Thunderbolt™ Minimally Invasive & Lancer™ Open Pedicle Screw System Instruction for Use

Rx only

NON STERILE

IMPLANTS

CE 2797

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USA

Important Note to Operating Surgeon:
The Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems are designed to provide biomechanical stabilization as an adjunct to fusion and should be used with anterior column support. Without anterior column support, its use may not be successful. Spinal fixation should only be undertaken after the surgeon has had hands on training in this method of spinal fixation and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A spinal technique is available for instructions on the important aspects of this surgical procedure.

Preoperative:
Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential adverse effects of the surgery. Only patients who meet the criteria described in the Indications section should be selected for implantation. Patient conditions and/or predispositions such as those addressed in the Contraindications section should be avoided. Care should be used in the handling and storage of the implant components. The implants should not be damaged. Implants should be protected from corrosive elements during storage. The type of construct required for the surgery should be determined prior to beginning the surgery. Implants and instruments must be inspected, cleaned, and sterilized prior to use in the operative field.

Intraoperative:
Caution should be used around the spinal cord and nerve roots, particularly when using screws. Damage to the nerves may cause loss of neurological functions. Breakage, slippage, misuse, or mishandling of the instruments or implant components, such as on sharp edges, may cause injury to the patient or operative personnel. The implants must be handled and contoured carefully so as to avoid notching or scratching the surface. Before closing the soft tissues, all of the nuts and set screws should be tightened firmly according to the operative surgical technique. The tightness of all set screws must be rechecked before wound closure to ensure that no loosening occurred during tightening or manipulation of the other implants. Explanted implants must never be reused.

Post-Operative:
The surgeon must consider removing the implant after healing, as the implants can loosen, fracture, or corrode even after fusion has occurred. The risks and benefits of a second surgery must be carefully evaluated. The patient must be adequately instructed regarding the risks and limitations of the implant, as well as postoperative care and rehabilitation. The patient should be instructed in the proper use of crutches, canes, external braces, or any other weight bearing or assist devices that may be required and limit those physical activities which would place excessive stresses on the implants or cause delay of the healing process. The patient should also be instructed in the proper methods to ambulate, climb stairs, get in and out of bed and perform activities of daily living, while minimizing rotational and bending stresses.

Description:
The Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems include implant components made of implant grade titanium alloy (Ti-6Al-4V ELI; ASTM F136) and cobalt chrome alloy (Co-28Cr-6Mo; ASTM F1537). The system also includes instruments made of PEEK (ASTM F2826), Tantalum (ASTM F560), stainless steel (ASTM F899/A564) and aluminum (ASTM B221). These components are available in various designs and sizes that allow the surgeon to build an implant construct suited to a patient's anatomical and physiological requirements.

The components include: polyaxial pedicle screws, set screws, rods, instruments and sterilizer trays. The Lancer™ Open Pedicle Screw System also includes connector and hook components.

Indications for Use:
The Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems are 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 disc disease (DDD; 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; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

When used in a posterior percutaneous approach with MIS instrumentation, the Thunderbolt 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/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used for posterior, non-cervical pedicle, and non-pedicle fixation, the Lancer™ Open Pedicle Screw System is indicated for the following: degenerative disc disease (DDD) (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. Overall levels of fixation are T1 to the Sacrum/Ilium. When used for fixation to the ilium, the lateral offset connectors of the Lancer™ Open Pedicle Screw System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

Contraindications:
Contraindications include, but are not limited to:
- infection, systemic or localized
- signs of local inflammation
- morbid obesity
- fever or leukocytosis
- mental illness
- alcoholism or drug abuse
- pregnancy
- severe osteopenia
- suspected or documented sensitivity or allergies to the implant materials
- presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device
- any condition having inadequate tissue coverage over the operative site
- any circumstances not described under Indications for Use
- patients unwilling or unable to follow post-operative instructions
- Use of the Lateral Offset Connectors of the Lancer™ Open Pedicle Screw System is contraindicated when the Sacrum is absent or insufficient for implantation of Pedicle Screws at the S1 or S2 spinal level.

Cautions:
- Mixing of dissimilar metals can accelerate the corrosion Process. Stainless steel and titanium components must NOT be used together.
- Do not use components of the Thunderbolt and Lancer Pedicle Screw Systems with components from any other manufacturer.
- As with all orthopedic implants, none of the Thunderbolt and Lancer Pedicle Screw Systems components should ever be reused under any circumstances.

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.
- Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis 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 severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebrae, 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.

- This device system is not intended to be the sole means of spinal support. It's use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.
- The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

MR Magnetic Resonance Environment

Non-clinical testing has demonstrated that the Thunderbolt Minimally Invasive and Lancer Open Pedicle Screw Systems are MR Conditional under a range of exemplar configurations. A patient with these devices implanted in a way substantially and effectively similar to tested configurations can be safely scanned in an MR system under the following conditions:

- System contains only rods, connectors, screws, offsets, and hooks.
- Rods are oriented primarily parallel to the axis of the bore of the magnet and screws are oriented substantially perpendicular to the axis of the bore of the magnet.
- Screws are nominal length 95mm or less.
- Rods and constructs are length 600mm or less.
- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field of 19 T/m (1900 G/cm).
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 11ºC after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends radially up to 4.2cm and 7.6cm (respectively) from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system and a spin echo pulse sequence in a 3.0T MR system.

Possible Adverse Effects:

Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects:

- early or late loosening of the components
- rod migration
- disassembly, bending, loosening, and/or breakage
- foreign body reaction to the implants including possible tumor migration
- skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- pressure on the skin from components where there is inadequate tissue coverage over the implant
- loss of proper spinal curvature, correction, height, and/or reduction
- infection
- hemorrhage of blood vessels and/or hematomas
- bone graft, intervertebral body and/or sacral fracture at, above, and/or below the level of surgery
- non-union or delayed union
- loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- neurovascular compromise including paralysis or other types of serious injuries
- gastrointestinal and/or reproductive system compromise, including sterility
- cessation of growth of the fused portion of the spine
- death

How Supplied:

NON STERILE The Thunderbolt Minimally Invasive and Lancer Open Pedicle Screw System instruments and implants are provided clean but non-sterile and must be sterilized prior to use. Instruments can be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination:

All instruments and implants are supplied to the health care facility clean but non-sterile. Implants are single use only but need to be sterilized before each use. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Implants that have been implanted and then removed must be discarded. Cleaning and disinfecting of instruments can be accomplished by using alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can 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 alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

These devices are packaged in a convenience caddy/case. All devices must be removed from the case, inspected, and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

Recommended Cleaning:

The terms "Steris 444", "Enzol®" and "Prolystica®" are tradenames of ultrasonic equipment and detergents utilized on the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer's instructions and labeling. When appropriate, disassemble instruments prior to cleaning.

Automated Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High

Phase	Time (min)	Temperature	Detergent
Pre-Wash 1	1:00	Cold Tap Water	N/A
Enzyme Wash	1:00	Hot Tap Water	Enzol® at 1 oz. per 1 gal. Water
Wash 1	2:00	60°C	Prolystica® 2x conc. Neutral at 1/8 oz. per 1 gal. Water
Rinse 1	1:00	Hot Tap Water	N/A
Drying	7:00	115°C	N/A

4. Remove instrument(s) from washer & visually inspect for soil. Repeat if necessary.

Mechanical Cleaning (Ultrasonic):

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner & sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner & thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel & filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary.

Manual Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & thoroughly rinse with reverse osmosis/ deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.

7. Dry instrument(s) using a clean, soft cloth & filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary.

Care and Handling:

- Torque wrenches require a calibration service therefore must be returned to ChoiceSpine every 6 months.
- Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless-Steel Surgical Instruments" for additional information.
- Before use, instruments should be visually inspected, and function should be tested to assure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear or have other irregularities, DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water.
  Excess lubricant should be wiped off prior to storage and sterilization.

Sterilization:

The Thunderbolt and Lancer Pedicle Screw System instruments and implants are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments and implants are recommended to be steam sterilized by the hospital using the following process parameters:

Steam Sterilizer Type: Pre-vacuum
Temperature: 132°C
Duration: 4 minutes
Drying Time: 40 minutes

All devices are to be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

This steam sterilization cycle is not considered by the FDA to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature). Alternative sterilization methods or cycles may be used but should be validated according to hospital practices and procedures. The use of an FDA cleared wrap is recommended to ensure devices remain sterile prior to implantation.

Single Use Only:

Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Storage and Handling:

Implants should be stored in the implant sterilization case in clean, dry, well-ventilated conditions away from floors, ceilings, and outside walls. Store and transport sterile implants in such a way as to maintain sterility and functional integrity. Do not use implants if the sterilization wrap is opened, damaged or wet. Implants and instruments should remain covered until needed to avoid contamination. Only those to be implanted should be handled.

Limitations and Restrictions:

Repeated sterilization according to these instructions has a minimal effect on ChoiceSpine devices. Sterilization equipment varies in performance characteristics and must be validated accordingly. The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of sterilizing these ChoiceSpine implants and instruments. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Patient Education:

It is essential to provide preoperative instructions to the patient. The patient should be made aware of the potential risks of the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken, or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Device Retrieval Efforts:

Should it become necessary to remove any or all of the Thunderbolt and Lancer Pedicle Screw System components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

Surgical Technique Manual:

The ChoiceSpine Thunderbolt Minimally Invasive Pedicle Screw System and Lancer Pedicle Screw System Surgical Technique Manuals are available by contacting ChoiceSpine Sales Support.

Caution:

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

Product Complaints:

The customer or health care provider should report any dissatisfaction with the product quality, labeling, packaging, or performance to ChoiceSpine immediately. Furthermore, if any of the implants "malfunction" (i.e., do not meet any of their performance specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of the patient, ChoiceSpine should be notified immediately by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Some components may not be currently available. Please contact your ChoiceSpine representative for additional information. The products discussed herein may be available under different trademarks in different countries. All copyrights and pending and registered trademarks are property of ChoiceSpine. For more information on a specific product or trademark, please contact your local ChoiceSpine representative.

Information:

See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

Summary of Safety & Clinical Performance and Periodic Summary Update Report can be found at https://ec.europa.eu/tools/eudamed

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

For product complaints please contact:

ChoiceSpine, LLC
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Telephone: 865-246-3333; Fax: 865-588-4045

For additional product information please contact:

ChoiceSpine, LLC
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EC REP

EMERGO EUROPE
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The Netherlands

Symbol Legend:

Symbol	Definition
	Do not reuse
	Caution, consult instructions for use for warnings and precautions
	Consult instructions for use
	Do not use if package is damaged
	Lot number
	Reference number
	Serial Number
	Sterilized by irradiation
	Use by
	Manufacturer
	Date of Manufacture
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non-Sterile
	European Medical Devices
	Authorized representative in the European Community
	MR Conditional
	Unique Device Identification
	Medical Device