Degenerative disc disease (DDD) (defined as back pain of discogenic origin
Contraindications include, but are not limited to:
• Connectors on the Lancer Open Pedicle Screw System must be used in
• Contraindications:
• 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 possible outcomes. Other poor candidates for spine fusion include obesity, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Wrist:
• The safety and effectiveness of pedicle screw systems have been established only for spinal conditions with significant mechanical instability or deformity. Patients requiring fusion with instrumentation and whose conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of the L-5-S-1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis of the thoracic, lumbar, and sacral spine, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition which prevents secure implant screw fixation

This device system is not intended to be the sole means of spinal care and handling:

• Torque wrenches require a calibration service therefore must be returned to ChoiceSpine every 6 months.

• Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant designed for orthopedic instruments. Lubricant should contain a chemico-physical preservative to prevent bacterial growth and be made with distilled water which lubricant should be wiped off prior to storage and sterilization.

Stabilization:
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 sterilized by the hospital using the following process parameters.

Steam Sterilizer Type: Pre-vacuum
Temperature: 134°C
Duration: 4 minutes
Drying Time: 40 minutes

All devices are to be wrapped in two-layer of 1-ply polypropylene wrap (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 method. By use of a steam heat sterilizer, adequate heat and moisture content must be provided to ensure that a steam sterilization process is performed. Devices sterilized in this manner are not intended to be used as single-use items. The user should use this process only for sterilizing items and accessories (such as steam sterilization pouches, chemical or biological indicators, and pouch holders) that have been cleaved by the FDA for the sterilization cycle specifications (time and temperature). Alternative sterilization methods or cycles may be used but should be validated in accordance with applicable FDA guidelines. An AAMI (American Association for Medical Instrumentation) certified sterilizer is recommended to ensure devices remain sterile prior to implantation.

Single Use Only
Never reuse any implant. An implant that has been twisted, bent, cut, broken, or deformed in any way, or altered in any manner may not function properly. If the scratches or dents appear intact, must be discarded. These devices are provided as single use only.

Storage and handling:
Implants should be stored in the sterilization case in clean, dry, and protected conditions. Do not use the implant if the packaging is opened, damaged, or wet. Implants and instruments should remain covered until needed to avoid contamination. Only those to be

Automated Cleaning:
1. Rinse instrument(s) under cool running tap water (< 35°C) to remove gross soil. Use a sterile syringe to flush through water & around screws, crucibles, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (<35°C) for at least one (1) minute. Use a soft brite brush as needed to remove soil, paying close attention to threads, crucibles, & hard to reach areas.
3. Load instrument(s) into the cleaner & sonicate for ten (10) minutes. The ultrasonic cleaner should be set up with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a clean, soft cloth & fiber, pressurized air (20 psi) to dry.

6. 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 water & around screws, crucibles, & hard to reach areas.
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3. Assemble instruments, should be handled.

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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 Lancer™ Open 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:

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.

Information:
See choicespine.com for more information.

For product complaints please contact:
ChoiceSpine, LLC
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
phone: 865-246-3333; fax: 865-588-4045

For additional Product information please contact:
ChoiceSpine, LLC
Customer Service Department
400 Erin Drive
Knoxville, TN 37919
phone: 865-246-3333; fax: 865-588-4045
customerservice@choicespine.com

Symbol Legend:

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<th>Definition</th>
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<td>Do not reuse</td>
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<tr>
<td>Consult instructions for use</td>
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<tr>
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<td>Non-Sterile</td>
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