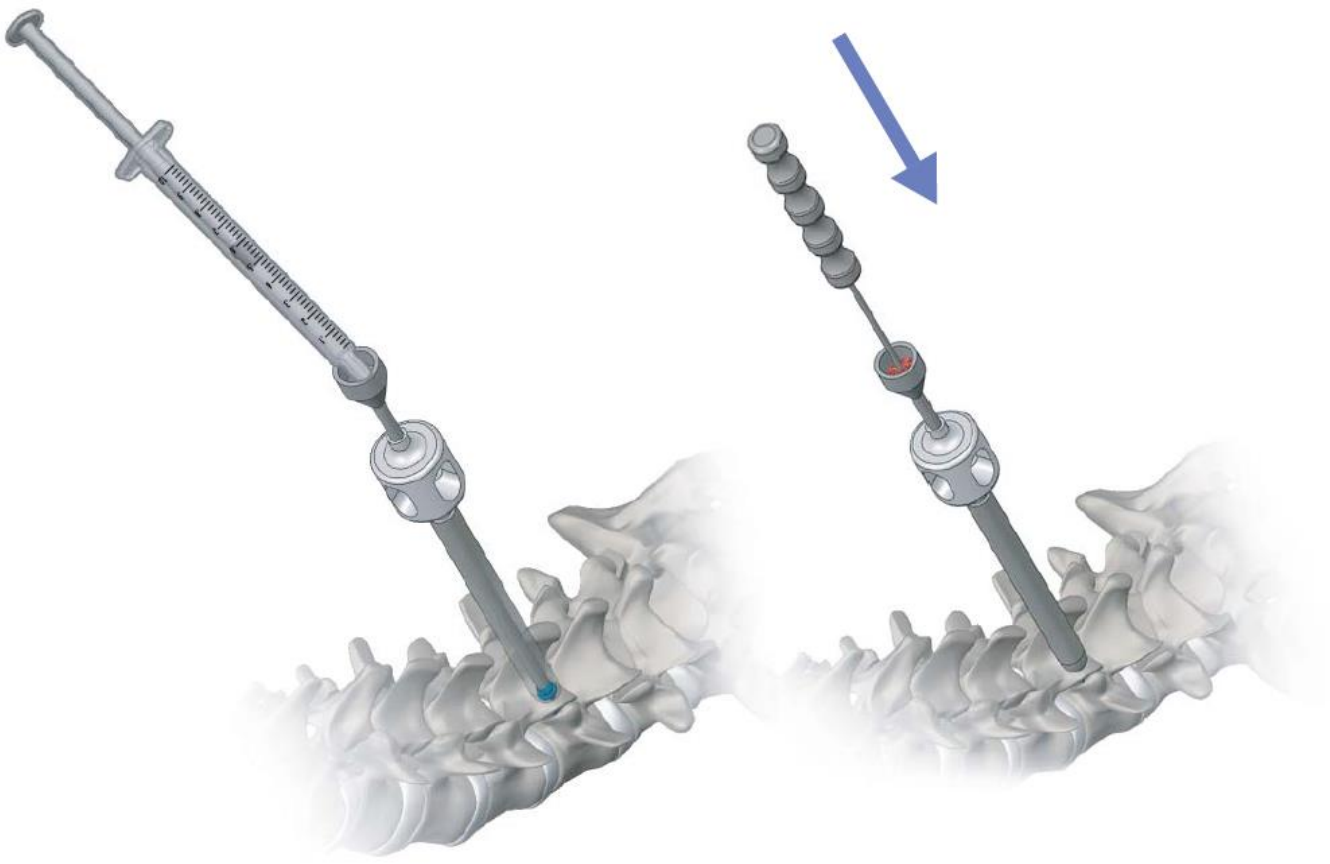


Revert to lateral imaging and continue to advance the Screw until the Screw head contacts the facet and greater resistance is encountered.



Step 8: Insert Bone Graft

Remove the Driver from the Sleeve and fasten the bone graft Funnel. Inject the Funnel with the appropriate amount of graft, using the Tamp to advance measured bone graft down into the cannula of the Facet Screw. Utilize autogenous bone graft material.



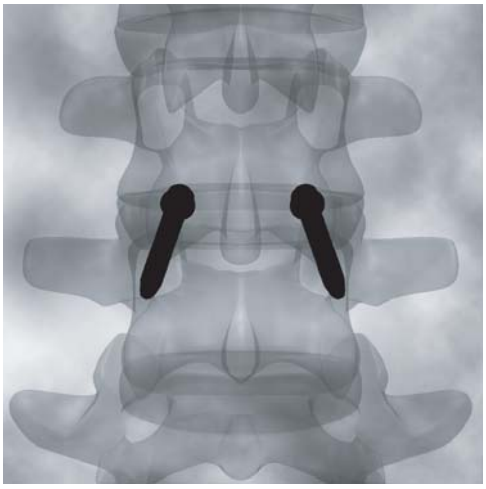
Use the table to determine the appropriate amount of graft relative to the Screw selected.

Part Number	DescripƟon	Volume
JR04-3220	5mm x 20mm screw	0.1 CC
JR04-3225	5mm x 25mm screw	0.12 CC
JR04-3230	5mm x 30mm screw	0.15 CC
JR04-3235	5mm x 35mm screw	0.17 CC
JR04-3240	5mm x 40mm screw	0.2 CC

Step 9: Remove Instruments and Repeat

Remove the Funnel and Driver Sleeve from the Screw and withdraw remaining instrumentation.

Repeat Screw Insertion steps and Bone Graft insertion on the opposite side.

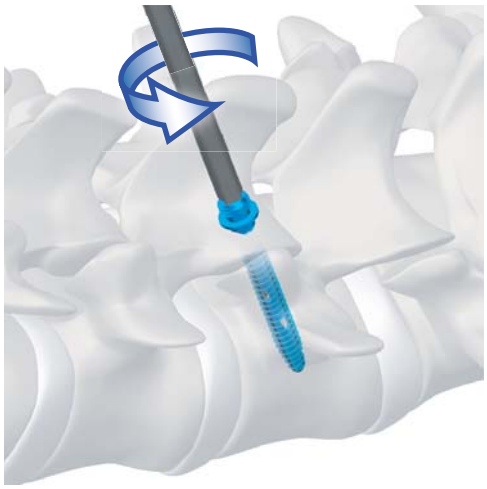


Implant Removal

To remove the Facet Screw:

1. Use the 2.4mm Drill to ream out the inner diameter of the screw to aid in removal.

2. Use the 2.4mm Drill to ream out the inner diameter of the screw to aid in removal.



Component Overview

Instruments
Jamshidi Needle & Cannula
Guidewire
Dilators
Drill Guide
Axial Handle
Cannulated Drill Bit
Depth Gauge
Driver Sleeve
Screw Driver
Bone Graft Funnel
Bone Graft Tamp
Removal Drill

Implants	
5mm x 20mm	fenestrated facet screw
5mm x 25mm	fenestrated facet screw
5mm x 30mm	fenestrated facet screw
5mm x 35mm	fenestrated facet screw
5mm x 40mm	fenestrated facet screw

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

CAUTION: Devices are supplied non-sterile. Clean and sterilize before use according to instrucθons.

CAUTION: Implant components are single-use. Do not reuse.

INDICATIONS:

The Spectrum Spine Fenestrated Facet Screw System (FFS) is indicated for the posterior surgical treatment at L1-S1 (inclusive) spinal levels for the following: Spondylolisthesis; Spondylolysis; Pseudarthrosis or failed previous fusions which are symptomaθc; Degeneraθve Disc Disease (DDD) as defined by back pain of discogenic origin with degeneraθon of the disc confirmed by history and radiographic studies and/or degeneraθve disease of the facets with instability. The system is intended for use with only autogenous bone graft material.

CONTRAINDICATIONS:

1. Prior fusion at the level(s) to be treated.
2. Paθents with probable intolerance to the materials used in the manufacture of this device.
3. Paθents with infecθon, inflammaθon, fever, tumors, elevated white blood count, morbid obesity, pregnancy, mental illness and other medical condiθons which would prohibit beneficial surgical outcome.
4. Paθent resistant to following post operaθve restricθons on movement especially in athleθc and occupaθonal acθviθes.
5. Use with components from other systems.
6. Grossly distorted anatomy caused by congenital abnormaliθes.
7. Any other medical or surgical condiθon which would preclude the potenθal benefit of spinal implant surgery.
8. Rapid joint disease, bone absorpθon, osteopenia, Osteoporosis is a relaθve contraindicaθon since this condiθon may limit the degree of obtainable correcθon, stabilizaθon, and/or the amount of mechanical fixaθon.
9. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
10. Any paθent having inadequate θssue coverage over the operaθve site or inadequate bone stock or quality.
11. Any paθent in which implant uθlizaθon would interfere with anatomical structures or expected physiological performance.
12. Any case not described in the indicaθons for use.
13. Reuse or mulθple use.

DESCRIPTION:

The Spectrum Spine Fenestrated Facet Screw System (FFS) is a permanent implant device made from Cobalt Chrome Alloy per ASTM 1537. It is to be implanted from the posterior approach. The device is provided in one diameter and mulθple lengths to accommodate the various anatomy of the spine. The device is intended to provide mechanical support and stability to the implanted level unθl biologic fusion is achieved.

PRECAUTIONS:

When implanting the Spectrum Spine FFS, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

WARNINGS:
Implants and instruments are provided non-Sterile and must be cleaned and sterilized before each use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.

This System is not to be used with bone cement. The Safety and efficacy of using bone cement with this system has not been established.

The Spectrum Spine FFS has not been evaluated for safety and compatibility in the MR environment nor has it been tested for heating or migration in the MR environment.

A successful result is not always achieved in every surgical case. This is especially true in spine surgery where many extenuating circumstances may compromise the results.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increase incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for this device.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

PREOPERATIVE MANAGEMENT:
1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the devices indications, contraindications and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts should be cleaned and sterilized before use.

INTRAOPERATIVE MANAGEMENT:
1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over tighten the screws.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
6. Implants should not be reused under any circumstances.

POSTOPERATIVE MANAGEMENT:
Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential.

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant device.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon.
3. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

POSSIBLE ADVERSE EFFECTS:

1. Early or late loosening of any or all of the components.
2. Disassembly, Bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implant.
4. Postoperative change in spine curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, persistent CSF leakage, meningitis.
7. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
8. Cauda equina syndrome, neurological deficit, paraplegia, reflex deficit, irritations, and/or muscle loss.
9. Loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
11. Fracture, micro fracture, damage or penetration of any spinal bone.
12. Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
13. Non-union (pseudo-arthrosis), delayed union, mal-union.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Death.
18. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.

CLEANING AND STERILIZATION:

The devices for this system are provided non-sterile. Therefore, these devices must be sterilized prior to using following the recommendations below. More detailed instructions can be found in “Instrument Care, Cleaning & Sterilization Instructions.”

Type	Minimum Temperature	Minimum Exposure Time	Minimum Dry Time
Prevacuum	132°C/270°F	4 minutes	30 minutes
Gravity	132°C/270°F	15 minutes	30 minutes

INFORMATION:

For additional information regarding the device or to order a surgical technique manual, please contact Spectrum Spine, LLC Customer Service at (404) 550-1335.