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CAUTION: Federal (USA)
Law Restricts This Device To
Sale By Or On The Order Of A
Physician.



Single Use Only



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0086

VALEO® PS PEDICLE SCREW SYSTEM

Like any other temporary internal fixation devices, VALEO® PS Pedicle Screw System spinal implants have a finite useful life. The patient's activity level has a significant impact on this useful life. Inform your patient that any activity increases the risk of loosening, bending, or breaking of the implant components. Instruct patients about postoperative activity restrictions and examine patients postoperatively to evaluate the fusion mass development and the implant status. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, tell the patient 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 pseudoarthrosis develops, or if patients have severe or multiple preoperative curves. You may remove these implants after bone fusion occurs. Discuss the possibility of a second surgical procedure with the patient and the risks associated with a second surgical procedure. If the implants do break, consider the patient's condition and the risks associated with the presence of the broken implant when deciding whether to remove them.

Description of Prosthesis

The VALEO® PS Pedicle Screw System is comprised of non-sterile, single use, titanium alloy components for creating an anterior or posterior spinal implant construct. The system attaches to the spine through a component system comprised of screws, hooks, and locking caps. The system is designed to stabilize the spine during the intervertebral fusion process.

Usage

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also in the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. Instruct the patient in the limitations of the metallic implant and warn the patient regarding weight bearing and body stresses on the appliance prior to firm bone healing. Warn the patient 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.

Do not use America® Spinal System components with components from other manufacturers.

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. Consider the patient's general medical condition and the potential risk to the patient of a second surgical procedure when deciding whether to remove the device.

Based on fatigue testing results, when using the VALEO® System components in a posterior construct, consider the implant levels, patient weight, patient activity level, other patient conditions, etc., which may impact system performance.

These devices are not intended or expected to be the only mechanism for spinal support. Without solid biological support provided by spinal fusion, the devices can not 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.

Indications

The VALEO® PS Pedicle Screw System is intended for noncervical pedicle fixation and noncervical nonpedicle fixation as an adjunct to fusion for the following acute and chronic instabilities or deformities for the T1-S1 vertebrae in skeletally mature patients: degenerative disc disease (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; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Contraindications

GENERAL CONTRAINDICATIONS include:

- ACTIVE SYSTEMIC INFECTION or an infection localized to the site of the proposed implantation.
- SEVERE OSTEOPOROSIS may prevent adequate fixation of screws and thus preclude the use of this or any other spinal instrumentation system.
- PATIENTS WHO HAVE BEEN SHOWN to be safely and predictably treated without internal fixation.
- OPEN WOUNDS.

RELATIVE CONTRAINDICATIONS include disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices. 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 may place undue stresses on the implant during bony healing and may be at higher risk for implant failure because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse.

POSTOPERATIVE MOBILIZATION Until X-rays confirm fusion mass maturation, external immobilization (such as bracing or casting) is recommended. Tell the patient not to place undue stress on the implant to avoid fixation failure.

Warnings and Cautions

THESE WARNINGS DO NOT include all possible adverse surgical effects, but are particular to metallic internal fixation devices. Explain general surgical risks to the patient before surgery.

WARNING The safety and effectiveness of pedicle screw spinal systems 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 neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Potential Risks

Identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

- CORRECT IMPLANT SELECTION IS VITAL.** Selecting the proper implant size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present implant size, shape, and strength limitations. 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.
- IMPLANTS CAN BREAK** when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that 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 among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.
- 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, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

Patient Selection

The following factors can be extremely important to the eventual success of the procedure:

- 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.
- SENILITY, MENTAL ILLNESS, ALCOHOLISM, OR DRUG ABUSE.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the device use, leading to implant failure or other complications.
- CERTAIN DEGENERATIVE DISEASES.** In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
- FOREIGN BODY SENSITIVITY.** No pre-operative 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.
- SMOKING.** Patients who smoke have been observed to experience higher rates of pseudoarthrosis 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.

WARNING: If bony fusion does not occur within an expected period of time, the screws may break due to the high and sustained loading of these devices. This has been noted in patients with pseudoarthrosis, delayed or non-union and can result in the need to revise the device(s).

Cautions

- ONLY EXPERIENCED SPINAL SURGEONS** with specific training in the use of this pedicle screw spinal system should implant pedicle screw spinal systems, because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- SURGICAL IMPLANTS MUST NEVER BE REUSED.** Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
- CORRECT IMPLANT HANDLING IS VITAL.** Only contour metal implants with proper equipment. Avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected.
- BENDING THE CONSTRUCT.** Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured contour a new construct correctly rather than reverse bending the over-contoured construct.
- IMPLANT REMOVAL AFTER HEALING.** If the device is not removed after the completion of its intended use, any of the following complications may occur:
 - CORROSION**, with localized tissue reaction or pain;
 - IMPLANT MIGRATION** resulting in injury;
 - RISK OF ADDITIONAL INJURY** from postoperative trauma;
 - BENDING, LOOSENING, AND/OR BREAKAGE**, which could make removal impractical or difficult;
 - PAIN, DISCOMFORT**, or abnormal sensations due to device presence;
 - POSSIBLE INCREASED RISK OF INFECTION**;
 - BONE LOSS** due to stress shielding. 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 or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove implant thus eliminating the risks involved in a second surgery.
- 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. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient 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

- NONUNION, DELAYED UNION.**
- IMPLANT BENDING** or fracture.
- IMPLANT LOOSENING.**
- METAL SENSITIVITY**, or allergic reaction to a foreign body.
- EARLY OR LATE INFECTION**.
- DECREASE IN BONE DENSITY** due to stress shielding.
- PAIN, DISCOMFORT**, or abnormal trauma due to device presence.
- NERVE DAMAGE** due to surgical scars or device presence. Neurological difficulties including radicular pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia.
- 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.
- DURAL TEARS** during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- BURSTITIS**.
- PARALYSIS**.
- ESOPHAGEAL PERFORATION**, erosion or irritation.
- SCREW BACK-OUT**, possibly leading to esophageal erosion, implant loosening, and/or reoperation for device removal.
- DAMAGE TO LYMPHATIC VESSELS** and/or lymphatic fluid exudation.
- SPINAL CORD IMPINGEMENT** or damage.
- FRACTURE OF BONY STRUCTURES**.
- DEGENERATIVE CHANGES** or instability in segments adjacent to fused vertebral levels.
- DEATH**.

Packaging and Sterility

In accordance with internal procedures, the components and associated instruments are packaged clean and non-sterile together in a metal or polymer sterilization case. Instruments and implants will be held in place by a variety of the following: metal, silicone, polymer and or nylon brackets, polymer or thermoplastic caddies and/or silicone mats. Sterilization cases will be labeled according to internal procedures. A variable quantity of cases will be placed with the Instructions for Use inside a shipping container. Distribution simulation testing has been conducted which simulates the potential hazards which may occur during high altitude transport, manual handling and vehicle transport. The shipping container is sufficient to withstand expected forces experienced during shipping.

The VALEO® Pedicle Screw implant components will be supplied non-sterile. All components are to be sterilized by the hospital prior to use by steam sterilization. The parameters for the steam sterilization are one of the three following methods:

	Method 1	Method 2	Method 3
Cycle	Unwrapped Pre-Vacuum	Wrapped Pre-Vacuum	Wrapped Gravity
Temperature	270°-275°F (132°-135°C)	270°-275°F (132°-135°C)	270°-275°F (132°-135°C)
Exposure	4 minutes	6 minutes	20 minutes

Validated by ISO 11134, AAMI TIR 12 to a SAL 10⁻⁶.