Raven™ Lumbar Plate System
Instruction for Use

Rx only

Implants

NON STERILE

Choice Spine, LLC
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Knoxville, TN 37919
USA

Description:

The Raven Lumbar Plate System is an anterior/anterolateral/lateral plate system that may be used in the thoracic, lumbar, and sacral spine (T1-S1). The Raven Lumbar Plate System consists of plates and screws manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136, as well as associated manual general surgical instrumentation. The implants are available in a variety of sizes to accommodate various patient anatomies.

Indications for Use:

The Raven Lumbar Plate System Anterior and Lateral Plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- Pseudoarthrosis;
- Spondylolysis;
- Spondylolisthesis;
- Spinal stenosis;
- Tumors;
- Trauma (i.e. Fractures or Dislocation);
- Deformities (i.e. Scoliosis, Kyphosis or Lordosis);
- Failed Previous Fusion

The Raven Lumbar Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

Contraindications:

Contraindications include, but are not limited to:

- Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any spinal instrumentation system.
- Any entity or condition that totally precludes the possibility of fusion (i.e. cancer, kidney dialysis, osteopenia) is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, foreign body sensitivity. In addition, the patient's occupation, activity level, or mental capacity may be relative contraindications to this. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stress on the implant during bony healing and may be at a higher risk of implant failure and nonunion.
- Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.
- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to implantation.

Precautions:

The implantation of anterior or lateral plate spinal systems must be performed only by experienced spinal surgeons with specific training in the use of this spinal plate 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 must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

Warnings:

- The Choice Spine Raven Lumbar Plate System is not intended for screw attachment or fixation to the posterior element (pedicles) of the cervical, thoracic or lumbar spine.
- The implants are single use only.
- The system components are supplied non-sterile therefore need to be sterilized before use.
- When using the plate anteriorly, always orient the plant along the midline of the spine.
- To optimize bony union, perform an anterior micro-discectomy or corpectomy as directed.
- To facilitate fusion, a sufficient quantity of autologous or allogeneic bone or other appropriate material should be used.
- Excessive torque applied to the screws when seating the plate may strip the threads in the bone.
- Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
- Do not reuse implants. Discard used, damaged or suspect implants. Reuse of single use devices could result in injury or re-operation due to breakage or infection. Do not re-sterilize single use implants that come in contact with body fluids.
- When choosing a metallic implant system, the surgeon should consider factors such as: levels of implantation, patient weight, patient activity level, and other patient specific conditions which may impact the performance of the system as it relates to fatigue of the implants.
- The Choice Spine Raven Lumbar Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Raven Lumbar Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Possible Adverse Effects:

The potential risks identified with the use of this system, which may require additional surgery include:

- Infection, early or late
- Mental sensitivity or allergic reaction to the implant
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Bending or fracture of implant
- Loosening of the implant
- Screw back out, possibly leading to implant loosening, and/or further surgical procedures device removal
- Nonunion, delayed union
- Decrease in bone density due to stress shielding
- Bursitis
- Nerve damage due to surgical trauma or presence of the device
- Neurological difficulties, such as, bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia
- Spinal cord impingement or damage
- Paralysis
- Degenerative changes or instability in segments adjacent to fused vertebral levels
- Dural tears
- Fracture of bone structure
- Further surgery, for instance for dural repair, a chronic CSF leak or fistula, and meningitis
- Lymphatic vessels damage and/or lymphatic fluid exudation
- Vascular damage due to surgical trauma or presence of the device (NOTE: Vascular damage could result in catastrophic or fatal bleeding. Positioning implants adjacent to large arteries or veins may result in erosion of these vessels and cause catastrophic bleeding in the last postoperative period)
- Death

How Supplied:

NON STERILE The Raven Lumbar Plate 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.

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

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.

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:

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

Inspection:

The implants should be inspected after processing, prior to sterilization. Any implant with damage, corrosion, discoloration, scratches, residue, or debris should be discarded.

Sterilization:

Choice Spine 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 (Alternative methods or cycles may be used but should be validated according to hospital practices and procedures):
All devices must be placed in appropriate caddy/case prior to steam sterilization.

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:

If the device has been opened, damaged or adulterated in any way it must not be used. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

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

Limitations and Restrictions:

Repeated sterilization according to these instructions has a minimal effect on Choice Spine 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 Choice Spine 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 Raven Lumbar Plate System components, please call Choice Spine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information

Surgical Technique Manual:

The Raven Lumbar Plate System Surgical Technique Manual is available by contacting Choice Spine Customer Service.

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.

Caution:

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

Information:

See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

For product complaints please contact:
Choice Spine, LLC
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, LLC
Customer Service Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045
customerservice@choicespine.com

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