



ChoiceSpine™

TigerShark™ Modular Interbody System

Instruction for Use



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Description:

The ChoiceSpine TigerShark M, Modular Interbody System, consists of implants with components that are both additively and traditionally manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001, Class C and Ti-6Al-4V ELI per ASTM F136 respectively). The device is provided in lengths of 24-32mm and final heights of 9-17mm with 6° and 12° lordotic options and contains a hollow core to receive autogenous and / or allogeneous bone graft.

Indications for Use:

The ChoiceSpine TigerShark M, Modular Interbody System, is an intervertebral body fusion device intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The device system is designed for use with autograft bone and/or allogeneous bone grafts composed of cancellous and /or corticocancellous bone grafts, and with supplemental internal fixation systems (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) cleared for use in the lumbosacral spine.

Contraindications:

Contraindications include, but are not limited to

- systemic, spinal, or localized infection;
- morbid obesity;
- active pregnancy;
- signs of local inflammation;
- fever or leukocytosis;
- prior fusion surgery at the involved level(s);
- cardiovascular complications;
- sensitivity/allergies to implant materials;
- any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count;
- grossly distorted anatomy due to congenital abnormalities;
- rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft);
- any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition;
- any case not described in the indications;
- any patient unwilling to cooperate with the postoperative instructions;
- any time implant utilization would interfere with anatomical structures or expected physiological performance

Warnings and Precautions:

The implantation of the TigerShark M Implant is a technically demanding procedure presenting a risk of serious injury to the patient and should only be performed by experienced spinal surgeons with specific training in the use of this system. In addition, based on the fatigue test results, the surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions (e.g.,

smoking, occupation), which may impact on the performance of the implants.

The TigerShark M 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 M in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Preoperative:

A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Failure rates in spinal fusion procedures are published, and spinal fusion failure is an accepted risk of the procedure. Preoperative planning and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implant are critical considerations in achieving a successful result.

The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The devices must be handled and stored carefully and protected from damage.

Proper selection of patients and good compliance of patients with post-surgical instructions are an integral part of the realization of a successful surgical procedure. All patients contemplating implantation of this device should be apprised of the risks associated with the procedure as well as the limitations regarding activities that the patient will face following surgery. Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.

Intraoperative:

The surgeon should follow established practices and specific instructions for implantation of the devices.

Bone grafts must be placed in the area to be fused. The device is not intended or expected to be the only mechanism of support of the spine. Regardless of the etiology of the spine pathology for which the implantation of this device was chosen, it is the expectation and requirement that adequate anterior column support exists, either by virtue of existing anatomy or by means of a spinal fusion or arthrodesis. Without solid biological anterior column support, the device cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-implant interface failure, implant failure, or bone failure.

The surgeon is expected to follow and exercise extreme care in the placement of implants, particularly in regard to neural elements.

Radiographs should be made if there is any question as to the location of the intended or actual placement of the implants.

Care must be taken during positioning the device in the intervertebral space so as not to apply excessive forces that could cause cracking of the device.

When implanting a multi-piece TigerShark M Implant:

Both endplate components must be inserted into the intervertebral space while simultaneously attached to the inserter rails; inserting a single endplate will not permit proper assembly of the device. Attention should be paid that the endplate components are locked to the inserter rails prior to insertion into the intervertebral space; failure to lock the endplate components to the inserter rails may result in dislodging from the inserter rails.

During device assembly, the alignment of the spacer within the inserter rails should be visually confirmed. Misalignment may compromise the ability of the implant to properly assemble.

Dural surface and traversing and exiting nerve roots must be protected at all times with appropriate technique and/or nerve root retractors based on the experience of the spinal surgeon.

After the spacer will no longer advance, completion of device assembly should be confirmed using fluoroscopy.

The device must be filled with autograft bone and/or allogeneous bone grafts after in-situ assembly through the opening in the rear; pre-filling of the spacer component may compromise the ability for the implant to assemble. When filling the assembled device an appropriately sized bone funnel or forceps may be used. The autogenous bone graft must be sufficiently morselized to facilitate filling the device; a tamp should be used to pack the device to ensure adequate fill.

Different manufacturers use different materials, varying tolerances and design configurations. The TigerShark M Implant must not be used with components from any other system or manufacturer since dimensional compatibility cannot be assured.

Postoperative:

The physician's post-operative 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. If partial weight-bearing is recommended or required prior to forming bony union, the patient must be warned that loosening or breakage of the implant is a complication which can occur as a result of excessive or early weight-bearing or excessive muscular activity. It is important that immobilization of the surgical site be maintained until bony union consolidated and been confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

The risk of loosening of an implant 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 such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

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 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. The device is not intended or expected to be the only mechanism of support of the spine. No implant can be expected to withstand the unsupported stresses of full weight bearing indefinitely. 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 decision to remove the implants should take into consideration the risk to the patient of additional surgeries, as well as the difficulty of removal. Implants must not be reused. Any implant, once used, should be discarded; even though it may appear undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

Potential Complications and Adverse Effects:

Possible complications and adverse effects include, but are not limited to

- loosening or fracture of the implants or instruments;
- nonunion or pseudoarthrosis, possibly requiring further surgery;
- infection;
- nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis, and cerebral spinal fluid leakage;
- sensitivity to a foreign body;
- pain or discomfort;
- bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra);
- hemorrhage of blood vessels and/or hematomas;
- misalignment of anatomical structures, including loss of proper spine curvature; correction, reduction and/or height;
- bone graft donor site pain;
- inability to resume activities of daily living;
- re-operation;
- death

How Supplied:



The TigerShark M Implants are supplied sterile (gamma radiation) to a sterility assurance level (SAL) of 10^{-6} and are intended for single use only. Never resterilize an implant. Resterilization may adversely affect implant materials and result in premature failure.



The TigerShark M 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. 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 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
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 & 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.

Inspection:

Any implant with damage, corrosion, discoloration, scratches, residue, or debris should be discarded.

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):

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.

Patient Education:

It is essential to provide pre-operative 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.

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 instrument 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 M components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information

Surgical Technique Manual:

The TigerShark™ M Surgical Technique Manual is available by contacting ChoiceSpine Sales Support.

Caution:

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

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
salessupport@choicespine.com

Product Complaints:

Any dissatisfaction with the product quality, labeling, or performance should be reported to ChoiceSpine immediately by the customer or health care provider. Furthermore, ChoiceSpine should be notified immediately of an implant malfunction 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 property of ChoiceSpine. For more information on a specific product or trademark, please contact your local ChoiceSpine representative

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

Symbol Legend: