The Royal Oak Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. The system is intended for posterior, pedicle fixation 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); spondylothesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fixation.

**CONTRAINdications:**

1. Disease conditions which 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.
2. Active systemic infection or infection localized to the site of the proposed implantation is contraindications to implantation.
3. 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 posterior spinal instrumentation system.
4. 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, pregnancy, certain degenerative disease, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may have, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant. See also the WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS sections of this insert.

**MATERIALS:**

The Royal Oak Pedicle Screw System components are provided in a surgical kit, which is comprised of implant caddies located within stainless steel and anodized aluminum instrument cases. All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use. The following sterilization cycle has been validated and shown to result in a 10^-6 Sterility Assurance Level (SAL).

**STERILIZATION:**

The Royal Oak Pedicle Screw System components are manufactured from implant grade titanium alloy (ASTM F136). Surgical instruments provided with the system are manufactured from stainless steel (ASTM F899). Do not use the Royal Oak Pedicle Screw System components with the components from any other system or company.

**CLEANING OF INSTRUMENTS:**

1. Within a maximum of two (2) hours after use, remove gross soil using absorbent paper wipes. Rinse with warm tap water for two (2) minutes.
2. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
3. Disassemble the implant driver by following the disassembly instructions. a. Assembled Device shown in Figure 1.

![Figure 1](Image)

b. Rotate inner shaft to align flats with tube body grooves and slide out as shown in Figure 2.

d. Remove inner shaft from tube body as shown in Figure 4.

e. Follow Cleaning Instructions to clean tube body and inner shaft shown separated in Figure 5.
4. Pre-Treatment required for any instrument(s) heavily soiled and/or containing dried organic material in accordance with Table 1.

<table>
<thead>
<tr>
<th>Step</th>
<th>Inspection</th>
<th>Enzymatic Wash</th>
<th>Hot Tap Water</th>
<th>Stenosis Prolystica 2X Concentrate (or equivalent) (1/8 oz/gal)</th>
<th>Steris Reliance® 444 Washer/Disinfector or equivalent</th>
<th>Load instruments such that contact is avoided and articulating instruments are in the open position.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pre-Treatment</td>
<td>Add one (1) ounce of Enzol® (or equivalent) to one (1) gallon of tap water. Using a soft bristle brush, clean the instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process.</td>
<td>04:00</td>
<td>Hot Tap Water</td>
<td>Steris Prolystica 2X Concentrate (or equivalent) (1/8 oz/gal)</td>
<td>Steris Prolystica 2X Concentrate Alkaline Cleaner (or equivalent) (1/8 oz/gal)</td>
<td>Automated Cleaning Parameters</td>
</tr>
</tbody>
</table>
| 2. Ultrasonic Clean (if required) | Add one (1) ounce of Enzol® (or equivalent) and one (1) gallon of warm tap water to an ultrasonic cleaner. Completely submerge instruments and sonicate for ten (10) minutes. | 02:00 | 65.5°C | Steris Prolystica 2X Concentrate Alkaline Cleaner (or equivalent) (1/8 oz/gal) | Not Applicable | Sterilization validation: Steam Cycle: Pre Vacuum Temperature: 270°F (132°C) Exposure Time: 4 minutes Dry Time: 30 minutes Wrap: 2 times utilizing FDA cleared wrap instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Instruments used in surgery should be re-sterilized after surgery. Implants should not be used as templates in surgery.

**POSTOPERATIVE MOBILIZATION:**

Careful patient handling for two (2) to four (4) months post-operatively is very important while the fusion mass matures and becomes able to share load with the implant. Until X-rays confirm maturation of the fusion mass, external mobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implant are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure. In younger patients, once the fusion mass has healed, the implants may be removed to allow the fused bone to return to a better state of load transfer. This is, as with all patient care, left to the discretion of the operating surgeon.
WARNINGs, PRECAUTIONS, AND ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES:

Following are specific warnings, precautions, and 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. In the U.S.A., this product has labeling limitations.
2. 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 neurologic impairment, fracture, dislocation, sclerosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
3. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines. Potential risks identified with the use of this device system, which may require additional surgery, include:
   a) Device component fracture.
   b) Loss of fixation.
   c) Non-union.
   d) Fracture of the vertebra.
   e) Neurological injury.
   f) Vascular or visceral injury.
4. 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.
5. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree of 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.
6. 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 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 compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with other metal objects, must be made from like or compatible metals.
7. 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 substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the device.
   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 relief.
   e) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
   f) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

WARNINGS, PRECAUTIONS, AND ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES:

POSSIBLE ADVERSE EFFECTS:
1. Non-union, delayed union.
2. Bending or fracture of implant. Fraying, kinking loosening, bending or breaking of any or all of the cable implant components.
3. Loosening of the implant.
4. Metal sensitivity or allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Loss of proper spinal curvature, correction height and/or reduction.
9. Cable cutting through soft osteoporotic, osteogenic, or cancellous bone.
10. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
12. Dural leak.
13. Paralysis.
15. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

LIMITED WARRANTY:
Royal Oak Pedicle Screw System products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than two (2) years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Royal Oak Medical Devices for current information.