CONTRAINDICATIONS
Connectors on the Lancer™ Open Pedicle Screw System must be contraindicated in the following: degenerative disc disease (DDD; defined as back pain of physiological requirements. The components include: polyaxial pedicle screws, set screws, rods, connectors, hooks, instruments and sterilizer trays.

INDICATIONS:
The Lancer™ Open Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. It is intended for 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 fusions.

When used for posterior, non-cervical, 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; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. Overall levels of fixation are T1 to the Sacrum/Ilum. When used for fixation to the ilum, the lateral offset connectors must be used. The Lancer™ Open Pedicle Screw System may be used in conjunction with pedicle screws placed at the T1 or S2 spinal level.

CONTRAINDICATIONS: Contraindications include, but are not limited to: - infection, systems or localized - signs of bone formation - morbid obesity - severe osteopenia or osteoporosis - kyphosis - atlantoaxial or occipitocervical instability - Paget's disease - drug abuse - pregnancy - severe osteopenia or osteoporosis

Lancer™ Open Pedicle Screw System Instruction for Use

POSSIBLE ADVERSE EFFECTS
- late or early loosening of the component - rod migration - disassembly - bending, loss of function, and/or breakage - foreign body reaction to the implants including possible tumor migration

The system should be carefully evaluated. The patient must be instructed in the proper methods to ambulate, climb stairs in an orderly fashion, avoid contact with bed and performing of daily living, while minimizing rotational and bending stresses.

DESCRIPTION:
The Lancer™ Open Pedicle Screw System includes implant components made of stainless steel (ASTM F89/F854 and aluminum (ASTM B821). These components are available in various designs and sizes so that the allow to the surgeon to select a implant component suited to a patient's anatomical and physiological requirements.

The components include: polyaxial pedicle screws, set screws, rods, connectors, hooks, instruments and sterilizer trays.

INDICATIONS:
The Lancer™ Open Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. It is intended for 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 for posterior, non-cervical, 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; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Important Note to Operating Surgeon:

Single Use Only:

Never use an implant. An 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.

Patient Education:

It is essential to provide pre-operative instructions to the patient. Surgery for degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Fusion surgery is occasionally committed for the treatment of degenerative disc disease (DDD) as defined above. This is a newly demanding procedure presenting a risk of serious injury to the patient. Patients who smoke have been shown to have an increased incidence of complications. The patient should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with severe muscle and bone quality, and neuro-para-lysis patients.

WARNING:
The safety and effectiveness of pedicle screw spinal implants have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion within the lumbar, thoracic, and sacral spine. The patient must be carefully evaluated. The patient must be instructed in the proper methods to ambulate, climb stairs in an orderly fashion, avoid contact with bed and performing of daily living, while minimizing rotational and bending stresses.

DESCRIPTION:
The Lancer™ Open Pedicle Screw System includes implant components made of stainless steel (ASTM F89/F854 and aluminum (ASTM B821). These components are available in various designs and sizes so that the allow to the surgeon to select a implant component suited to a patient's anatomical and physiological requirements.

The components include: polyaxial pedicle screws, set screws, rods, connectors, hooks, instruments and sterilizer trays.

INDICATIONS:
The Lancer™ Open Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. It is intended for 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 for posterior, non-cervical, 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; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Important Note to Operating Surgeon:

Single Use Only:

Never use an implant. An 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.

Patient Education:

It is essential to provide pre-operative instructions to the patient. Surgery for degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Fusion surgery is occasionally committed for the treatment of degenerative disc disease (DDD) as defined above. This is a newly demanding procedure presenting a risk of serious injury to the patient. Patients who smoke have been shown to have an increased incidence of complications. The patient should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with severe muscle and bone quality, and neuro-para-lysis patients.

WARNING:
The safety and effectiveness of pedicle screw spinal implants have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion within the lumbar, thoracic, and sacral spine. The patient must be carefully evaluated. The patient must be instructed in the proper methods to ambulate, climb stairs in an orderly fashion, avoid contact with bed and performing of daily living, while minimizing rotational and bending stresses.

DESCRIPTION:
The Lancer™ Open Pedicle Screw System includes implant components made of stainless steel (ASTM F89/F854 and aluminum (ASTM B821). These components are available in various designs and sizes so that the allow to the surgeon to select a implant component suited to a patient's anatomical and physiological requirements.

The components include: polyaxial pedicle screws, set screws, rods, connectors, hooks, instruments and sterilizer trays.

INDICATIONS:
The Lancer™ Open Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. It is intended for 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 for posterior, non-cervical, 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; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Important Note to Operating Surgeon:

Single Use Only:

Never use an implant. An 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.

Patient Education:

It is essential to provide pre-operative instructions to the patient. Surgery for degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Fusion surgery is occasionally committed for the treatment of degenerative disc disease (DDD) as defined above. This is a newly demanding procedure presenting a risk of serious injury to the patient. Patients who smoke have been shown to have an increased incidence of complications. The patient should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with severe muscle and bone quality, and neuro-para-lysis patients.

WARNING:
The safety and effectiveness of pedicle screw spinal implants have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion within the lumbar, thoracic, and sacral spine. The patient must be carefully evaluated. The patient must be instructed in the proper methods to ambulate, climb stairs in an orderly fashion, avoid contact with bed and performing of daily living, while minimizing rotational and bending stresses.

DESCRIPTION:
The Lancer™ Open Pedicle Screw System includes implant components made of stainless steel (ASTM F89/F854 and aluminum (ASTM B821). These components are available in various designs and sizes so that the allow to the surgeon to select a implant component suited to a patient's anatomical and physiological requirements.

The components include: polyaxial pedicle screws, set screws, rods, connectors, hooks, instruments and sterilizer trays.

INDICATIONS:
The Lancer™ Open Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. It is intended for 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 for posterior, non-cervical, 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; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.
Recommended Cleaning:

The terms “Steris™ ProLytica™” and ProLytica® are Trademarks of ultrasonic equipment and detergents utilized on the recommendation of physicians. Any site-specific washer or equivalent ultrasonic detergent can be utilized when used in accordance with the manufacturer’s instructions and labeling.

AUTOMATED CLEANING:

1. Rinse instrument(s) under cool running tap water (<35 °C) to remove gross soil. Use a sterile syringe to flush through & around cracks, crevices, & hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in rinse with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
4. Remove instrument(s) from washer & 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 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.

MECHANICAL CLEANING (ULTRASONIC):

1. Rinse instrument(s) under cool running tap water (<35 °C) to remove gross soil. Use a sterile syringe to flush 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 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 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 Choice Spine every 6 months.
- Refer to ASTM standard F2344-06, “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.

Lancer™ Open Pedicle Screw System Instruction for Use

### STERILIZATION:

The Lancer™ Open Pedicle Screw System components are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Implants and instruments are recommended to be steam sterilized by the hospital utilizing the following process parameters. All devices must be placed in appropriate caddy/case prior to steam sterilization. (Alternative methods or cycles may be used, but should be validated according to hospital practices and procedures).

**Steam Sterilization Type: Pre-vacuum**

- **Temperature**: 132°C
- **Duration**: 4 minutes
- **Drying Time**: 40 minutes

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 cleaned 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.

### SURGICAL TECHNIQUE MANUAL:


**PRODUCT COMPLAINTS:**

The customer or health care provider should report any dissatisfaction with the product quality, labeling, packaging or performance to Choice Spine 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, Choice Spine 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.

For product complaints please contact:

Choice Spine, LP
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
phone: 865-246-3333; fax: 865-588-4045

For additional Product information please contact:

Choice Spine, LP
Customer Service Department
400 Erin Drive
Knoxville, TN 37919
phone: 865-246-3333; fax: 865-588-4045
customerservice@choicespine.net

### Symbol Legend:

- **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-Stereile**
- **European Medical Devices**
- **Authorized representative in the European Community**