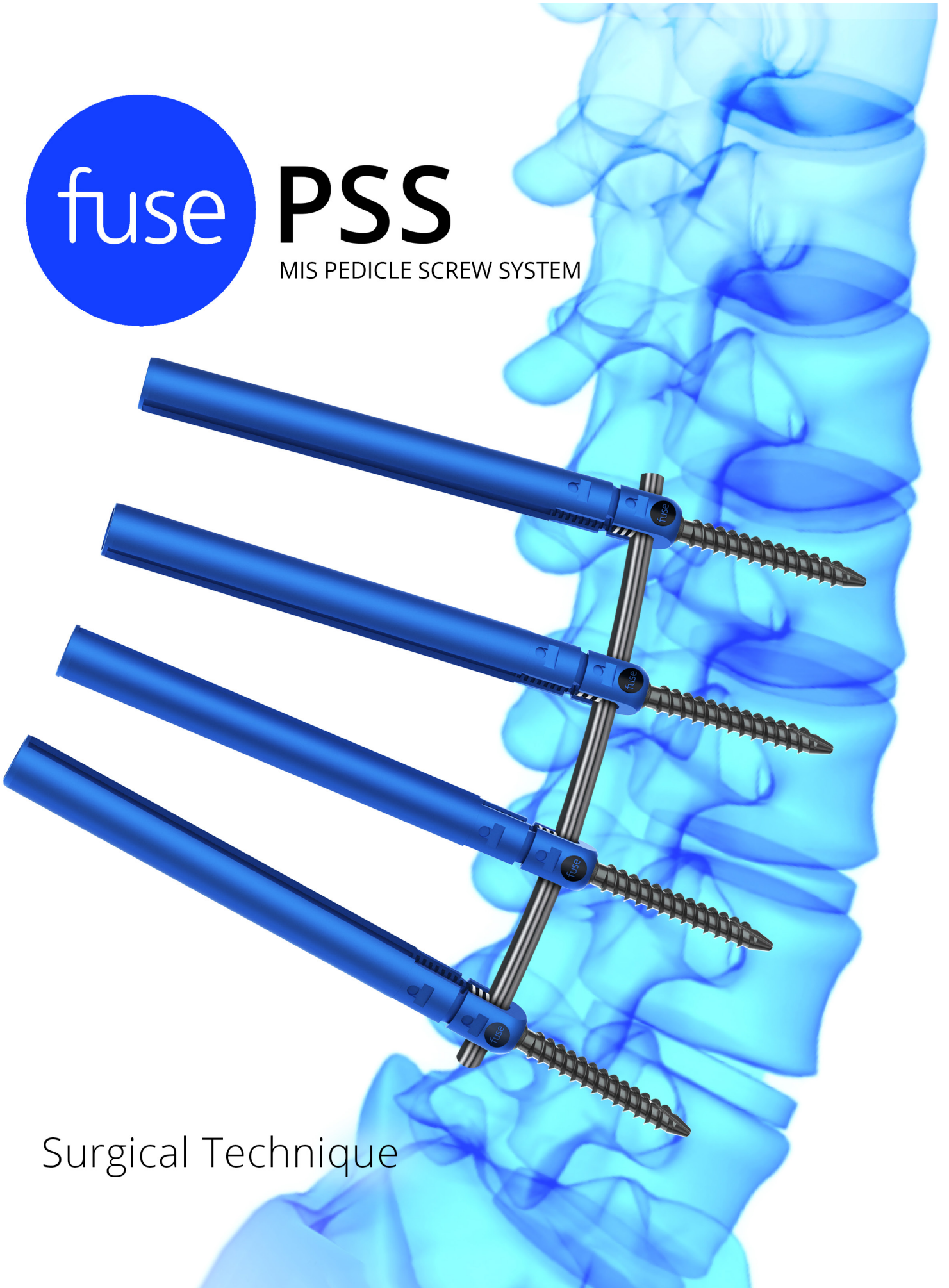
fuse

PSS

MIS PEDICLE SCREW SYSTEM



Surgical Technique

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1. DESCRIPTION OF DEVICE

The Fuse Pedicle Screw System consists of implants and instruments such as 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. It is manufactured from Ti6Al-4V alloy conforming to ASTM F136.

2. INDICATIONS

The Fuse 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.

3. SURGICAL TECHNIQUE

3.1 Preparation of Pedicle:

Insert a Jam Shidi/targeting needle through the skin to the intersection of the facet and transverse process to the level of the pedicle. Verify the Jam Shidi is safely and correctly placed using imaging. Once confirmed, advance the needle partially through the pedicle until ideal depth is reached, typically 1cm past the posterior margin of the vertebral body. Confirm location/placement with imaging.

Remove the inner stylus/trocar in order to insert a **K-Wire** to the desired depth (50% of the vertebral body). Remove the Jam Shidi, while maintaining the K-Wire at the desired depth (Figure 1).

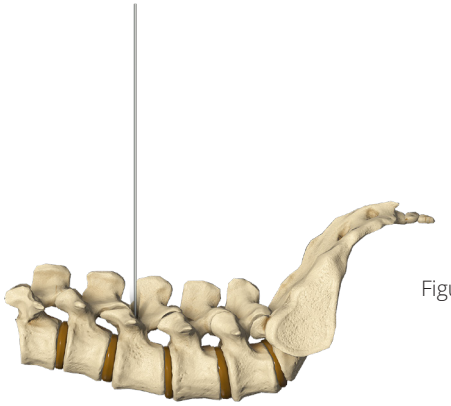

Figure 1

3.2 Dilation:

While keeping the K-Wire steady, place the **Small Dilator** over the K-Wire through the incision (Figure 2). Advance the Small Dilator over trough the tissue while twisting and directing it toward the pedicle. Verify dilator positioning with imaging. Slide the **Medium Dilator** over the Small Dilator, with the **Large Dilator** to follow. Confirm seating by utilizing the imaging and removed inner dilators, leaving just the large. (Figure 3).

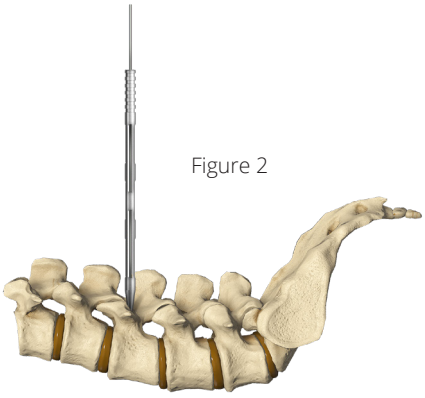

Figure 2

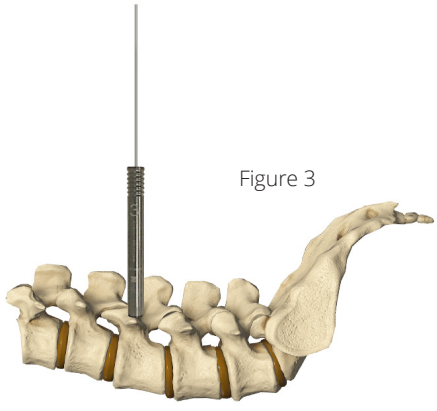

Figure 3

1. K-Wire
   FZ-K55N18-1

2. Small Dilator
   FZ-1-013

3. Medium Dilator
   FZ-1-014

4. Large Dilator
   FZ-1-015

3.3 Screw Insertion:

Prepare the pedicle canal using the **Cannulated Tap**. Select the properly sized tap according to screw diameter as seen in the table below. Note: Taps are already undersized by .5mm. Connect the Cannulated Tap onto the **Ratcheting Straight Handle** or the **Ratcheting T-Handle** and insert over the K-Wire through the Dilator. Rotate the handle clockwise to tap down to the desired depth, making sure the K-Wire does not advance as the tap advances. (Figure 4).

Screw Diameter (mm)	Screw Tap Size (mm)
5.5	5.5
6.5	6.5
7.5	7.5

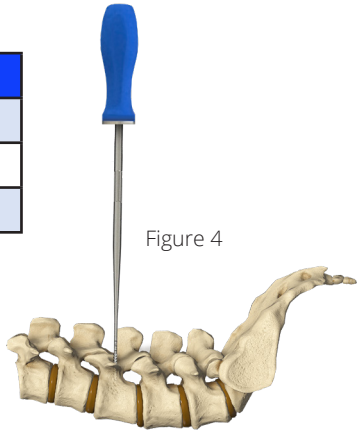

Figure 4

Select desired screw and insert onto to **MIS Screwdriver** (Figure 5). Seat tip of driver into the tulip of the screw. Rotate the barrel clockwise until tight. The tip of the screw is then placed over the K-Wire and into the prepared pathway and screwed down until the last thread is flush with the bony surface (Figure 6). Make sure the K-Wire does not advance as the screw advances.

Figure 5

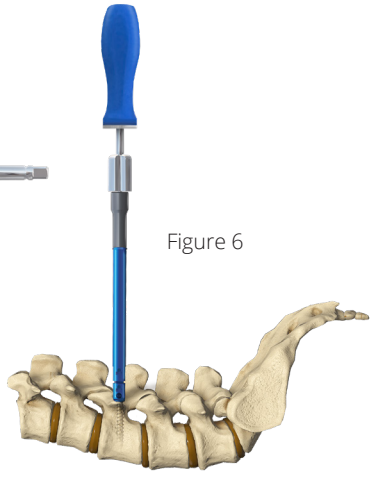

Figure 6

Once the screw is inserted, the MIS Screwdriver is disengaged from the screw by rotating the barrel counterclockwise and the K-Wire and dilator are removed. Repeat for additional screws.

5. Ratcheting Straight Handle
FZ-1-010

6. Ratcheting T-Handle
FZ-1-006

7. Cannulated Tap
FZ-1-0XXC

8. Screw Driver MIS/ Reduction
FZ-1-050

3.4 Screw Adjustment:

If required, utilize the **Screw Adjuster** to adjust the screw insertion depth. Attach either the Straight Handle Driver or T-Handle Driver to the Screw Adjuster and insert through the top of the screw tabs into the tulip of the screw. Rotate either clockwise or counterclockwise to advance or retract the screw for desired depth (Figure 7).

Figure 7

4.4 Tulip Positioning:

Align tulip windows by rotating the tulip at its base using the **Tulip Positioner** (Figure 8).

Figure 8

9. Screw Adjuster
   FZ-1-046

10. Tulip Positioner/Rod Pusher
    FZ-1-016

4.5 Rod Selection/Insertion:

Determine the desired rod length by using the **MIS Rod Caliper**, which recommends going up by 5mm from the displayed measurement. (Figure 9).

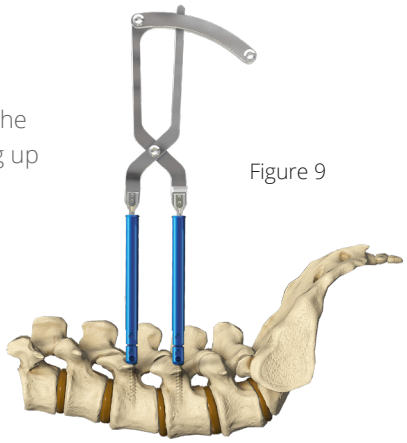

Figure 9

Once the rod is ready for insertion, load the rod onto the **MIS Rod Inserter.** Load the **MIS Curved Rod** onto the MIS Rod Inserter by attaching the notched end into the slot on the Rod Inserter and rotating the locking mechanism clockwise (Figure 10). With the rod securely attached, insert the rod through the extended tabs and into the pedicle screws until fully seated into the screw heads (Figure 11).

Figure 10

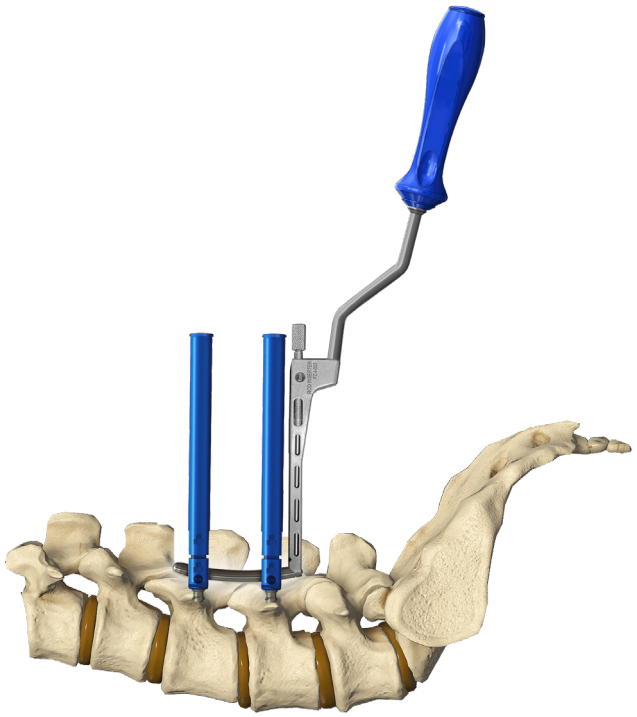

Figure 11

11. MIS Rod Caliper
    FZ-1-048

12. MIS Rod Inserter
    FZ-1-033

13. MIS Curved Rod
    FZ-MCSSXX

4.6 Set Cap Insertion:

Screw the **Set Cap** into the head of the pedicle screw in a clockwise direction (Figure 12), ensuring all Set Caps are fully reduced and provisionally tightened. Failure to do so provides opportunity for misalignment.

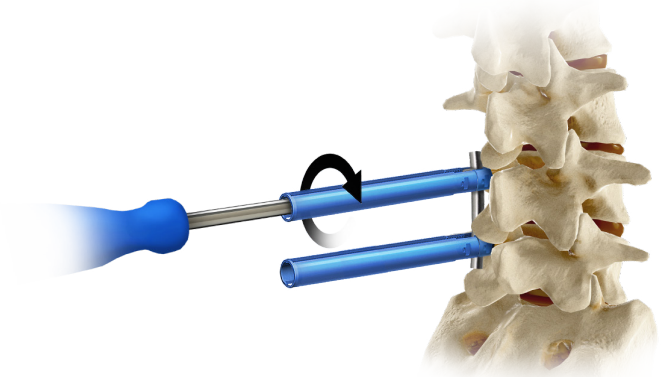

Figure 12

4.7 Reduction:

Perform reduction using the inner threads of the break away towers. If additional reduction is needed use the dial down MIS Rod Reducer (Figure 13).

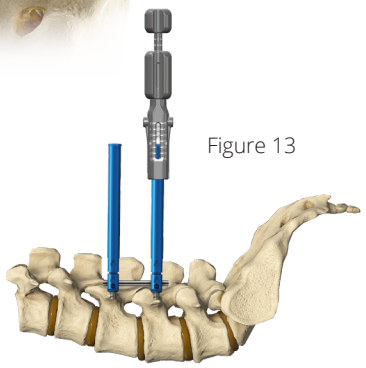

Figure 13

4.8 Compression/Distraction:

Compression and distraction can occur by using the MIS Compressor/ Distractor after final tightening of at least one Set Cap to the rod after final tightening of at least one Set Cap to the rod.

4.9 Final Tightening:

Insert the **Counter Torque** over the rod. Load the **Final Tightener** onto the **Torque Limiting T-Handle** (Figure 14). Seat the Final Tightener into the Set Caps and rotate clockwise until the Torque Limiting T-Handle produces an audible click, indicating that final tightening has been achieved (Figure 15).

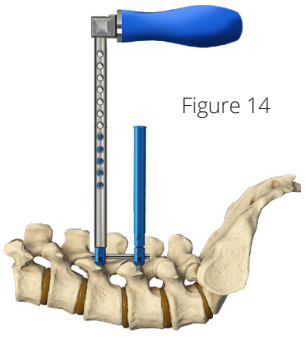

Figure 14

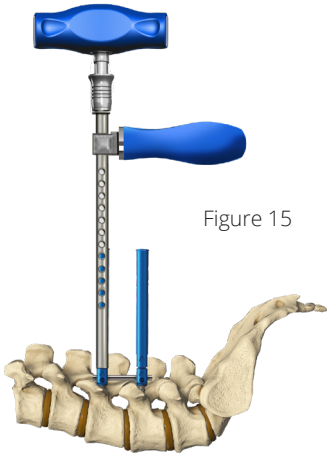

Figure 15

14. Set Cap Driver
FZ-1-002

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

16. Set Cap | FZ-SC100

17. MIS Rod Reducer
FZ-I-052

18. MIS Compressor/ Distractor
FZ-1-032

19. Counter Torque
FZ-1-037

20. Final Tightener
FZ-1-004

21. Torque Limiting T Handle
FZ-I-006

4.10 Extended Tab Removal:

Use the **Cutting Pliers** first to snip the ring at the top of the extended tabs on the MIS Pedicle Screw, then use the **Barrel Tab Breaker** for tab removal by moving side to side until they break free (Figure 16).

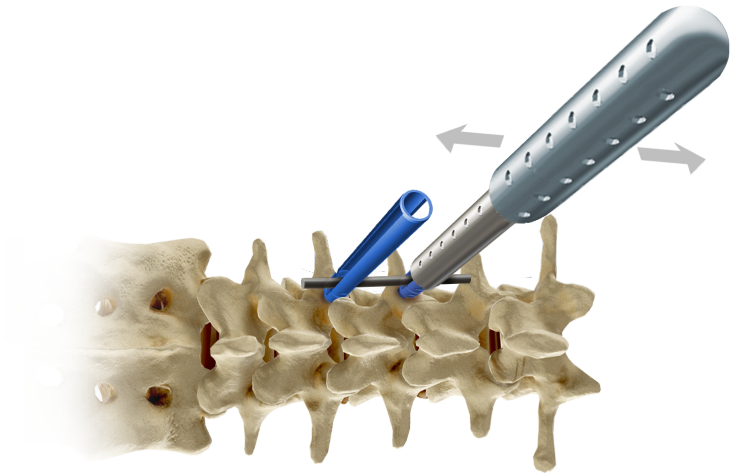

Figure 16

4.11 Removal:

Insert the **Counter Torque** over the rod and set cap. Load the Final Tightener onto the Ratcheting T Handle and" loosen the Set Caps by turning counterclockwise, loosen the set caps by turing counterclockwise. The Set Cap Driver can then be used to remove the Set Cap from the pedicle screw and out of the Counter Torque. Once the Set Caps are removed, remove the rods. Utilize the Screwdriver, MIS / Reduction to remove the pedicle screws.

22. Cutting Pliers
FZ-1-005

23. Barrel Tab Breaker
FZ-1-012

FUSE CANNULATED PSS IMPLANTS

High-Top Screws

Catalog No.	Description
FZ-TC5535CA	5.5x35mm, Pedicle Screw Tall-Top MIS
FZ-TC5540CA	5.5x40mm, Pedicle Screw Tall-Top MIS
FZ-TC5545CA	5.5x45mm, Pedicle Screw Tall-Top MIS
FZ-TC5550CA	5.5x50mm, Pedicle Screw Tall-Top MIS
FZ-TC6530CA	6.5x30mm, Pedicle Screw Tall-Top MIS
FZ-TC6535CA	6.5x35mm, Pedicle Screw Tall-Top MIS
FZ-TC6540CA	6.5x40mm, Pedicle Screw Tall-Top MIS
FZ-TC6545CA	6.5x45mm, Pedicle Screw Tall-Top MIS
FZ-TC6550CA	6.5x50mm, Pedicle Screw Tall-Top MIS
FZ-TC6555CA	6.5x55mm, Pedicle Screw Tall-Top MIS
FZ-TC7530CA	7.5x30mm, Pedicle Screw Tall-Top MIS
FZ-TC7535CA	7.5x35mm, Pedicle Screw Tall-Top MIS
FZ-TC7540CA	7.5x40mm, Pedicle Screw Tall-Top MIS
FZ-TC7545CA	7.5x45mm, Pedicle Screw Tall-Top MIS
FZ-TC7550CA	7.5x50mm, Pedicle Screw Tall-Top MIS
FZ-TC7555CA	7.5x55mm, Pedicle Screw Tall-Top MIS

Straight Rods

Catalog No.	Description
K55N18-1	18in, Nitinol Blunt K-Wire
K55S18-1	18in, Stainless Blunt K-Wire
K55N24-1	24in, Nitinol Blunt K-Wire
K55S24-1	24in, Stainless Blunt K-Wire

Open Curved Rods

Catalog No.	Description
FZ-MC5540	5.5x40mm, Curved Rod MIS
FZ-MC5545	5.5x45mm, Curved Rod MIS
FZ-MC5550	5.5x50mm, Curved Rod MIS
FZ-MC5555	5.5x55mm, Curved Rod MIS
FZ-MC5560	5.5x60mm, Curved Rod MIS
FZ-MC5565	5.5x65mm, Curved Rod MIS
FZ-MC5570	5.5x70mm, Curved Rod MIS
FZ-MC5575	5.5x75mm, Curved Rod MIS
FZ-MC5580	5.5x80mm, Curved Rod MIS
FZ-MC5585	5.5x85mm, Curved Rod MIS
FZ-MC5590	5.5x90mm, Curved Rod MIS
FZ-MC5595	5.5x95mm, Curved Rod MIS
FZ-MC55100	5.5x100mm, Curved Rod MIS
FZ-MC55110	5.5x110mm, Curved Rod MIS
FZ-MC55120	5.5x120mm, Curved Rod MIS
FZ-MC55130	5.5x130mm, Curved Rod MIS
FZ-MC55140	5.5x140mm, Curved Rod MIS
FZ-MC55150	5.5x150mm, Curved Rod MIS

Set Caps

Catalog No.	Description
FZ-SC100	Set Cap

FUSE CANNULATED 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
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

IMPLANT SET INSTRUMENTS

Catalog No.	Description
FZ-I-005	Cutting Pliers
FZ-I-012	Barrel Tab Breaker
FZ-I-013	Dilator, Small
FZ-I-014	Dilator, Medium
FZ-I-015	Dilator, Large
FZ-I-033	MIS Rod Inserter
FZ-I-048	MIS Rod Caliper
FZ-I-050	Screw Driver, MIS/Reduction
FZ-I-032	MIS Compressor/Distractor
FZ-I-052	MIS Rod Reducer

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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Please refer to package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.

FPSS-STG-002 Rev A
DC-0485