CTL MEDICAL®

PICASSO II™

MIS SPINAL SYSTEM

Instruction for use

PURPOSE

The PICASSO II™ MIS Spinal System is intend to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine with open surgery or minimal invasive surgical approach.

DESCRIPTION

The PICASSO II™ MIS Spinal System consists of a variety of shapes and sizes of rods, screws, crosslink, set screw. PICASSO II™ MIS Spinal System implant components are made out of medical grade titanium alloy described by such standards as ASTM 136. CTL Medical expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made implied warranties of merchant-ability and fitness for a particular purpose or uses are specifically excluded. See the PICASSO II™ MIS Spinal System catalog for further information about warranties and limitations of liability. Never use stainless steel and titanium implant components in the same construct. To achieve best result, do not use any of the PICASSO II™ MIS Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or CTL Medical document. As with all orthopaedic and neurosurgical implants, none of the PICASSO II™ MIS Spinal System components should ever be refused under any circumstances.

INDICATIONS

The PICASSO II™ MIS Spinal System is intended to 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 sacral spine. The PICASSO II™ MIS Spinal System can also be used in an open approach and a percutaneous approach with MIS instrumentation. The PICASSO II™ MIS Spinal System is intended for noncervical pedicle fixation for the following indications: 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 for lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity 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 these devices for any other conditions are unknown. The PICASSO II™ MIS Spinal System has not been evaluated for safety and compatibility in the MR environment. The PICASSO II™ MIS Spinal System has not been tested for heating or migration in the MR environment.

PRE-OPERATIVE PRECAUSIONS

Anyone using CTL Medical products can obtain a Surgical Technique brochure by requesting one from a distributor or from CTL Medical directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version CTL Medical devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. 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 provided by CTL Medical. 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. 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 CTL Medical Surgical Technique. Extreme care must be taken when the instruments are used near vital organs, nerves or vessels. Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

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

PRECAUTIONS

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 the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

MRI Safety Information: PICASSO II™ MIS Spinal System has not been evaluated for safety and compatibility in the MR environment. PICASSO II™ MIS Spinal System has not been tested for heating, migration or image artifact in the MR environment. The safety of the PICASSO II™ MIS Spinal 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.

CONTRAINDICATIONS

-Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:
-Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
-Insufficient quality or quantity of bone which would inhibit rigid device fixation.
-Previous history of infection.
-Excessive local inflammation.
-Open wounds.
-Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
-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.
-Patients having inadequate tissue coverage of the operative site.
-Pregnancy.
-A condition 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.
-Foreign body sensitivity.Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
-Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congeni-tal 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.
-These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.
-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.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to CTL Medical.

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 are complete. Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise unfunctional.

STORAGE AND HANDLING
CTL Medical PICASSO II™ MIS Spinal Device should be stored in a dry environment, protected from direct sunlight and at an ambient temperature in their original packaging.

CLEANING AND STERILIZATION
Implants are supplied non-sterile and are for single use only. So all implants used in surgery must be sterilized by the hospital prior to use. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury, illness or death. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Otherwise, Instruments are supplied nonsterile 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 Medical package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to CTL Medical. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

NOTE: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.
All products should be treated with care. Improper use or handing may lead to damage and/or possible improper functioning of the device.

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 removable parts. Methods of cleaning PICASSO II™ reusable 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 reusable 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 precleaning.

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 Steps:
1.Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Scrub usinga soft- bristled brush to gently clean the device until all visible soil has been removed.
2. Remove the device from the enzyme solution and rinse in tap water for 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 45-50kHz.
4. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
5. Repeat sonication and rinse steps above.
6. Remove excess moisture from the instrument with a clean, absorbent, and non-shedding wipe.

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 given 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^{o}C for 3 minutes
   ii. Perform the ultrasound rinsing repeatedly subjected 3 times for 3 minutes using the purified water at 35-45^{o}C.
   iii. Dry at 100^{o}C (±5^{o}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.

CAUTION:
Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean. Verify that the instruments are in 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. Sterilization: recommended method to achieve a degree of sterility equal to at least 10^{-6}.The gravity displacement sterilization parameters we suggested comply with FDA recognized consensus standards such as "ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities" for details regarding the common steam sterilization parameters available on FDA cleared sterilizers used in health care facilities'
CTL Medcial recommends the following parameters:

METHOD	Steam	Steam
Cycle	Gravity	Pre-Vacuum
Temperature	132°C(270°F)	132°C(270°F)
Exposure	15 minutes	4 minutes
Dry time	45 minutes*	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 system should be used to enclose the case or tray in order to maintain sterility.

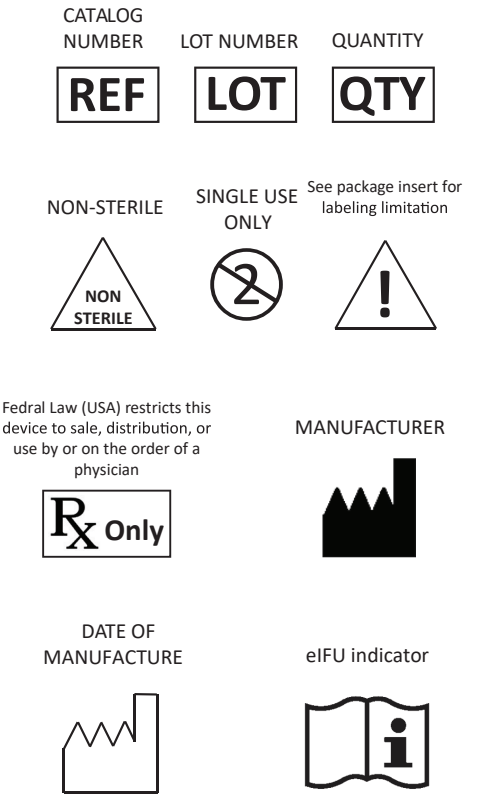
LIMITS ON REPROCESSING
Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on CTL Medical implants and instruments.

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, should notify the distributor or CTL Medical.

Further, 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 Medical 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. 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.

FURTHER INFORMATION
Recommended directions for use or surgical technique manual of this system are available at no charge upon request. If further information is needed or required, please contact CTL Medical.

SYMBOL TRANSLATION



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