DESCRIPTION:
The S128 Anterior Lumbar Interbody Fusion (ALIF) System is an internal spinal fusion system comprised of PEEK or Titan Interbody cages, Titanium screws and Titanium Cover Plate assemblies. The system also includes several instruments that assist in proper implantation; these instruments include: Trial Sizers, Cage Inserters, and Cover Plate Inserters.

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 S128 Anterior Lumbar Interbody Fusion (ALIF) System are made of the following materials:
1. Titanium Alloy: Ti6Al4V
2. Polyetheretherketone (PEEK): according to ASTM F-2026
3. Titanium: according to ISO 13789-1996 and ASTM F-560

INDICATIONS FOR USE:
The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral 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 retroolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

GENERAL CONDITIONS OF USE:
The safe implantation of Anterior Lumbar Interbody Fusion (ALIF) Systems requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the S128 Anterior Lumbar Interbody Fusion (ALIF) 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 S128 Anterior Lumbar Interbody Fusion (ALIF) System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress. After spinal fusion occurs, these devices serve no functional purpose and may be removed. The decision to explant...with due regard to the risks associated with a second surgery compared to the benefits of such. The S128 ALIF System has been tested as a monoblock construct.

CONTRAINDICATIONS:
Contraindications to using the S128 Anterior Lumbar Interbody Fusion (ALIF) System are similar to those of other Anterior Lumbar Interbody Fusion (ALIF) Systems and consist of the following:
1. 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.
2. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
3. 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.
4. Patients with a suspected or documented metal allergy or intolerance.
5. Inadequate tissue coverage over the operative site.
6. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
7. 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.

CONTRAINDICATIONS:
These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fusion 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 system, 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 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 union 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 severe complications as well as other 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 corrosion 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.
2. The patient's mental capacity, 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. 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.
4. 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.
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.
1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, 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 body weight.

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.

4. Non-sterile; the S128 Anterior Lumbar Interbody Fusion System implants and instruments are provided non-sterile, and therefore, must be sterilized before each use.

5. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

6. 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 kosen, 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.

7. Renovis Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The implants in the S128 ALIF 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.

ADVISE 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 (tum, 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.

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 Trivanium™ 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:
1. Receipt – Carefully unwrap and handle non-sterilized implants and 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.

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/or possible traceability to the manufacturer.

CLEANING:
All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device. Renovis Instrument 4001-001 provides more detailed information about proper cleaning of the instruments in the S128 ALIF System.

STERILITY:
Renovis S128 ALIF Implants are provided non-sterile, and must be sterilized before use. Sterilization is recommended as follows:

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Dynamic-air-removal Steam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preconditioning Pulses</td>
<td>4</td>
</tr>
<tr>
<td>Minimum Temperature</td>
<td>132° C (270° F)</td>
</tr>
<tr>
<td>Exposure</td>
<td>4 Minutes</td>
</tr>
<tr>
<td>Drying Time</td>
<td>40 Minutes</td>
</tr>
</tbody>
</table>

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.

Do not sterilize implants in contact with instruments or implants of other materials. Metallic oxide could transfer to the implant, initiating an unacceptable conditioning.

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

Refrences: References to relevant literature including the Surgical Technique Manual 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.