BLACKBIRD ™ Spinal System
Instruction for Use

Rx only | 2 Implants | NON STERILE

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USA

Important Note to Operating Surgeon:

The ChoiceSpine BLACKBIRD Spinal System is designed to provide biomechanical stabilization as an adjunct to fusion. 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.

General Description:

The ChoiceSpine BLACKBIRD Spinal System is a comprehensive system for posterior fixation of the cervical and upper thoracic spine. It is to be implanted posteriorly. The system is composed of polyaxial screws and smooth shaft polyaxial screws in various sizes, set screws, straight rods, pre-bent rods, transition rods, cross connectors, lateral offset connectors, rod transition connectors, and hooks. All implant components will be made from Ti 6Al 4V-ELI alloy or Cobalt-28 Chromium-6 Molybdenum Alloy per ASTM F1537. Associated instrumentation will accompany the implant components. Instruments will be made from biocompatible materials.

Indications for Use:

The ChoiceSpine BLACKBIRD Spinal System is intended to be used in skeletally mature patients as an adjunct to fusion for stabilization of the cervical spine & thoracic spine (C1-T3) for the following conditions:

- degenerative disc disease (DDD; defined as neck pain of discogenic origin with degeneration of the disk as confirmed by history & radiographic studies)
- spondylolisthesis
- trauma
- fracture / dislocation
- spinal stenosis
- atlanto/axial fracture with instability
- tumor
- revision of previous cervical spine surgery

The use of polyaxial screws is limited to the thoracic spine (T1-T3) "for anchoring the construct only" and not intended to be placed in the cervical spine. The use of the rods and hooks are intended to provide stabilization and promote fusion in the cervical / upper thoracic (C1-T3) spine. This system can be linked to a Ø6.0 mm rod system such as the ChoiceSpine Starfire™ Pedicle Screw System.

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

Cautions, Precautions, Warnings, Possible Adverse Effects

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 BLACKBIRD Spinal System with components from any other manufacturer.
- As with all orthopedic implants, none of the BLACKBIRD Spinal System 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. Its 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 ChoiceSpine BLACKBIRD 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.

The BLACKBIRD Spinal System has not been evaluated for safety and compatibility in the MR environment. The BLACKBIRD Spinal System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the BLACKBIRD Spinal System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 technique guide. The tightness of all the 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 post-operative 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.

Possible Adverse Effects/Complications:

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 ChoiceSpine BLACKBIRD Spinal System devices are provided clean but non-sterile and must be sterilized prior to use. Implants are intended for single use only. 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.

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:

ChoiceSpine instruments are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments 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):

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

All devices are to be wrapped in two-layer 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 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. 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. S/he 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 BLACKBIRD Spinal 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 BLACKBIRD Spinal System Surgical Technique Manual is available by contacting ChoiceSpine Customer Service.

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.

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:
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 or 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