TIGERSHARK® Interbody Fusion System
Instruction for Use

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General Description:
The ChoiceSpine TIGERSHARK Interbody Fusion System consists of implants made of titanium alloy (Ti-6AI-4V ELI per ASTM F3001, Class C). The spacers have a basic rectangle shape, a hollow center for placement of bone graft and a smooth bullet shaped distal surface. They are available in an assortment of height, length and anteroposterior angulation combinations to accommodate many different anatomic requirements. The implants are delivered via a posterior, transforaminal, or lateral approach. The devices are manufactured using the Electron Beam Melting (EBM) additive manufacturing method.

Indications for Use:
The ChoiceSpine TIGERSHARK Interbody Fusion System is indicated for spinal procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have six (6) months of non-operative treatment. This device is designed to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. This device is designed for use with supplemental fixation that is cleared for use in the lumbar spine.

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

MR Magnetic Resonance Environment
The TIGERSHARK Interbody Fusion Systems are MR Conditional. A patient with these devices can be safely scanned in an MR system under the following conditions:
- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field of 19 T/m (1900 G/cm).
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 11ºC after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to extend beyond 35mm from the contour of the device when imaged with a gradient echo pulse sequence in a 3.0T MR system.

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 Interbody Fusion System implants should ever be reused under any circumstances.

Precautions:
- The TIGERSHARK Interbody Fusion System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.
- The implants should not be reused, even if they appear in a perfect state. Any implant that has been used, twisted, bent, implanted and then removed, even if it appears intact, must be discarded.
- The TIGERSHARK Interbody Fusion System is used to augment the development of a spinal fusion by providing temporary stabilization. This device 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 Interbody Fusion System as much as possible before implantation and always with the utmost care. The 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
- Death

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

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 ChoiceSpine TIGERSHARK Interbody Fusion System should be verified prior to every surgical procedure.

The type and size of implant appropriate to 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.

Intended Clinical Benefit:

The intended benefit is to establish segment stability, directly addressing patient symptoms associated with spinal complications.

How Supplied:

STERILE R The TIGERSHARK Interbody Fusion 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.

NON STERILE The TIGERSHARK Interbody Fusion 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 "Steris 444", "Prolystica™", and "Enzol®" are tradenames of ultrasonic equipment and detergents utilized in the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when 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 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 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 (20psi).
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 assure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, and 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.

Sterilization:
ChoiceSpine TIGERSHARK Interbody Fusion System 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. The use of an FDA cleared wrap is recommended to ensure devices remain sterile prior to implantation.

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.

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. Instrument and Implant disposal should follow local hospital disposal instructions, or the explanted implants may be returned to ChoiceSpine for disposal.

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 Interbody Fusion 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 ChoiceSpine TIGERSHARK Interbody Fusion System Surgical Technique Manual is available by contacting ChoiceSpine Sales Support.

Product Complaints:
The customer or healthcare 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.

Some components may not be currently available. Please contact your ChoiceSpine representative for additional information. The products discussed herein may be available under different trademarks in different countries. All copyrights and pending and registered trademarks are the property of ChoiceSpine. For more information on a specific product or trademark, please contact your local ChoiceSpine representative.

Product Lifetime
The intention of the spinal implants are to provide short-term stability while fusion occurs. The implant devices are mechanically tested in static and dynamic loading. Dynamic testing to 5,000,000 cycles is intended to represent the number of cycles experienced by a patient over a two-year period based on a moderate activity level. Within a two-years of implantation, fusion is expected to occur which would alleviate the need for the implants to withstand loading. The minimum expected fusion expectancy would be one year therefore the lifetime range of our devices is one to two years. The device is intended to remain in the patient for the lifetime of the patient if fusion occurs.

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.

Summary of Safety & Clinical Performance and Periodic Summary Update Report can be found at https://ec.europa.eu/tools/eudamed

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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
salessupport@choicespine.com

EC REP
Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
Netherlands

Symbol Legend:

Note: The symbols legend above includes all symbols relative to ChoiceSpine portfolio. All the applicable symbols will either appear on the label or the IFU.

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

CE	European Medical Devices
EC REP	Authorized representative in the European Community
MR	MR Conditional
UDI	Unique Device Identification
MD	Medical Device