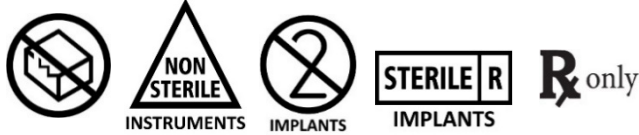





TIGERSHARK™ Cervical Spacer System

Instruction for Use



 ChoiceSpine, LLC
400 Erin Drive, Knoxville, TN 37919
USA

General Description:

The TIGERSHARK Cervical Spacer System consists of intervertebral body fusion devices comprised of titanium alloy (Ti-6Al-4V ELI per ASTM F3001, Class C). The spacers have a basic oval shape that coincides with the shape of vertebral bodies and a hollow center for placement of bone graft. They are available in an assortment of heights and in multiple angles of lordosis to accommodate different anatomic requirements. The devices are manufactured using the Electron Beam Melting (EBM) additive manufacturing method.

Indications for Use:

The TIGERSHARK Cervical Spacer System is intended for anterior cervical spine intervertebral body fusion at one level from the C2-C3 disc space to the C7-T1 disc for the treatment of degenerative disc disease (DDD) in skeletally mature patients who have had six (6) weeks of non-operative treatment. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The TIGERSHARK Cervical Spacer System is to be used with supplemental fixation and with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft to facilitate fusion.

Contraindications:

Contraindications for the TIGERSHARK 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
- Conditions, such as morbid obesity, which may put excessive stress on the bone and implants
- Severe osteopenia or osteoporosis may prevent adequate fixation
- Suspected or documented metal allergy
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or lifestyle may interfere with their ability to follow post-operative instructions
- Pregnancy

Warnings:

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
- A satisfactory outcome is enhanced by the selection of the appropriate device size and angle.
- The ChoiceSpine TIGERSHARK Spinal Implant 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 TIGERSHARK in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.

Cautions:

- 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.
- As with all orthopedic implants, none of the TIGERSHARK Cervical Spacer System implants should ever be reused under any circumstances.

Precautions:

- The TIGERSHARK Cervical Spacer System should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques as this is a technically demanding procedure.
- The spacers should not be reused even if they appear in a perfect state. Any spacer that has been used, twisted, bent, implanted and then removed, even if it appears intact, must be discarded.
- The TIGERSHARK Cervical Spacer System is used to augment the development of a spinal fusion by providing temporary stabilization.
- The device (spacer) 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) and loads from weight bearing and activity will affect the implant's longevity.
- Refrain from handling the TIGERSHARK Cervical Spacers as much as possible before implantation, and always handle it with the utmost care. TIGERSHARK Cervical Spacers (in their original packaging) must be stored with care in a clean and 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.

Potential Complications and Adverse Effects:

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and 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
- Loss of neurological function, including paralysis, spinal cord impingement or damage
- Dural tears, CSF leak or fistula or meningitis
- Bone graft donor complications, including pain, fracture or wound healing problems
- Vascular damage resulting in excessive bleeding and displaced devices adjacent to large vessels could cause vessel erosion and catastrophic bleeding
- Loss or impairment of bowel, sexual, and/or bladder function and other types of urological compromise
- Possible local or systemic adverse reactions from potential long-term degradation of the polymer or mechanical grinding causing wear debris
- Bone loss due to resorption or stress shielding
- Pseudoarthrosis
- Death

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

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 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. Preoperative, intraoperative and postoperative conditions should be considered.

Preoperative:

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the device and the potential adverse effects of the surgery.

Only patients that meet the criteria described in the Indications for Use should be selected.

Patient conditions and/or predispositions such as those mentioned in the Contraindications should be avoided.

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:

The surgeon must be fully conversant with all aspects of the surgical technique.

Proper function of the surgical instruments specific to the TIGERSHARK Cervical Spacer System should be verified prior to every surgical procedure.

The appropriate type and size of implant for the patient and the positioning of the implant are important.

Postoperative:

Patients must be informed of the precautions to be taken in their everyday life to enhance a maximum implant service life.

Regular post-operative follow-up is recommended to detect early signs of implant failure and to consider necessary action.

How Supplied:

STERILE The TIGERSHARK 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.



The TIGERSHARK 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.

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 instruments are packaged in a convenience caddy/case. All instruments 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 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 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 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 instrument(s) and 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 and around cracks, crevices, and 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, and hard to reach areas.
5. Use a sterile syringe to flush detergent through and around cracks, crevices, and hard to reach areas.
6. Remove instrument(s) from detergent and 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 and sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner and thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel and 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 and around cracks, crevices, and 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, and hard to reach areas.
5. Use a sterile syringe to flush detergent through and around cracks, crevices, and hard to reach areas.
6. Remove instrument(s) from detergent and 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 and 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.
- Prior to 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:

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.

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.

Device Retrieval Efforts:

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

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 TIGERSHARK Cervical Spacer System Surgical Technique Manual is available by contacting ChoiceSpine Sales Support.

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
 Sales Support Department
 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