

Renovis Surgical's Tesera™ SC - Stand-alone Cervical Interbody Fusion System

DESCRIPTION

The Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System is an internal spinal fixation system comprised of Titanium Interbody cages, Titanium screws and a Titanium and Nitinol cover plate assembly. The system also includes several instruments that assist in proper implantation; these instruments include: Trials, Sizers, Cage Inserters, and Cover Plate Inserters.

Tesera SC ACF Implant – Summary Description

Dimensions(mm)	
M/L	16, 17.5
A/P	13.5, 15
H	6-12
Lordosis	2°, 7°
Number of screws	3
Screw Diameter (mm)	3.5, 4.0
Screw Length (mm)	12, 14, 16, 18, 20
Cover plate (mm)	5.25 H; 12.5 W

For implant and instrument parts numbers, as well as implant dimensions, refer to the Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System Surgical Technique.

IMPORTANT NOTE

This product is marketed 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 Tesera SC Anterior Cervical Fusion (ACF) System are made of the following materials:

1. Cages and Screws: Titanium Alloy: Ti6Al4V according to ASTM F-136
2. Cover Plate: Titanium Alloy: Ti6Al4V according to ASTM F-136 and Nitinol Alloy according to ASTM F-2063

INDICATIONS FOR USE

The Renovis Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2-T1. Renovis Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation.

The Tesera SC ACF System is a stand-alone system when used with the cover plate and screws provided, and requires no additional supplemental fixation. When used as a stand-alone system, the cages require the use of three (3) screws and the cover plate assembly.

When used without the cover plate and three screws the Tesera SC ACF System is a non-stand-alone system and requires additional supplemental fixation cleared by the FDA for use in the cervical spine to augment stability.

GENERAL CONDITIONS OF USE

The safe implantation of Tesera SC Anterior Cervical Fusion (ACF) System requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the Tesera SC ACF System should be performed only by experienced spinal surgeons with specific training in the use of interbody fusion. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The Tesera SC ACF 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 Tesera SC ACF System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress. The Tesera SC ACF System has been tested as a stand-alone construct. If used without the integrated screws and cover plate, it requires additional supplemental fixation cleared in the cervical spine.

CONTRAINDICATIONS

Contraindications to using the Tesera SC Anterior Cervical Fusion System are similar to those of other Anterior Cervical Discectomy and Fusion (ACDF) 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 with conditions that may place excessive stresses on bone and implant, such as severe obesity, pregnancy or degenerative diseases. The decision to use this system in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
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 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 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. 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.
2. 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.
3. 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.
4. 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 system 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, 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 weight bearing.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The devices must be handled and stored carefully to protect from damage. They should be carefully unpacked and inspected for damage prior to use.
3. 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.
4. Correct implant handling is vital. Do not use the implant if damage is suspected. Do not use implants that exhibit surface or configuration damage.
5. The Tesera SC Anterior Cervical Fusion System implants are provided sterile. Do not re-sterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after expiration date.

Renovis Surgical's Tesera™ SC - Stand-alone Cervical Interbody Fusion System

- The Tesera SC Anterior Cervical Fusion System instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized before each use.
- Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
- 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. 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 may be particularly at risk during postoperative rehabilitation.

MAGNETIC RESONANCE (MR) ENVIRONMENT

- Implants: The Renovis Stand-alone Anterior Cervical Fusion (ACF) implants 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 artifacts in the MR environment. The safety of the Renovis Stand-alone Anterior Cervical Fusion (ACF) implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- Instruments: Renovis instruments used with the stand-alone Anterior Cervical Fusion (ACF) implants may be manufactured from ferromagnetic materials and may be MR unsafe. Potential risks of placing instruments in or near the magnetic field include:
 - Movement of ferromagnetic components through magnetically induced force and torque.
 - Localized heating of components caused by radio frequency induction heating.
 - Image artifacts created by interaction between metallic components and the magnetic field.

ADVERSE EFFECTS

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:

- 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.
- 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 formation 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.

- 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

- 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.
- Transport - Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
- Storage - Store implants and instruments prior to use in such a manner as to maintain the devices' 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.
- 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 to provide 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.

INSTRUMENTS – DECONTAMINATION AND CLEANING

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 devices. More information is provided in Renovis Surgical Instruments IFU (p/n 4001-001).

Instruments that are specifically designed for use with the Tesera SC ACF System include trials, sizers, implant/cage inserters and the cover plate inserter. Other instruments are also provided for use with the Tesera SC ACF System. For a list of all instruments, refer to the Tesera SC ACF System Surgical Technique manual.

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

- Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. ENZOL® Enzymatic Detergent). Fully immerse the devices and allow them to soak for a minimum of 5 minutes.
- Pre-Cleaning:** Prepare a room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and remove gross contaminants by thoroughly brushing devices with a soft bristled brush ensuring all

hard to reach areas are accessed.

- Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and sonicate for a minimum of 10 minutes. For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place and do not touch or overlap.
- Rinsing:** Thoroughly rinse the devices with deionized or distilled water for a minimum of 2 minutes. Repeat rinsing a total of three (3) times.
- Drying:** Allow devices to air dry for a minimum of 20 minutes prior to inspection for moisture and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.
- Inspection:** After cleaning/disinfection, instruments should be visually inspected for contamination. If contamination is still visible, repeat steps 3, 4 and 5. If instruments continue to have visual contamination, they should not be used and should be disposed of.
- Preparation and Assembly:** Visually inspect all instruments for misalignment, burrs, bent, or fractured tips. Do not use if any of this damage is observed. Place instruments 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 qualified the above 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.

INSTRUMENTS 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 Minute Minimum 40 Minute Maximum

The Tesera SC System instrument case has a nylon pin mat that is available upon request. When the nylon pin mat is present, the Tesera SC 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.

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.

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

Comments regarding this device can be directed to:

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