OsteoCentric® Pedicle Fastener System
Instructions for Use

Non-Sterile | Prescription Use Only | Do Not Reuse

IMPORTANT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

This document is designed to assist in using the OsteoCentric Pedicle Fastener System. It is not a reference for surgical techniques.

CAUTION

Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

Single-Use Device

As with all orthopedic implants, implants and implanted system components should never be reused under any circumstances. An implant, once used, should be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns which may lead to failure.

Device Description

The OsteoCentric Pedicle Fastener System is a system of fasteners, and rods for use in spinal fixation. The components are assembled by the surgeon into a construct to stabilize the spine during spinal fusion procedures. The Osteocentric Pedicle Fastener System includes components made of implant grate titanium alloy (Ti6Al4V ELI; ASTM F136).

Indications For Use

The OsteoCentric Pedicle Fastener System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The OsteoCentric Pedicle Fastener System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origins 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 in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the OsteoCentric Pedicle Fastener System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origins 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 in skeletally mature patients.

Contraindications

OsteoCentric Pedicle Fastener System components are contraindicated in the following patient situations:

1. Recent infection (systemic, spinal or localized);
2. Morbid obesity;
3. Mental illness;
4. Drug or alcohol abuse;
5. Fever or leukocytosis;
6. Pregnancy;
7. Metal sensitivity or allergy to implant materials;
8. Severe osteopenia;
9. Presence of congenital abnormalities;
10. Spinal anatomy, tumors or any other complication which prevents secure implantation or decreases the useful life of the device;
11. Any condition where the device will interfere with anatomical structures or physiological performance (including inadequate tissue coverage over the operative site) for pedicle fastener cases;
12. Missing or congenitally deformed pedicles of the fifth lumbar (L5) vertebrae;
13. Patients unable or unwilling to follow postoperative care instructions;
14. Any circumstances not described in the indications for use.

Warnings

1. The safety and effectiveness of the pedicle fastener system has 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 (grade 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 (pseudarthrosis). The safety and effectiveness of these devices for other conditions are unknown.
2. Mixing different metal types can accelerate the corrosion process. Stainless steel and titanium implants must not be used together when building a construct. Component parts from other manufacturers should not be used with the OsteoCentric Pedicle Fastener System. As with all spinal implants, components should never be reused under any circumstances.
3. The OsteoCentric Pedicle Fastener System is not intended as the sole means of spinal support. Its use without a bone graft or in cases that develop into a non- union will not be successful. No spinal implant can withstand the loads of the body without the development of a solid fusion mass the spinal implant will eventually bend, loosen or fracture.
4. Proper implant selection and patient compliance with post-operative precautions will greatly affect the surgical outcome. Patients who smoke have been shown to have an increased level of non-unions. Therefore, these patients should be advised of this fact and warned of the potential consequences.

Precautions

1. The implantation of pedicle fastener systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle fastener system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
2. The surgeon must confirm that all necessary implants and instruments are on hand for the planned surgical construct. The implant components should be handled and stored carefully and protected from any damage including corrosive environments. They should be carefully unpacked and inspected for any damage. The implants and instruments must be cleaned and sterilized before use.
3. The patient must be adequately instructed as to the risks and limitations of the implant as well as postoperative care and rehabilitation.
4. The patient should be instructed in the limitation of physical activities which would place excessive stresses on the implant or cause a delay of the healing process. The patient should also be instructed in the use of any required weight bearing or assist devices as well as in the proper methods of ambulation, climbing stairs, getting in/out of bed or other daily activities while minimizing rotational and bending stresses.
5. The surgeon must consider removal of the implant after healing as the implant can loosen, fracture or corrode even after fusion has occurred. The risks and benefits of a second surgery must be carefully evaluated.

Adverse Effects

While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of materials foreign to the body that are placed within the body to support potential fusion of the spine. However, due to the many biological, mechanical and physiochemical factors that affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Possible adverse effects include, but are not limited to the following:

- Bending, loosening or fracture of the implants or instruments
- Loss of fixation
- Sensitivity to a metal foreign body (including possible tumor formation)
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which might result in skin breakdown and/or wound complications
- Non-union or delayed union
- Infection
- Nerve or vascular damage due to surgical trauma (including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage)
- Gastrointestinal, urological and/or reproductive system compromise (including sterility, impotency and/or loss of consortium)
- Pain or discomfort
- Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra)
- Hemorrhage of the blood vessels and/or hematomas
- Malalignment of anatomical structures (including loss of proper spinal curvature, correction, reduction and/or height)

- Bursitis
- Bone graft donor site pain
- Inability to resume normal daily living activities
- Reoperation or revision
- Death

Implant Selection

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice, which depends on each patient. Patients' overweight may be responsible for additional stresses and strains on the device, which can speed up metal fatigue and/or lead to deformation or failure of the implants. The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods only is recommended if necessary, according to the surgical technique of each system. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods, which have been repeatedly or excessively contoured, must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the OsteoCentric Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

Preoperative

- Surgical Technique Guides may be requested.
- The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by OsteoCentric Spine. Example: The forces exerted when repositioning the instrument in-situ must not be excessive as this is likely to cause injury to the patient.
- To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable OsteoCentric Spine Surgical Technique Guide.
- Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.
- Unless otherwise specified on the label, the instruments may be reused after decontamination, cleaning, and sterilization.

Intraoperative

- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological function.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.

- The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to ensure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field.
- Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
- **Caution:** Do not over tap or use a fastener that is either too long or too large. Over tapping or using an incorrectly sized fastener may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If fasteners are being inserted into spinal pedicles, use as large a fastener diameter as will fit into each pedicle.
- Before closing the soft tissues, all of the locking fasteners should be tightened firmly. Recheck the tightness of all locking fasteners after finishing to be sure that none have loosened during the tightening of the other implants. Failure to do so may cause loosening of the other components.

Postoperative

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. The physician may recommend external support from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass. External immobilization by bracing or casting may be employed. The patient should be instructed regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants that may lead to fixation or implant failure and accompanying clinical problems. The patient should also be instructed to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

Cleaning and Decontamination

All instruments and implants are supplied to the health care facility clean but non-sterile. Implants are single use only but need to be sterilized before each use. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Implants that have been implanted and then removed must be discarded.

All packaging should be sealed and intact upon receipt. If the packaging or product is damaged, it should not be used and should be returned immediately.

1. Rinse the device with warm water for approximately two (2) minutes while brushing with a soft bristled brush to remove most or all of the visible gross debris from the device. Pay careful attention to any pivots, threads, recesses or crevices on the devices.
2. Ultrasonically clean the device with an enzymatic detergent for five (5) minutes. Scrub the devices using a cleaning brush to remove any visible debris from all crevices.
3. Rinse and flush the device for four (4) minutes with warm tap water.
4. Conduct final verification of the cleaning process by visually inspecting the device under normal room lighting conditions to verify that all of the foreign material has been removed.
5. Visually inspect all reusable devices for signs of wear and tear before each use. Any devices with corrosion, discoloration, or burrs should be disposed of properly

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

Sterilization

The OsteoCentric Pedicle Fastener System is supplied clean but not sterile. Sterilize the devices using the cases and trays provided. Sterilization should be achieved by high temperature steam. All packaging materials should be removed prior to sterilization. The following cycle has been validated for a sterility assurance level (SAL) of 10-6.

Method	Steam
Cycle Type	Pre-Vacuum
Temperature	132ºC (270ºF)
Full Cycle Time	4 minutes
Minimum Dry Time	60 minutes

After sterilization, remove the device from the autoclave and allow to cool. Ensure that the components are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

Other sterilization methods have not been validated and may damage the product resulting in a device malfunction, injury to the patient, or both.

Only use FDA-cleared sterilization wraps or another appropriate FDA-cleared accessory that has been validated to allow sterilant penetration and to subsequently maintain sterility.

The manufacturer and distributor assume no responsibility for cleaning and re-sterilization of reusable instruments performed by the individual or hospital.

Point of Use Care

Wipe blood and/or debris from device immediately following the surgical procedure to prevent it from drying onto the surface. Flush cannulated devices with water to prevent the drying of soil and/or debris to the inside. Soiled devices should be separated from non- contaminated devices to avoid contamination of personnel or surroundings. Devices should be covered with a towel dampened with water to prevent blood and/or debris from drying.

Single-use Device

Products intended for single-use must not be re-used. Contaminated implants must not be reprocessed. Any implant that has been contaminated (from contact with patient materials, physiological fluids or tissues) or damaged should never be used again and must be properly discarded according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Combination of Medical Devices

OsteoCentric has not tested compatibility between the Pedicle Fastener System and other devices provided by other manufacturers and assumes no liability in such instances.

MRI Safety Information

The OsteoCentric Pedicle Fastener System fasteners have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the OsteoCentric Pedicle Fastener System fasteners in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Packaging

The implants are delivered in packages; these must be intact at the time of receipt. The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

Storage and Handling

Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity. Handle all implants and instruments with care to prevent damage.

Product Complaints

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and/or its performance, should notify OsteoCentric Spine or its representative. Moreover, if a device has malfunctioned, OsteoCentric Spine or its representative must be advised immediately.

If an OsteoCentric Spine product has ever worked improperly and could have caused or contributed to the serious injury or death of a patient, the distributor or OsteoCentric Spine Representative must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please include the device name, reference number, lot number of the component(s), your name and address, and an exhaustive description of the event to help OsteoCentric Spine understand the causes of the complaint.

Product Information Disclosure

OSTEOCENTRIC SPINE HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. OSTEOCENTRIC SPINE EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. OSTEOCENTRIC SPINE SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. OSTEOCENTRIC SPINE NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. OSTEOCENTRIC SPINE INTENDS THAT THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS HAVING RECEIVED PROPER TRAINING IN THE USE OF THE DEVICE.

Symbols Glossary

Symbol	Symbol Title	Reference Number	Explanatory Text
	Catalogue number	5.1.6. (1)	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Batch Code	5.1.5. (1)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Prescription only	N/A	Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Consult instructions for use	5.4.3 (1)	Indicates the need for the user to consult the instructions for use.
	Do not reuse	5.4.2 (1)	Indicates a medical device that is not to be re-sterilized. (Implants, single-use instruments)
	Manufacturer	5.1.1.(1)	Indicates the medical device manufacturer.
	Date of Manufacture	5.1.3. (1)	Indicates the date when the medical device was manufactured.
	Non-Sterile	5.2.7 (1)	Indicates a medical device that has not been subjected to a sterilization process.
	Do not use if package is damaged - consult instructions for use	5.2.8 (1)	Indicates that a medical device should not be used if package has been opened or damaged. User should consult the instructions for use for additional information.
	Use-by Date	5.1.4 (1)	Indicates the date after which the medical device is not to be used.

(1) ISO 15223-1:2021(E) Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

Manufacturer

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To request a surgical technique guide, additional product information, or to report any adverse experience, please contact customer service at **1-800-969-0639**.

Note

This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice.

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