WARNING: If bony fusion does not occur within an expected period of time, the screws may break due to the high and discontinuous forces exerted during the motion of the spinal column. Additionally, patients with pseudoarthrosis, delayed or non-union and can result in the need to revise the device(s).

Only experienced spinal surgeons with specific training in the use of this pedicle screw spinal system should implant pedicle screw spinal systems, because this is a technically demanding procedure presenting a risk of serious injury to the patient.

ADVERSE AFFECTS: Additional spinal support in the form of anterior column integrity or associated anterior column reconstruction.

These warnings do not include all possible adverse surgical effects, but are particular to metallic internal fixation devices. Explain general surgical risks to the patient before surgery.

WARNINGs AND CAUTIONS: Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loosening, migration, subsidence, fracture, neurological injury, and vascular or visceral injury.

Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it is difficult to achieve a lasting benefit from the implant.

Recent or active infection, particularly if in or adjacent to the spine or spinal structures. Untreated infection may result in potential device failure

Pain, discomfort, or abnormal sensations due to device presence; Risk of additional injury from postoperative trauma; Implant migration resulting in injury; Bone loss due to stress shielding. Carefully weigh the risks versus benefits when deciding whether to remove the implant. For patients with low activity level, the surgeon may choose not to remove implant thus eliminating the risks involved in a second surgery. Adverse effects may include:

In the event that the device causes discomfort or pain, the device should be removed unless the discomfort or pain is mild and does not interfere with daily activities.

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In the event that the device causes discomfort or pain, the device should be removed unless the discomfort or pain is mild and does not interfere with daily activities.

Correct implant handling is vital. Only contour metal implants with proper equipment. Avoid any notching, scratching or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.

Mixing metals can cause corrosion. There are many forms of corrosion damage, and some of these are more severe than others. Universal contamination can result from the corrosion of the implant. The presence of corrosion can actually affect fatigue life of the implant. The amount of metal compounds released into the body will depend on the number of implants used and the amount of time that the implants are in the body. Internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected.

Correct implant selection is vital. Selecting the proper implant size, shape, and design increases the potential for successful fixation. All the proteins should be used to obtain alignment and normal healing occurs.

The Renovis S 100 Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in an effort to promote fusion. Use only with the S 100 Pedicle Screw System. Improper implant selection may result in failure of the device to perform as intended.

S 100 Pedicle System has not been evaluated for safety and compatibility in the MR environment. The S 100 Pedicle System has not been tested for heating or migration in the MR environment.

Bending the construct. Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured, contour a new construct correctly rather than reverse bending the over-contoured construct.

Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures involving prosthetic devices. Smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
Surgical Technique:

**Patient Positioning**

Patient positioning is a preoperative procedure involving a suitable positioning method, such as the use of a surgical table or a prone position, to ensure optimal access and visualization of the surgical field.

**Surgical Exposure**

Exposure is accomplished using a standard midline incision over the spinous processes, followed by a subperiosteal dissection to the desired level. The dura is then opened using a scalpel or a cautery device.

**Placement of Complications**

NOTE: Dissection and placement of bone grafts typically involves preparation of pedicle screws' pilot holes, but before actual pedicle screw insertion. Medications to prevent fusion technique is critical to the success of the procedure.

**Pedicle Screws**

As all surgical procedures involve placing screws instrumentation systems, preoperative evaluation of CT scans and MRI scans is essential in planning the appropriate angle, size, and depth of pedicle screws. Insertion or removal of a number of pedicle screws placement must be carefully planned to ensure optimal safety and efficiency.

**Entry Point**

Identify the pedicle entry point at the intersection of the horizontal line bisecting the middle of the transverse processes and the vertical line connecting the lateral edges of the process anteriorly. Proceed with the procedure at the proper site and contact to ensure optimal safety.

**Corticotomy**

After confirmation that the entry point is correct and suitable, a small cortical opening is created using an awl or a ball tipped feeler gage. The opening is then expanded using a burr or a ball-tipped feeler gage to ensure optimal safety and efficiency.

**Screw Orientation**

The polyaxial design of the S 100 Pedicle Screw System helps limit the degree of rod bending necessary for achieving adequate alignment. If necessary, each rod may be contoured using a rod bender or a bending tool to enhance contouring and to ensure complete contact with the body's transverse plane of each pedicle screw. Care should be taken in all planes of the body to achieve a balanced contour.

**Placement**

Bone is placed within the open portion of the body's transverse plane of the pedicle screw. The polyaxial design of the S 100 Pedicle Screw System allows for optimal alignment and orientation.

**Locking Caps**

Locking caps are inserted into the pedicle screw bodies after the rod has been placed into position. Locking caps should be firmly tightened at this point but should not be over-tightened as this may cause damage to the locking mechanism.

**Bending Rods**

After the rod is secured in place, bending rods are placed along the length of the body. The rod is then bent using a rod bender or a bending tool to enhance the contouring and to ensure complete contact with the body's transverse plane of each pedicle screw.

**Surgical Exposure**

Exposure is accomplished using a standard midline incision over the spinous processes, extended to include one level above and one level below the intended pedicle screw levels. The procedure is repeated at each intended level of pedicle screw insertion. Utilize a ball-tipped feeler gage to palpate the superior, inferior, medial, and lateral walls of the pedicle canal.

**Contour**

Rods included in the S 100 Pedicle Screw System are available in straight and lordotic contours of various lengths. The contour selection is based on surgeon preferences and is dependent on the specific contour goals of each individual procedure. Rod length determination should allow for at least 5mm extension beyond the most superior and most inferior pedicle screw bodies.

**Closure**

A layered closure of the deep fascia, superficial fascia, subcutaneous tissue, and skin is performed in a standard fashion. Drains are used at the discretion of the surgeon and decided on a case-by-case basis.

**Transverse Links**

One or more transverse links may be placed between adjacent rods to enhance torsional stability of the overall construct. The transverse link is inserted when the rod length has been extended as appropriate, and after the rod is contoured using a rod bender or bending tool.

**Rods**

The polyaxial design of the S 100 Pedicle Screw System helps limit the degree of rod bending necessary for achieving adequate alignment. If necessary, each rod may be contoured using a rod bender or a bending tool to enhance contouring and to ensure complete contact with the body's transverse plane of each pedicle screw. Care should be taken in all planes of the body to achieve a balanced contour.

**Sterilization**

Renovis S 100 Pedicle Screws are provided non-sterile. Sterilization is recommended as follows:

- **Drying Time**

<table>
<thead>
<tr>
<th>Exposure</th>
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<tbody>
<tr>
<td>4 Minutes</td>
<td>40 Minutes</td>
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**References to relevant literature including the Surgical Technique Manual may be obtained by calling Renovis Surgical Technologies, LLC at +1.909.557.2360.**

**Caution:** Federal Law USA restricts this device to sale by or on the order of a physician.