2. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzoll® 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
   ![Figure 1](image1)

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

   Figure 2
   ![Figure 2](image2)

   c. Rotate inner shaft 90 degrees to align large flats with groove as shown in Figure 3.

   Figure 3
   ![Figure 3](image3)

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

   Figure 4
   ![Figure 4](image4)

   e. Follow Cleaning Instructions to clean tube body and inner shaft shown separated in Figure 5.

   Figure 5
   ![Figure 5](image5)

4. Pre-Treatment required for any instrument(s) heavily soiled and/or containing dried organic material in accordance with Table 1.

   Table 1 Cleaning Instructions

<table>
<thead>
<tr>
<th>Step</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   1. Pre-Treatment
      Rinse in warm running tap water until all traces of cleaning solution are removed. Visually inspect for any remaining soil and repeat the above steps if necessary. Allow to dry, and then transfer to the cleaning step.

   2. Ultrasonic Clean (if required)
      Add one (1) oz. of Enzoll® (or equivalent) and one (1) gallon of warm tap water to an ultrasonic cleaner. Completely submerge instruments and sonicate for ten (10) minutes.

   3. Ultrasonic Rinse
      To remove the detergent, thoroughly rinse each instrument with deionized water including all holes and cannulations. Inspect each instrument for evidence of organic matter. Repeat the sonication and rinse if needed.

   4. Automated Washer
      Place instrument(s) in an automated washer (e.g. Steris Reliance® 444 Washer/Disinfector or equivalent). Load instruments such that contact is avoided and articulating instruments are in the open position.

   Automated Cleaning Parameters

<table>
<thead>
<tr>
<th>Step</th>
<th>Time (mm:ss)</th>
<th>Temp. (°C)</th>
<th>Cleaning Agent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Enzymatic Wash</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hot Tap Water</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Steris Prolystica 2X Concentrate (or equivalent) (1/8 oz./gal)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wash</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>65.5°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Steris Prolystica 2X Concentrate Alkaline Cleaner (or equivalent) (1/8 oz./gal)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rinse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>70°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>80°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

   5. Inspection
      Visually inspect each instrument for evidence of organic matter. Repeat the cleaning process if necessary. If instruments are wet, use a lint-free wipe to dry.

   Inspection:
   1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
   2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation. Instruments with moving parts should be operated to check correct operation (medical grade lubricating oil suitable for steam sterilization can be applied as required).
   3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your sales representative for a replacement.
   4. If corrosion is noted, do not use and contact customer service or your sales representative for a replacement.

   Implant Driver Assembly:
   Assemble the implant driver by following the assembly instructions below.
   1. Align large flats on inner shaft to groove on the tube body threaded end and insert Figure 6 (below).

   Figure 6
   ![Figure 6](image6)

   2. With threaded end inserted, rotate inner shaft 90 degrees to align the small flats with the body tube grooves Figure 7 (above).

   Figure 7
   ![Figure 7](image7)

   3. Insert inner shaft into tube body, rotate 90 degrees and push towards large end to expose 1/4” drive Figure 8 (below).

   Figure 8
   ![Figure 8](image8)

   4. Assembled device ready for placement in tray Figure 9 (above).

   Figure 9
   ![Figure 9](image9)

   Sterilization:
   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).

   Method: 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 REQUIREMENT 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) Infection.
   d) Fracture of the vertebral body.
   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 varies extensively. 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.

**PRECAUTIONS:**

1. THE IMPLANTATION OF PEDICLE SCREW SPINAL SYSTEMS SHOULD BE PERFORMED ONLY BY EXPERIENCED 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.
2. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
3. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of the metal implants should only be performed 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 fatigue life and may cause failure.
4. REMOVAL OF THE IMPLANT AFTER HEALING. Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing. Particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.
5. ADAPTELY INSTRUCT THE PATIENT. Postoperative care and the patient’s ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or otherwise uncooperative patient should not be allowed to use the implant.
6. MAGNETIC RESONANCE IMAGING (MRI) ENVIRONMENT. The Royal Oak Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The Royal Oak Pedicle Screw System has not been tested for heating or migration in the MR environment.
7. PATIENT SELECTION. Based on fatigue testing results, when using the Royal Oak Pedicle Screw System, 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 this system.

**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.

Distributed by:

Royal Oak Medical Devices
2967 Waterview Drive
Rochester Hills, MI 48309
Phone: 248-853-1450
Email: customerservice@royaloakmed.com

For product information, questions pertaining to sales and service, or to request a surgical technique manual, please contact your local sales representative or Royal Oak Medical Devices customer service.

LC-019 Rev 2 3/22/2016 ECR# 1414