

Zyfix®

Facet Fusion System



SURGICAL TECHNIQUE

The logo for Zyfix, featuring the word "Zyfix" in a blue, sans-serif font, followed by a registered trademark symbol (®). The background of the slide consists of several overlapping, diagonal, light gray bands that create a sense of depth and movement.

Zyfix®

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ZYFIX® FEATURES

Dual-Thread Screws



Single-Thread Screws



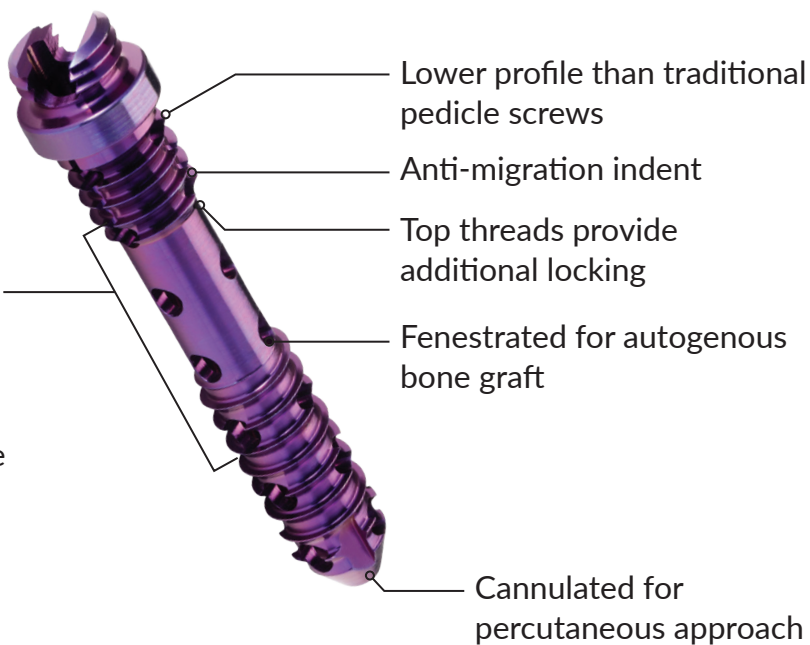
6.0mm diameter screws

Simple Instrumentation

Multiple surgical approaches

Different thread pitches provide increased superior to inferior facet compression

*Optional 11mm washer available



Zyfix® Screws and Washer

Item Number	Description
X076-0020	6.0mm x 25mm Dual Thread Screw
X076-0021	6.0mm x 30mm Dual Thread Screw
X076-0022	6.0mm x 35mm Dual Thread Screw
X076-0023	6.0mm x 40mm Dual Thread Screw
X076-0024	6.0mm x 45mm Dual Thread Screw
X076-0029	6.0mm x 20mm Single Thread Screw
X076-0037	11mm Washer

SURGICAL TECHNIQUE – ZYFIX® PERCUTANEOUS APPROACH

This information is intended exclusively for experts in the field, particularly physicians, and is not intended for laypersons.

Information on the products and procedures contained herein is general in nature and does not represent medical advice or recommendations. As with any technical guide, this information does not constitute any diagnostic or therapeutic statement with regard to a given medical case. An evaluation, examination, and advising of the patient are absolutely necessary for the physician to determine the specific requirements of the patient, and any appropriate adjustments needed, and the foregoing are not to be replaced by this document in whole or in part.

Information contained in this document was gathered and compiled by experts in the field and company employees to the best of their knowledge. Care was taken to ensure the information contained herein is accurate and understandable. The company does not assume any liability for the accuracy and/or completeness of the quality of the information, and is not liable for any losses whatsoever of any kind or any nature that may be caused by the use of said information.

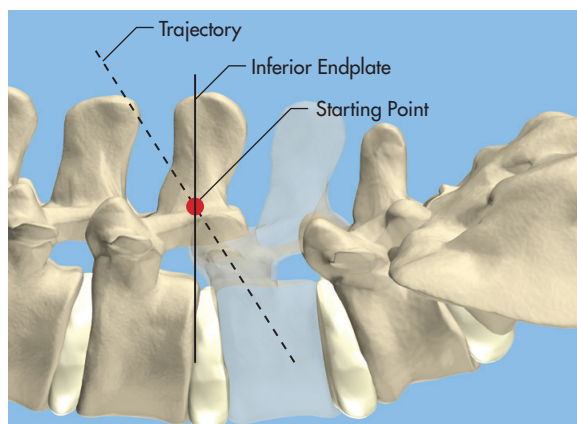
Note : Bilateral screws are required for adequate fixation strength.

Note : For Percutaneous Approach Technique, use the long instruments.

OR SETUP AND PREPARATION:

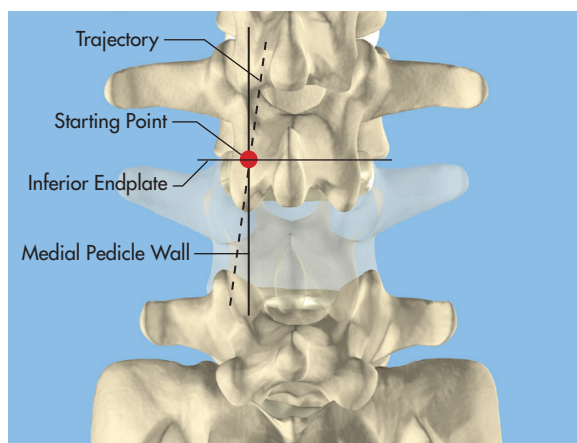
Step 1: Patient Positioning

- The patient is positioned on the operating table in the prone position. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral region.



Step 2: Skin Marking and Fluoroscopic Preparation

- A skin mark should be made at the superior edge of the spinous process of the rostral vertebrae to be fixated, approximately 8mm from midline. A multi-planar fluoroscope should be positioned such that AP, lateral and trajectory views can be achieved without obstruction.



Step 3: Targeting

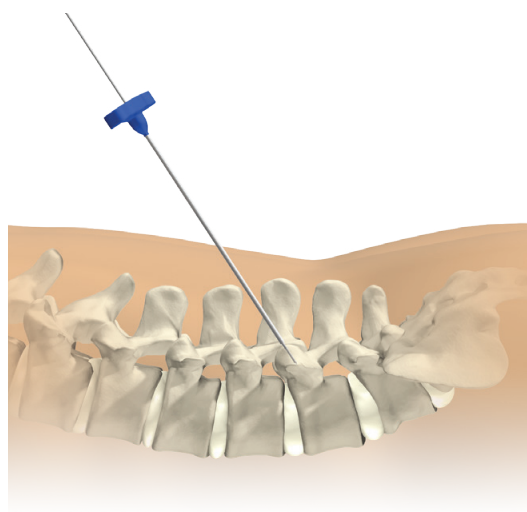
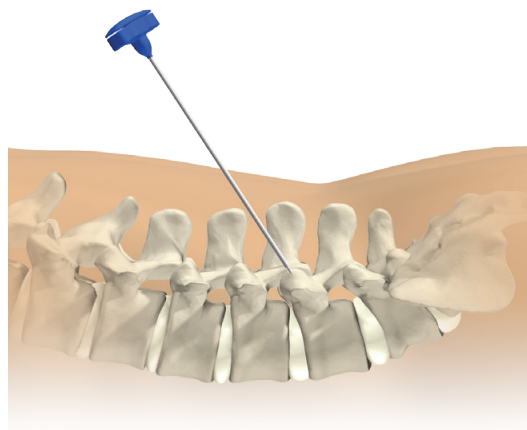
- Under fluoroscopic guidance, target a bone-entry point at the junction of the pars interarticularis and the inferior facet of the rostral vertebra to be fixated, with a trajectory into the superior facet of the caudal vertebra and proximal pedicle.

Advance a Jamshidi-type cannulated needle down this trajectory under fluoroscopic guidance. Confirm that the needle tip remains within bone at all times. Note that the needle trajectory will be approximately 20 degrees off the sagittal plane, directed laterally.

Warning: Under no circumstance should the needle or other instrument be placed with a sagittal or medial trajectory. Perforation of the dura and/or damage to neurological structures can occur.

Place the K-wire through the Jamshidi needle and tap the K-wire into the vertebral body with the mallet, confirming with fluoroscopy. The K-wire is available with either blunt or trocar tip.

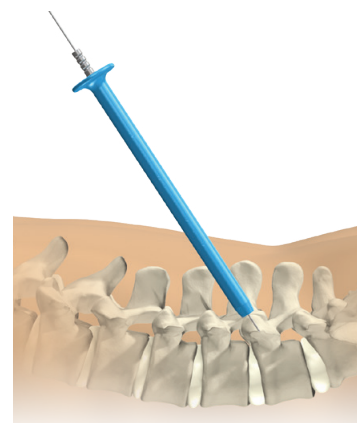
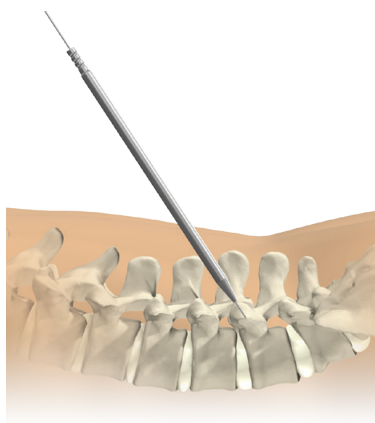
For the remainder of the procedure, the K-wire location should be monitored to ensure the tip is not unintentionally advanced or has not backed out. While holding the K-wire to ensure it stays in position, remove the Jamshidi needle.



Step 4: Dilation

- Place Inner Dilator over K-wire until fully seated.

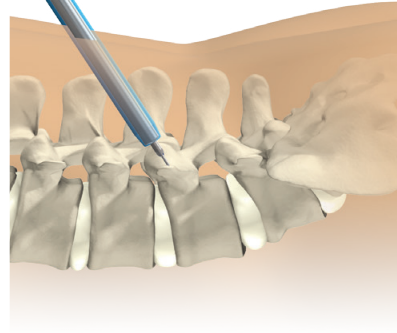
Next, place Long Outer Dilator over Inner Dilator until fully seated, then remove Inner Dilator.



Step 5: Bone Awl (Optional)

- Place the Bone Awl over the K-wire. Use the Mallet to lightly impact the Bone Awl while advancing to appropriate depth while monitoring under fluoroscopy and monitoring the position of the K-wire.

Note : Bone Awl has a 10mm trocar tip.

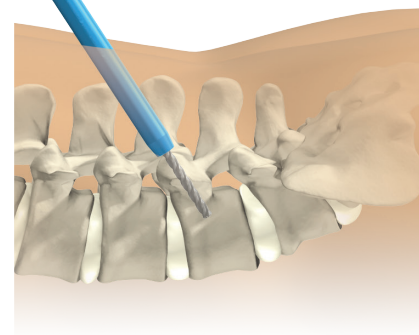
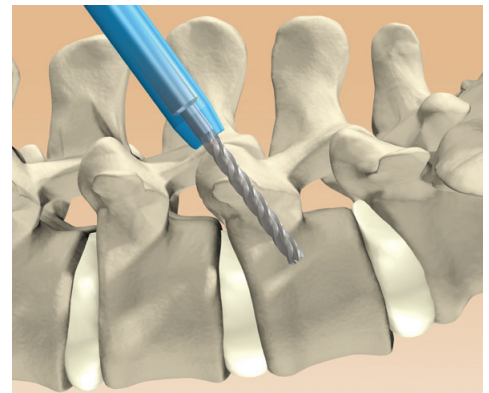


Step 6: Drilling

- Attach the Ratcheting Screwdriver Handle to the Cannulated Drill. Under fluoroscopic guidance, place the Drill over the K-wire and through the Long Outer Dilator. Carefully drill through the facet joint and maintain the trajectory into inferior proximal pedicle. Remove the Drill.

CAUTION - Care must be taken to avoid over-drilling into any structure outside of the cortical bone margin.

Note: Drill is approximately 8% undersized. Depth markings are provided at the top of the drill to indicate depth.

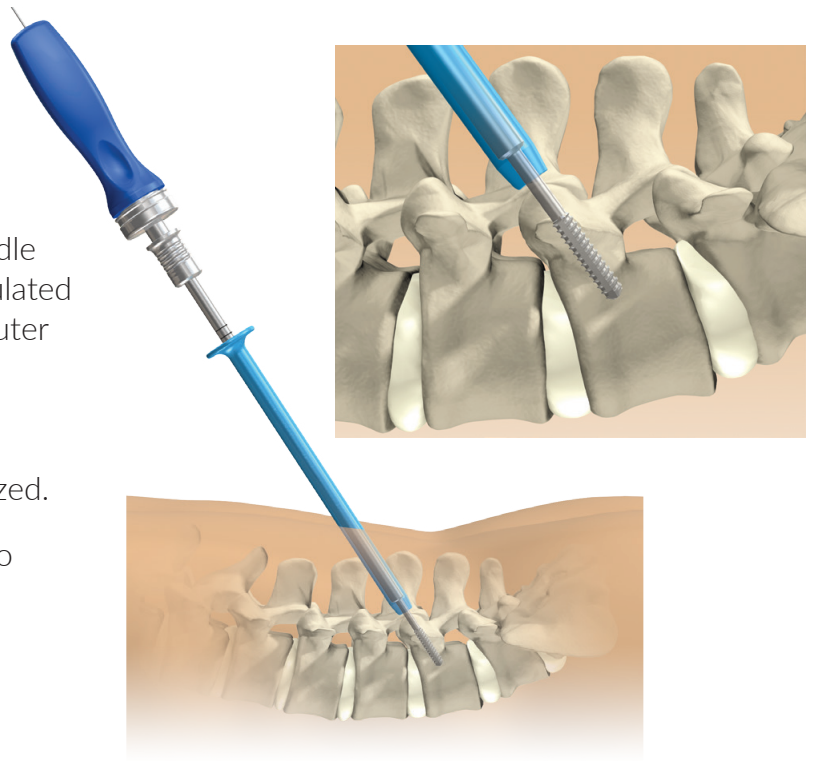


Step 7: Tapping

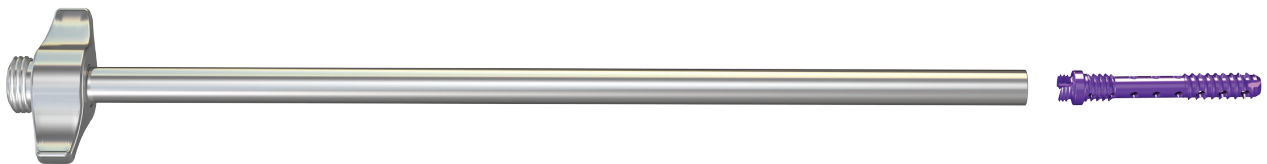
- Attach the Ratcheting Screwdriver Handle to the Cannulated Tap. Place the Cannulated Tap over the K-wire and through the Outer Dilator, then tap to desired depth. Remove the Tap.

Note : Tap is approximately 8% undersized.

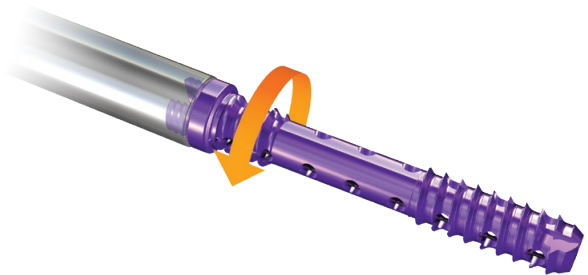
Note : Optionally, a Rasp can be used to decorticate and prepare the facet joint.



Step 8: Screw Loading



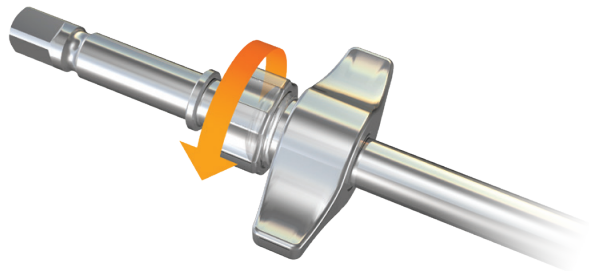
- After confirmation of preferred screw length, rotate the Long Access Sleeve counterclockwise onto the screw.



Step 9: Screwdriver Assembly



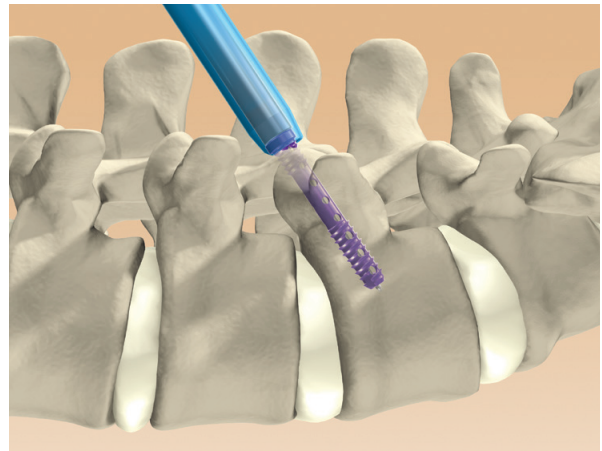
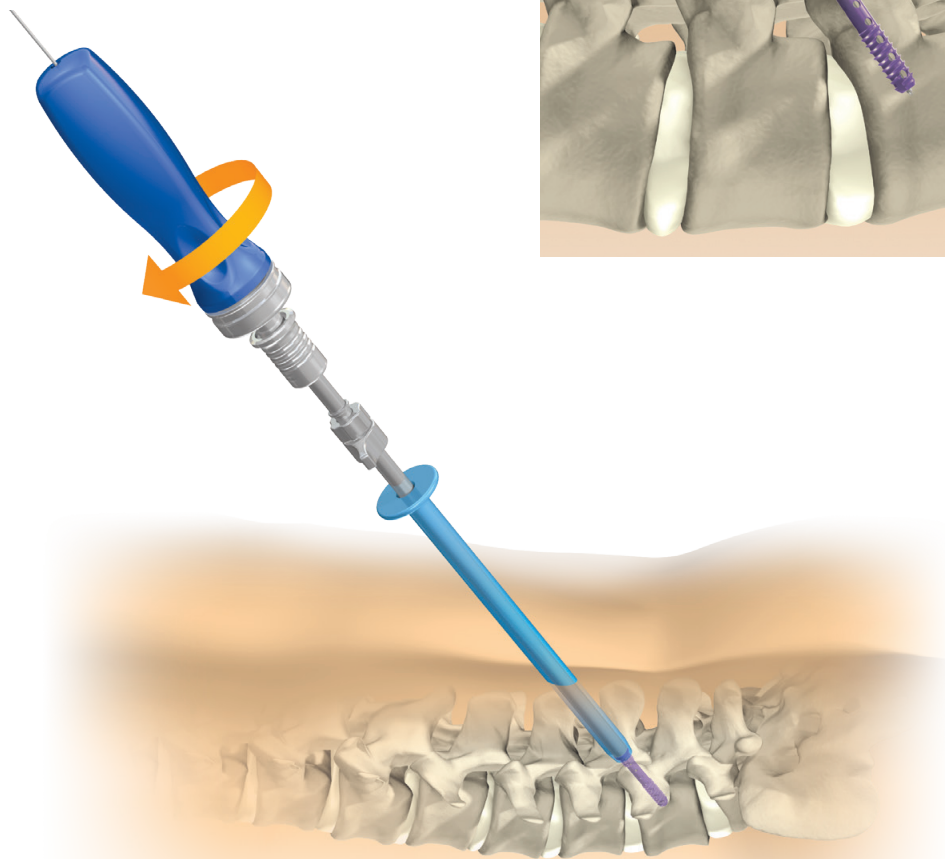
- Slide the Long Screwdriver Shaft into Long Access Sleeve and align with screw at distal tip. Turn locking nut clockwise to tighten and attach Ratcheting Screwdriver Handle for final assembly.



Step 10: Screw Placement

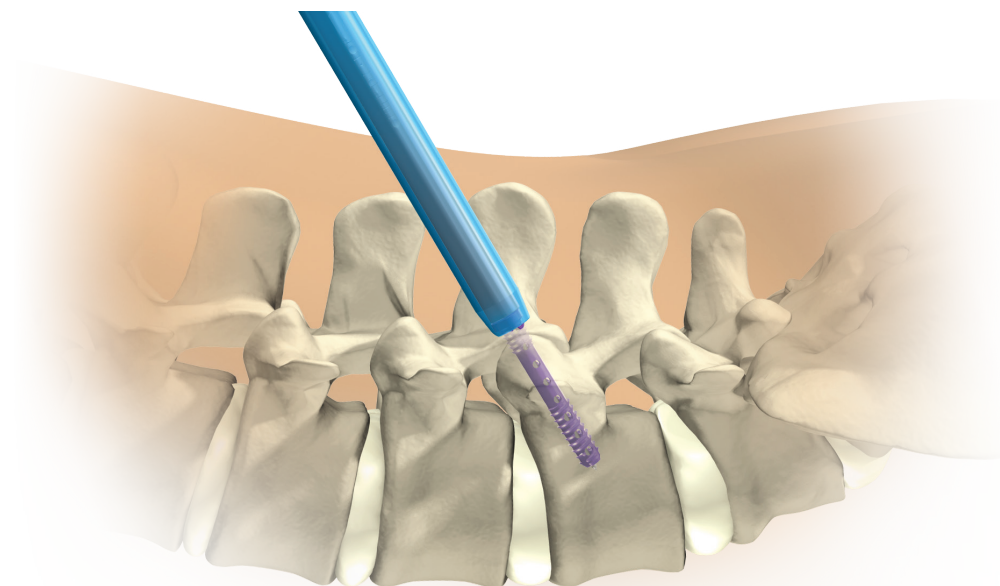
- Place the Screwdriver Shaft over the K-wire and through the Outer Dilator. The screw should be rotated gradually under fluoroscopic guidance to confirm distal entry into the inferior facet. The screw should be rotated until the screw head contacts the superior facet. Over-tightening of the screw can result in facet fracture.

CAUTION - Bilateral screws are required for adequate fixation strength.



Step 11: Screw Placement Confirmation

- Interoperative fluoroscopy should be performed to confirm final screw position. Additionally, neurophysiologic testing of the screw is recommended to confirm that there is no nerve conductance.

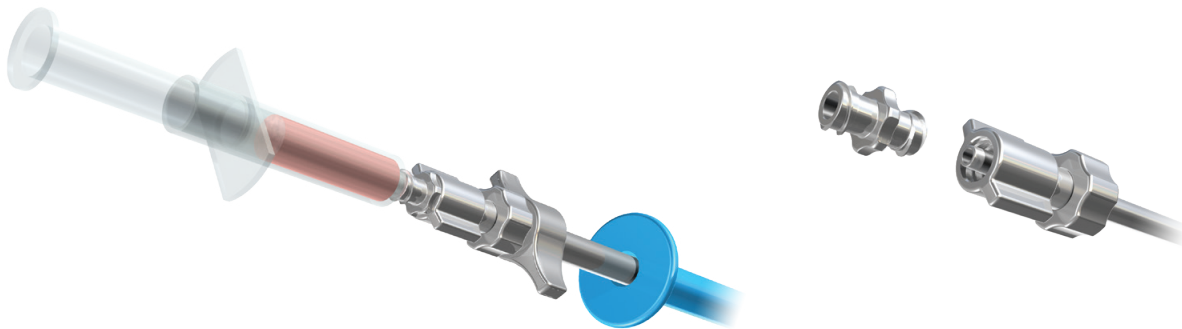


Step 12: Bone Marrow Aspirate Delivery

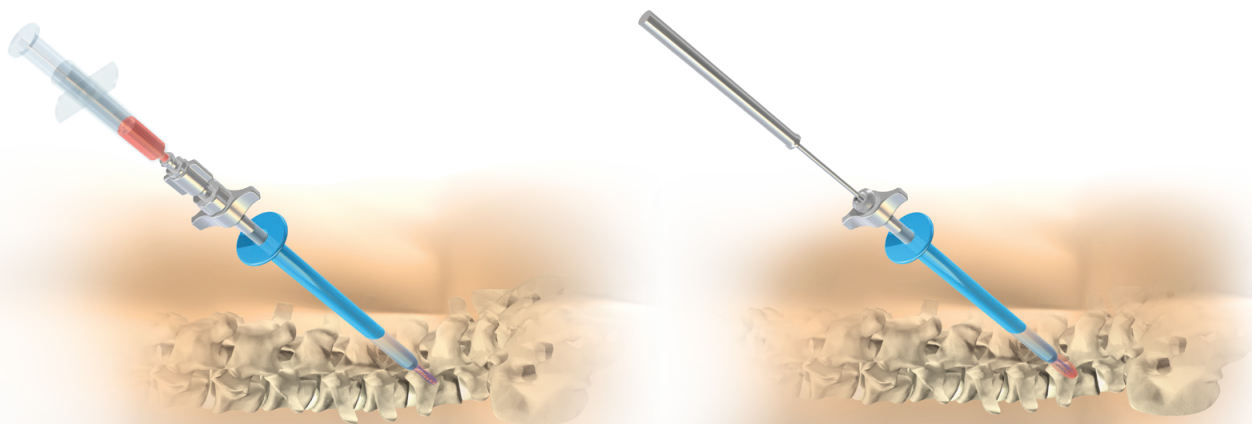
1. Remove K-wire, then remove Long Screwdriver Shaft by rotating the locking nut counterclockwise.
2. Slide the Long Luer Shaft through the Long Access Sleeve and align with screw at distal tip. You may need to rotate the Luer shaft up to 180 degrees in order to get full engagement into the implanted screw. Rotate the locking nut, clockwise, to tighten for proper placement.



3. Attach syringe to the Long Luer Shaft directly or use Female to Female Adapter, if needed.



4. Deliver the BMA into the Luer Shaft. Remove the syringe and Long Luer Shaft, then pack into the implant using the Graft Packer, if desired.



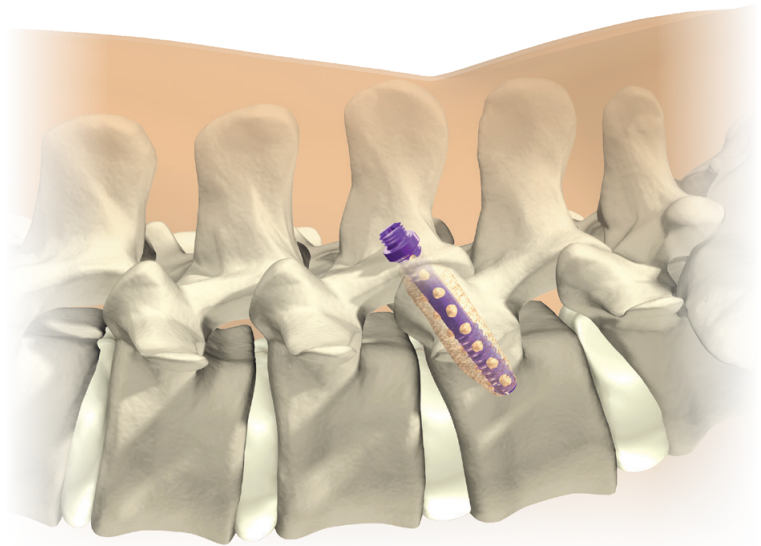
Note : Graft Packer has positive stop at implant head to prevent over-insertion.

Bone Marrow Aspirate Volumes (approximate)

Part Number	Screw Length	Volume (cc)
X076-0029	20mm, Single Thread	0.23
X076-0020	25mm, Dual Thread	0.27
X076-0021	30mm, Dual Thread	0.32
X076-0022	35mm, Dual Thread	0.37
X076-0023	40mm, Dual Thread	0.41
X076-0024	45mm, Dual Thread	0.46

Step 13: Final Construct

- Remove the Long Luer Shaft, Long Access Sleeve and Long Outer Dilator and close the surgical site.



System Removal/Revision

If the screw needs to be repositioned or removed, reattach the screw (refer to Steps 8 and 9) then rotate Screwdriver Shaft counterclockwise to remove.

SURGICAL TECHNIQUE – ZYFIX® OPEN APPROACH

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Note : Bilateral screws are required for adequate fixation strength.

Note : For Percutaneous Approach Technique, use the long instruments.

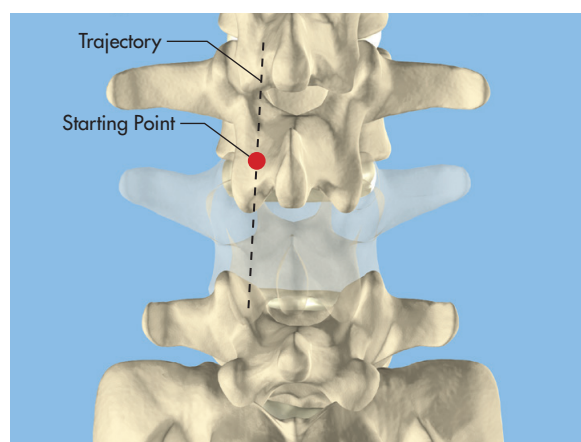
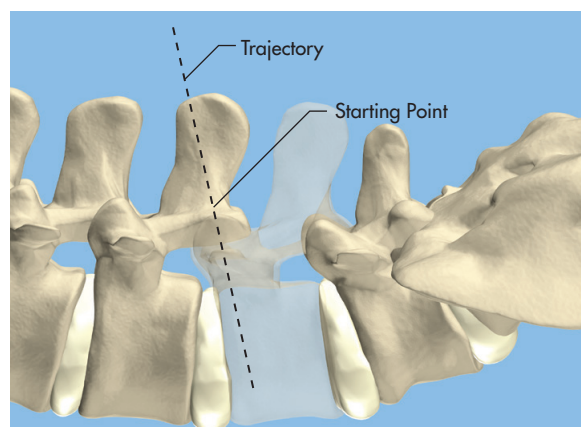
OR SETUP AND PREPARATION:

Step 1: Patient Positioning

- The patient is positioned on the operating table in the prone position. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral region.

Step 2: Exposure

- The surgical approach is carried out through a standard midline incision to the spinal column over the anatomic position of the spinous process. The exposure of the spinous process should extend one additional level. The laminae, pedicles, superior and inferior facets of the levels to be fused should be visualized directly and/or by intraoperative fluoroscopy.



Visually target a bone-entry point at the junction of the pars interarticularis and the inferior facet of the rostral vertebra to be fixated. With a trajectory into the superior facet of the caudal vertebra and proximal pedicle, advance a Jamshidi-type cannulated needle under fluoroscopic guidance. Confirm that the needle tip remains within bone at all times. Note that the needle trajectory will be approximately 20 degrees off the sagittal plane, directed laterally.

Warning: Under no circumstance should the needle or other instrument be placed with a sagittal or medial trajectory. Perforation of the dura and/or damage to neurological structures can occur.

Place the K-wire through the Jamshidi needle and tap the K-wire into the vertebral body with the mallet, confirming with fluoroscopy. The K-wire is available with either blunt or trocar tip.

For the remainder of the procedure, the K-wire location should be monitored to ensure the tip is not unintentionally advanced or has not backed out. While holding the K-wire to ensure it stays in position, remove the Jamshidi needle.

Step 2b: Alternate Trans-Facet Approach.

- If a direct trans-facet approach (King approach) is desired, locate the facet entry point at the junction of the pars interarticularis and the inferior facet of the rostral vertebra to be fixated. The screw trajectory should proceed approximately 45 degrees laterally and perpendicular to the facet joint surface. The screw should be driven until bicortical penetration is achieved through the superior facet joint of the caudal vertebral to be fixated.

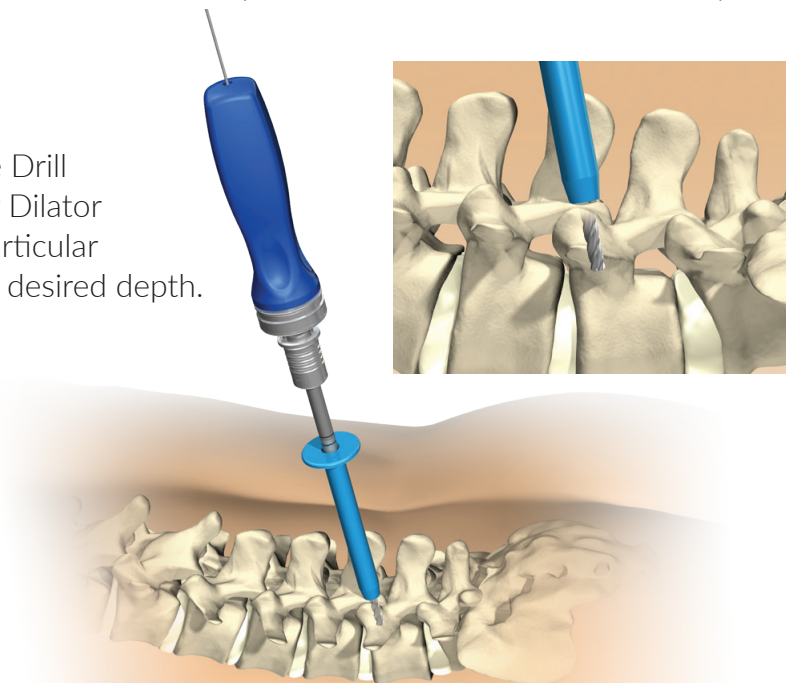
CAUTION - Do not advance the screw more than 5mm past the cortex of the lateral facet pillar.

Step 3: Drilling

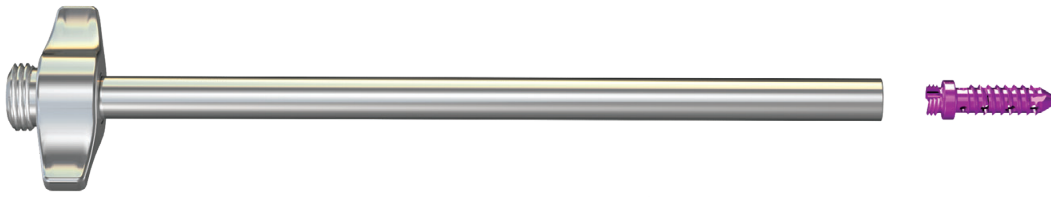
- Under fluoroscopic guidance, place the Drill over the K-wire and through the Outer Dilator (if using). Then place over the inferior articular process just medial to the joint. Drill to desired depth.

CAUTION - Care must be taken to avoid over-drilling into any structure outside of the cortical bone margin.

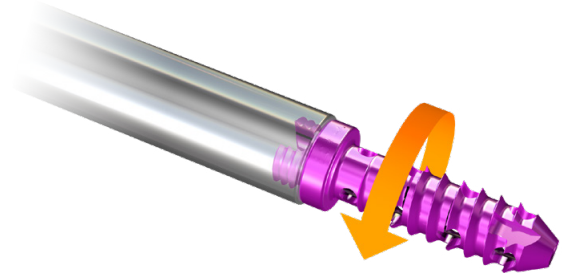
Note: Drill is approximately 8% undersized.



Step 4: Screw Loading



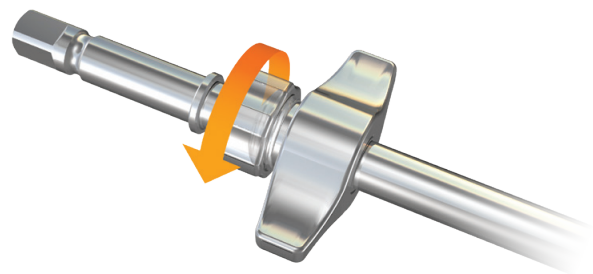
- After confirmation of preferred screw length, rotate the Short Access Sleeve counterclockwise onto the screw.



Step 5: Screwdriver Assembly



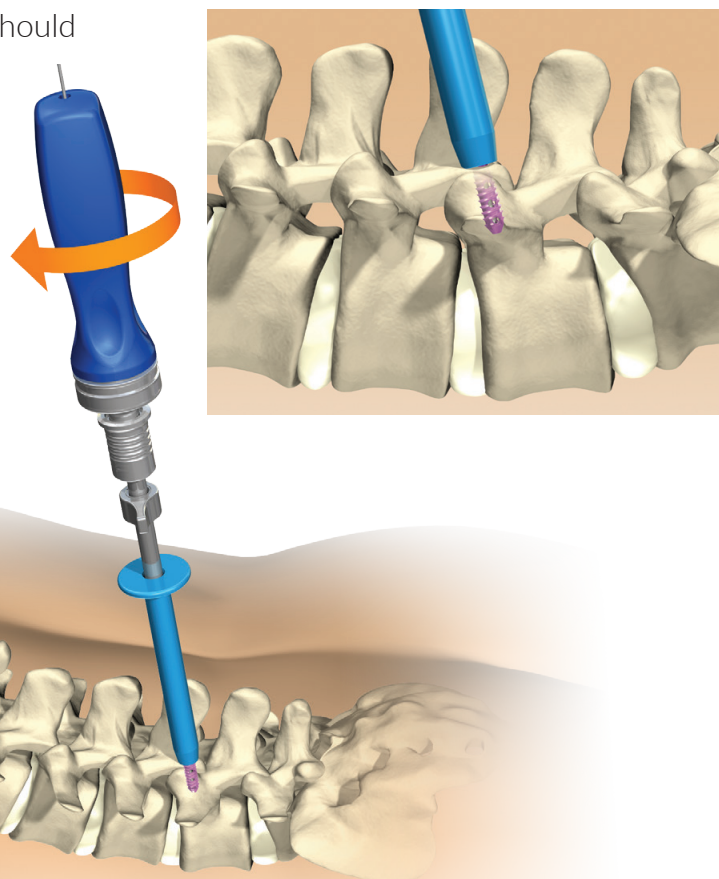
- Slide Short Screwdriver Shaft into Short Access Sleeve and align with screw and distal tip. Turn locking nut clockwise to tighten and attach ratcheting Screwdriver Handle for final assembly.



Step 6: Screw Placement

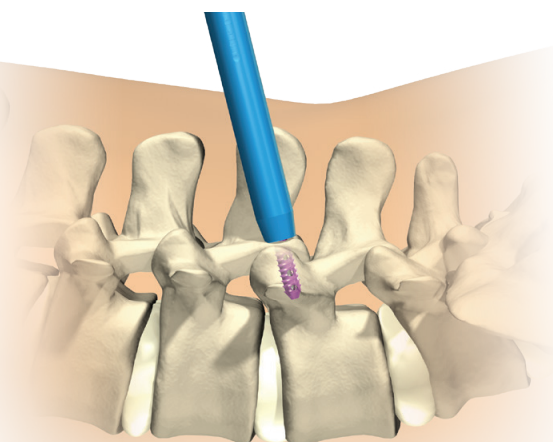
- Place the Screwdriver Shaft over the K-wire and through the Outer Dilator. The screw should be rotated gradually under fluoroscopic guidance to confirm distal entry into the inferior facet. The screw should be rotated until the screw head contacts the superior facet. Over-tightening of the screw can result in facet fracture.

CAUTION - Bilateral screws are required for adequate fixation strength.



Step 7: Screw Placement Confirmation

- Intraoperative fluoroscopy should be performed to confirm final screw position. Additionally, neurophysiologic testing of the screw is recommended to confirm that there is no nerve conductance.

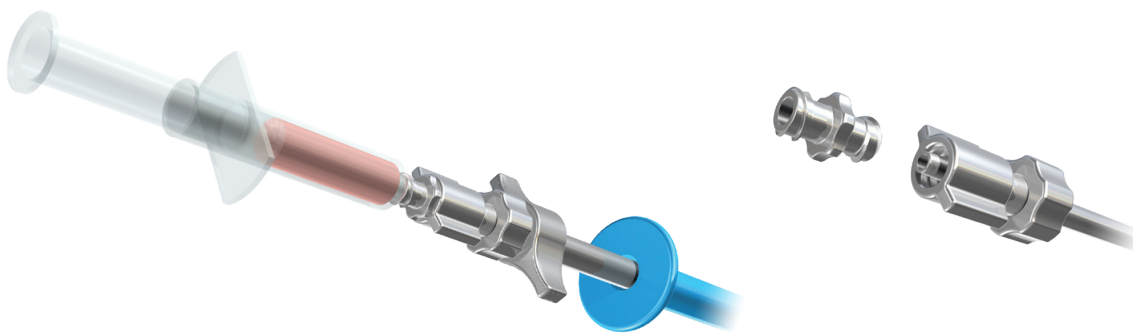


Step 8: Bone Marrow Aspirate Delivery

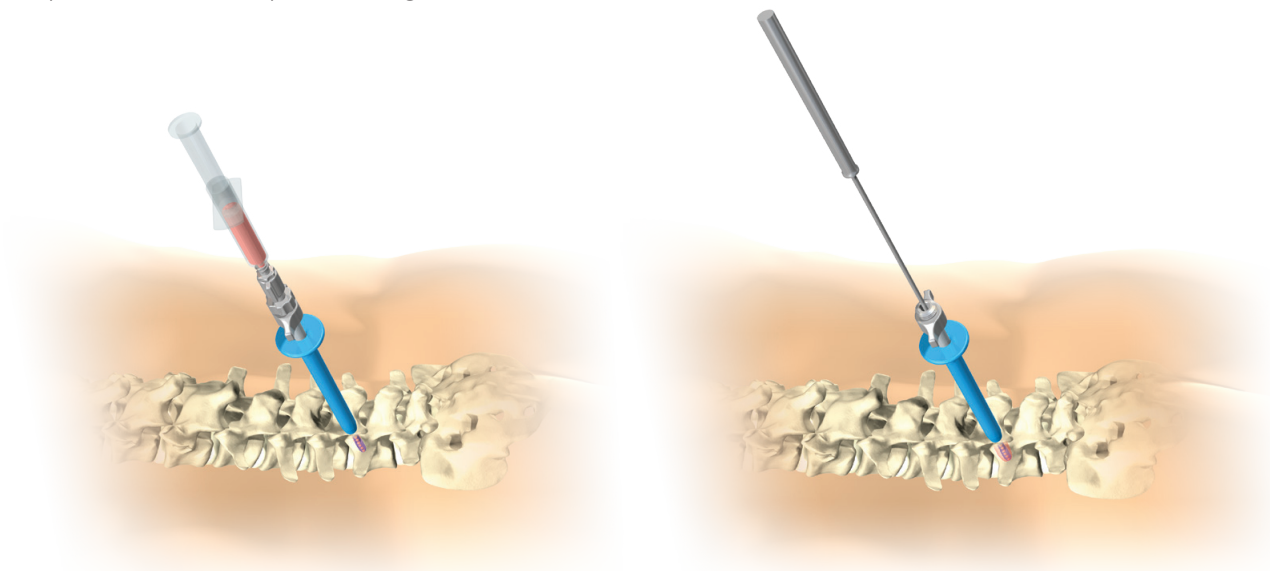
1. Remove K-wire, then remove Short Screwdriver Shaft by rotating the locking nut counterclockwise.
2. Slide the Short Luer Shaft through the Short Access Sleeve and align with screw at distal tip. You may need to rotate the Luer shaft up to 180 degrees in order to get full engagement into the implanted screw. Rotate the locking nut, clockwise, to tighten for proper placement.



3. Attach syringe to the Short Luer Shaft directly or use Female to Female Adapter, if needed.



4. Deliver the BMA into the Luer Shaft. Remove the syringe and Short Luer Shaft, then pack into the implant using the Graft Packer, if desired.



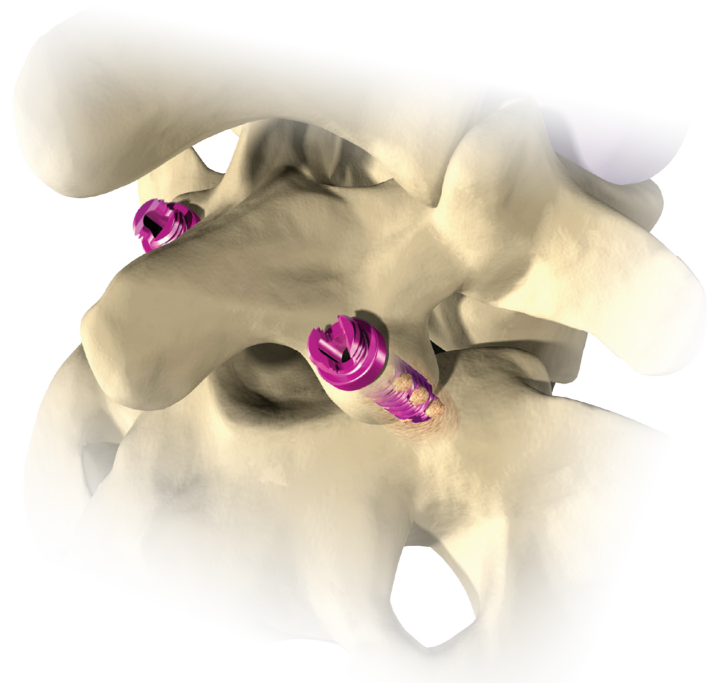
Note : Graft Packer has positive stop at implant head to prevent over-insertion.

Bone Marrow Aspirate Volumes (approximate)

Part Number	Screw Length	Volume (cc)
X076-0029	20mm, Single Thread	0.23
X076-0020	25mm, Dual Thread	0.27
X076-0021	30mm, Dual Thread	0.32
X076-0022	35mm, Dual Thread	0.37
X076-0023	40mm, Dual Thread	0.41
X076-0024	45mm, Dual Thread	0.46

Step 9: Final Construct

- Remove the Short Luer Shaft and Short Access Sleeve and close the surgical site.



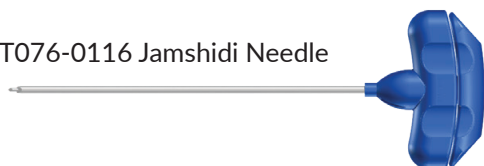
System Removal/Revision

If the screw needs to be repositioned or removed, reattach the screw (refer to Steps 8 and 9) then rotate Screwdriver Shaft counterclockwise to remove.

ZYFIX® INSTRUMENTS

Percutaneous Approach Instruments

T076-0116 Jamshidi Needle



T076-0103 K-wire, Trocar



T076-0108 K-wire, Blunt



T076-0113 Cannula Cleaner



T076-0051 Outer Dilator, Radiolucent, 7.25in., Long



X063-0055 Mallet



T076-0050 Inner Dilator



N6000473 Ratcheting Screwdriver Handle



T076-0043 4 Flute Drill, Cannulated



T076-0044 Tap, Cannulated



T076-0040 Access Sleeve, Long



T076-0063 Screwdriver Shaft, Long



T076-0065 Luer Shaft, Long



T076-0054 Graft Packer



ZYFIX® INSTRUMENTS

Open Approach Instruments

T076-0103 K-wire, Trocar



T076-0108 K-wire, Blunt



T076-0113 Cannula Cleaner



T076-0050 Inner Dilator



T076-0052 Outer Dilator, Radiolucent, 4.5in., Short



T076-0046 2 Flute Drill, Non-cannulated, Short



T076-0059 Access Sleeve, Short



T076-0064 Screwdriver Shaft, Short



T076-0066 Luer Shaft, Short



N6000473 Ratcheting Screwdriver Handle



T076-0054 Graft Packer



Optional Instruments

T076-0075 Luer Adapter, Female to Female



X063-0066 Rasp



T076-0056 Bone Awl



NOTES

NOTES

NOTES



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INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

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