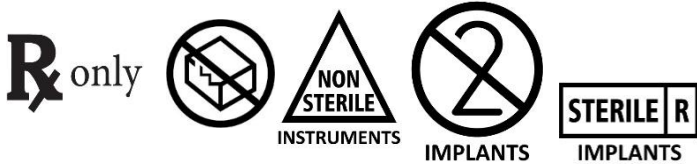




BLACKHAWK® TI STANDALONE CERVICAL SPACER SYSTEM

Instruction for Use



 ChoiceSpine, LLC
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USA

Important Note to Operating Surgeon:

The Blackhawk® Ti Standalone Cervical Spacer System is designed to provide biomechanical stabilization to the cervical vertebral column. 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.

Preoperative:

A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are critical considerations in achieving a successful result. Longevity of the implant depends on the weight and activity level of the patient, patient mortality, or need for component replacement secondary to patient weight and activity level.

Only patients that meet the criteria described in the indications should be selected. Patient conditions such as those addressed in the contraindications should be avoided.

An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Care should be used in the handling of the implant components. The implants should not be scratched or otherwise damaged.

Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should verify that all parts and necessary instruments are present before the surgery begins.

Intraoperative:

The instructions in any available applicable surgical technique should be carefully followed.

Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.

To assure proper fusion below and around the location of the instrumentation, autograft should be used. Autograft must be placed in the area to be fused and the graft material must extend from the upper to the lower vertebrae to be fused.

It is recommended to use an imaging system to verify that the implant is properly placed and correctly aligned within the disc space. Ensure the device is properly placed in its final location prior to deploying the internal anchors. Note that the convex version has a pronounced radial dome on the superior side. There is an arrow on the posterior end of the device to indicate which side is domed. The implant should be placed such that the arrow points to the superior side of the disc space (i.e., cephalad).

Different manufacturers use different materials, varying tolerances and design configurations. Components of the Blackhawk® Ti Standalone Cervical Spacer System

must not be used with components from any other system or manufacturer.

Postoperative:

The physician's post-operative directions and warnings to the patient and the corresponding patient compliance are extremely important. It is recommended that regular, long-term postoperative follow-up be undertaken to detect early signs of component wear and to consider the course of action to be taken if such events occur.

Periodic x-rays should be taken to detect evidence of positional changes, failed fusion, and/or device fracture. In such cases, patients should be closely monitored, and the benefits of revision surgery should be considered to avoid further deterioration.

All patients should be instructed on the limitations of the device and the possibility of subsequent surgery. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion. The patient should be advised not to smoke or consume alcohol during the autogenous bone graft healing process.

If a non-union develops or the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the device(s).

Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Blackhawk® Ti Standalone Cervical Spacer System components should ever be reused under any circumstances.

Description:

The Blackhawk® Ti Standalone Cervical Spacer System is a stand-alone anterior cervical interbody device consisting of a titanium alloy (Ti-6Al-4V ELI) implant cage per ASTM F3001, nitinol internal locking components per ASTM F2063, two internal titanium alloy (Ti-6Al-4V ELI) anchors per ASTM F136, and a titanium alloy (Ti-6Al-4V ELI) locking cam per ASTM F136. The system includes instruments made of Stainless Steel (ASTM A564/F899).

They are intended for use as interbody fusion devices and offered in a variety of heights, footprints, and lordotic angles to accommodate varying anatomical conditions. The device features a chamber intended to be filled with autogenous bone and/or allogenic bone graft material. The Blackhawk® Ti Standalone Cervical Spacer System is used with two internal bladed anchors that lock on deployment and provide additional fixation.

The integrated fixation anchors may not provide adequate stability for all situations. The surgeon should consider the appropriate fixation required for each patient and determine if additional supplemental fixation may be needed. When used without the supplied fixation, The Blackhawk® Standalone Ti Cervical Spacer is intended for use with supplemental fixation (e.g., an anterior plate, posterior pedicle screws).

Indications for Use:

The Blackhawk® Ti Standalone Cervical Spacer System is a stand-alone anterior cervical interbody fusion device indicated for use in a skeletally mature patient with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Blackhawk® Ti Standalone Cervical Spacer System is to be used with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, to facilitate fusion.

Contraindications:

Contraindications for the Blackhawk® Ti Standalone Cervical Spacer System are similar to those of other systems of similar design, and include, but are not limited to:

- Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
- Morbid obesity
- Pregnancy
- Grossly distorted anatomy due to congenital abnormalities
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
- Rapid joint disease, bone absorption, osteopenia, osteomalacia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.

- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Suspected or documented material allergy or intolerance
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or lifestyle may interfere with their ability to follow post-operative instructions
- Any case not needing an autogenous bone and/or allogenic bone graft and fusion?
- Any condition not described in the Indications for Use

Cautions, Warnings and Precautions and Possible Adverse Effects

Cautions:

- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- If the packaging of the sterile packed implants is compromised, the sterility of the device will be compromised, and the implant must be discarded.
- If the expiry date on the packaging has been exceeded, the implant must be discarded.
- 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 Blackhawk® Ti Standalone Cervical Spacer System with components from any other system.

As with all orthopedic implants, none of the Blackhawk® Ti Standalone Cervical Spacer System implants should ever be reused under any circumstances.

Warnings and Precautions:

- The Blackhawk® Ti Standalone Cervical Spacer System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Further, the proper selection and compliance of the patient will greatly affect the results. The surgeon should consider the patient conditions (e.g., smoker, malnutrition, obesity, alcohol and drug abuse, poor muscle and bone quality), which may impact system performance.
- The internal anchors must be deployed when using the Blackhawk® Standalone Ti System. Autogenous bone and or/allogenic bone grafting must be part of the spinal fusion procedure in which the Blackhawk® Ti Standalone Cervical Spacer System is used. Use of this product without an autogenous bone and or/allogenic bone graft may not be successful. The spinal implant cannot stand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device will eventually occur.
- The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Titanium 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. Great care should be taken during the patient/implant selection and implant placement. Postoperative management to minimize stresses on the implant is crucial because stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete. If this happens, it could result in further injury or the need to remove the device prematurely.
- 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 Blackhawk® Ti Standalone Cervical Spacer System has not been evaluated for safety and compatibility in the MR environment. The Blackhawk® Ti Standalone Cervical Spacer System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Blackhawk® Ti Standalone Cervical Spacer System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Possible Complications and Adverse Effects:

Potential complications and adverse effects include, but are not limited to:

- Early or late loosening of the components
- Disassembly, bending or breakage of any or all of the components
- Foreign body (allergic) reaction to the implants
- Infection
- Non-union (pseudarthrosis), delayed union, mal-union
- Loss of neurological function, including paralysis (complete or incomplete),

radiculopathy, dysesthesia, hyperesthesia, anesthesia, paresthesia, development or continuation of pain, numbness, neuroma, tingling sensation, dural tears, neuropathy, neurological deficits (transient, permanent, or delayed), reflex deficits, bilateral paraplegia, and/or arachnoiditis

- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence
- Misalignment of anatomical structures or loss of spinal mobility
- Autogenous bone graft donor complications including pain, fracture or wound healing problems
- Atelectasis
- Retropulsion of graft
- Injury to the neck, including the esophagus, trachea, carotid artery, larynx, or laryngeal nerves
- Early or late hoarseness, dysphagia, or dysphonia
- Vascular damage resulting in excessive bleeding
- Fracture, damage, degenerative changes or instability of any bone above and/or below the level of surgery
- Bone loss due to resorption or stress shielding
- Death

Additional surgery may be necessary to correct some of these possible adverse effects.

How Supplied:

STERILE The Blackhawk® Ti Standalone Cervical Spacer System implants are supplied “STERILE” (gamma radiation) with a SAL of 10⁻⁶ and intended for single use only. The sterility can only be assured if the packaging is intact. Do not use this device if the sterile packaging has been opened or damaged. Contact your local sales representative or distributor for replacement. Remove all packaging material prior to use. Only sterile implants should be used in surgery. Consult the Instructions for Use for the reusable surgical instruments.



The Blackhawk® Ti Standalone Cervical Spacer System instruments 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 are supplied to the health care facility clean but non-sterile. 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.

Caution: Delays in reprocessing and prompt removal of soil on a device could create conditions favorable to microbial growth, which may increase the challenge to subsequent steps such as cleaning and disinfection/sterilization. Organic contamination may inactivate or prevent full penetration of a disinfectant or sterilant.

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.

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.

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
Prewash 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 Concentrate 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.

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):

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:

Implants should be stored in their original, sealed packaging in clean, dry conditions. The packaging should not be exposed to direct sunlight, ionizing radiation, extreme temperatures, or particulate contamination. In order to ensure sterility, implants must be used before the end of the expiration date indicated on the outer package label. Prior to use, inspect the packaging and labeling for integrity. 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.

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 instruments. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Caution:

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

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 Blackhawk® Ti Standalone Cervical Spacer System Surgical Technique Guide is available by contacting ChoiceSpine Customer Service.

Product Lifetime:

The Blackhawk® Ti Standalone Cervical Spacer System has completed its product

lifetime once the fusion mass has attained adequate strength to sustain the stability and integrity of the spinal segment without necessitating external support (typically six (6) to twelve (12) months, depending on the condition(s) treated and the procedure performed).

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.

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
Sales Support
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045
salesupport@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
	MR Conditional
	Unique Device Identification
	Medical Device