INSTRUCTIONS FOR USE (IFU)

Fuse PSS Pedicle Screw System

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

Important Note To Operating Surgeon

FUSE PSS Pedicle Screw System implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves.

The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

Description:

The FUSE PSS Pedicle Screw System consists of longitudinal rods, and polyaxial screws. It is manufactured from Ti-6Al-4V alloy conforming to ASTM F136.

Indications:

The FUSE PSS Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; tumor; pseudoarthrosis; and failed previous fusion.

Cleaning:

1. Fuse instruments are provided clean but not sterile.
2. All instruments must be thoroughly cleaned after each use.
3. Instruments requiring disassembly for cleaning should be completely disassembled prior to cleaning.

From Point of Use:

Whenever possible, do not allow blood, debris or body fluids to dry on the instruments. For best results and to prolong the life of the surgical instruments, reprocess immediately after use.

Preparations for Cleaning:

1. All instruments with moving parts (e.g., knobs, triggers, hinges) should be placed in the open position to allow access of the cleaning fluid to area which are difficult to clean.
2. Soak the instruments for a minimum of 10 minutes in sterile water prior to the manual or automated cleaning process.
3. Use a soft cloth or a soft plastic bristle brush to remove any visible soil from the instruments prior to manual or automated cleaning. Use a soft plastic bristle brush or a pipe cleaner to remove soil from any inner lumens.

Manual Cleaning:

1. Upon completing the preparation for the cleaning procedure, prepare the Cidex® OPA solution per the Directions for Use label.
2. Immerse instruments in room temperature solution.
3. Manually agitate instruments in Cidex® OPA Solution for a minimum of 12 minutes at 20°C or higher to destroy all pathogenic microorganisms.
4. If visible soil is noted, scrub instruments with a soft plastic bristle brush and use brush or a pipe cleaner long enough to reach the entire length of any interior lumen(s) to remove the soil.
5. Rinse the instruments in USP <1231> purified water for 1.5 minutes.
6. Manually dry the device or hang the device to dry on an appropriate rack so as to not retain any water.
7. Inspect the instruments for visible soil.
8. If visible soil is noted, repeat the steps listed above.

Automated Cleaning:

1. Upon completing the preparation for the cleaning procedure, set up the washer/disinfector detergent dose per the Cidex® OPA Directions for Use label.
2. If visible soil is noted, scrub instruments with a soft plastic bristle brush and use the brush or pipe cleaner long enough to reach the entire length of any interior lumen(s) to remove the soil.
3. Place scrubbed instruments into the washer baskets.
4. Orient instruments in the automated washer's carriers as recommended by the washer manufacturer.
5. The following automated cleaning cycle is recommended (minimum recommended times are provided for each stage):
    a. Pre-Wash 1: cold potable water, 2 minutes
    b. Enzyme/Detergent treatment:
        i. Spray with enszyme/detergent, 20 seconds
        ii. Soak, 1 minute
        iii. Rinse with cold potable water, 15 seconds
        iv. Rinse with cold potable water, 15 seconds
    c. Wash ≥ 65°C, 2 minutes using Cidex® OPA
    d. Rinse 1: hot potable water, 15 seconds
    e. Rinse 2: hot potable water, 15 seconds
    f. Rinse 3: hot potable water, 15 seconds
    g. Rinse 4: hot potable water, 15 seconds
    h. Thermal rinse ≥ 93°C, 1 minute
    i. Heated USP <1231> Purified Water Rinse 1: re-circulating 10 seconds

j. Heated USP <1231> Purified Water Rinse 2: non-re-circulating 10 seconds
k. Dry at 115°C, 7 minutes

6. Inspect the instruments for visible soil.
7. If visible soil is noted, repeat the above listed steps until no visible soil is noted.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage instruments. These solutions should not be used.

Note: Visually inspect instruments after cleaning and prior to each use. Discard or return to CPM Medical any instruments that are broken, discolored, corroded, have cracked components, pits, gouges, or are otherwise found defective. Do not use defective instruments.

Sterilization:

Implants and instruments of the FUSE PSS Pedicle Screw System are supplied clean and not sterile. Sterilization should be performed in the FUSE PSS Pedicle Screw System medical grade instrument tray or appropriate FDA-cleared sterilization packaging materials (pouch, wrap, etc.). ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components. In a properly functioning calibrated steam sterilizer effective sterilization may be achieved using the following parameters:

Method	Time	Temperature	Dry Time
Pre-Vacuum	4 minutes	270° F (132° C)	30 minutes

Usage:

WARNING: The safety and effectiveness of Fuse PSS Pedicle Screw System have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

PRECAUTION: The implantation of Fuse PSS Pedicle Screw System components should be performed only by experienced spinal surgeons with specific training in the use of this system and due to this being a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device. Refer to the individual system surgical technique manuals for additional important information. A surgical technique can be obtained from the local representative or CPM Medical Consultants, LLC.

The FUSE PSS Pedicle Screw System components should not be used with components from other manufacturers. Stainless steel components may interfere with the quality of imaging obtained using MRI.

During the surgical procedure, the rods may be cut to size and shaped to provide correction and maintain proper anatomic lordotic and kyphotic alignment.

After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the spinal pathology, for which implantation of these devices was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion, the devices cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure.

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

Postoperative Mobilization:

Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

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 or 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 bony healing and may be at higher risk for implant failure. See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this insert.

Warnings, Precautions and Possible Adverse Effects Concerning Temporary Metallic Internal Fixation Devices:

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

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 withstand indefinitely 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 obtain 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, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during 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, accelerates 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 metals.
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.
    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, orthopaedic 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 an extended period.
    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.
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 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 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 paraesthesia.
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 bony structures.
18. Degenerative changes or instability in segments adjacent to fused vertebral levels.

MR Safety Information

The FUSE PSS Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the FUSE PSS Pedicle Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Symbol Glossary

Symbol	Title/ Standard	Meaning
Rx only	21 CFR 801.109b Prescription Only	Indicates that a practitioner licensed by the law of the state in which the practitioner practices to use or order the use of the device
REF	ISO 15223-1 5.1.6 Catalogue Number	Indicates the manufacturers catalogue number so that the medical device can be identified.
LOT	ISO 15223-1 5.1.5 Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified
MATL	Material	Indicates the material of the device
QTY	Quantity	Indicates the quantity of devices.
	ISO 15223-1 5.4.2 Do not re-use	Indicates a medical device that is intended for one single use only.
	ISO 15223-1 5.2.8 Do not use if package is damaged	Indicates a product should not be used if the package is damaged or opened and the user should consult the instructions for use for additional information.
	ISO 15223-1 5.4.3 Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 5.4.3 Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
NON STERILE	ISO 15223-1 5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	ISO 15223-1 5.1.1 Manufacturer	Indicates the medical device manufacturer.
MD	ISO 15223-1 Medical Device Symbol	Indicates that the item is a medical device.
UDI	ISO 15223-1 5.7.10 Unique Device Identifier	Indicates a carrier that contains unique device identifier information.

Additional Information:

Comments, questions, or concerns regarding the use of this device should be directed to the following:

Website www.FuseMedical.Com
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Phone 469-862-3030
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