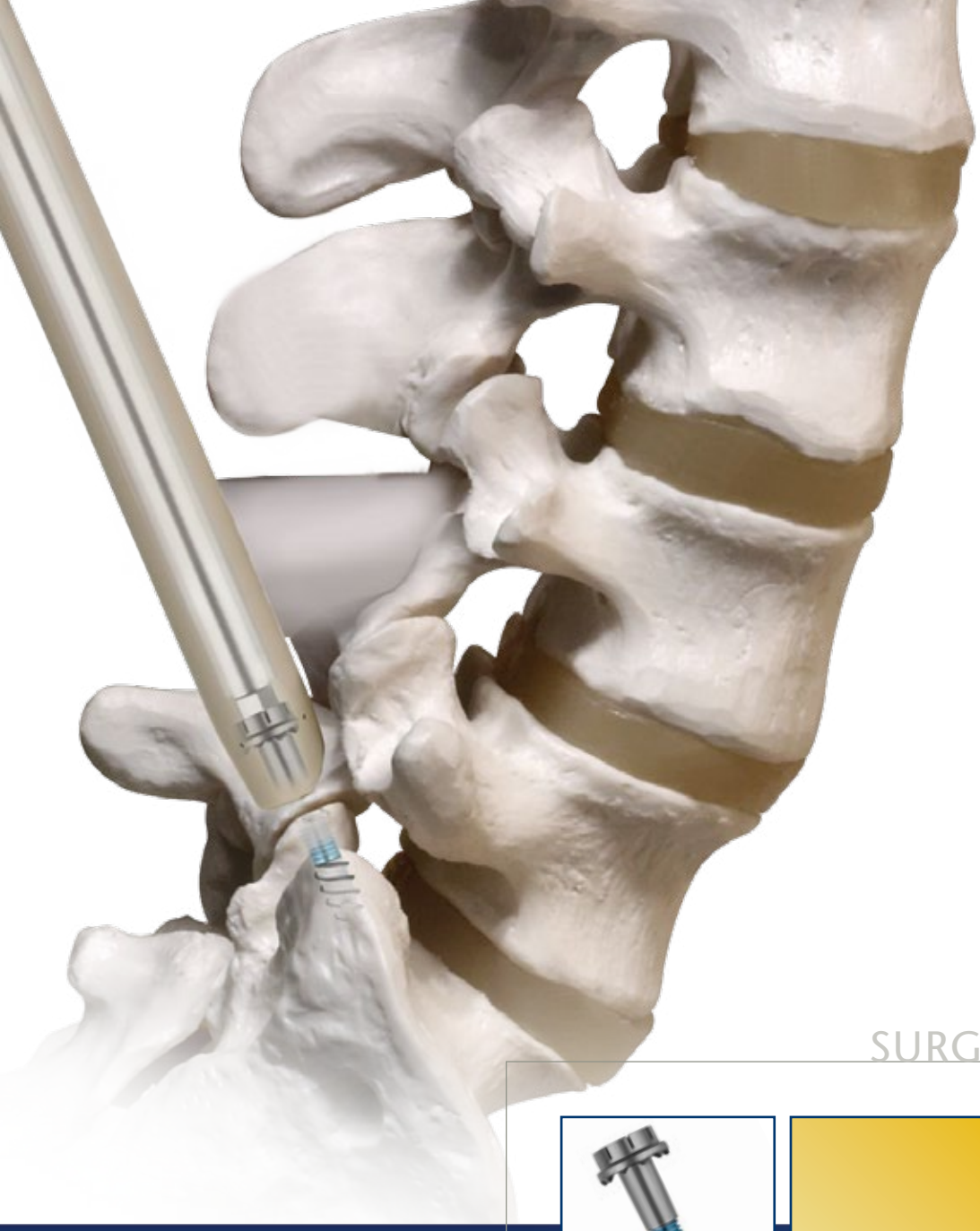
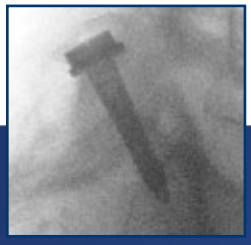


Life moves us

SURGICAL TECHNIQUE


ZYFUSE®

Facet Fixation System

GLOBUS MEDICAL

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

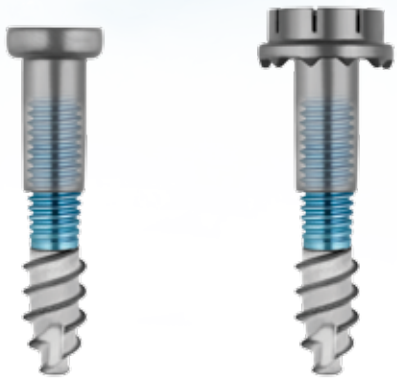
The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com

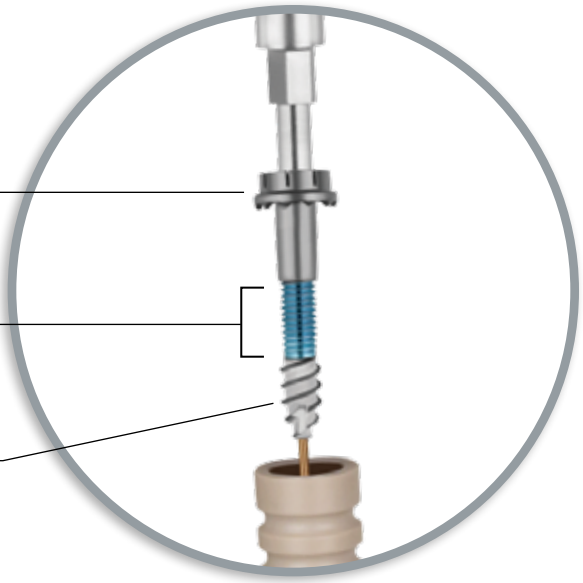
ZYFUSE®

Facet Fixation System



ZYFUSE® was designed to improve upon traditional facet fixation in offering a flexible approach with a robust system design, and a wide range of features but limited procedural steps. The unique ZYFUSE® implant design allows compression and intraoperative flexibility to adjust the screw length, without compromising implant position. In addition, our consolidated delivery allows insertion and compression to occur with a single instrument. ZYFUSE® was designed to support a percutaneous method, preserving patient anatomy in support of improved function and surgical outcomes.

ZYFUSE®
FACET FIXATION SYSTEM



Optional load-distributing washer improves fixation and minimizes implant backout

Unique implant design allows up to 10mm of compression across the facet joint

Dual lead HA-coated threads facilitate faster insertion and promote bony ongrowth

Flexible Nitinol K-wire has superior strength, elasticity and eliminates kinking

Radiolucent working port protects surrounding tissue and allows complete visualization

Flexible Approach

Versatile system design includes instruments to facilitate a minimally invasive or traditional approach.

Optimized Implant Design

Unparalleled design allows compression and intraoperative flexibility to adjust the implant length up to 10mm, without compromising the position of the bone threads.

Consolidated Delivery

Streamlined instrumentation consolidates key procedural steps associated with traditional facet fixation to help promote quicker implant delivery and reduce surgical time.

CONTENTS

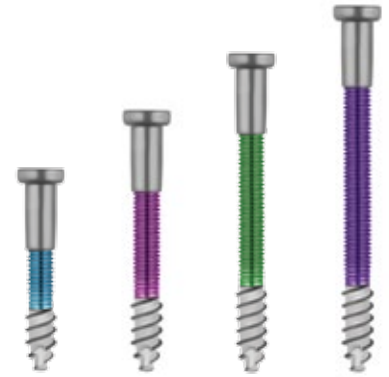
The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Technique Guide may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

IMPLANT OVERVIEW

ZYFUSE® Screws

- Cannulated implants to support 1mm K-wire
- Hydroxyapatite (HA) coated bone threads
- Screw diameters 5.0mm and 6.0mm
- Screw lengths 30mm to 60mm, in 10mm increments
- Available with and without washers
- Titanium alloy

50° total washer angulation



30mm 40mm 50mm 60mm

Screws without washers

30mm 40mm 50mm 60mm

Screws with washers

MARS™ Compatible Working Ports

- Radiolucent material
- Beveled edge for docking onto vertebrae
- Slot for table arm attachment
- Port diameters 13mm, 17mm and 21mm
- Individually sterile packed

13mm

17mm

Beveled tip

21mm

10mm from radiographic marker to port tip

INSTRUMENT OVERVIEW

Preparation Instruments

Awl 602.104

Straight Awl 676.506

Jamshidi Needle 623.102S

1mm K-Wire, 650mm, Nitinol 647.009

1mm K-Wire, 650mm, Steel 647.007

K-Wire Inserter 602.802

Facet Reamer, 12mm, Small 647.012

Facet Reamer, 20mm, Large 647.020

Drill Bits & Taps

Tap 4.8mm 647.148

Tap 5.8mm 647.158

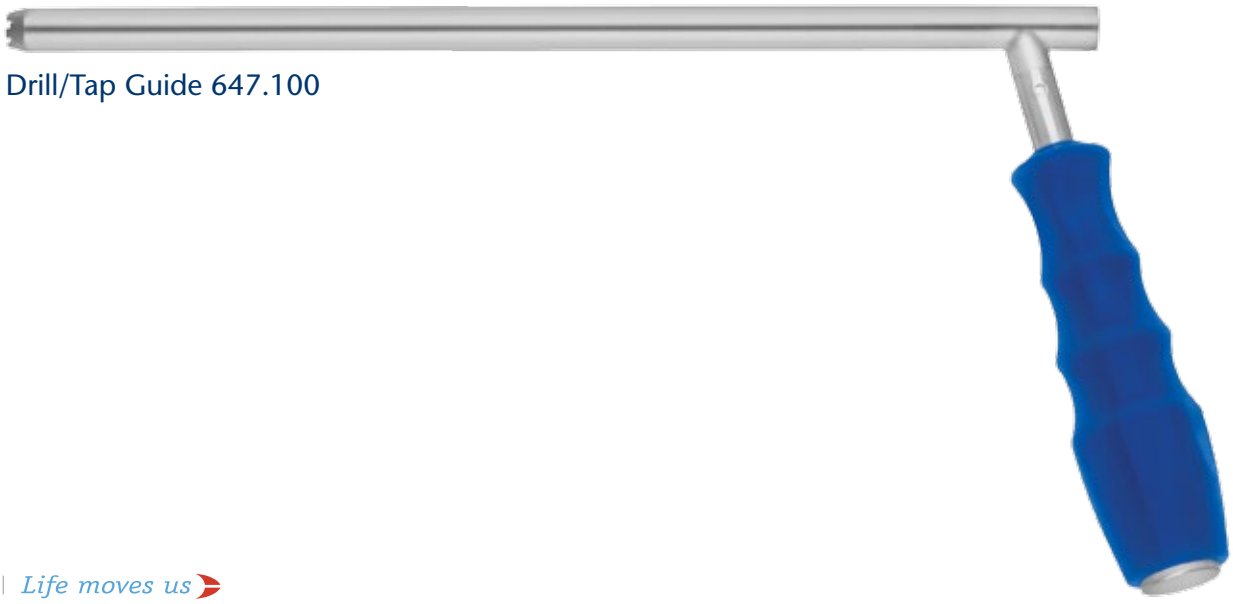
K-Wire Depth Gauge 647.011

Cannulated Drill Bit 3.7mm 647.037

Solid Drill Bit 3.7mm 647.038

Cannulated Drill Bit 4.7mm 647.047

Solid Drill Bit 4.7mm 647.048



Drill/Tap Guide 647.100

Cannulas

Cannula 1.5mm 647.201

Cannula 5mm 647.205

Sterile Dilator Pack 647.200S

Cannula 9mm

Cannula 13mm

Cannula 17mm 647.217S

MARS™ Compatible Working Ports*

Working Port 13mm 647.313S

Working Port 17mm 647.317S

Working Port 21mm 647.321S

MARS™ Compatible Working Ports* (cont'd)

Port Mount 13mm 647.413

Port Lock 13mm 647.513

Port Mount 17mm 647.417

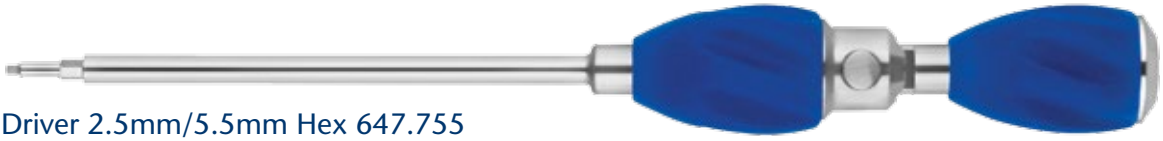
Port Lock 17mm 647.517

Port Mount 21mm 647.421

Port Lock 21mm 647.521

* If table mounting is desired, **Port Mounts** and **Port Locks**, along with the Table Arm (632.750) from the MARS™ Instruments II set, are required.

Implant Instruments



Driver 2.5mm/5.5mm Hex 647.755

Rescue Driver, 6.0mm Hex 647.660

Screw Extractor Tip K-Wire 647.800

Screw Extractor Tip 2.5mm Hex 647.801

2.5mm Screw Removal Tool 648.303

Quick Connect Handles

Quick Connect Ratcheting Handle 648.401

Quick Connect Handle 648.400

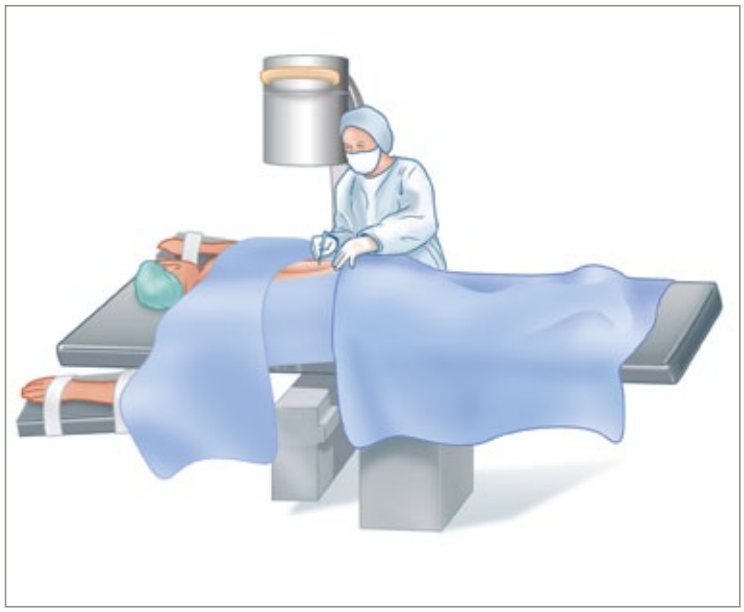
Quick Connect T-Handle 601.800

ZYFUSE® SURGICAL TECHNIQUE

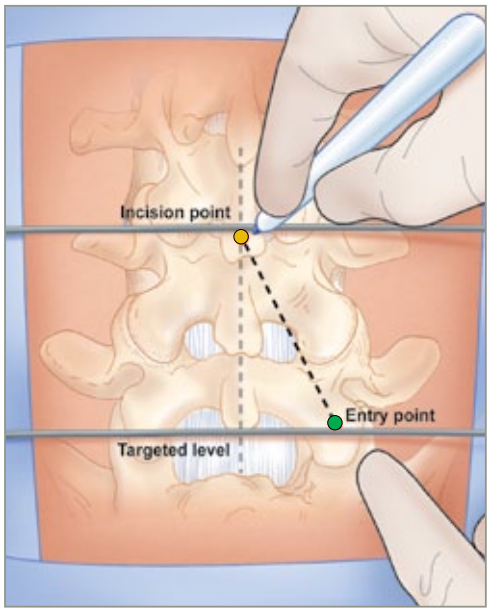
PERCUTANEOUS APPROACH

Step 1 Positioning

The patient is placed under anesthesia and positioned prone with the lumbar spine in extension and hips in flexion. Fluoroscopy should be used to ensure that the spine is oriented in a true AP position to begin the procedure. The table should be adjusted so that the C-arm provides true AP images when at 0° and true lateral images at 90°. Using fluoroscopy and a k-wire, mark the incision point, targeted level and corresponding trajectory.



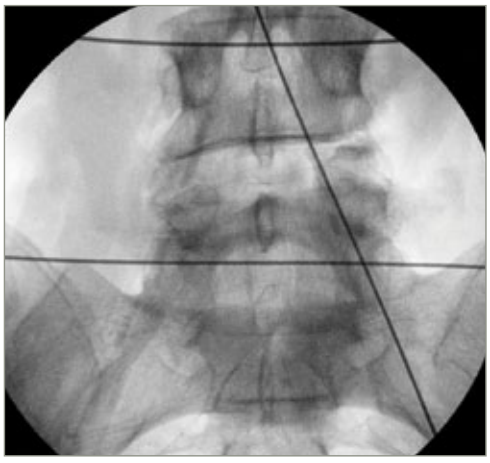
Patient positioning



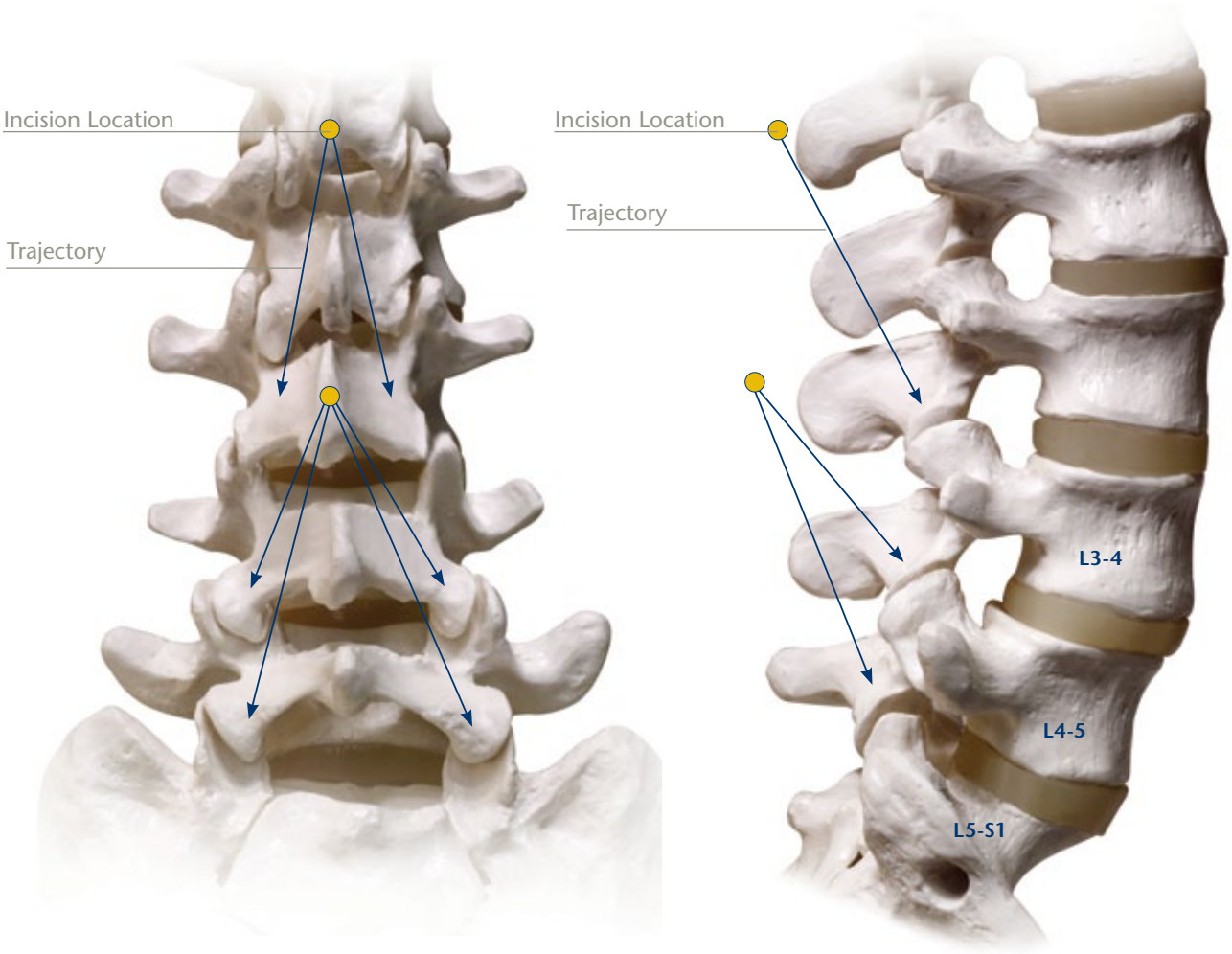
Initial starting point

A 13mm midline incision is made approximately 1–2 levels above the targeted segment, as shown on page 12, and continues through the dorsal fascia on either side of the spinous process.

Note: Exact incision location may vary based on patient anatomy.



Trajectory

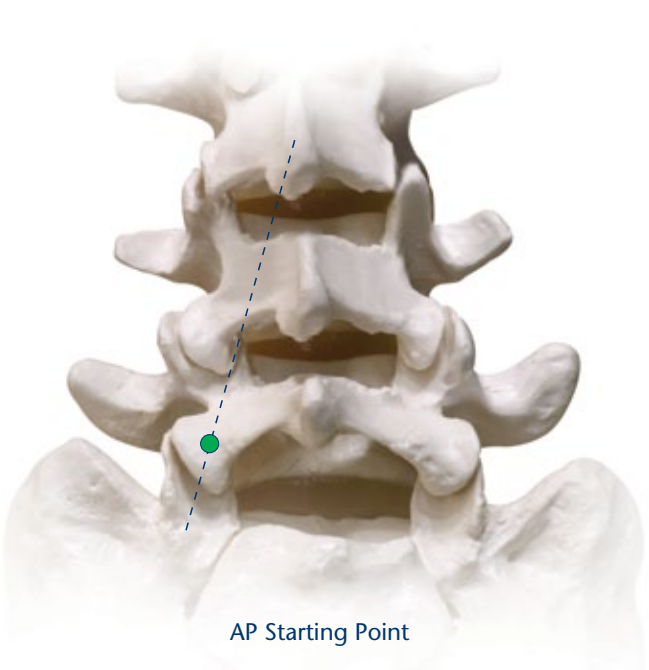


Approximate Caudal-Axial Angulation[1]		
Level	Caudal	Axial
L3/L4	26°	15°
L4/L5	29°	15°
L5/S1	31°	15°

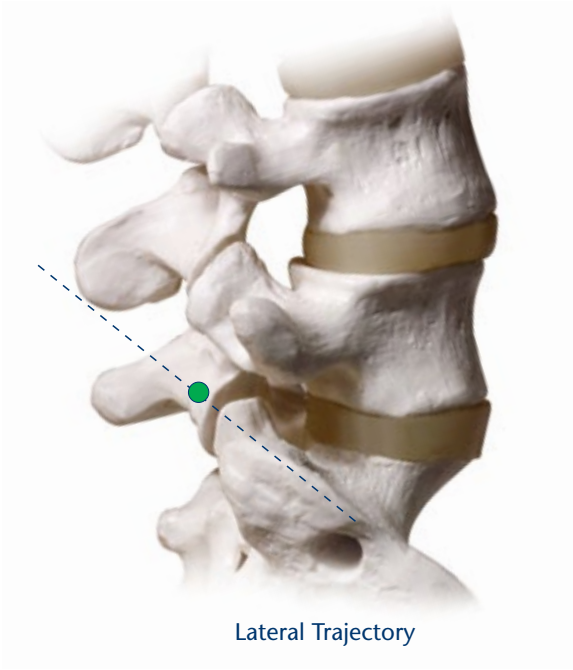
Step 2 Needle Placement

**For purposes of this technique, placement is shown through the L5/S1 facet joint.*

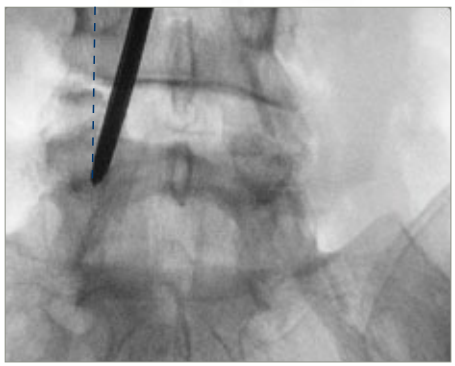
Introduce the **Jamshidi Needle** by angulating the distal tip downward and outward, parallel to the caudal edge of the lamina at an angle of approximately 31° and 15° laterally, with the proximal portion of the needle resting against the spinous process.[1] The starting point at every level from L3-S1 in the medial-lateral direction should occur at the medial aspect of the superior pedicle.[1] This trajectory should form a line which passes through the medial aspect of the inferior pedicle, as shown below. Dock the needle tip on the joint and flip to lateral fluoroscopy to confirm the correct trajectory.

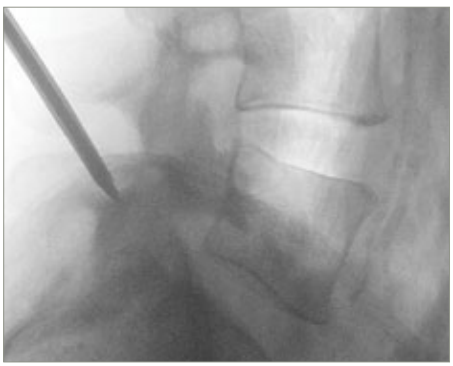


AP Starting Point



Lateral Trajectory



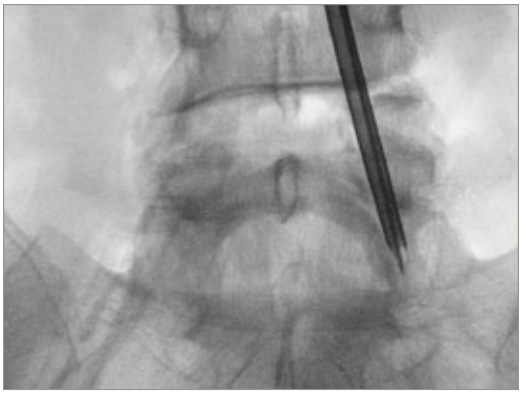


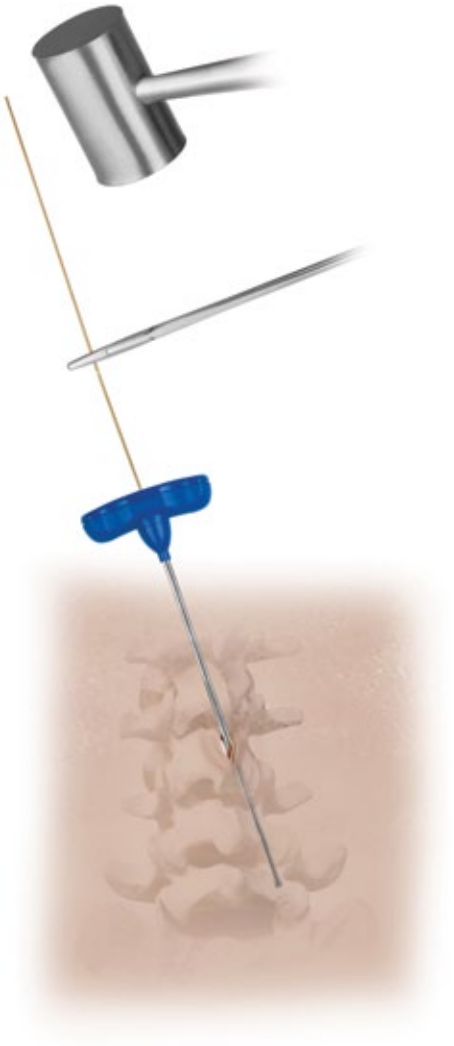
The ideal trajectory will be parallel to the caudal edge of the lamina at approximately a 31° angle, with the path remaining in the lateral borders of the pedicle. Once correct placement has been confirmed through AP and lateral fluoroscopy, the needle may pass through the joint by impaction with a mallet.

Optional method: If surgeon prefers to drill the **K-Wire** through the joint, a stainless steel K-wire should be utilized for this method.

Step 3 K-Wire Insertion

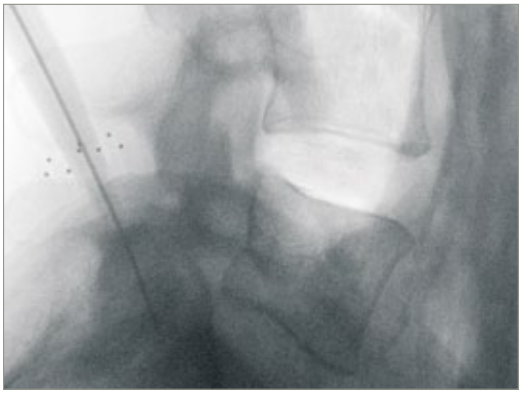
Remove the internal stilet from the Jamshidi Needle with caution so as to not compromise the position of the needle, and introduce the K-wire through the opening. Utilizing a K-wire gripper and mallet, gently tap the K-wire into the bone, ensuring that the wire does not advance more than 10mm past the tip of the needle. Flip the C-arm to a lateral view and continue in this view for the remainder of the procedure.

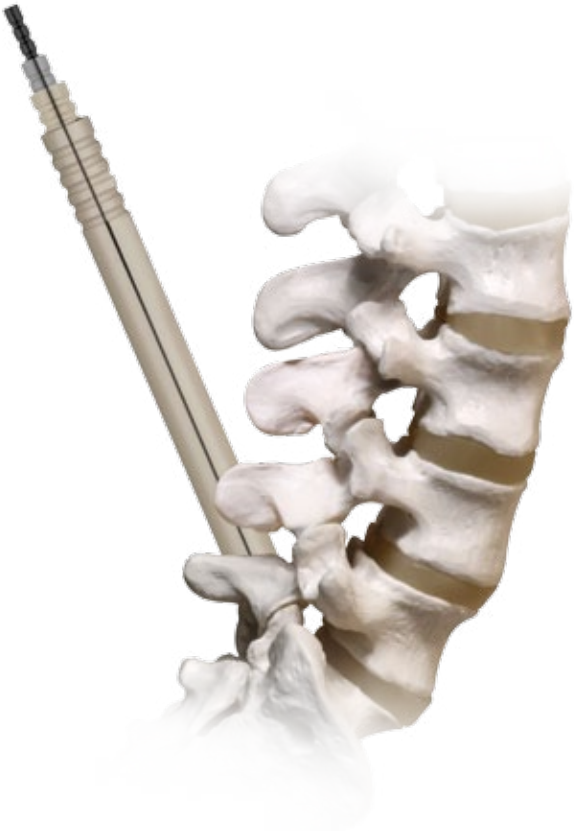




Step 4 Tissue Dilation

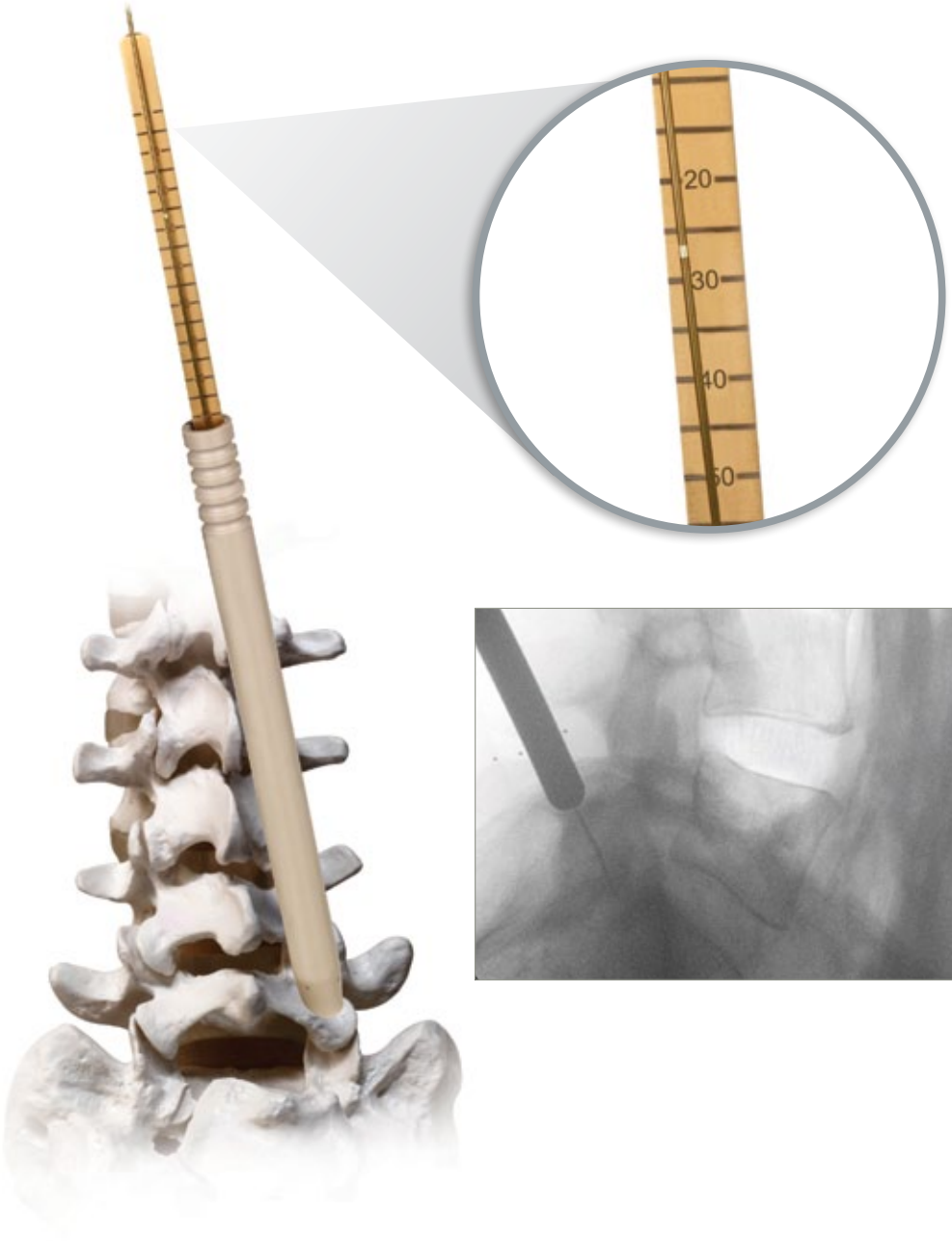
Dilation of the tissue occurs sequentially through a four-stage process of increasing diameters: 1.5mm, 5mm, 9mm and 13mm. The vertical line on the side of the **Cannulas** must face midline to minimize muscle creep. To ensure that the cannulas are fully seated, the arrows on the proximal side of the cannulas should be visible after each stage. Small radiographic beads are located 10mm from the tip of each cannula for radiographic visualization.





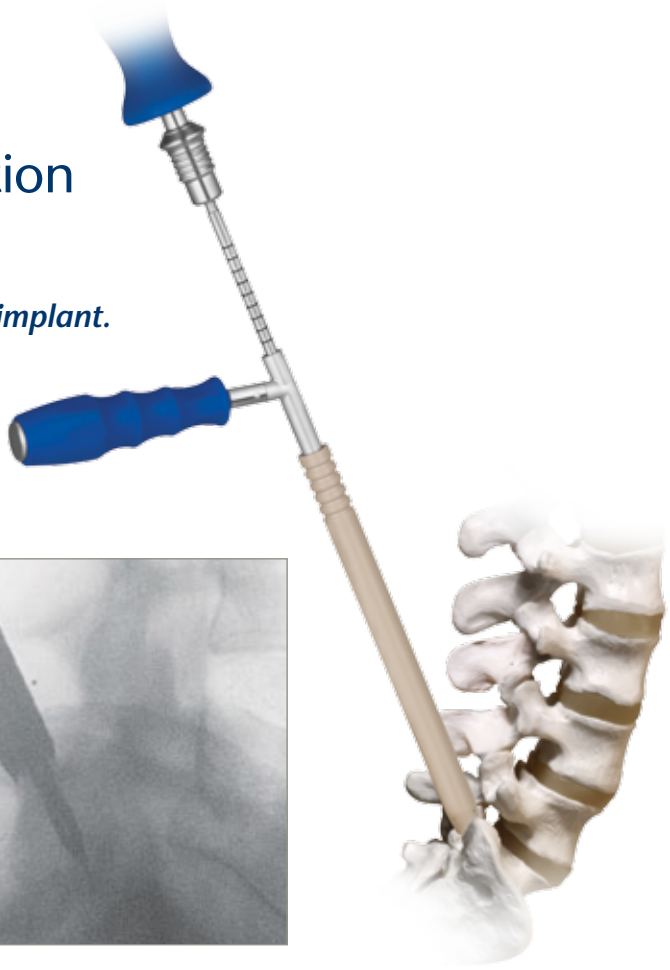
Step 5 Measuring Implant Length

Remove the first three stages of cannulas, leaving the 13mm cannula in place, taking care not to displace the K-wire during this step. Slide the **K-Wire Depth Gauge** over the K-wire using the demarcation in the center of the wire as a guide to determine appropriate implant length. If the measurement is between implant sizes, round up to the next screw length.



Step 6 Hole Preparation

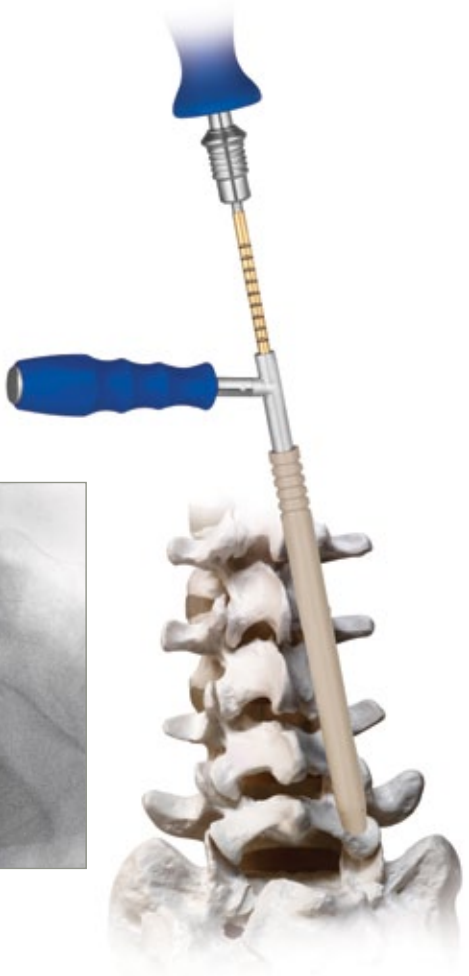
Drilling and tapping are required to facilitate proper advancement of the implant.



Drilling

Slide **Drill-Tap Guide** over the K-wire and through the 13mm cannula. To measure drill depth, attach the corresponding **Drill** to the desired handle and insert through the Drill-Tap Guide. Utilize lateral fluoroscopy to ensure that the trajectory is correct and drill using the incremental markings on the drill as a guide.

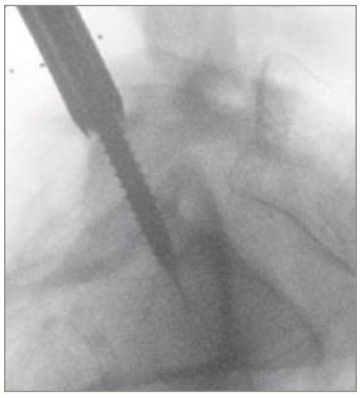
Note: The 3.7mm drill corresponds to a 5mm implant. The 4.7mm drill corresponds with a 6mm implant.



Tapping

Remove the drill and insert the corresponding **Tap** using the incremental markings on the Tap to measure depth.

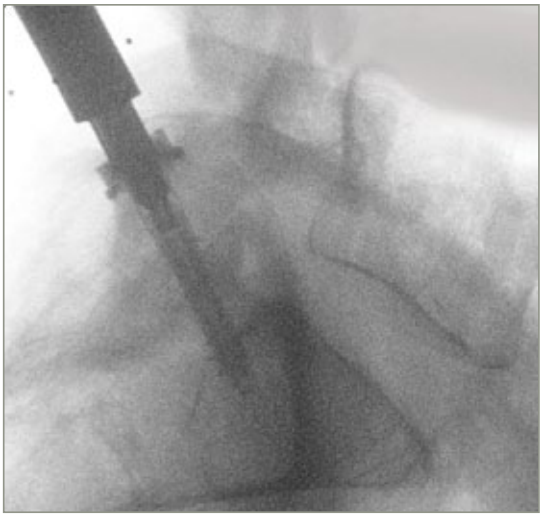
Note: The 4.8mm tap corresponds to a 5mm implant. The 5.8mm tap corresponds to a 6mm implant.



Step 7 Implant Placement

Insertion

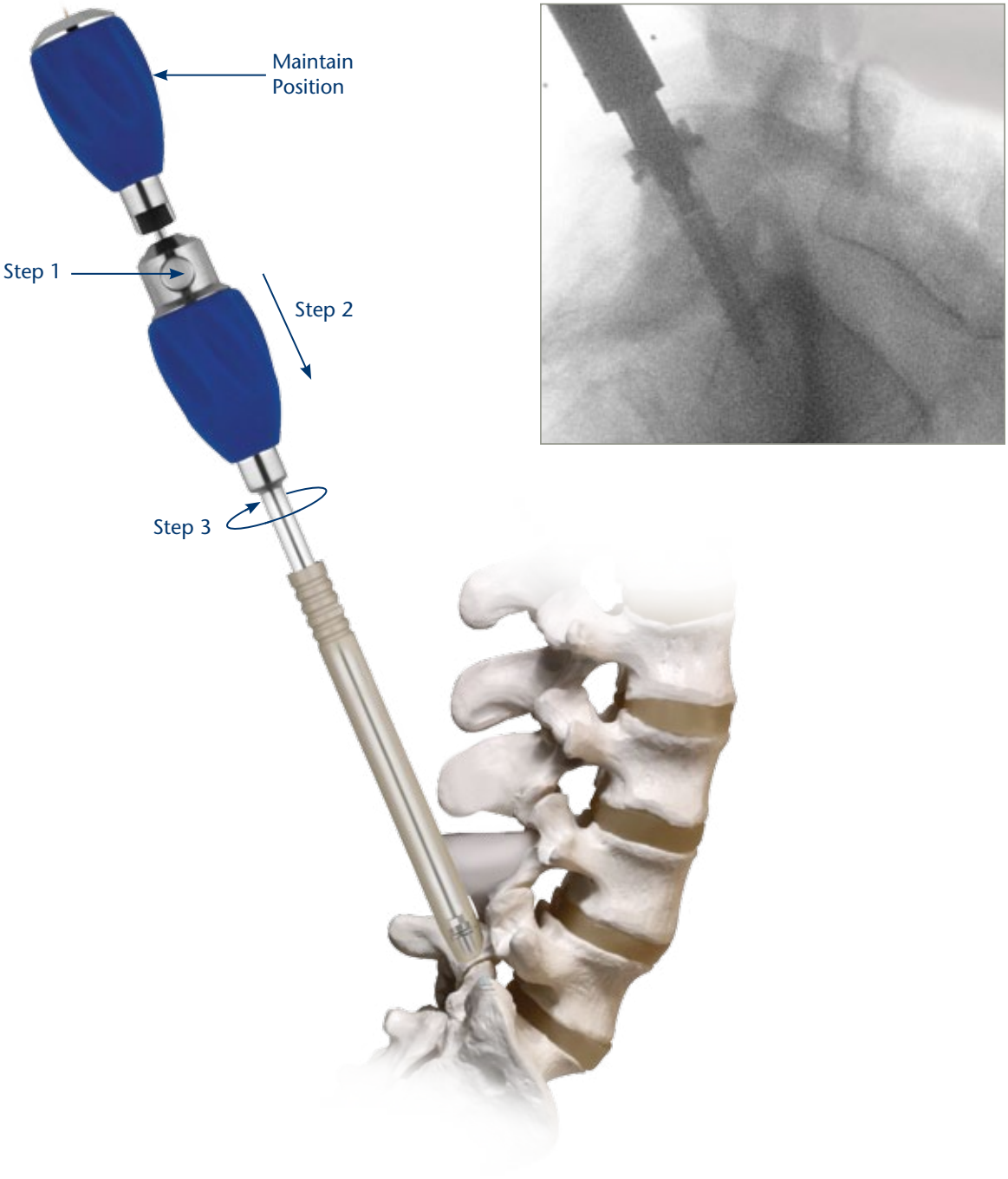
After selecting the desired ZYFUSE® implant size, assemble the implant onto the **Driver 2.5mm/5.5mm Hex**, ensuring that both handles are locked together. Drive the assembly over the K-wire and rotate both handles clockwise to advance the ZYFUSE® implant. Fluoroscopy is required throughout this step to ensure proper trajectory and placement. Remove the K-wire once the threads have gained initial purchase within the facet.



Compression

Once the desired thread location within the pedicle has been achieved, the compression feature may be engaged. Press the release button and lower the bottom handle of the driver, ensuring that the second hex has fully engaged within the implant during this step. Holding the top handle steady, rotate the bottom handle clockwise to compress the implant. Resistance will increase during compression but fluoroscopy should be used to confirm compression and implant placement. To ensure secure implant purchase, do not overcompress – two finger tight only.

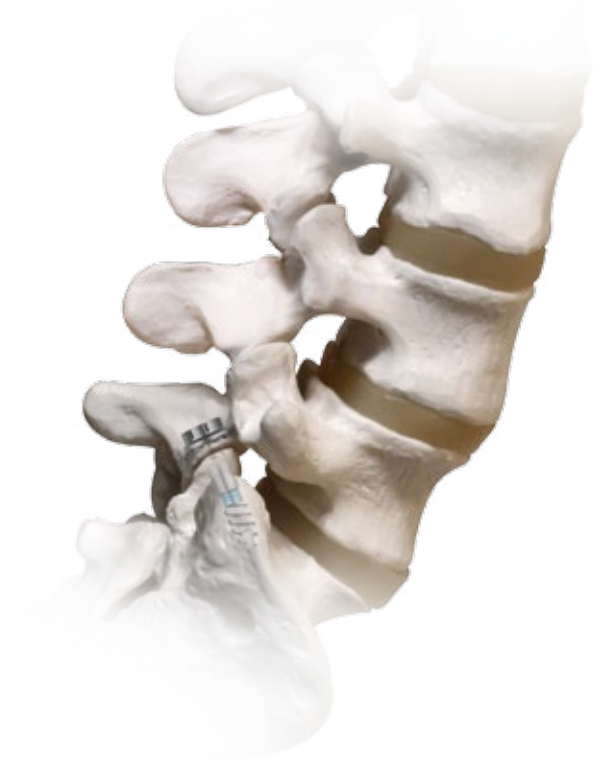
Pull up on both handles to release the driver from construct. Remove the cannula.

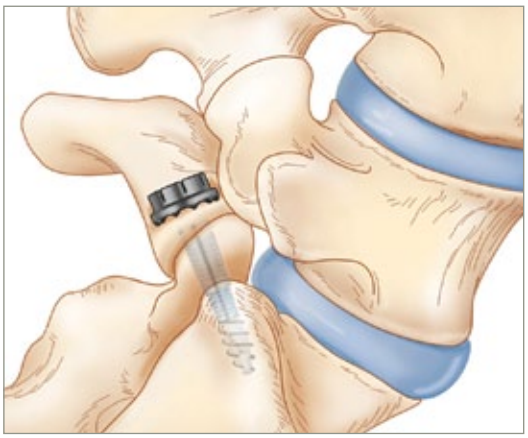


Final Construct

Lateral View

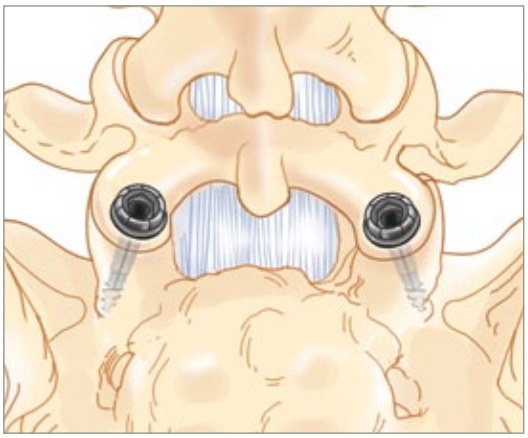
From a lateral view, the implant should be placed in the bottom half of the pedicle, at the pedicle–vertebral body junction.[2]



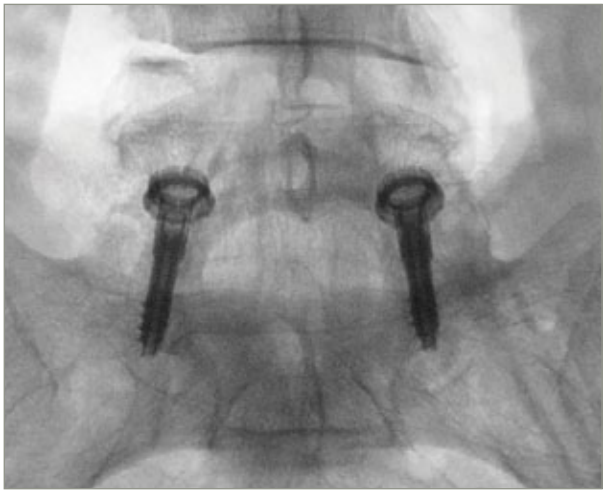


AP View

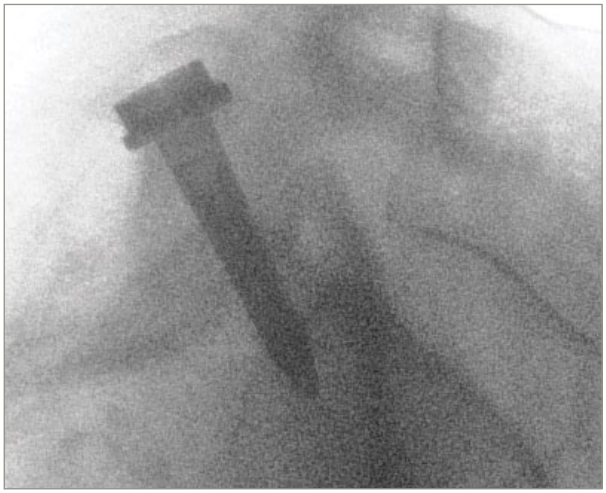
From an AP view, the implant should terminate in the inferolateral quandrant of the pedicle.[2]



Confirm Placement



AP View – Final placement



Lateral View – Final placement

References

1. Ferrara LA, Secor JL, Jin BH, et al. A biomechanical comparison of facet screw fixation and pedicle screw fixation: effects of short-term and long-term repetitive cycling. Spine 2003; 28:1226–34.

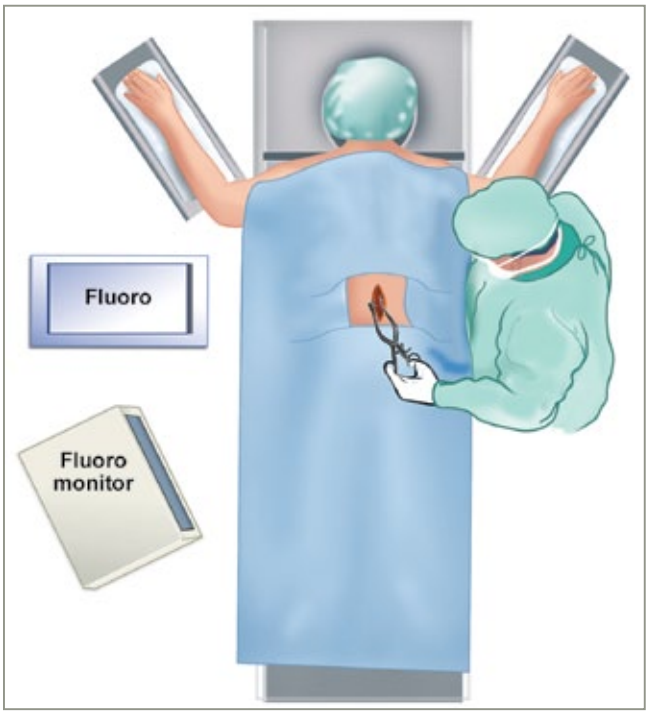
2. Su BW, Cha TD, Kim PD, et al. An anatomical and radiographic study of lumbar facets relevant to percutaneous transfacet fixation. Spine 2009; 34:11 384-390.

ZYFUSE® SURGICAL TECHNIQUE

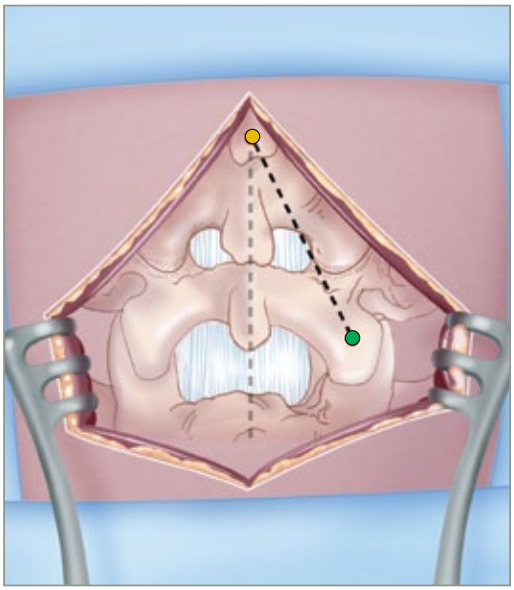
OPEN APPROACH

Step 1 Positioning

The patient is placed under anesthesia and positioned prone with the lumbar spine in extension and hips in flexion. Fluoroscopy should be used to ensure that the spine is oriented in a true AP position to begin the procedure. The table should be adjusted so that the C-arm provides true AP images when at 0° and true lateral images at 90°. Fluoroscopy should be utilized in this method to ensure ideal implant placement.



Patient positioning

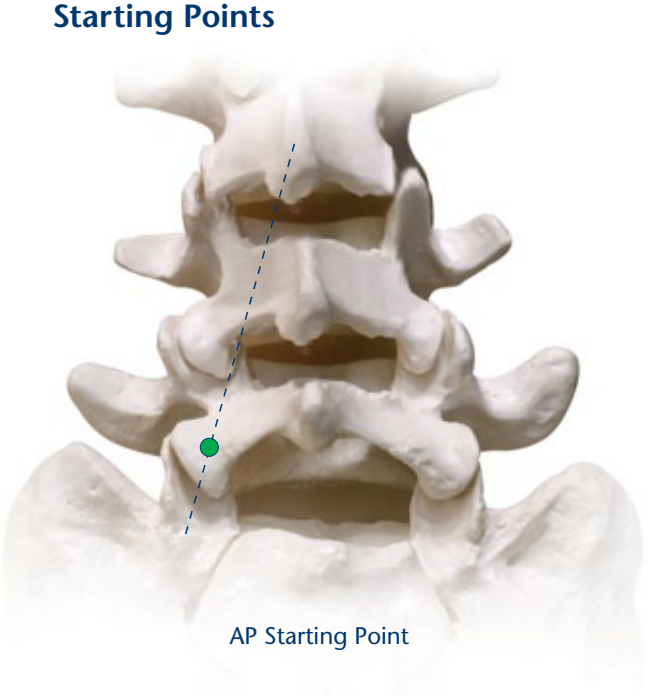


Initial starting point

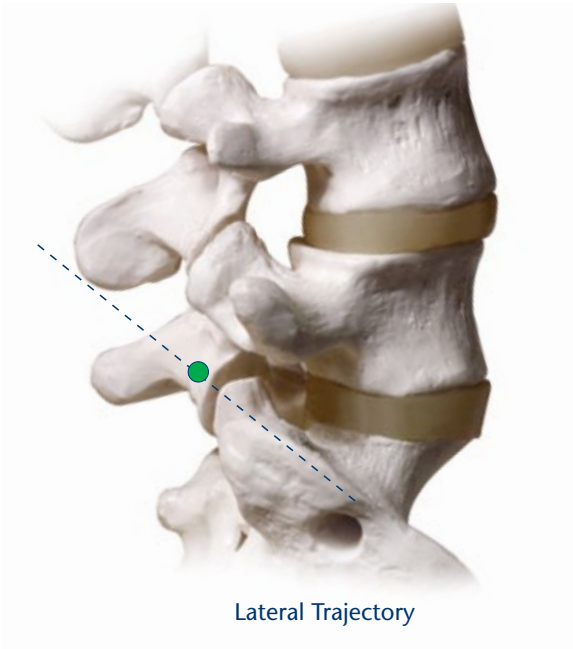
Trajectory

Approximate Caudal-Axial Angulation[1]		
Level	Caudal	Axial
L3/L4	26°	15°
L4/L5	29°	15°
L5/S1	31°	15°

Starting Points



AP Starting Point



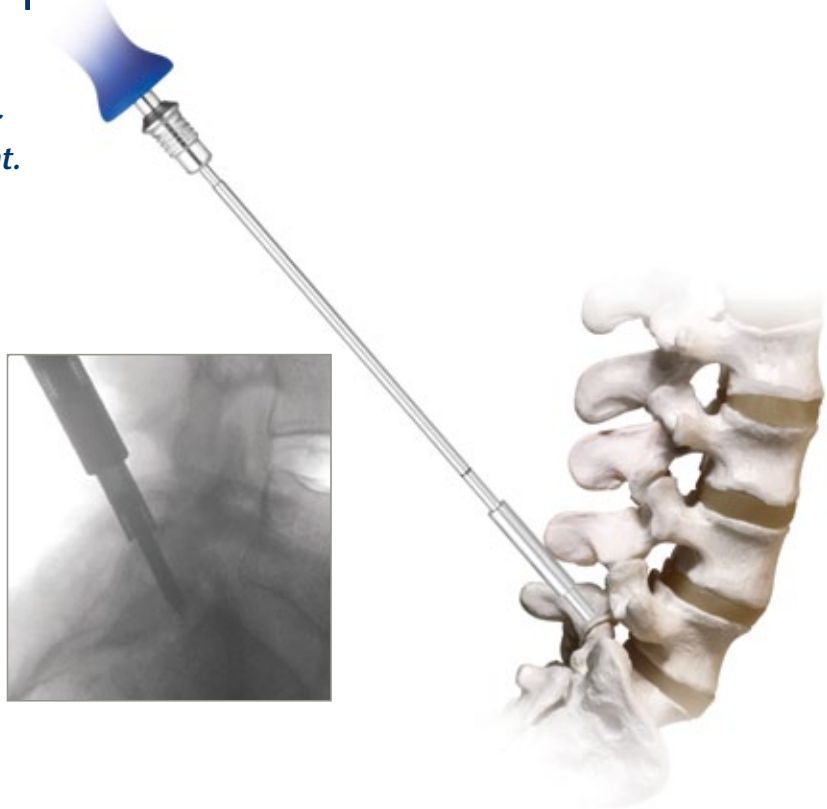
Lateral Trajectory

Step 2 Hole Preparation

Drilling and tapping are required to facilitate proper advancement of the implant.

Pilot Hole

Introduce the **Awl** by angulating the distal tip downward and outward, parallel to the caudal edge of the lamina at an angle of approximately 31° and 15° laterally, with the shaft resting against the spinous process.[1] Confirm the trajectory through



Pilot Hole (cont'd)

fluoroscopy in the lateral position, prior to impaction. Using a small mallet, impact the awl through the joint to create a pilot hole.

Optional: If surgeon prefers to drill through the joint, the awl is still required to initiate a pilot hole, to ensure that the drill does not become displaced during hole preparation.

Drilling

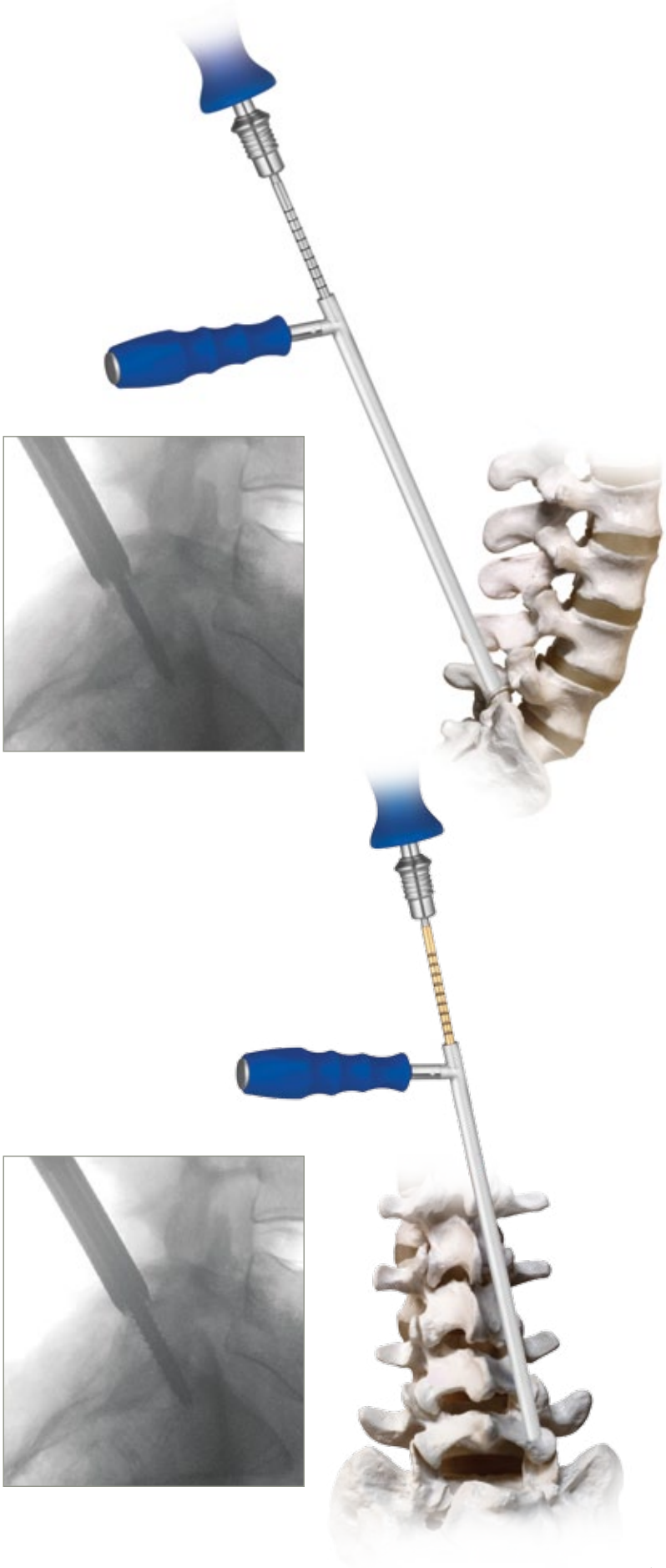
Position the **Drill-Tap Guide** on the surface of the facet. Attach the corresponding **Drill** to the desired handle (straight or ratcheting) and insert through the Drill-Tap Guide. Use lateral fluoroscopy to ensure that the trajectory is correct and drill for the appropriate length implant, using the incremental markings on the drill as a guide.

Note: The 3.7mm drill corresponds to a 5mm implant. The 4.7mm drill corresponds to a 6mm implant.

Tapping

Remove the Drill and insert the corresponding **Tap** using the incremental markings on the Tap to measure depth.

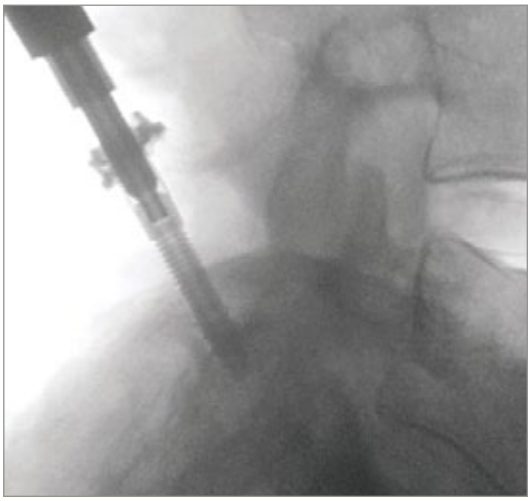
Note: The 4.8mm tap corresponds to a 5mm implant. The 5.8mm tap corresponds to a 6mm implant.



Step 3 Implant Placement

Insertion

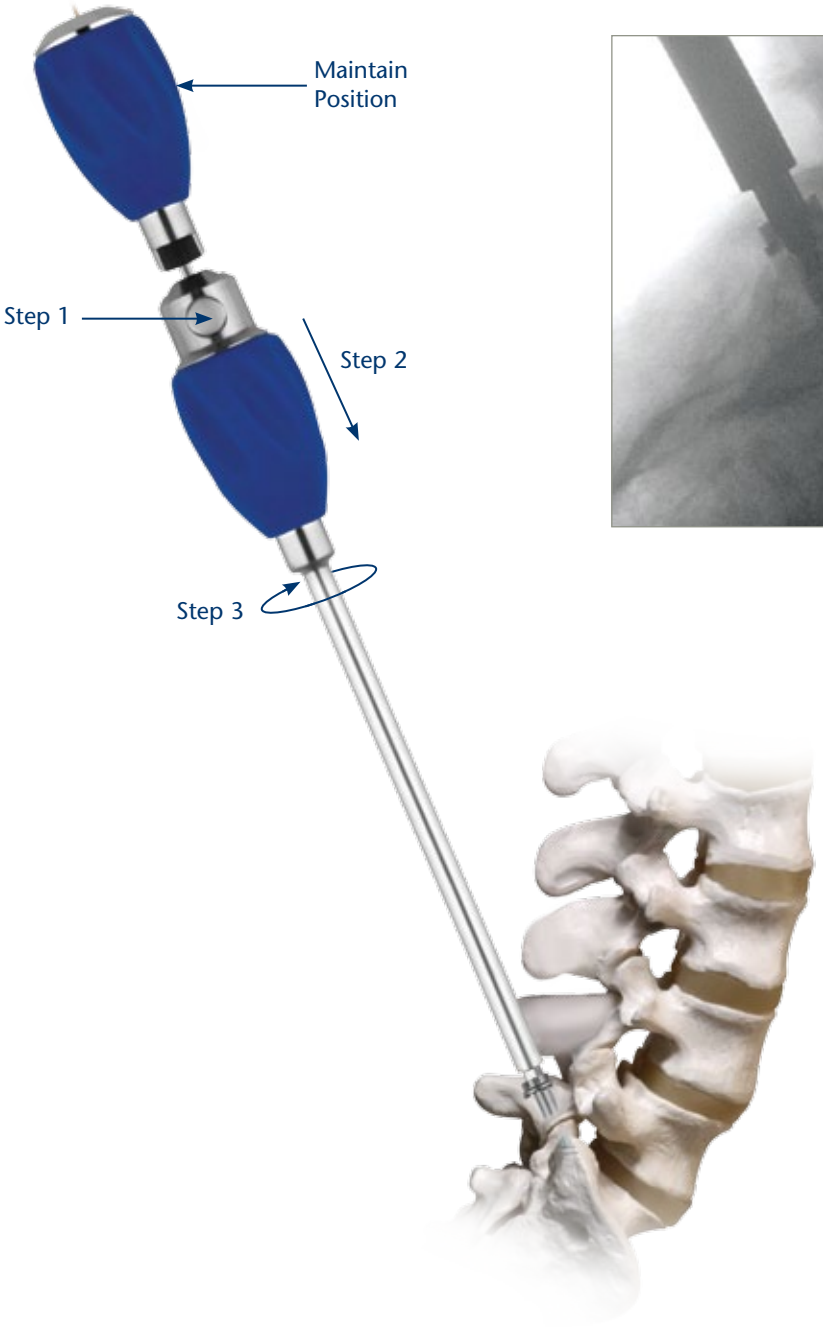
After selecting the desired ZYFUSE® implant size, assemble the implant onto the **Driver 2.5mm/5.5mm Hex**, ensuring that both handles are locked together. Rotate both handles clockwise to advance the ZYFUSE® implant. Fluoroscopy is required throughout this step to ensure proper trajectory and placement.

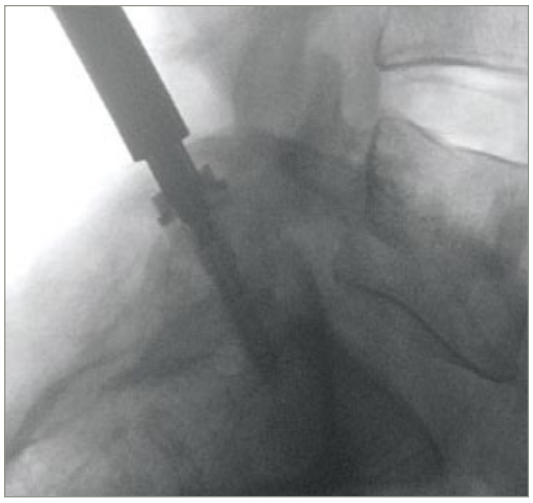


Compression

Once the desired thread location within the pedicle has been achieved, the compression feature may be engaged. Press the release button and lower the bottom handle of the driver, ensuring that the second hex has fully engaged within the implant during this step. Holding the top handle steady, rotate the bottom handle clockwise to compress the implant. Resistance will increase during compression but fluoroscopy should be used to confirm compression and implant placement. To ensure secure implant purchase, do not overcompress – two finger tight only.

Pull up on both handles to release the driver from construct.

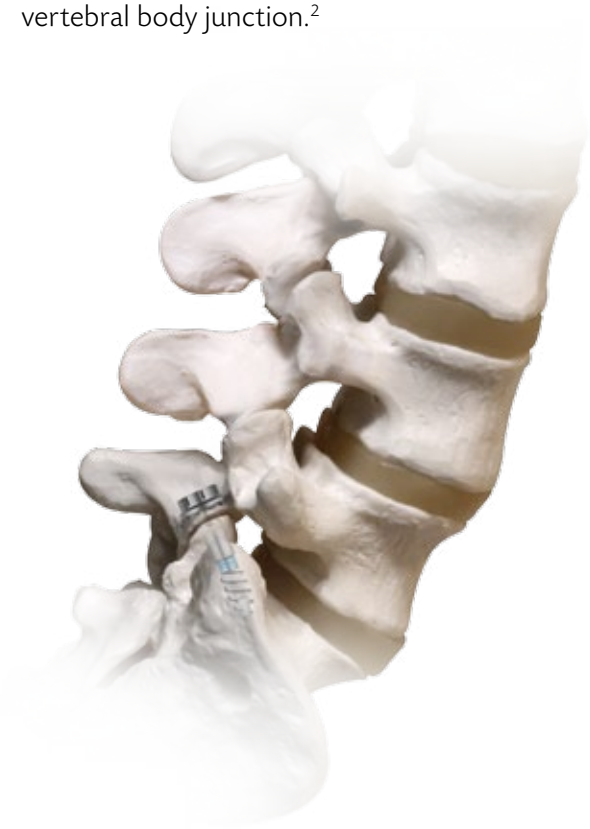


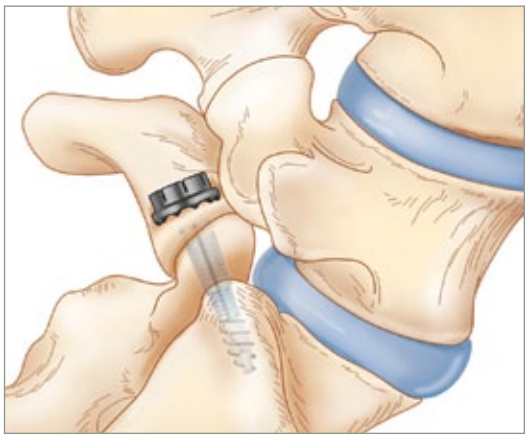


Final Construct

Lateral View

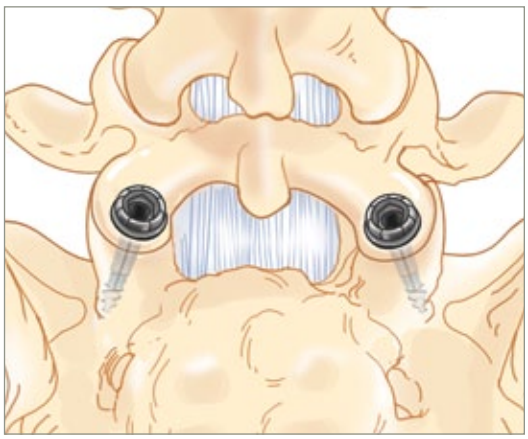
From a lateral view, the implant should be placed in the bottom half of the pedicle at the pedicle–vertebral body junction.[2]



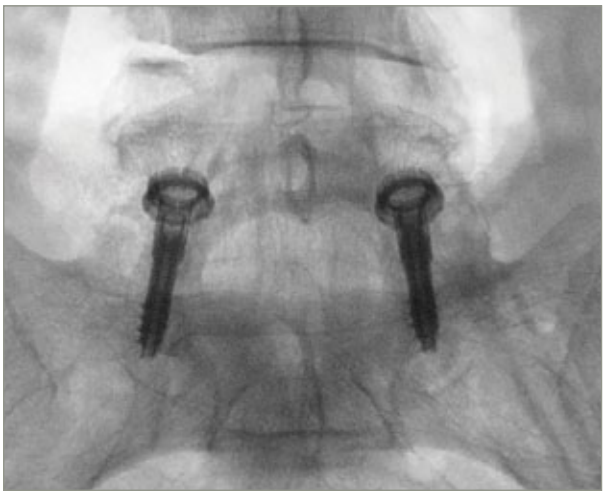


AP View

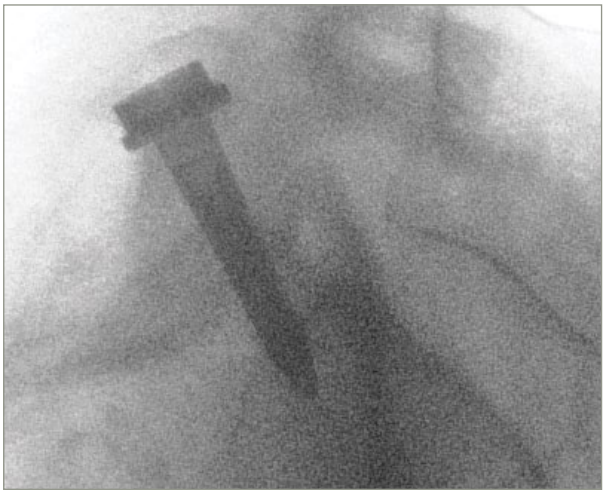
From an AP view, the implant should terminate in the inferolateral quandrant of the pedicle.[2]



Confirm Placement



AP View – Final placement



Lateral View – Final placement

References

1. Ferrara LA, Secor JL, Jin BH, et al. A biomechanical comparison of facet screw fixation and pedicle screw fixation: effects of short-term and long-term repetitive cycling. Spine 2003; 28:1226–34.

2. Su BW, Cha TD, Kim PD, et al. An anatomical and radiographic study of lumbar facets relevant to percutaneous transfacet fixation. Spine 2009; 34:11 384-390.

ZYFUSE® IMPLANT SET

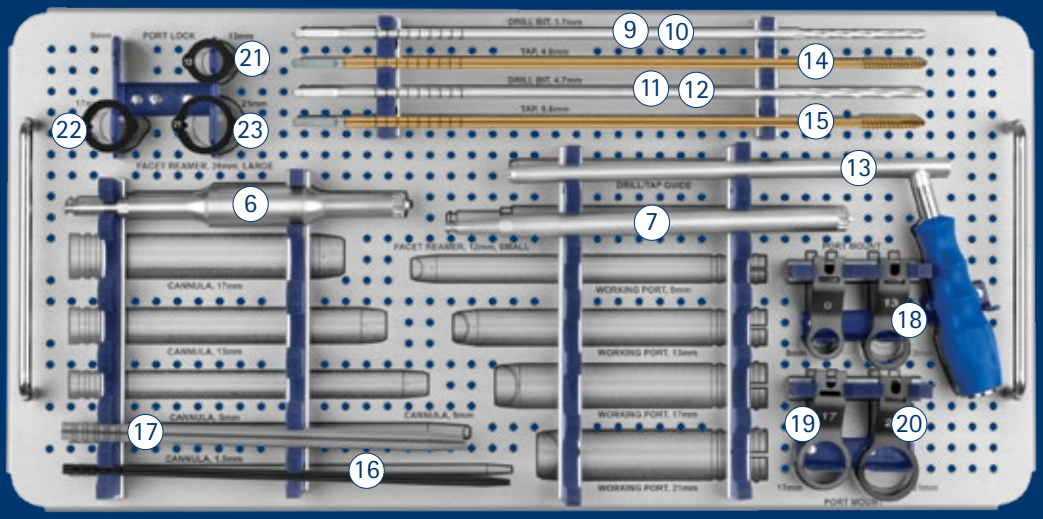
ZYFUSE® Fixation System Set 947.901

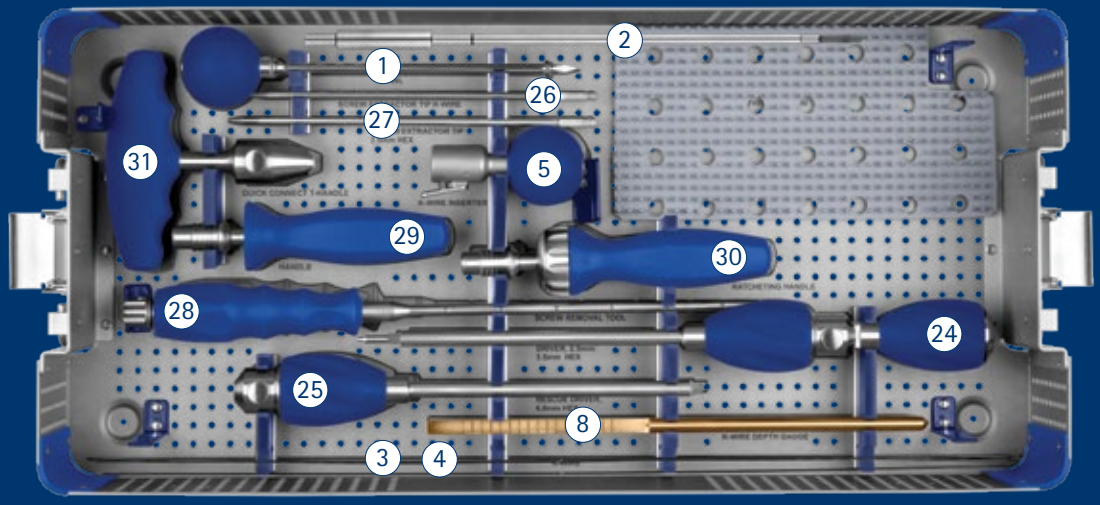
ZYFUSE® Fixation HA Coated Screws

Length	Diam 5.0mm	Qty	Diam 5.0mm (with washer)	Qty	Diam 6.0mm	Qty	Diam 6.0mm (with washer)	Qty
30mm	147.530S	4	147.531S	4	147.630S	4	147.631S	4
40mm	147.540S	4	147.541S	4	147.640S	4	147.641S	4
50mm	147.550S	4	147.551S	4	147.650S	4	147.651S	4
60mm	147.560S	4	147.561S	4	147.660S	4	147.661S	4

Sterile Instruments		Qty
647.200S	Sterile Dilator Pack (9 & 13mm)	2
647.217S	Cannula, 17mm	1
647.313S	Working Port, 13mm	1
647.317S	Working Port, 17mm	1
647.321S	Working Port, 21mm	1
947.002	ZYFUSE® Soft Case	

ZYFUSE® INSTRUMENT SET





ZYFUSE® Instrument Set 947.902

Preparation Instruments			Qty
1	602.104	Pedicle Awl	1
2	676.506	Straight Awl	1
	623.102S	Jamshidi Needle	3
3	647.007	K-Wire, 650mm Steel	3
4	647.009	K-Wire, 650mm Nitinol	3
5	602.802	K-Wire Inserter	1
6	647.012	Facet Reamer, 12mm, Small	1
7	647.020	Facet Reamer, 20mm, Large	1

Drill Bits & Taps			Qty
8	647.011	K-Wire Depth Gauge	1
9	647.037	Drill Bit, Cannulated 3.7mm	1
10	647.038	Drill Bit, Solid 3.7mm	1
11	647.047	Drill Bit, Cannulated 4.7mm	1
12	647.048	Drill Bit, Solid 4.7mm	1
13	647.100	Drill/Tap Guide	1
14	647.148	Tap, 4.8mm	1
15	647.158	Tap, 5.8mm	1

Cannulas			Qty
16	647.201	Cannula, 1.5mm	1
17	647.205	Cannula, 5mm	1
18	647.413	Port Mount, 13mm	1
19	647.417	Port Mount, 17mm	1
20	647.421	Port Mount, 21mm	1
21	647.513	Port Lock, 13mm	1
22	647.517	Port Lock, 17mm	1
23	647.521	Port Lock, 21mm	1

Implant Instruments			Qty
24	647.755	Driver, 2.5mm / 5mm Hex	1
25	647.660	Rescue Driver, 6.0mm Hex	1
26	647.800	Screw Extractor Tip, K-wire	1
27	647.801	Screw Extractor Tip, 2.5mm Hex	1
28	648.303	Screw Removal Tool	1

Quick Connect Handles			Qty
29	648.400	Quick Connect Handle, Cannulated	1
30	648.401	Quick Connect Ratcheting Handle, Cannulated	1
31	601.800	Quick Connect T-Handle	1

	947.001	ZYFUSE® System Graphic Case	

IMPORTANT INFORMATION ON THE ZYFUSE® FACET FIXATION SYSTEM

DESCRIPTION

The ZYFUSE® Facet Fixation System consists of screws designed to compact juxtaposed facet articular processes to enhance spinal fusion. The cannulated, partially threaded screws are available with or without a washer, and in various diameters and lengths to accommodate patient anatomy. The ZYFUSE® Facet Fixation System implants are fabricated from medical grade titanium alloy as specified in ASTM F136, F1295 and HA coated as specified in ASTM F1185. Due to the risk of galvanic corrosion following implantation, titanium alloy implants should not be used in the same construct as stainless steel implants.

INDICATIONS

The ZYFUSE® Facet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from L1 to S1. For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle.

The ZYFUSE® Facet Fixation System is indicated for treatment of any or all of the following: pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; spondylolisthesis; spondylolysis; degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; degeneration of the facets with instability and trauma including spinal fractures and/or dislocations.

CONTRAINDICATIONS

The contraindications include, but are not limited to: active infectious process or significant risk of infection (immunocompromise); local inflammation, fever, or leukocytosis, morbid obesity; pregnancy; mental illness; distorted anatomy caused by congenital abnormalities; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities; rapid joint disease, bone absorption osteopenia, and/or osteoporosis; suspected or documented metal allergy or intolerance; any case where metals must be mixed from different components; any case where the implant components selected for use would be too large or too small to achieve a successful result; any case where fracture healing is not required; any patient in which implant utilization would interfere with anatomical structures or expected physiological performance; any patient unwilling to follow post-operative instructions; any case not described in the indications.

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

WARNINGS

Possible adverse effects which may occur include, but are not limited to: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials including metallosis, staining, tumor formation and/or autoimmune disease; infection; device fracture or failure; device migration or loosening; decrease in bone density; loss of spinal mobility or function; inability to perform activities of daily living; fracture of any spinal bone including the pedicles, spinous process, pars interarticularis, vertebral body, or sacrum; change in spinal curvature or disc height; herniated nucleus pulposus, disc degeneration or disruption; graft donor site complications including pain, fracture and wound healing problems; tissue damage, pain, discomfort, or abnormal sensations due to the presence of the device or implantation surgery; scar formation causing neurologic compromise or pain; injury to nerves including loss or decrease of neurologic function, paralysis, dural tears, development of radiculopathy, numbness or tingling; cauda equine syndrome; injury to vessels, hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, or other types of cardiovascular system compromise; injury to organs including urinary retention, loss of bladder control, or other types of urologic system compromise; gastrointestinal system compromise; reproductive system compromise including sterility, sexual dysfunction; development of respiratory problems including pulmonary embolism; venous thrombosis, lung embolism and cardiac arrest; and death. Additional surgery may be necessary to correct some of these effects.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

The components of this system are manufactured from titanium alloy. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.

PRECAUTIONS

Implantation of these devices should be performed only by experienced spinal surgeons with specific training in the use of the system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implants.

Surgical implants must never be reused. An explanted metal implant must never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery. To insert a cannulated screw, a guide wire may be used, followed by a sharp tap. Ensure that the guide wire, if used, is not inserted too deep, becomes bent, and/or breaks. Also ensure that the guide wire does not advance during tapping or screw insertion. Remove the guide wire and confirm that it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.

Correct handling of the implant is extremely important. Contouring of metal implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as

IMPORTANT INFORMATION ON THE ZYFUSE® FACET FIXATION SYSTEM

an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Correct selection of the implant is extremely important. The potential for success on fracture fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can minimize risks, size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load- bearing. A higher risk of device loosening, bending, or breaking exists with fractures involving severe comminution, displacement or other difficult fracture management situations.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to constantly changing environment of salts, acids and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn can enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys in conjunction with each other.

CLEANING

Cleaning instruments by hand, when properly carried out, causes less damage than mechanical cleaning. When cleaning instruments by hand, the following should be observed:

1. Clear any corners or recesses of all debris (Note: extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.)
2. Remove all traces of blood and other such residues immediately. Do not allow these to dry.
3. The instruments should be submerged (if applicable) and cleaned with a commercially available manual cleaner (i.e. Instraclean from Calgon or Medline High Suds Detergent) prepared according to the manufacturer's recommendation.
4. A soft nylon bristled brush is then used to manually clean the devices while immersed in the cleaning solution. Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
5. The instruments should be thoroughly rinsed after cleaning. Distilled water should be used.
6. Dry instruments immediately after cleaning

CONTACT INFORMATION

Globus Medical may be contacted at the phone number listed on this insert. A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

ZYFUSE® implants are provided sterile or non-sterile; HA coated ZYFUSE® implants are provided only sterile. ZYFUSE® instruments may be provided sterile or non-sterile. Sterile ZYFUSE® implants and instruments are sterilized by gamma radiation to ensure a sterility level of 10^{-6} SAL. The expiration date is provided on the package label.

Non-sterile ZYFUSE® implants and instruments have been validated to assure a Sterility Assurance Level (SAL) of 10^{-6}. The use of an FDA cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.*

Implants:
These devices may be supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132° - 135°C (270° - 275° F)	28 Minutes	0 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132° - 135°C (270° - 275° F)	4 Minutes	0 Minutes

Instruments:
These devices may be supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132° - 135°C (270° - 275° F)	25 Minutes	45 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132° - 135°C (270° - 275° F)	15 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

REV C

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