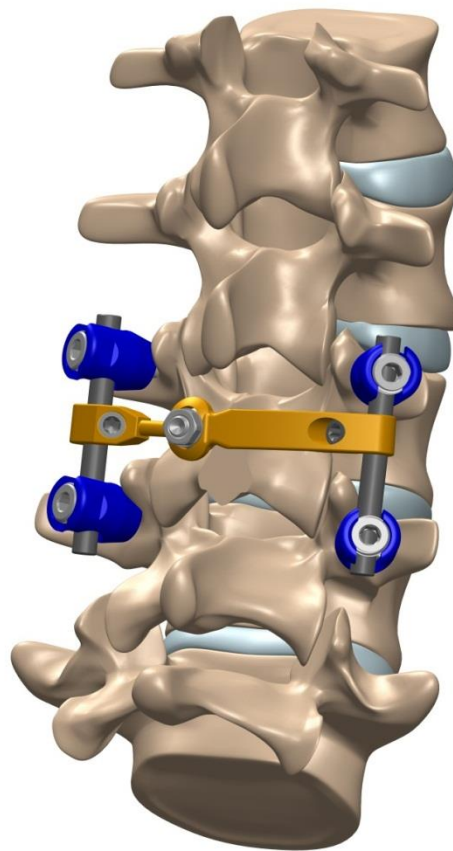


ROMD

Royal Oak Pedicle Screw System Surgical Technique



Device Description

The Royal Oak Pedicle Screw System is comprised of polyaxial pedicle screws in various diameters and lengths, spinal rods in various lengths, cross-connectors and set screws. The Royal Oak Pedicle Screw System can be used for single or multiple level fixation. All implant components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

Surgical Procedure

The following surgical technique illustrates a thoracolumbar pedicle screw fixation procedure. Depending on surgeon preference, a preoperative CT scan should be considered where anatomical variability could affect the stability of an implant, determination of proper sizing of implants and choice of implants or procedures.

Patient Positioning

Place patient in a prone position on a lumbar frame that promotes suitable exposure and restores lordotic curvature of the lumbar spine. Radiographic equipment may be used to assist in confirming the affected disc level(s) and implants for intraoperative placement of the implants.



Spinal Frame Table

Exposure

A midline incision is created to expose the previously palpated spinal processes and laminae which are to be fused or stabilized.

Dissection of the perispinal musculature in a subperiosteal plane is performed to allow exposure of the tips of the transverse processes or edges of the lateral masses while preserving the integrity of the facet joint capsules above and below the fusion construct. After soft tissue retraction is complete, the appropriate posterior decompression of the cord is performed. Preparation of the relevant posterior spinal elements is achieved by removing the soft tissue and decorticating the facets and lamina prior to marking the entry location for the polyaxial screws.

Preparation for Screw Placement

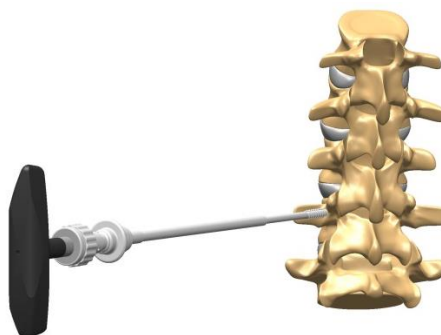
Determine the desired penetration depth from radiographic films or fluoroscopy. K-wires or pedicle markers may be placed into the pedicle throughout the preparation and their position confirmed on AP and lateral radiographs, ensuring proper orientation and trajectory.

Using a Bone Awl (2371021), create an appropriate entry point through the cortical wall into the pedicle. Probes (2181021 & 2181031) and Sounders (2171040 & 2171050) are available to palpate the prepared pedicle to confirm pedicle wall integrity.

- Bone Awl (2371021)
 - Straight Probe (2181021)
 - Curved Probe (2181031)
 - Straight Sounder (2171040)
 - Curved Sounder (2171050)
-
- The image contains three illustrations showing the use of surgical instruments on a lumbar vertebra model. The first illustration shows a Bone Awl (2371021) being used to create an entry point into the pedicle. The second illustration shows a Straight Probe (2181021) or Curved Probe (2181031) being used to palpate the prepared pedicle. The third illustration shows a Straight Sounder (2171040) or Curved Sounder (2171050) being used to confirm pedicle wall integrity.

Tap the pedicle using an appropriate size Bone Tap (listed below), with a T-Ratchet Handle (2321021) or Straight Ratchet Handle (2311021).

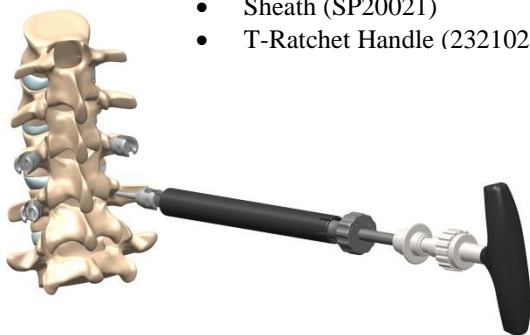
- Straight Ratchet Handle (2311021)
- T-Ratchet Handle (2321021)
- Bone Taps
- Ø 4.5mm Bone Tap (SP20013)
- Ø 5.5mm Bone Tap (SP20014)
- Ø 6.5mm Bone Tap (SP20015)
- Ø 7.5mm Bone Tap (SP20016)



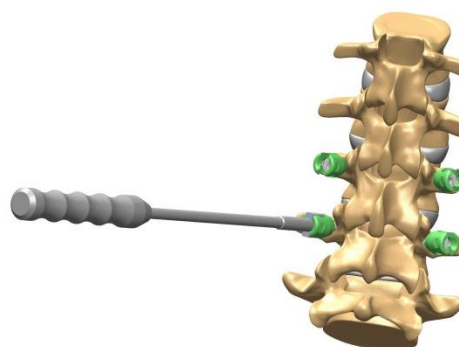
Insert Pedicle Screw

Using the Implant Driver (SP20004), a T-Ratchet Handle (2321021) or Straight Ratchet Handle (2311021), and Sheath (SP20021). Verify the Ratchet is set to the desired operating direction. Insert the appropriate sized polyaxial pedicle screw into the prepared pedicles. Drive pedicle screw to the desired depth. Confirmation of screw position can be made by either radiographs or fluoroscopy. Insert the remaining screws using the same technique. Using the Head Tilting (SP20005) tool, ensure the polyaxial pedicle screw head moves freely and then position the head for the rod placement.

- Implant Driver (SP20004)
- Sheath (SP20021)
- T-Ratchet Handle (2321021)



- Head Tilting (SP20005)



Bend Rod & Insert

After all pedicle screws are placed, use the Trial Rod (2351021) to mock up an appropriate bend to match the desired Lordotic Curvature, if required. Choose the appropriate rod (varying lengths available) and bend it using the Rod Bender (2231020) or In-Situ Left and Right (2261010L & 2261020R). Insert the rod into the cup of the Pedicle Screw using the Rod Holder-Forcep (2271020) or optional Rod Holder (2272020).

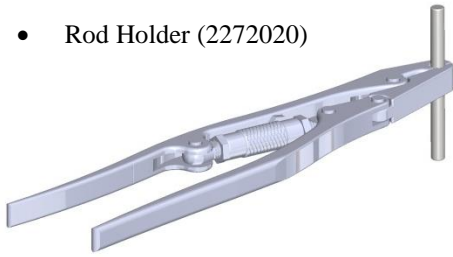
Warning: Do not reverse bend the rods, as this may compromise the mechanical integrity of the rod.

- In Situ Left (2261010L)
- In Situ Right (2261020R)



- Rod Bender (2231020)

- Rod Holder (2272020)



- Rod Holder- Forcep (2271020)



Insert Set-screw

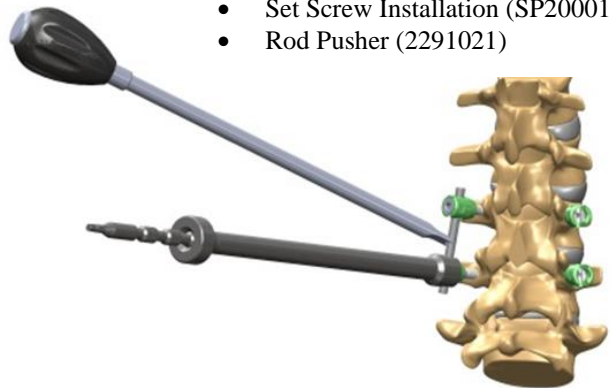
Place the Rod Reducer (2361020), over the pedicle screw cup and rod, pull the trigger multiple times until you reach the “Fully Seated” position.

Load set screws onto the Set Screw Installation (SP20001) Tool and slide both into the Rod Reducer. First rotate the Set Screw Installation Tool Counter Clockwise a half turn and then start rotating Clockwise to ensure proper thread alignment of the set screw. Hand tighten the set screw.

- Rod Reducer (2361020)
- Set Screw Installation (SP20001)



- Set Screw Guide (SP20012)
- Set Screw Installation (SP20001)
- Rod Pusher (2291021)

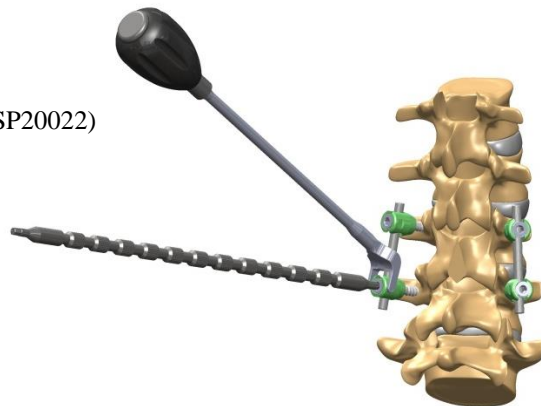


Other optional methods: Place the Set Screw Guide (SP20012) tool over the Pedicle Screw Cup and rod. Load set screw onto the Set Screw Installation (SP20001) Tool and slide both into the Guide. First rotate the Set Screw Installation Tool Counter Clockwise a half turn and then start rotating Clockwise to ensure proper thread alignment of the set screw.

WARNING: Do Not use the set screw to drive or otherwise force the rod into the pedicle screw cup.

Use the Rod Pusher (2291021), the Rod Persuader (SP20002 or SP20022) to fully seat the rod into the pedicle screw cup.

- Rod Persuader (SP20002 or SP20022)

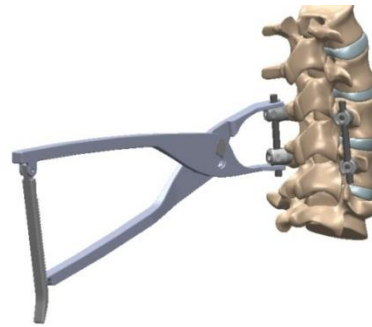


Compress/Distract Rods

After all cup set-screws have been inserted, compression and distraction may be performed, if necessary, by sequentially tightening the set-screws as compression/distraction force is applied using the Compressor (2201120) or Distractor (2211120) forceps.

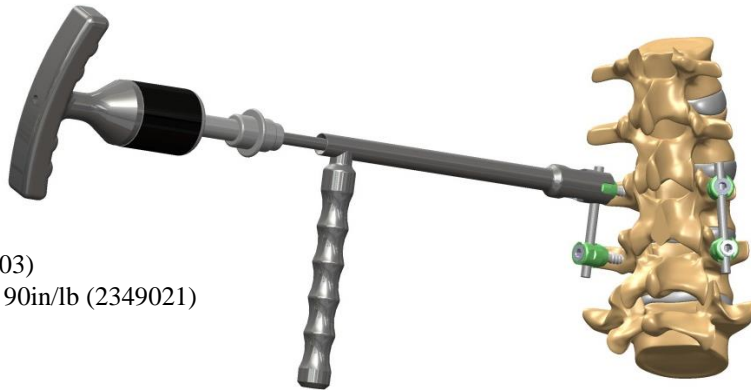


- Compressor (2201120)
- Distractor (2211120)



Final Tightening of Cup Set-screw

Place the Anti-Torque (SP20000) instrument over pedicle screw and rod. Insert the Set Screw Driver (SP20003) into the Torque Limiting Handle, 90 in/lb., (2349021) and through the anti-torque instrument. Turn the Torque Limiting Handle clockwise to tighten. Repeat this step for the remaining set-screws.



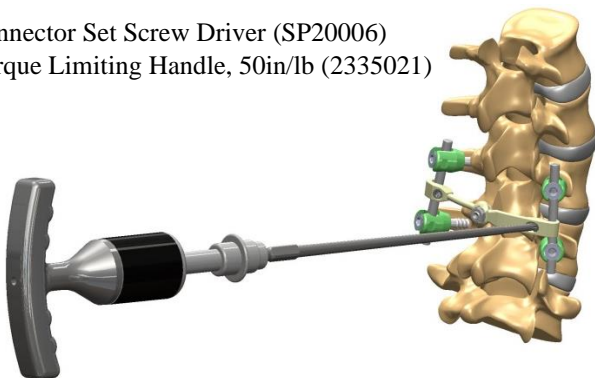
- Anti-Torque (SP20000)
- Set Screw Driver (SP20003)
- Torque Limiting Handle, 90in/lb (2349021)

Insert Cross Connector

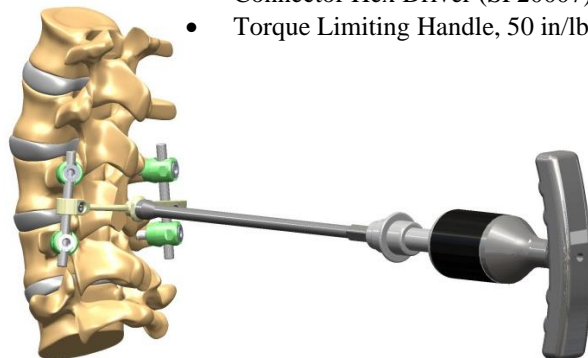
Cross connectors are used to improve construct stability by creating a bridge between two rods. To adjust cross connectors for varying distances between two rods, slide the ends in/out to find the best fit. Secure cross connectors to rods using the Connector Set Screw (SP20006) driver with the Torque Limiting Handle, 50 in/lb, (2335021) and fasten the connector lock set-screw on each end.

Please note that Torque Limiting Handle (2335021) is not to be used in place of Ratchet Handles noted on page 3.

- Connector Set Screw Driver (SP20006)
- Torque Limiting Handle, 50in/lb (2335021)



- Connector Hex Driver (SP20007)
- Torque Limiting Handle, 50 in/lb (2335021)



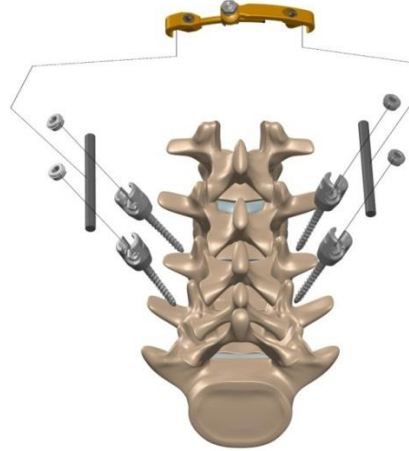
Final locking of the connector is achieved by fastening the connector lock nut at the top of the cross connector utilizing the Connector Hex Driver (SP20007) with the Torque Limiting Handle, 50 in/lb, (2335021).

Construct Revision/Removal

To adjust/remove the cross connector, loosen the top connector lock nut using the connector hex driver, turning in a counter-clockwise direction. In order to remove the cross connector from the rods, completely disengage the cross connector set-screws from the rods by turning the set screw driver in a counter-clockwise direction and remove connector using forceps. To adjust the cross connector, loosen connector set-screws enough to facilitate movement and placement; retighten cross connector set-screws by turning the connector set-screw driver in a clockwise direction.

To loosen/remove the rods, use the set-screw driver, turning in a counter-clockwise direction to loosen/remove the cup set-screw. If cup set-screw is removed, the rods can then be removed using rod holding forceps. If set-screw is loosened, rod adjustments are feasible.

To remove polyaxial pedicle screws, place the implant driver into the pedicle screw. While applying a small amount of downward pressure, rotate implant driver until engagement occurs between implant driver and polyaxial screw. Turn implant driver in a counter-clockwise direction until screw is completely disengaged from bone.



POSTOPERATIVE MOBILIZATION

Careful patient handling for two to four 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.

INDICATIONS:

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); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

CONTRAINDICATIONS:

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.

Active systemic infection or infection localized to the site of the proposed implantation are 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 posterior 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, 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, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.

Following are specific warnings and precautions that should be understood by the surgeon and explained to the patient. General surgical risks should be explained to the patient prior to surgery.

WARNINGS:

IN THE U.S.A., THIS PRODUCT HAS LABELING LIMITATIONS.

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, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

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:

- Device component fracture.
- Loss of fixation.
- Non-union.
- Fracture of the vertebra.
- Neurological injury.
- Vascular or visceral injury.

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 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 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 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.

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 substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the device.
- 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, orthopaedic devices can only be considered a delaying technique or temporary relief.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

PRECAUTIONS

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.

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.

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.

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 refracture. 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.

ADEQUATELY 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 demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

MAGNETIC RESONANCE (MR) 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.

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 the performance of this system.

This product is NOT provided sterile and is for single use only.

See also the Warnings, Precautions and Possible Adverse Effects sections of the Royal Oak Pedicle Screw System product insert.

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.



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For product information, questions pertaining to sales and service, or to obtain a copy of the instructions for use, please contact your local sales representative or ROMD, LLC customer service.

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