

**CAUTION:** USA law restricts this device to sale by or on the order of physician.

**IMPORTANT NOTE TO OPERATING SURGEON**

Osseus Black Diamond Pedicle Screw spinal 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 so lid 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 is 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**

**OSSEUS BLACK DIAMOND PEDICLE SCREW SPINE SYSTEM**

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

**INDICATIONS**

The Osseus Black Diamond 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 spondylolisthes is with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

The Osseus Black Diamond Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthes is (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis; and failed previous fusion.

**CLEANING/DISINFECTION**

**Preparation for cleaning:**

Clean the device until there is no visual contamination of the instruments directly after application (within a maximum of 2 h).

For this use only running water or a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency, be suitable for the disinfection of instruments and be compatible with the instruments (see "Material Resistance"). For manual removal of impurities only a soft brush or a clean soft t issue is to be used, in no case metal brushes or steel wool.

Rinse all lumens five (5) times by application of a single-use syringe (minimum volume 10ml).

**Manual cleaning:**

1. Soak instruments for a minimum of one (1) minute in enzymatic detergent.
2. Use a cleaning brush and/or cloth to remove visible soil.
3. Rinse thoroughly with warm water.
4. Check the instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible. Devices with challenging design features (cannulations, T-handle interfaces, hinged instruments, instruments with crevices):
  1. Immerse instrument and soak for a minimum of five (5) minutes in enzymatic detergent.
  2. Use cleaning brushes/ pipe cleaners to remove additional soil from challenging design features:
    - a. Scrub interfaces several times using a twisting action if possible. If components of the instrument can be retracted or moved, it is necessary to retract or open the part in order to access and clean these areas.
    - b. Scrub inside cannulas/holes with a tight-fitting brush or pipe cleaner using a twisting action. The brush or pipe cleaner should be of an appropriate size to ensure that full depth of the feature is reached.
    - c. Scrub around hinged/mating surface areas with a brush or pipe cleaner.
    - d. Scrub crevices using a cleaning brush or pipe cleaner.
3. Sonicate instrument in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner containing warm enzymatic detergent.
4. Rinse thoroughly with warm water, making sure to irrigate the challenging design features. If the components of the instrument are moveable or can be retracted , it is necessary to retract or open the part for thorough rinsing at these locations. Blind holes should be repeatedly filled and emptied.
5. Check instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

**Automatic washing:**

**Pre-cleaning:**

Devices without challenging design features:

- Pre-cleaning is not required for used reusable medical devices and containment devices that do not have dried-on soil. They can be placed directly into the automatic washer for cleaning.

**Devices with challenging design features:**

1. Immerse in enzymatic detergent for five minutes and scrub cannulas, holes, hinged mating surfaces, joints, and crevices with tight-fitting brushes (pipe cleaners, etc.) and where possible, use a twisting action.
2. Sonicate in fully opened position for a minimum of ten (10) minutes in warm enzymatic detergent.
3. Rinse with warm water.

**Automatic Washing Cycle:**

1. Load the instruments in the washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and cannulations and holes positioned to drain).
2. Run the automatic wash cycle- Minimum cycle parameters:
  - five minute cold prewash
  - five minute enzyme wash at 43° C minimum temperature
  - five minute detergent wash at 55° C minimum temperature
  - one minute rinse at 45° C minimum temperature
3. Check instruments for visible soil (see "Verifying cleaning"). Repeat cleaning if soil is visible and reinspect.

**Verifying cleaning:**

1. After thoroughly cleaning, visually inspect devices under normal lighting for the removal of visible soil.
2. For difficult to view design features, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood.
 

**Note:** Rinse the instruments thoroughly with warm water following hydrogen peroxide testing.
3. Repeat cleaning if not visibly clean and re-inspect.

**Inspection and function testing:**

Device/ Feature	Flaw
All reusable devices	Visually inspect for damage or wear.
Hinged instruments	Check for smooth movement of hinge without excessive "play."
Locking mechanisms	Check for action.
Cutting features	Check edges for distortion/large nicks. Edges should be continuous.
Trials	Articular surfaces should be smooth and free of cracks and deep nicks.
Mating parts	Check to make sure that mating parts fit together without complications.
Reamer/drill bits	Inspect "chuck" end for burrs and distortion that might hinder insertion into a drill.
Hammering surfaces	Inspect for burrs and large nicks.
Driving instruments	Inspect plastic ends for cracks and large nicks.
Metal surfaces	Inspect for corrosion and major deformation.

**Maintenance:**

- For devices with hinged/mating surfaces, surgical-grade lubricant should be added to the hinged area while in the open position.
- If the any of instruments exhibit any of the flaws listed above adequately dispose of the devices.

**STERILIZATION**

Implants and instruments of the Osseus Black Diamond Pedicle Screw System are supplied clean and not sterile. 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:

Cycle:	Pre-Vacuum
Temperature:	132° C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	40 Minutes
Condition:	Wrapped
Wrap:	The wrap should be FDA cleared for the proposed cycle specifications

**USAGE**

**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 spondylolisthes is (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthes is 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 pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is 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 Osseus Fusion Systems, LLC.

Osseus Black Diamond Pedicle Screw System components should not be used with components from other manufacturers. Stain less 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 system infection or infection localized to the site of the proposed implantation is 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 contra indication. 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

- MAGNETIC RESONANCE ENVIRONMENT.** The Osseus Black Diamond Pedicle Screw System intervertebral body fusion devices have not been evaluated for safety and compatibility in the MR environment. The Osseus Black Diamond Pedicle Screw System intervertebral body fusion devices have not been tested for heating or migration in the MR environment.
- 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.
- 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 the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
- 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 metals.
- PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
  - 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.
  - 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.
  - 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.
  - 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.

- 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.
- 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

- 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.
- 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.
- 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.
- 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

- Bending or fracture of implant.
- Loosening of the implant.
- Metal sensitivity or allergic reaction to a foreign body.
- Infection, early or late.
- Nonunion, delayed union.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
- Bursitis.
- Paralysis.
- 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.
- Death.
- 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.
- Screw backout, possibly leading to 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.

Symbol	Used For	Symbol	Used For
	Single use only		Catalog number
	Lot number		Use by YYYY-MM-DD or YYYY-MM
	See package insert for labeling limitations		Do not use if package is damaged or open
	Non-sterile. To be sterilized prior to use.		CAUTION: USA law restricts this device to sale by or on the order of physician.