CTL MEDICAL

RAPHAEL™

PEDICLE SCREW SYSTEM

Instruction For Use

Precautions
The implantation of the Raphael Pedicle Screw System should be performed only by experienced spinal surgeons with specific training in the use of this System because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Warning
The safety and effectiveness of Raphael Pedicle Screw System have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability of deformity of the thoracic, lumbar and when used in conjunction with the Raphael Hook System, the 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.

Caution
FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Important Note
Users with product inserts that are over two years old at the time of surgery are advised to ask for an updated version. For product information, questions pertaining to sales and service, or to request a surgical technique manual, please contact your local sales representative or CTL Medical customer service.

Description
The Raphael Pedicle Screw System is a top-loading multiple component, posterior spinal fixation system which consists of pedicle screws, rods, set screws, hooks, connectors, and a transverse (cross) linking mechanism. The Raphael Pedicle Screw System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The System implant components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. Various sizes of these implants are available.

Materials
All components are made of Ti6Al4V ELI alloy, a titanium based alloy which complies with ASTM F136.

Indications or Use
The Raphael Pedicle Screw System is a posterior pedicle screw system indicated for the treatment of severe Spondylolisthe-sis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Raphael Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

The Raphael Hook System is intended for use as a posterior, noncervical, nonpedicle system indicated for degenerative disc disease (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. The Raphael Hook System can be used in conjunction with the Raphael Pedicle Screw System.

Note: The Raphael System's Surgical Technique Manual should be followed carefully. Important information on the proper usage of implants and instruments is included. To obtain the surgical manual, please contact CTL Medical or your local distributor.

Note: The Raphael System has not been evaluated for safety and compatibility in the MR environment. The Raphael Sys-tem has not been tested for heating, migration or image artifact in the MR environment. The safety of the Raphael Pedicle Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. Mixed metals such as titanium and stainless steel components should not be used together. Components of this system should not be used with components of any other system or any other manufacturer.

General Conditions of Us
- The implants must be implanted only by physicians having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with the surgical and medical indications, the potential risks and limitations related to this type of surgery, the contra-indications, side effects, and precautions defined, and in the knowledge of the nature and metallic, metallurgic and biological characteristics of the implants to be used.
- It is recommended that Raphael System implants should not be used together with implants from a different source, a different manufacturer, or made from a different material.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modifications due to the stresses and strains placed on it, or small defects may exist, which may lead to the fracture of the implant.

Contraindication
- Any active or suspected latent infection in or about the spine.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation
failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot
provide adequate support and/or fixation to the devices.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can
lead to failure of the fixation of the device or to failure of the device itself.
- Recent infection, fever, or leukocytosis.
- Bony abnormalities preventing safe screw fixation.
- Open wounds
- Metal sensitivity, documented or suspected
- Bone absorption, osteopenia and/or osteoporosis. (Osteoporosis is a relative contraindication, as the condition may limit the degree of correction obtainable and the amount of mechanical fixation.)
- Patient having inadequate tissue coverage over the operative site.
- Pregnancy
- Excessive local inflammation
- Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, eleva-tion of white blood cell count (WBC), or marked left shift in the WBC differential count.

Potential Adverse Effects
- Late bone grafting or no visible fusion mass and pseudarthrosis
- Neurological complications, paralysis, soft tissue lesions, pain due to the surgical procedure,
the breakage, the deformation and/or migration of the implant
- Pedicle failure while preparing and inserting pedicle screw
- Superficial or deep-set infection and inflammatory phenomena
- Allergic reaction to the Ti6Al4V ELI alloy
- Reduction in bone density due to a different distribution of mechanical stresses
- Pain and abnormal sensations due to hardware bulkness
- Neurological and spinal dura mater lesions from surgical trauma
- Bursitis
- Presence of microparticles around the implants
- Growth of the fused vertebrae is altered
- Partial loss of the degree of correction achieved during surgery
- Modification of spinal curvature and stiffness of the vertebral column
- The above list of potential adverse effects is not exhaustive. These side effects can sometimes necessitate further surgical treatment.

Precaution
Based on the fatigue testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the pedicle screw system. The implantation of the pedicle screw system should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant(e.g., substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may be so advanced at the time of implantation that they may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal fixation systems requires detailed knowledge of spinal surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome.
- Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
- Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants.
- Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
- The implantation of pedicle screw spinal systems should be performed only by experienced spinal 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.

•Based on fatigue testing results, when using the Raphael Ped-icle Screw System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

Warning

•The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
•Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
•Discard all damaged or mishandled implants.
•Never reuse an implant, even though it may appear undamaged.
•Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.
•Contouring or bending of a screw or hook may reduce its fatigue strength and cause failure under load. If spinal screws or hooks are bent or otherwise damaged during insertion or adjustment, they must not be implanted and must be replaced. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted.
•Mixing Metal: Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals.
•Because different manufactures employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the Raphael System should not be used in conjunction with components from any other manufacture's spinal system. Any such use will negate the responsibility of CTL Medical for the performance of the resulting mixed component implant.
•Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically.
•Any decision by a physician to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.
•Implant removal should be followed by adequate postoperative management to avoid fracture.
•The surgeon should consider the level of implantation, the weight of the patient, the patient's activity level or general conditions and any other factor which may have an impact on the performance of the system based on published fatigue test results of the system.

Packaging, Labeling and Storage

•The implants are supplied non-sterile. They must be cleaned and sterilized (see below).
•The implants are delivered in packages; these must be intact at the time of receipt. All the legal information required for this type of implant is given on the label of each package.
•The implants may be delivered as a complete set: implants and instrumentation are set out
on specially designed trays or in boxes which can be sterilized directly.
•Use care in handling and storage of implant components. Cutting, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instrument components or implants have been damaged during storage or prior procedures.

The Raphael System is provided non sterile (implants and instrumentation) and must be cleaned and sterilized before use according to the procedures detailed below.

Cleaning of Instruments:

Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Disassemble instruments with re-movable parts. Methods of cleaning Raphael re-usable instruments are provided in these instructions, a manual method and a method using an automated washer disinfector. Whenever possible the automated method should be used. The automated cleaning process is more reproducible and, therefore, more reliable, and staff are less exposed to the contaminated devices and the cleaning agents used. Whichever method is used, staff should use suitable protective clothing and equipment at all times. In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product. The guidance provided by the detergent manufacturer concerning concentrations and temperatures shall be observed. If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient. CTL Medical does not recommend any specific cleaning and/or disinfection agent. For cleaning or disinfecting reusable instruments, only specifically formulated cleaning agents and/or disinfectants should be used. Do not alter the concentrations specified by the detergent manufacturer. The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing re-usable instruments should be carefully considered. Application of freshly pre-pared purified water/highly purified water or sterile water for rinsing purposes with less than 100 cfu/ml and Mineral residues from hard water, as well as higher contamination with microorganisms and endotoxins, can result in staining of the device or prevent effective cleaning and decontamination.

Cleaning and Decontamination

•All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field.
•CAUTION: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
•Implants removed from a patient or that contact bodily tissues or fluids should never be reused.
•In a clean metal pan, prepare an enzymatic detergent bath according to the detergent manufacturer's instructions.
•Allow the devices to soak in enzymatic detergent bath for 20 minutes.
•While in detergent bath, using a soft bristled brush, gently clean the devices, paying attention to pivots, threads, recesses, crevices, cannulas and other difficult to clean areas, until all visible debris is removed.
•Remove the devices from the enzymatic detergent bath and rinse with tap water for a minimum of 1 minute.
•Prepare an enzymatic detergent bath in a sonicator.
•Ultrasonically clean the individual devices in the enzymatic bath for ten (10) minutes.
•Remove from sonicator and rinse the devices in DI water for a minimum of 1 minute.
•Dry the devices with a clean, soft cloth.
•Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.
•Verify that the instruments are in operation condition.

Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and they must not be used.
All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Cleaning Instructions:
Point of Use
•Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe.
•Place devices in a tray of distilled water or cover with damp towels.
•Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
•Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Preparation Before Cleaning
•Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
•Where applicable, multi-component instruments should be disassembled for appropriate cleaning.
•Disassembly, where necessary is generally self-evident. Care should be exercised to avoid losing small screws and components.
•All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

Cleaning/Disinfection Options:
1.Manual - Enzymatic soak and scrub followed by sonication.
2.Combination Manual/Automated - Enzymatic soak and scrub followed by an automated washer/disinfector cycle.
3.Automated cycle - Not recommended without manual pre-cleaning.

Manual Cleaning/Disinfection Procedure
Note: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

Manual Cleaning Instructions

1.Completely submerge instruments in enzyme solution and allow the devices to soak in enzymatic detergent bath for 20 minutes. Scrub using a soft-bristled, nylon brush until all visible soil has been removed.
2. Remove the devices from the enzymatic detergent bath and rinse with tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
3. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50 kHz.
4.Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the devie or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
5.Repeat the sonication and rinse steps above.
6.Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and they must not be used.
All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.
Sterilization Procedures
Following is the recommended method to achieve a degree of sterility equal to at least 10-6

Combination Manual/Automated Cleaning Steps:
1.Completely submerge the instruments in enzyme solution and allow to soak for 10 minutes. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be give to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush.
2. Remove devices from the enzyme solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
3. Place instruments in a suitable washer/disinfector basket and process through a standard washer/disinfector instrument cycle.
i. Rinse 3 times using tap water for 30 seconds after wash using the enzymatic detergent in the ultrasound cleaner at 35-45°C for 3 minutes.
ii. Perform the ultrasound rinsing repeatedly subjected 3 times for 3 minutes using the purified water at 35-45°C.
iii. Dry at 100°C (±5°C) for 30 minutes.

Note: Use of a sonicator at 45-50kHz will aid in thorough cleaning of devices.
Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

INSPECTION
1.Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2.Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3.If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your CTL Medical representative for a replacement.
4.If corrosion is noted, do not use and contact customer service or your CTL Medical representative for a replacement.

Method	Steam
Cycle	Pre-Vacuum
Temperature	132°C (270°F)
Exposure	4 minutes
Dry time	45 minutes*

Method	Steam
Cycle	Gravity
Temperature	132°C (270°F)
Exposure	15 minutes
Dry time	45 minutes*

*(15 Min Open Door Time + 30 Min Cool-Down Time)

It is important to note that an FDA-cleared sterilization wrap, package or sterilization container sytsem should be used to enclose the case or tray in order to maintain sterility.

This pre-vacuum sterilization cycle 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 sterilizer 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).

Because of the potential risk of transmission of Creutzfeldt Jakob disease, some Health Care Authorities recommend sterilization according to these parameters, especially for surgical instruments that could come into contact with the central nervous system. Remove all packaging materials pri-or to sterilization. Use only sterile products in the operative field.

LIMITS ON REPROCESSING
Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on CTL Medical implants and instruments.

Recall
The guarantee is only applicable if the device is used in accordance with normal conditions
as defined in these instructions and in conformity with the recommended surgical technique.

Guarantee
The guarantee is only applicable if the device is used in accordance with normal conditions, as defined in these instructions and in conformity with the recommended surgical technique.

SYMBOL TRANSLATION

LOT NUMBER

CATALOG NUMBER

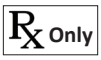
QUANTITY

NON-STERILE

SINGLE USE ONLY

See package insert for labeling limitation

Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.



MANUFACTURER

DATE OF MANUFACTURER

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