BLACKBIRD™ HLS (Hinged Laminoplasy System) Instruction for Use

Rx only | 2 Implants | NON STERILE

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Important Note to Operating Surgeon:

The ChoiceSpine BLACKBIRD HLS (Hinged Laminoplasty System) intended for use in the (C3-T3) region of the spine in Laminoplasty procedures. 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 surgical technique is available for instructions on the important aspects of this surgical procedure.

The purpose of the ChoiceSpine BLACKBIRD HLS (Hinged Laminoplasty System) is to provide a means to prevent expulsion of graft material after a laminoplasty has been performed.

Device Description:

The proposed ChoiceSpine BLACKBIRD HLS (Hinged Laminoplasty System) is an implant system that consists of various plates and screw configurations.

The proposed plates are available in various configurations to address surgeon and patient needs as necessary. The proposed plate devices come preformed with holes for bone screws. The plate offered can be affixed to allograft or autograft material and secured with a bone screw from the system. A hinge plate is provided when additional stabilization is necessary. Screws are used to attach the plates to bone and are available in a variety of lengths and diameters to fit patient anatomy. The system components are made from medical grade Titanium Alloy Ti-6AI-4V ELI (ASTM F136), 17-4 SS (ASTM F899), 465 SS (ASTM A564), and 6061 T6 Aluminum (ASTM B221 and B209).

Indications for Use:

The Choice BLACKBIRD HLS (Hinged Laminoplasty System) is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The ChoiceSpine BLACKBIRD HLS (Hinged Laminoplasty System) is used to hold or buttress the allograft or autograft material in place in order to prevent the graft material from expulsion or impinging the spinal cord.

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 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
- rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis
- Any medical or surgical condition which would preclude potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevated white blood count (WBC), or a marked left shift in the WBC differential count
- Suspected or documented metal allergy or
- intolerance
- Any case needing to mix metals from different components
- Any case not needing a laminoplasty procedure
- Any patient having inadequate tissue coverage over the operative site, or inadequate bone stock or bone quality
- Any time implant utilization would interfere with anatomical structures or expected physiological performance
- Any patient who will not follow postoperative instructions, such as drug/alcohol abuse patients, and are unwilling to restrict postoperative activities
- Any case not described in the Indications
- Any patient unwilling to follow the postoperative instructions

Possible Adverse Effects:

- Early or late loosening of the components
- Implant migration
- Disassembly, bending, loosening, slippage, and/or breakage of any or all of the components or instruments
- Foreign body reaction to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring
- Pressure on the skin possibly resulting in skin breakdown from component parts where there is inadequate tissue coverage over the implant. Implant or graft extrusion through the skin. Wound complications.
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Bone fracture or stress shielding at, above, or below the level of surgery
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis or other types of serious injury. Cerebral spine fluid leakage.
- Gastrointestinal, urological, and/or reproductive system compromise, including sterility, impotency, and/or loss of consortium.
- Hemorrhage of blood vessels and/or hematomas
- Discitis, arachnoiditis, and/or other types of inflammation
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus
- Inability to resume activities of normal daily living
- Death

Warnings and Precautions:

- A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This system is intended to be used to provide protection of the spinal canal. The safety and effectiveness of the device when implanted in the anterior spine have not been established.
- Preoperative and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the BLACKBIRD HLS (Hinged Laminoplasty System) by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results.
- **PHYSICIAN NOTE**: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.
- The ChoiceSpine BLACKBIRD HLS (Hinged Laminoplasty 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 in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Implant Selection:

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure.

Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending, loosening, or migration of the device, which may result in further injury or the need to remove the device prematurely.

Preoperative:

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Use care in the handling and storage of implant components. Implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The system components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
- Unless sterile packaged, all parts should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:

- Any instruction manuals, if available, should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Never over-tighten screws so as to prevent stripping of the threads. Recheck the tightness of all screws after finishing to ensure that none have loosened during the tightening of the other screws. Failure to do so may cause loosening.

Postoperative:

- The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.
- Detailed instructions on the use and limitations of the device should be given to the patient. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls, sudden jolts, or sudden blows to the spine.
- To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation that may cause sharp forces to the posterior cervical spine.

How Supplied:

NON STERILE The ChoiceSpine BLACKBIRD HLS 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 implants are supplied to the hospital clean but non-sterile and require sterilization before each use. The implants are packaged in a convenience caddy/case. If implants are contaminated with bone and/or body fluids, please return them to ChoiceSpine for disposal. All devices including the implant caddies must be placed back into the autoclave case prior to sterilization.

All instruments are supplied to the hospital clean but non-sterile and require sterilization before each use. All instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned before sterilization and reintroduction into a sterile surgical field. Cleaning and disinfecting of instruments can be performed with alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners follow 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 "Steris 44", "Enzol®" and "Prolystica®" are tradenames of ultrasonic equipment and detergents utilized in 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 & 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 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 instruments and inspect for soil, repeat cleaning 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 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:

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 BLACKBIRD HLS (Hinged Laminoplasty 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 using 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 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.

Surgical Technique Manual:

The BLACKBIRD HLS (Hinged Laminoplasty System) Surgical Technique Manual is available by contacting ChoiceSpine Customer Service.

Device Retrieval Efforts:

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

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
customerservice@choicespine.com

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
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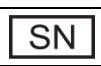
Symbol Legend:

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