RENOVIS

S180 Lateral Lumbar Interbody Fusion System, Sterile Packaging

IFU 4180-001, Rev B

Instructions For Use

DESCRIPTION:
The S180 Lateral Lumbar Interbody Fusion System is an internal spinal fixation system comprised of Titanium Interbody cages. The system also includes several instruments that assist in proper implantation; these instruments include: Trials, Shavers, and Cage Inserter.

S180 System Implants – Summary	
Dimensions(mm) A/P M/L H	 18, 22 30, 35, 40, 45, 50, 55, 60 8-21
Lordosis	0°, 7°, 12°, 18°, 25°, 30°
Number of screws	0
Screw Diameter (mm)	n/a
Screw Length (mm)	n/a
Cover plate (mm)	n/a

For implant and instrument part numbers, as well as implant dimensions, refer to the Renovis S180 System Surgical Technique (p/n 4180-002).

IMPORTANT NOTE:
This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

MATERIAL:
All implant components of the S180 Lateral Lumbar Interbody Fusion System are made of the following materials:

1. Titanium Alloy: Ti6Al4V according to ASTM F-2924

INDICATIONS FOR USE:
The Renovis S180 Lateral Lumbar Interbody Fusion System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Patients should be skeletally mature and have at least six months of non-operative treatment prior to treatment with the devices. The Renovis S180 System must be used with supplemental fixation cleared by FDA for use in the lumbar spine. Renovis S180 System implants are to be used with autogenous bone graft.

GENERAL CONDITIONS OF USE:
The safe implantation of S180 Lateral Lumbar Interbody Fusion implants requires an in-depth knowledge of human vertebral anatomy as well as the specific patient's anatomical variations. The implantation of the S180 Lateral Lumbar Interbody Fusion System should be performed only by experienced spinal surgeons with specific training in the use of interbody fusion techniques and implants. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The S180 Lateral Lumbar Interbody Fusion System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material. Under no circumstances should any component of the S180 Lateral Lumbar Interbody Fusion System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress. The S180 Lateral Lumbar Interbody Fusion System has not been tested as a standalone construct.

CONTRAINDICATIONS:
Contraindications to using the S180 Lateral Lumbar Interbody Fusion System are similar to those of other Lumbar Interbody Fusion Systems and consist of the following:

1. Prior fusion at the level(s) to be treated
2. Any condition not describe in the Indications for Use
3. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
4. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
5. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
6. Patients with a suspected or documented metal allergy or intolerance.
7. Inadequate tissue coverage over the operative site.
8. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
9. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and pregnancy.

POTENTIAL RISKS:
Potential risks identified with the use of this device, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection and neural-protection is vital. Selecting the proper implant size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present implant size, shape, and strength limitations. 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.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that 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 among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.

3. 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, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

PATIENT SELECTION:
The following factors can be extremely important to the eventual success of the procedure:

1. 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.
2. Senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the device use, leading to implant failure or other complications.
3. Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
4. Foreign body sensitivity. No pre-operative 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.
5. Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis 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.

WARNINGS AND CAUTIONS:
Only experienced spinal surgeons with specific training in the use of interbody fusion systems should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient. 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.

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, share, and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. Single use only. 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.
3. Correct implant handling is vital. These devices may not be contoured. Avoid any notching, scratching or reverse bending of the devices when handling. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected. Do not use implants that exhibit surface or configuration damage.
4. The S180 Lateral Lumbar Interbody Fusion System implants are provided sterile. For Sterile-packaged implants, do not resterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after expiration date.
5. The S180 Lateral Lumbar Interbody Fusion System instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized before each use.
6. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
7. 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. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient 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. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
8. Renovis Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The implants in the S180 System are manufactured from non-ferromagnetic materials as listed in the materials section of this IFU. Potential risks of placing implants in or near the magnetic field include:
    a. Movement of ferromagnetic components through magnetically induced force and torque.
    b. Localized heating of components caused by radio frequency induction heating.
    c. Image artifacts created by interaction between metallic components and the magnetic field.

ADVERSE AFFECTS:
In addition to the obvious risk that any orthopedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in literature that a variety of metals, polymers, chemicals, and other materials used in the manufacturing of orthopedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
2. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While the formation of wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface. Additionally, thoroughly irrigate the wound to prevent debris associated with implantation from remaining in the disc space prior to wound closure.
3. Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Ti-6AL-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

HANDLING OF IMPLANTS AND INSTRUMENTS:

1. Receipt – Carefully unwrap and handle non-sterilized instruments upon receipt to avoid scratching, marking, or abrasion by other implants, instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration. Implants are provided sterile. Wrappings should not be removed by receiving personnel.
2. Transport - Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
3. Storage - Store implants or instruments prior to use in such a manner as to maintain the device's surface finish or configuration, or both. Stock Rotation—The principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant's surface, sterility, and configuration. Keep implants made of different metals separated. Store the implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.
4. Traceability - Implants are identified by a catalog number or lot number, or both, on the package label and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting, and traceability to the manufacturer.

IMPLANT - STERILITY:
All implants are sterilized by exposure to a minimum dose of 25kGy of gamma radiation.
Do not resterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after the expiration date.

MRI SAFETY:
The Renovis S180 Lateral Lumbar Interbody Fusion System components are manufactured from non-ferromagnetic materials. The implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Renovis S180 Lateral Lumbar Interbody Fusion System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

INSTRUMENTS – CLEANING, DECONTAMINATION AND STERILIZATION:

Instruments that are specifically designed for use with the S180 Lateral Lumbar Interbody Fusion System include trials, shavers, cage inserter, and disc preparation. For a list of all instruments, refer to the Renovis S180 Lateral Lumbar Interbody Fusion Surgical Technique (p/n 4180-002).

All instruments must be thoroughly cleaned before each sterilization (including first use) and introduction into a sterile field. All devices should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device. More information is provided in Renovis Surgical Instruments IFU (p/n 4001-001).

Keep devices moist and do not allow blood and/or bodily fluids to dry on the devices. The decontamination process should begin immediately after completion of the surgical procedure.

Renovis rigid instrument cases may be washed and/or disinfected by using an automated washer-disinfection unit utilizing thermal disinfection. Temperatures, cycles, and disinfectant type used as instructed by manufacturer of washer-disinfection unit. Devices must be processed separately from trays and cases. All devices must be thoroughly cleaned before use.

All instruments must be thoroughly cleaned, decontaminated and sterilized as follows (and as per Renovis Surgical Instrument IFU, p/n 4001-001):

1. **Pre-Cleaning:** Disassemble devices where applicable. The majority of the surgical instruments and trial devices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts.
2. **First Rinse:** Rinse devices under running tap water for a minimum of 2 minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris. Actuate devices with moving parts. Clear lumens/cannula/channels/holes of all debris using an appropriately sized bottle brush.
3. **Decontamination:** Soak the devices completely in an enzymatic cleaner or detergent solution* (e.g. ENZOL® Enzymatic Detergent). Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentration. Fully immerse the devices and allow them to soak for a minimum of 20 minutes. Following soak, use a soft-bristled brush to assist in the removal of gross soil, debris or contaminants, ensuring hard to reach areas are accessed and articulating devices with moving parts.
4. **Rinsing:** Remove the devices from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Use a syringe, pipette or water jet to flush lumens/cannula/channels/holes. Articulate devices with moving parts under running water in order to rinse thoroughly.
5. **Washing:** Immerse devices in the ultrasonic washer/cleaner with enzymatic cleaner or detergent solution* (e.g. ENZOL® Enzymatic Detergent) and sonicate for a minimum of 15 minutes. Follow the manufacturer's specifications for suggested water level, temperature, water quality and concentration of enzymatic cleaner or detergent.
6. **Rinsing:** Thoroughly rinse the devices with purified water for a minimum of 2 minutes. Use a syringe, pipette or water jet to flush lumens/cannula/channels/holes. Articulate devices with moving parts under running water in order to rinse thoroughly. Repeat rinsing a total of three (3) times.
7. **Inspection:** After cleaning/disinfection, devices should be visually inspected for contamination. If contamination is still visible, repeat steps 2, 3, 4, 5, 6 and 7. If devices continue to have visual contamination, do not use devices and contact Renovis Customer Service for further instructions.
8. **Drying:** Allow devices to air dry for a minimum of 20 minutes prior to inspection and sterilization preparation. Devices must be thoroughly dried to remove residual moisture before they are stored.
9. **Preparation and Assembly:** After cleaning/disinfection and inspection, any disassembled devices should be reassembled and visually inspected. Check for misalignment, burrs, bent, or fractured tips. Do not use if any of this damage is observed. Mechanically test the working parts to verify that each instrument functions correctly. Place devices into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines. FDA cleared sterilization wrap must be used.

* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. Renovis has validated the above manual cleaning method with the provided solution examples. Other cleaning/disinfection methods may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.

STERILIZATION

Sterility: Renovis Instruments are provided non-sterile. Sterilization is recommended as follows:

Cycle	Dynamic-air-removal Steam
Minimum Temperature	132° C (270° F)
Exposure	4 Minutes
Drying Time	30 Minutes Minimum, 40 Minutes Maximum

This sterilization cycle (drying time) is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and a new cycle must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

The S180 Lateral Lumbar Interbody Fusion System instrument case has a nylon pin mat that is available upon request. The nylon pin mat fits within the instrument case bottom tray to hold miscellaneous instrumentation during transport and sterilization. When the nylon pin mat is present, the S180 Lateral Lumbar Interbody Fusion System instrument case requires a 40 minute dry time. It is the responsibility of the end-user (i.e. hospital) to ensure steam sterilization and dry time parameters including a dry time of 40 minutes. Any other modifications to the instrument case and nylon pin mat require the end user to validate appropriate steam sterilizer and dry time parameters.

The packaging in which non-sterile instruments are supplied should not be used for sterilization methods in the hospital. Repackaged and resterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

References: References to relevant literature including the Surgical Technique (p/n 4180-002) may be obtained by calling Renovis Surgical Technologies, Inc. at 1-800-RENOVIS.

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

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