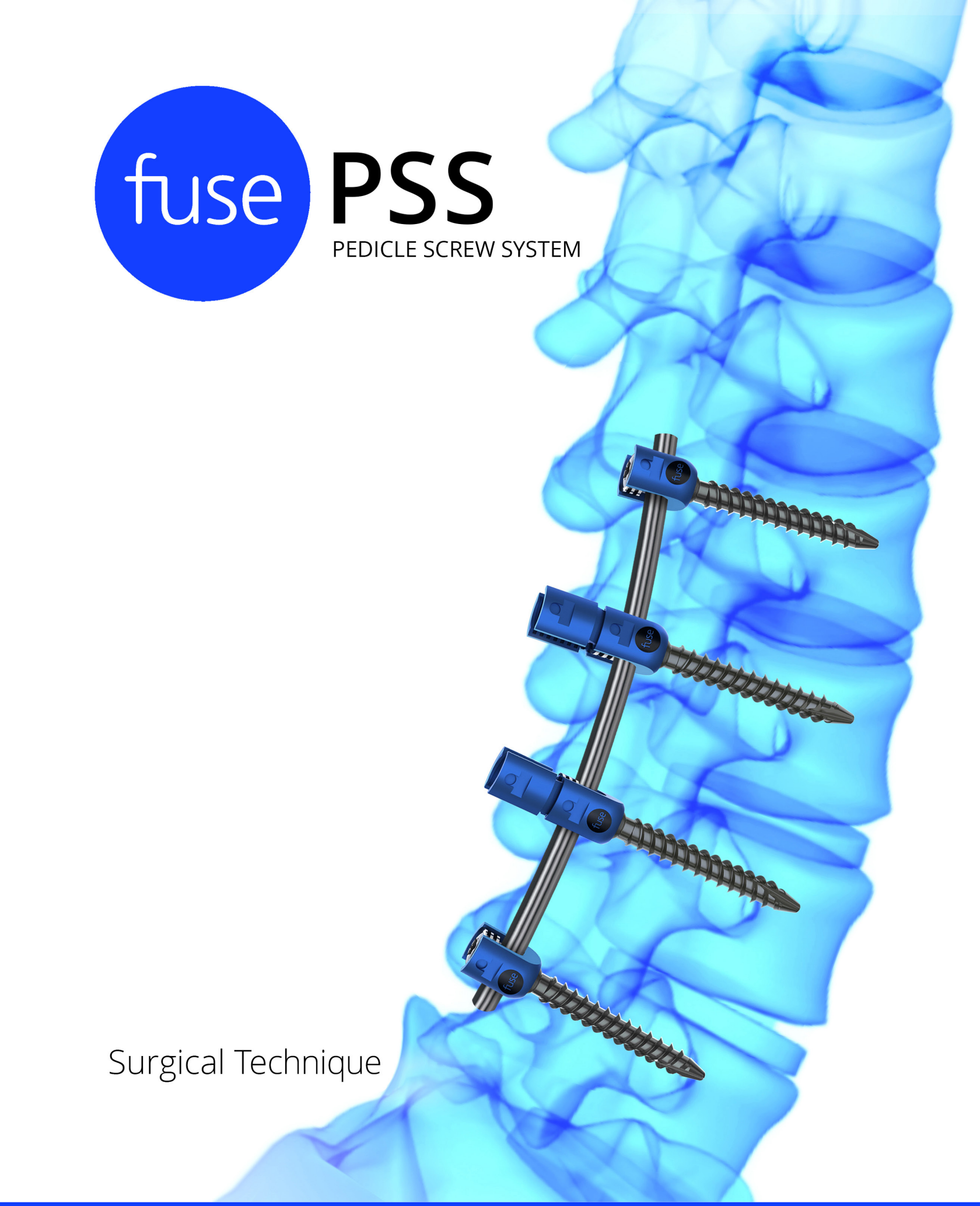
fuse

PSS

PEDICLE SCREW SYSTEM



Surgical Technique

Open Pedicle Screw System

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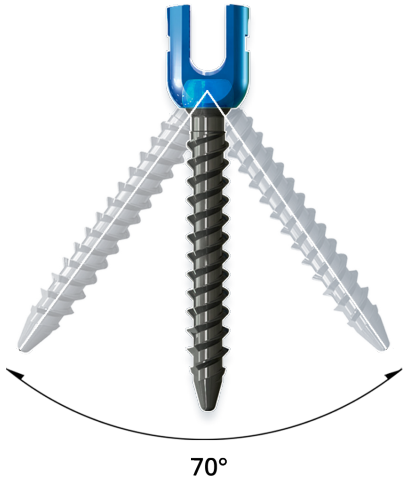
1. DESCRIPTION OF DEVICE

The Fuse PSS Pedicle Screw System consists of implants and instruments including screws, rods, set screws, and dedicated surgical instruments. It is a spinal fixation system designed to provide vertebral stabilization of spinal segments in the thoracic, lumbar, and sacral regions. Manufactured from Ti6Al-4V, the Fuse PSS Pedicle Screw System conforms to ASTM F136 standards.

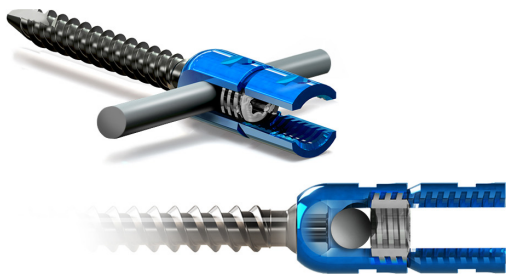
2. INDICATIONS

The Fuse PSS Pedicle Screw System is intended to provide stabilization and immobilization of spinal segments in patients being treated for various acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (DDD), spondylolisthesis; trauma; spinal stenosis; curvatures; and failed previous fusion.



Low-top Features

- Low profile
- Polyaxial design
- Dual-lead thread
- Self-tapping



Mid-top Features

- 20mm internal reduction
- Breakaway tabs

Cannulated options available

3. SURGICAL TECHNIQUE

3.1 Preoperative Preparation:

- Make sure to review and inspect all instrumentation/implants prior to sterilization.
- Replace and/or add any needed instruments or implants for surgery.

3.2 Surgical Preparation:

Position patient prone on table while applying fluoroscopy and preoperative imaging. Determine the location of the incision (typically 3-4.5 cm from the midline over the lumbosacral junction) and make incision. Dissect the paraspinous muscles laterally and clear all soft tissue from the posterior elements to the transverse process in a subperiosteal fashion. Utilize image guidance to aid in the placement of posterior instrumentation. Probe fluoroscopy can be used for pedicle screw placement and positioning.

3.3 Preparation of Pedicle:

After exposing the pedicle screw entry points, create a starting hole by tapping on the **Bone Awl** using a mallet to advance it into the pedicle. Confirm proper placement and desired depth within the vertebral body using AP/ lateral imaging (Figure 1).

The Bone Awl inserts to a depth of 20mm

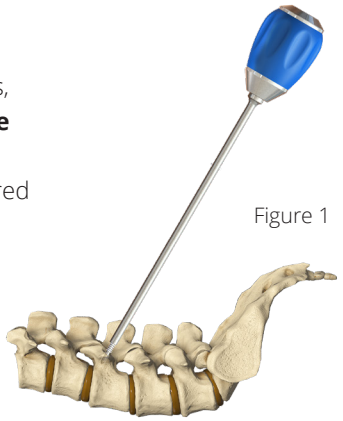


Figure 1

3.4 Probe Pedicle:

Determine optimal **Probe** for the approach. Rotate the Probe upon entry to create a path of least resistance. Utilizing the calibration on the shaft, measure depth from the initial entry point (Figure 2).

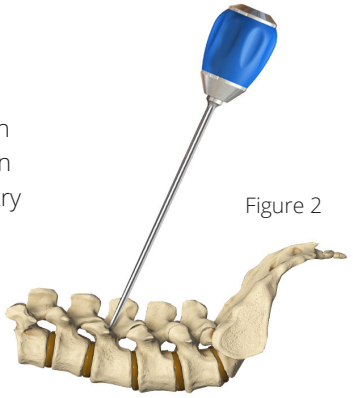


Figure 2

3.5 Test the Pathway:

Utilize the **Straight Sounding Probe** or **Curved Sounding Probe** to check the pathway and verify the pedicle wall has not been breached (Figure 3).

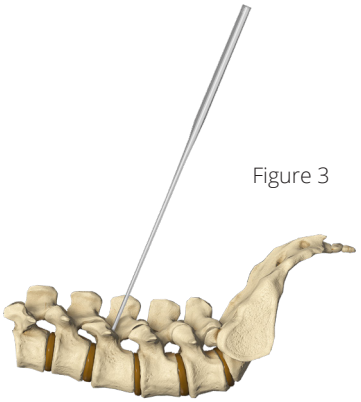


Figure 3

1. Bone Awl
   FZ-I-039

2. Lenke Probe Straight
   FZ-I-022

3. Lenke Probe Curved
   FZ-I-041

4. Sounding Probe
   Straight
   FZ-I-020

5. Sounding Probe
   Curved
   FZ-I-021

3.6 Screw Insertion:

Depending on bone density at the insertion site, a **Tap** may be utilized to ease the insertion of the screw. Load the Tap to the **Ratcheting Straight Handle** or **Ratcheting T-Handle** (Figure 4).

Figure 4

Advance the **Tap** clockwise into the insertion site until the desired depth has been reached. Remove Tap by rotating counter clockwise (Figure 5).

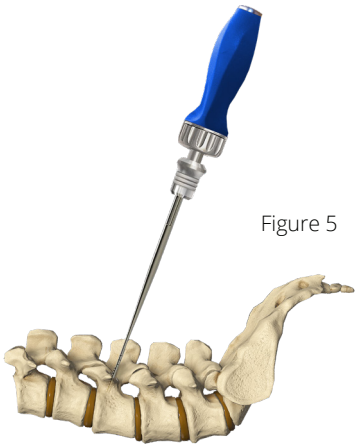


Figure 5

Connect the **Open Screw Driver** to the Straight or T-Handle. Load the **Pedicle Screw** tulip to the tip of the Open Screw Driver and secure the screw by turning the dial on the driver clockwise to thread it securely in the tulip (Figure 6).

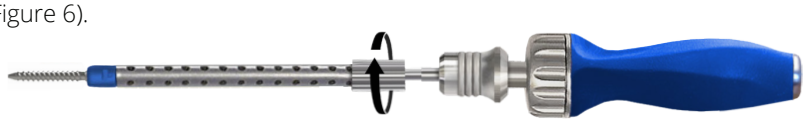


Figure 6

If **Mid Top Reduction Screws** are desired, use the **Screw Driver, MIS/ Reduction** and load into the Mid Top Reduction Screw tulip in the same manner as the Low Top Screw (Figure 7).

Figure 7

6. Ratcheting Straight Handle
   FZ-I-010

7. Ratcheting T-Handle
   FZ-I-049

8. Tap, Non-Cannulated
   FZ-I-045, 055, 065, or 075)

9. Tap, Cannulated
   FZ-I-045c, 055c, 065c, or 075c)

10. Screw Driver, Open
    (Low-top screws only)
    FZ-I-003

11. Screw Driver, MIS/ Reduction
    (Mid-top screws only)
    FZ-I-050

3.6 Screw Insertion cont...

Advance the screw into the pedicle until the tulip head of the screw seats to desired position at the base of the facet joint. Rotate the dial on the Screwdriver counterclockwise to release the screw. Repeat these steps for each additional screw (Figure 8).

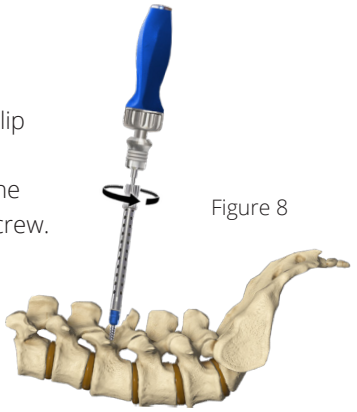


Figure 8

For depth adjustments, connect the **Screw Adjuster** to either the Ratcheting Straight Handle or Ratcheting T-Handle and rotate in correspondence with the desired depth under fluoroscopy (Figure 9).

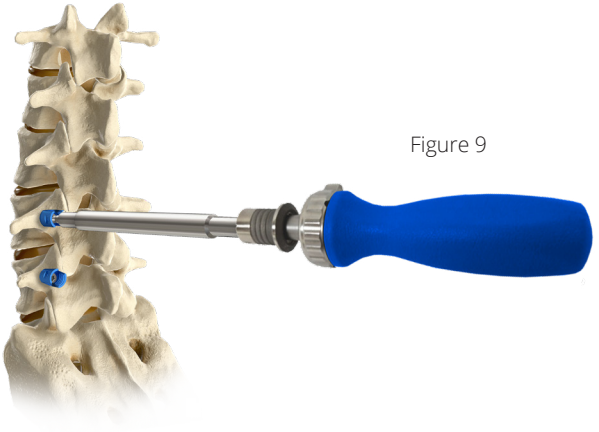


Figure 9

3.7 Tulip Positioning:

Prior to inserting rods, align tulip windows by rotating the tulip at its base using the **Tulip Positioner** (Figure 10).

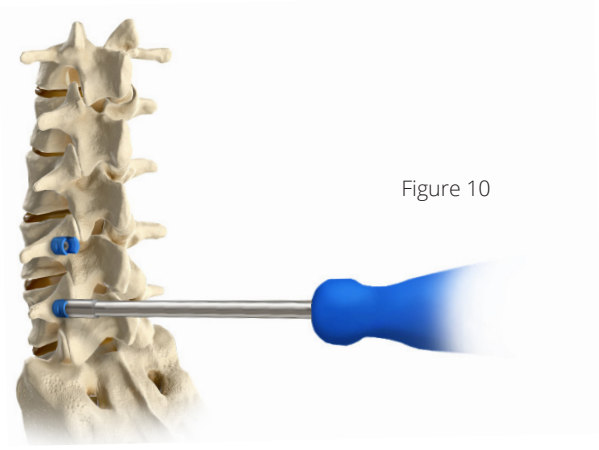


Figure 10

12. Screw Adjuster
    FZ-I-046

13. Tulip Positioner/
    Rod Pusher
    FZ-I-016

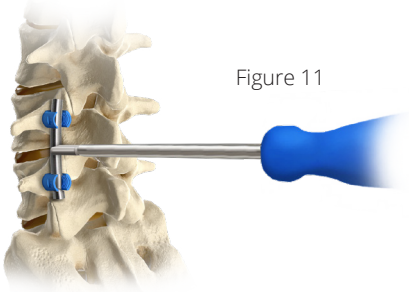
3.8 Rod Selection/Insertion:

Determine the desired rod length by using the **Rod Template**. Insert Rod using the **Rod Holder**. Use **Rod Bender** if additional contouring is required (Figure 11).

Figure 11

3.9 Rod Reduction:

Option 1: Rod Pusher. Use the **Tulip Positioner/Rod Pusher** to seat the rod within the tulip (Figure 11).



Option 2: Rod Rocker. Secure the **Rod Rocker** to the tulip head by squeezing the handles. Use the Rod Rocker to lever the rod into the tulip of the opposing pedicle screw (Figure 12).

Figure 12

Option 3: Rod Reducer. Secure the **Rod Reducer** to the tulip and rotate the handle clockwise to reduce the rod into the tulip (Figure 13).

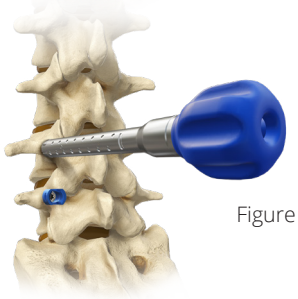


Figure 13

3.10 Set Cap Insertion:

After the rods have been seated within the pedicle screws, place the **Set Caps** onto the tip of the **Set Cap Driver** (Figure 14) or **Set Cap Driver Quick Connect** with the Ratcheting Straight or T-Handle Driver, and insert into the head of the Pedicle Screws.

Figure 14

14. Rod Template
FZ-I-040

15. Rod Holder
FZ-I-011

16. Rod Bender
FZ-I-036

17. Rod Rocker
FZ-I-044

18. Rod Reducer
FZ-I-047

19. Set Cap Driver, QC
FZ-I-002Q

20. Set Cap Driver
FZ-I-002

3.10 Set Cap Insertion cont.:

Screw the Set Cap into the head of the Pedicle Screw in a clockwise direction (Figure 15). If Reduction Screws were used, ensure all Set Caps are fully reduced and provisionally tightened. Failure to do so provides opportunity for misalignment.

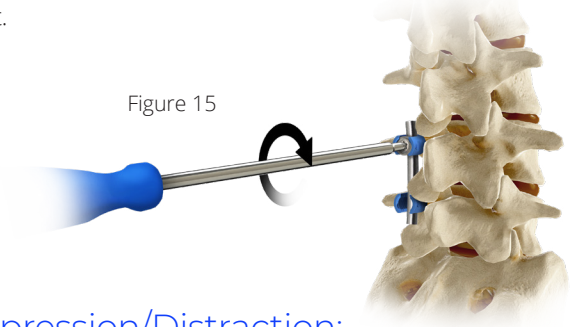


Figure 15

3.11 Compression/Distraction:

When a **Distractor** or **Compressor** is needed, tighten one Set Cap completely with the Set Cap Driver (this end will be the fixed point). Then, place your Set Cap Driver on the opposing screw's Set Cap and turn it counterclockwise 1/4 turn. Place the Distractor or Compressor on the construct and squeeze the handles to create the desired position, then tighten the other Set Cap (Figure 16).

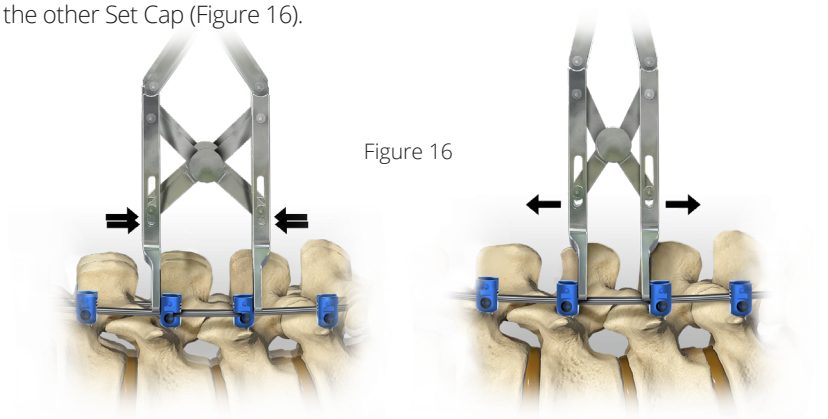


Figure 16

3.12 Final Tightening:

Insert the **Counter Torque** over the rod and screw head (Figure 17). Assemble the **Final Tightener** onto the **Torque Limiting T-Handle.** While engaging the Set Caps with the Final Tightener, rotate the Final Tightener clockwise until the Torque Limiting T-Handle produces an audible click, indicating the final tightening is achieved (Figure 18).

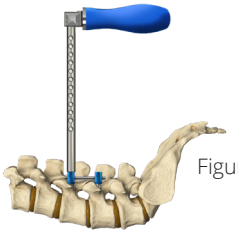


Figure 17

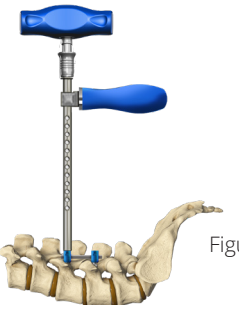


Figure 18

Always ensure the Counter Torque is fully seated on the rod and the instrument is perpendicular to the rod during the Set Cap tightening.

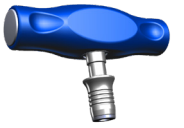
21. Compressor
FZ-I-018

22. Distractor
FZ-I-019

23. Counter Torque
FZ-I-037

24. Final Tightener
FZ-I-004

25. Torque Limiting T-Handle
FZ-I-006



3.13 Reduction Tab Removal:

When completion of the construct is finalized, if Mid Top Reduction screws were implanted, remove the reduction tabs from the screw heads by using the **Reduction Tab Breaking Pliers**. Repeat for all screws with tabs prior to close (Figure 19).

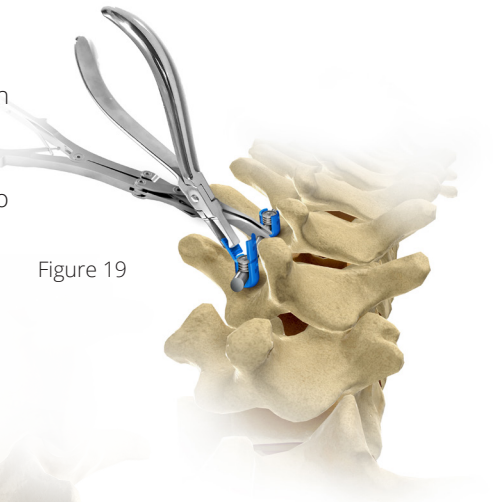
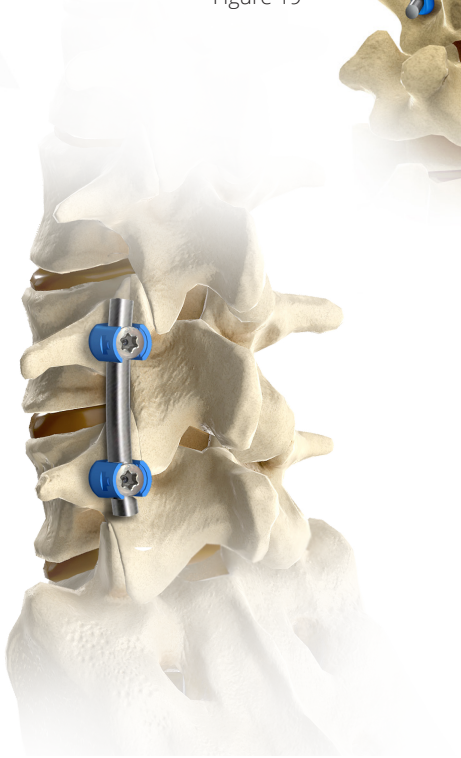


Figure 19

26. Reduction Tab Breaking Pliers FZ-I-051

Final Look:



3.14 Construct Removal:

Insert the Counter Torque over the rod and Set Cap. Using the Final Tightener with a Ratcheting T-Handle, turn the Ratcheting T-Handle counterclockwise to loosen the Set Caps. Once loosened, the Set Cap Driver can also be used to remove the Set Cap from the pedicle screw through the Counter Torque. Once the Set Caps are removed, remove the rods. Utilize the Open Screwdriver with the Ratcheting Straight or T-Handle to back out and remove the pedicle screws.

FUSE PSS IMPLANTS

Low-Top Screws

Catalog No.	Dimensions
	Diameter x Length
FZ-LN4525A*	4.5mm x 25mm
FZ-LN4530A*	4.5mm x 30mm
FZ-LN4535A*	4.5mm x 35mm
FZ-LN4540A*	4.5mm x 40mm
FZ-LN4545A*	4.5mm x 45mm
FZ-LN4550A*	4.5mm x 50mm
FZ-LN5530A	5.5mm x 30mm
FZ-LN5535A	5.5mm x 35mm
FZ-LN5540A	5.5mm x 40mm
FZ-LN5545A	5.5mm x 45mm
FZ-LN5550A	5.5mm x 50mm
FZ-LN6530A	6.5mm x 30mm
FZ-LN6535A	6.5mm x 35mm
FZ-LN6540A	6.5mm x 40mm
FZ-LN6545A	6.5mm x 45mm
FZ-LN6550A	6.5mm x 50mm
FZ-LN6555A	6.5mm x 55mm
FZ-LN7530A	7.5mm x 30mm
FZ-LN7535A	7.5mm x 35mm
FZ-LN7540A	7.5mm x 40mm
FZ-LN7545A	7.5mm x 45mm
FZ-LN7550A	7.5mm x 50mm
FZ-LN7555A	7.5mm x 55mm

** Special Request*

Mid-Top Reduction Screws

Catalog No.	Dimensions
	Diameter x Length
FZ-MN5530A	5.5mm x 30mm
FZ-MN5535A	5.5mm x 35mm
FZ-MN5540A	5.5mm x 40mm
FZ-MN5545A	5.5mm x 45mm
FZ-MN5550A	5.5mm x 50mm
FZ-MN6530A	6.5mm x 30mm
FZ-MN6535A	6.5mm x 35mm
FZ-MN6540A	6.5mm x 40mm
FZ-MN6545A	6.5mm x 45mm
FZ-MN6550A	6.5mm x 50mm
FZ-MN6555A	6.5mm x 55mm
FZ-MN7530A	7.5mm x 30mm
FZ-MN7535A	7.5mm x 35mm
FZ-MN7540A	7.5mm x 40mm
FZ-MN7545A	7.5mm x 45mm
FZ-MN7550A	7.5mm x 50mm
FZ-MN7555A	7.5mm x 55mm

Set Caps

Catalog No.	Description
FZ-SC100	Set Cap

Open Curved Rods

Catalog No.	Dimensions
	Diameter x Length
FZ-TC5535	5.5mm x 35mm
FZ-TC5540	5.5mm x 40mm
FZ-TC5545	5.5mm x 45mm
FZ-TC5550	5.5mm x 50mm
FZ-TC5555	5.5mm x 55mm
FZ-TC5560	5.5mm x 60mm
FZ-TC5565	5.5mm x 65mm
FZ-TC5570	5.5mm x 70mm
FZ-TC5580	5.5mm x 80mm
FZ-TC5590	5.5mm x 90mm
FZ-TC55100	5.5mm x 100mm
FZ-TC55110	5.5mm x 110mm
FZ-TC55120	5.5mm x 120mm
FZ-TC55130	5.5mm x 130mm
FZ-TC55140	5.5mm x 140mm
FZ-TC55150	5.5mm x 150mm

Straight Rods

Catalog No.	Dimensions
	Diameter x Length
FZ-T55150	5.5mm x 150mm
FZ-T55200	5.5mm x 200mm
FZ-T55300	5.5mm x 300mm
FZ-T55400	5.5mm x 400mm
FZ-T55500	5.5mm x 500mm

FUSE PSS INSTRUMENTS

Catalog No.	Description
FZ-I-002	Set Cap Driver
FZ-I-002Q	Set Cap Driver, QC
FZ-I-003	Screw Driver, Open
FZ-I-004	Final Tightener
FZ-I-006	Torque Limiting T-Handle
FZ-I-010	Ratcheting Straight Handle
FZ-I-049	Ratcheting T-Handle
FZ-I-011	Rod Holder
FZ-I-016	Tulip Positioner / Rod Pusher
FZ-I-018	Compressor
FZ-I-019	Distractor
FZ-I-020	Sounding Probe Straight
FZ-I-021	Sounding Probe Curved
FZ-I-022	Lenke Probe Straight
FZ-I-041	Lenke Probe Curved
FZ-I-036	Rod Bender
FZ-I-037	Counter Torque
FZ-I-039	Bone Awl
FZ-I-042	In-Situ Rod Bender
FZ-I-044	Rod Rocker

Catalog No.	Description
FZ-I-046	Screw Adjuster
FZ-I-047	Rod Reducer
FZ-I-045	4.5mm Tap, Non-Cannulated
FZ-I-045C	4.5mm Tap, Cannulated
FZ-I-055	5.5mm Tap, Non-Cannulated
FZ-I-055C	5.5mm Tap, Cannulated
FZ-I-065	6.5mm Tap, Non-Cannulated
FZ-I-065C	6.5mm Tap, Cannulated
FZ-I-075	7.5mm Tap, Non-Cannulated
FZ-I-075C	7.5mm Tap, Cannulated

ADDITIONAL INSTRUMENTS

Catalog No.	Description
FZ-I-040	Rod Template
FZ-I-050	Screw Driver, MIS/Reduction
FZ-I-051	Reduction Tab Breaking Pliers

WARNINGS & PRECAUTIONS

CONTRAINDICATIONS

Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system. Any entity or condition that totally precludes the possibility of fusion (i.e., cancer, kidney dialysis, or osteopenia) is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation, activity level, or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bone healing and may be at higher risk for implant failure.

WARNINGS

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.
The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to indefinitely withstand the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.
Internal fixation appliances are load-sharing devices, which are used to maintain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will dictate, among other conditions, the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. MIXING METALS CAN CAUSE CORROSION.
There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metal.

4. PATIENT SELECTION.
In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

A. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

WARNINGS & PRECAUTIONS (Cont'd)

B. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

C. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

D. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.

E. Foreign body sensitivity. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

F. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

1. SURGICAL IMPLANTS MUST NEVER BE REUSED.
An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.
Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

3. CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING.
If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

WARNINGS & PRECAUTIONS (Cont'd)

4. ADEQUATELY INSTRUCT THE PATIENT.
Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as a normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

POSSIBLE ADVERSE EFFECTS

1. Bending or fracture of the implant.
2. Loosening of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Infection, early or late.
5. Nonunion, delayed union.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
9. Bursitis.
10. Paralysis.
11. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
12. Death.
13. Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
14. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
15. Damage to lymphatic vessels and/or lymphatic fluid exudation.
16. Spinal cord impingement or damage.
17. Fracture of bone structures.
18. Degenerative changes or instability in segments adjacent to fused vertebral levels.

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