Hawkeye™ Ti Vertebral Body Replacement (VBR) System

Instruction for Use

Rx only 2 Implants NON STERILE

Choice Spine
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Knoxville, TN 37919

General Description:

The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System is intended for use in the thoracolumbar spine (T1-L5) and cervical spine (C2-T1) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The Choice Spine HAWKEYE™ Ti VBR System is intended for use with supplemental fixation & is to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The Choice Spine HAWKEYE™ Ti VBR System consists of spacers comprised of Ti6AL-4V ELI (ASTM F136 or ASTM F3001).

The spacers have a basic oval/trapezoidal shape, a hollow center for placement of bone graft, and angled ridges or "teeth" on both the superior & inferior surfaces for resisting migration. They are available in an assortment of heights & in multiple angles of lordosis to accommodate different anatomic requirements.

Indications for Use:

The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) and cervical spine (C2-T1).

When used in the cervical spine (C2-T1), the HAWKEYE™ Ti VBR devices are intended for use in the skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used in the thoracolumbar spine (T1-L5), the HAWKEYE™ Ti VBR Spacers are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

These devices are intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e.,posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

Contraindications:

Contraindications for the Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System are similar to those of other systems of similar design, & include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Conditions, such as morbid obesity, which may put excessive stress on the bone & implants
3. Severe osteopenia or osteoporosis may prevent adequate fixation.
4. Suspected or documented metal allergy
5. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow postoperative instructions
6. Pregnancy
7. Patients who are unwilling to restrict activities or follow medical advice
8. Use with components of other systems.
9. Patients with physical or medical conditions that would prohibit beneficial surgical outcome

Warnings:

1. Mixing of dissimilar metals in the supplemental fixation to be used with this VBR System can accelerate the corrosion process. Stainless steel & titanium implants must NOT be used together in building a construct.
2. A satisfactory outcome is enhanced by the selection of the appropriate spacer size & angle.

MRI Safety Information

3. The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System has not been evaluated for safety & compatibility in the MR environment. The Choice Spine HAWKEYE™ Ti VBR System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Choice Spine Hawkeye™ Ti Vertebral Body Replacement device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions:

1. The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System should be implanted only by surgeons who are fully experienced in the use of such implants & the required specialized spinal surgery techniques as this is a technically demanding procedure.
2. The spacers should not be reused, even if they appear in a perfect state. Any spacer that has been used, twisted, bent, implanted & then removed, even if it appears intact, must be discarded.
3. The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System is not intended to be the sole means of spinal support – supplemental internal fixation must be used. Bone grafting must be part of the spinal fusion procedure. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e. scratches, notches) & loads from weight bearing & activity will affect the implant's longevity.
4. Refrain from handling the spacers as much as possible before implantation, & always handle it with the utmost care. The devices (in their original packaging) must be stored with care in a clean & dry place away from radiation or extreme temperatures. Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases.
5. Metal sensitivity has been reported following exposure to orthopedic implants and instruments. The most common sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.

Instructions for Use

A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Preoperative planning & operating procedures, including knowledge of surgical techniques, proper reduction, & proper selection & placement of the implant are critical considerations in achieving a successful result. Preoperative, intraoperative & postoperative conditions should be considered.

Preoperative:

1. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the device & the potential adverse effects of the surgery.
2. Only patients that meet the criteria described in the indications should be selected.
3. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery.

Intraoperative:

1. The surgeon must be fully conversant with all aspects of the surgical technique.
2. Proper function of the surgical instruments specific to the Choice Spine Vertebral Body Replacement (VBR) System should be verified prior to every surgical procedure.
3. The appropriate type & size of implant appropriate to the patient & the positioning of the implant are important.

Postoperative:

1. Patients must be informed of the precautions to be taken in their everyday life to enhance a maximum implant service life.
2. Regular post-operative follow-up is recommended to detect early signs of implant failure & to consider necessary action.

Potential Complications & Adverse Effects:

Potential complications & adverse effects for this system are similar to those of other spinal instrumentation systems, & include, but are not limited to:

1. Early or late loosening of the components
2. Disassembly, bending or breakage of any or all of the components
3. Foreign body (allergic) reaction to the implants
4. Infection
5. Loss of neurological function, including paralysis, spinal cord impingement or damage
6. Dural tears, CSF leak or fistula or meningitis
7. Bone graft donor complications including pain, fracture or wound healing problems
8. Vascular damage resulting in excessive bleeding & malposition devices adjacent to large vessels could cause vessel erosion & catastrophic bleeding.
9. Loss or impairment of bowel, sexual, and/or bladder function & other types of urological compromise
10. Possible local or systemic adverse reactions from potential long-term degradation of the polymer or mechanical grinding causing wear debris
11. Bone loss due to resorption or stress shielding
12. Pseudoarthrosis
13. Death

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

How Supplied:

The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System devices are provided 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 must first be cleaned using methods recommended in this document or established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using methods recommended in this document or established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed 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. Also, certain instruments may require dismantling before cleaning.

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 and inspected and cleaned via one of the appropriate methods below. All devices must be placed back into the caddy and case prior to steam sterilization.

Recommended Cleaning:

The terms "Steris 444", "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 1oz 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 Enzo® 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:

- Torque wrenches require service every 6 months, 3000 cycles or 200 autoclave cycles.
- 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, are 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:
The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System components are provided non-sterile & must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Implants & instruments are recommended to be steam sterilized by the hospital using the following parameters:

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

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. Alternative methods or cycles may be used, but should be validated according to hospital practices & procedures.

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 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.

Device Retrieval Efforts:
Should it become necessary to remove any or all of the Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) 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 choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System Surgical Technique Guide is available by contacting Choice Spine Customer Service.

Caution:

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

Information:
See www.choicespine.com/patents.html for patent information.

For product complaints please contact:
Choice Spine, LP
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045

For additional Product information please contact:
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customerservice@choicespine.com

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