INSTRUCTIONS FOR USE

Important Information - Please Read Prior to Use

ENGLISH

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DEVICE SYSTEM NAME:

Pedicle Fixation Platform

which includes:

SEURAT™ Universal Pedicle Screw System
DALI™ Spinal Fixation System
RAPHAEL™ Pedicle Screw System
Taurus™ Pedicle Screw System
PICASSO™ MIS Spinal System
Preference™ Pedicle Screw System

PURPOSE

The CTL Amedica Pedicle Fixation Platform is intended to help provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine

DESCRIPTION

The CTL Amedica Pedicle Fixation Platform is a family of toploading, multiple component, posterior spinal fixation systems which consist of pedicle screws, rods, set screws, hooks, connectors, and transverse (cross) linking mechanisms. Various sizes and configurations of implants are available. The CTL Amedica Pedicle Fixation Platform will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion.

The CTL Amedica Pedicle Fixation Platform provides options that can be used in an open approach and/or percutaneously using a minimally invasive (MIS) surgical approach. The CTL Amedica Pedicle Fixation Platform may be used in both an open approach and percutaneous approach with MIS instrumentation.

Both implants and instrument are supplied non-sterile and may be fabricated from one or more of the following: medical grade titanium alloy (Ti-6Al-4V ELI), cobalt-28 chromium-6 molybdenum alloy, and stainless steel materials that conform to ASTM 1537, ASTM F136 and ASTM F899.

INDICATIONS

The CTL Amedica Pedicle Fixation Platform is intended to provide immobilization and stabilization of the spinal segments, (T1 – S2/ilium) or as an anterolateral fixation system (T8-L5, Seurat only), in skeletally mature patients as an adjunct to fusion.

The Fixation Platform comprises of posterior non-cervical pedicle as well as non-cervical non-pedicle systems 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 platform is comprised of screws, set screws, rods, hooks, crosslinks and connectors.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Any of the following circumstances and/or present abnormalities, but not limited to this list, may affect the normal process of bone remodeling and reduce the chances of a successful outcome:

1. Bone absorption, osteopenia and/or osteoporosis that are documented or suspected (Osteoporosis is a relative contraindication, as the condition may limit the degree of correction obtainable and the amount of mechanical fixation.)
2. Bone quality and/or quantity that are insufficient and compromised by disease, infection, or prior implantation which would inhibit rigid device fixation.
3. Condition(s) of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
4. Excessive local inflammation
5. Recent fever or leukocytosis
6. Infections in and/or about the site of spine that are active or suspected latent, or certain metabolic disorders affecting osteogenesis. Previous history of infection.
7. Mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care. Neuromuscular deficit places an unusually heavy load pedicle screw constructs during the healing period.
8. Metal sensitivity and/or foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
9. Obesity 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
10. 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, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.
11. Pregnancy
12. Inadequate tissue coverage at operative site.
13. Tumors involving the spine that are primary or metastatic
14. Wound(s) that are open
15. Any case that requires mixing of metals from two different components or systems with the exception of CTL components and systems, which have been tested and validated.

Surgeons should warn patients of the above listed potential adverse effects, including the finite service life of the device and the need for post- operative protection of the implant.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events or complications associated with spinal fusion surgery with implantable devices are possible. A listing of possible adverse events or complications includes, but is not limited to:

1. Allergic reaction to the Ti6Al4V ELI alloy. Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
2. Bone loss or decrease in bone density, possibly caused by stress shielding
3. Bursitis
4. Cauda equina syndrome, neurological complications and deficits (transient or permanent), neuropathy, paralysis, paraplegia, paraparesis, reflex, soft tissue lesions due to the surgical procedure, breakage, deformation and/or migration of the implant, and/or neurological and spinal dura mater lesions from surgical trauma
5. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
6. Change in mental status.
7. Death.
8. Deficits, arachnoiditis, and/or muscle loss
9. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
10. Disassembly, bending, and/or breakage of any or all of the components.
11. Dural tears, pseudo-meningocele, fistula, persistent CSF leakage, meningitis.
12. Early or late loosening of the components. Implant migration.
13. Altered growth of the fused vertebrae.
14. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
15. Infection.
16. Late bone grafting or no visible fusion mass and pseudoarthrosis
17. Modification of spinal curvature and stiffness of the vertebral column
18. Non-union (or pseudoarthrosis), delayed union, and/or malunion.
19. Pain and abnormal sensations due to hardware bulkiness or pain due to the surgical procedure, breakage, deformation and/or migration of the implant,
20. Pedicle failure while preparing and inserting pedicle screw
21. Postoperative partial loss of the degree of correction achieved during surgery such as change in spinal curvature, loss of correction, height, and/or reduction.
22. Presence of micro particles around the implants
23. Reduction in bone density due to a different distribution of mechanical stresses
24. Scar formation possibly causing neurological compromise around nerves and/or pain.
25. Superficial or deep-set infection and inflammatory phenomena
26. Tissue or nerve damage, irrigation, and/or pain caused by improper positioning and placement of implants or instruments.
27. Urinary retention or loss of bladder control or other types of urological system compromise.

The above list of potential adverse effects is not exhaustive. These side effects may sometimes necessitate additional surgical treatment in order to correct the occurrence of these anticipated adverse events.

Optional – Implant Removal: The insertion instruments can be used to engage the implant securely. The implant can then be extracted by following the implantation process in the reverse order. Please refer to the associated surgical technique guide for full implant removal instructions.

WARNING(S)

- The benefit of spinal fusions utilizing any pedicle fixation system has not been adequately established in patients with stable spines.
- The safety and effectiveness of The CTL Amedica Pedicle Fixation Platform has been established only for spinal conditions requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of the CTL Amedica Pedicle Fixation Platform for any other condition is unknown.
- Potential risks associated with the use of this system, which may require additional surgery, include but are not limited to: device component fracture, loss of fixation, non-union, and fracture of the vertebra, neurological injury, and vascular or visceral injury.
- 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 any implant may reduce its fatigue strength and cause failure under load. If an implant(s) is/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.
- The Pedicle Fixation Platform's Surgical Technique Guides should be followed carefully. Important information on the proper usage of implants and instruments is included. To obtain the surgical technique guide, please contact CTL Amedica or your local distributor.
- Some degree of corrosion occurs on all implanted metal and alloys. When dissimilar metals contact one other, it may accelerate this corrosion process. 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. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase.
- Because different manufactures employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the CTL Amedica Pedicle Screw Platform should not be used in conjunction with components from any other manufacture's spinal system. Any such use will negate the responsibility of CTL Amedica for the performance of the resulting mixed component implant construct.
- 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 since the removal of 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.
- DO NOT reuse any of the CTL Amedica Pedicle Screw Platform's implant components under any circumstances, as with all orthopedic and neurosurgical implants. Never reuse an implant, even though it may appear undamaged. Discard all damaged or mishandled implants.
- DO NOT use non-approved metal implant variations in the same construct.
- DO NOT use any of CTL Amedica Pedicle Screw Platform's implant components with components from any other system or manufacturer unless specifically allowed to do as noted in a CTL Amedica document.
- The subject system has not been evaluated for safety and compatibility in the MRI environment nor has been tested for heating or migration in the MRI environment.

PRECAUTION(S)

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

CAUTION (For US Audiences Only): FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.

Because this is a technically demanding procedure presenting a risk of serious injury to the patient, the implantation of pedicle fixation systems should be performed only by experienced spine surgeons with knowledge of preoperative and surgical techniques, cautions, and potential risks associated with such spinal surgery, and with specific training in the use of this pedicle fixation system. 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.

CHOICE OF IMPLANTS

Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all implants, the durability of these components is affected by numerous biologic, biomechanical, and other extrinsic factors, which limit their service life. Particularly, spinal implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones.

Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

In addition, strict adherence to the indications, contraindications, warnings, and precautions 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 MAY PRESENT LIMITATIONS ON THE SIZE, SHAPE, AND STRENGTH OF THE IMPLANTS.

PREOPERATIVE

1. Select only patients that meet the criteria described in the indications.
2. Avoid patient conditions and/or predispositions such as those addressed in the aforementioned contraindications.
3. Use care when handling and storing the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. Further information on the use of this system will be made available upon request from a distributor or from CTL Amedica directly.
5. Those using brochures published more than two years before the surgical intervention are advised to obtain an updated version.
6. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present- prior to the surgery beginning.
7. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
8. Unless sterile packaged, clean and sterilize all parts before use. Make additional sterile components available in case of an unexpected need.
9. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal fixation systems which requires detailed knowledge of spinal surgery.

INTRA-OPERATIVE

1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. At all times, use extreme caution around the spinal cord and nerve roots. Damage to the nerves may cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. To ensure proper fusion below and around the location of the instrumentation, use autograft. Autograft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
5. Do not use bone cement since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
6. When using the subject pedicle screw system, the physician/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.
7. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique guide. To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable surgical technique guide. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.
8. Take care 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.
9. Take extreme care when using instruments near vital organs, nerves or vessels. Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.
10. Wherever possible or necessary, use an imaging system to facilitate surgery.
11. To ensure maximum stability, use two or more cross connectors on two bilaterally placed continuous rods whenever possible.

POST-OPERATIVE

1. Failure to immobilize a delayed or non-union of bone may result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual bending, loosening, or breakage of the device. It is important that immobilization of the union is established and confirmed by roentgenographic examination. Where there is a non-union, or if the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs.
2. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow the maximum chances for a successful surgical result, do not expose the patient or device to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation.

4. 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. The patient should be advised not to smoke or consume excess alcohol during the bone healing process.
5. 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.
6. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
7. 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.
8. 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 upon it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
9. Patients should be advised that with implants, before receiving any subsequent surgery, such as a dental procedure, prophylactic antibiotics may be considered – especially for high risk patients.
10. Pedicle screw system implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer, or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis.
11. Implant removal should be followed by adequate postoperative management to avoid fracture.
12. Treat any and all retrieved devices such that reuse in another surgical procedure is not possible.

PACKAGING

The components and associated instruments are packaged clean and non-sterile together in a metal or polymer sterilization case. Instruments and implants will be held in place by a variety of the following: metal, silicone, polymer and or nylon brackets, polymer or thermoplastic caddies and/or silicone mats. Sterilization cases will be labeled according to internal procedures. A variable quantity of cases will be placed inside a shipping container. Distribution simulation testing has been conducted which simulates the potential hazards which may occur during manual handling and vehicle transport. The shipping container is sufficient to withstand expected forces experienced. Accept components only if received with the factory packaging and labeling intact. Carefully inspect all sets before use. In particular, check for completeness of the set and integrity of the components and/or instruments. Any damaged packaging and/or product must be returned to CTL Amedica.

EXAMINATION

Instruments must always be examined by the user prior to use in surgery. Examination should be thorough, and in particular, should take into account a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, bruising or distortion, and that all components of the instrument is complete. Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise non-functional.

STORAGE AND HANDLING

Store CTL Amedica Pedicle Fixation Platform implants in their original packaging in a dry environment that is protected from direct sunlight and that is at an ambient temperature.

CLEANING AND STERILIZATION

- Implants are supplied non-sterile and are for single use only. All implants used in surgery must be sterilized by the hospital prior to use. Instruments are supplied non-sterile and may be re-used. Instruments must be thoroughly cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Unless just removed from an unopened CTL Amedica package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners prior to sterilization and introduction into a sterile surgical field or (if applicable) return of the product to CTL Amedica.

MANUAL CLEANING PROCEDURE

1. Use the neutral pH enzyme soaking solution that has been prepared
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes (water temperature: 35- 45°C). Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).

   Note: For any assembled instruments, disassembly is required prior to submerging.

   Note: The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas (water temperature: 35- 45°C).
4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
6. Rinse instrument in purified water (from one or any combination of the following processes: ultra- filter, RO, DI and/ or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
7. Repeat Steps 5 and 6 with freshly prepared cleaning solution.
8. Dry the instrument with a clean, disposable, absorbent, nonshedding wipe.
9. Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean.
10. Verify that the devices are visually clean

CAUTION: Avoid the use of corrosive products and/or instruments including abrasive sponges and metal brushes. Visually inspect the devices under normal room lighting condition to verify thorough cleanliness, and that all foreign debris has been removed. Verify that the instruments are in visually clean.

AUTOMATED CLEANING PROCEDURE

CTL Medical does not recommend automated washer/disinfector systems as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

CAUTION:

- Avoid the use of corrosive products and/or instruments including abrasive sponges and metal brushes.
- Visually inspect the devices under normal room lighting condition to verify thorough cleanliness, and that all foreign debris has been removed.
- Verify that the instruments are visually clean.

STERILIZATION

All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. The gravity displacement sterilization parameters we suggested comply with AAMI ST79. CTL Amedica recommends the following parameters:

METHOD	Steam	Steam
Cycle	Gravity	Pre-Vacuum
Temperature	132°C(270°F)	132°C(270°F)
Exposure Time	15 min (Dry time 45 min)	4 min(Dry time 30 min)

It is important to note that a sterilization wrap, package or sterilization container system should be used to enclose the case or tray in order to maintain sterility.

Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be re-sterilized.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance of the system should notify the distributor or CTL Amedica. Furthermore, if any of the implanted spinal system component(s) ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any CTL Amedica product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. Affected product shall be returned to CTL Amedica if applicable. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

DISPOSAL INSTRUCTIONS

If product return is not possible then the affected product shall be maintained and/or disposed of according to the policies of the user facility.

FURTHER INFORMATION

Recommended directions for use of this system are available at no charge upon request. If further information is needed or required, please contact CTL Amedica.

No other warranties, express or implied, are made implied warranties of merchantability and fitness for a particular purpose or uses are specifically excluded. See WARRANTIES & LIMITATIONS OF LIABILITY section for further information.

SYMBOL TRANSLATION

CE Mark is applicable for only the following systems:
SEURAT™ Universal Pedicle Screw System
RAPHAEL™ Pedicle Screw System
PICASSO™ MIS Spinal System

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