General Description: The TiGER SHARK™ Interbody Fusion System consists of implants made of titanium alloy (Ti-6Al-4V ELI per ASTM F136, Class C). TheTiGER SHARK™ Interbody Fusion System is indicated for placement of bone graft and a smooth bullet shaped dorsal side. They are manufactured using the Electron Beam Melting (EBM) additive manufacturing method.

Indications for Use: The TiGER SHARK™ 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-L5. DDD is defined as one or more of the following pathways: degenerative disc disease, disc herniation, degenerative disc degeneration, and instability. The disc confirmed by patient history and radiographic tests. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have at least 6 months of non-operative treatment. This device is designed to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or cortical-cancellable bone graft. This device is designed for use with supplemental fixation that is cleared for use in the lumbar spine.

Contraindications: Contraindications for the TiGER SHARK™ 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 same or spinal structures
- Conditions, such as sepsis, which may potentiate or exacerbate the infection
- Severe osteoporosis or osteopenia may prevent adequate fixation
- Suspected or documented metal allergy

Use of these implants is relatively contraindicated in patients whose occupation or life circumstances.

Use of these implants is absolutely contraindicated in patients who have had a major allergy reaction.

Prerequisites: The TiGER SHARK™ Interbody Fusion System should only be implanted by surgeons who are fully experienced in the use of these implants and the required specialized spinal surgical techniques. The surgeon may need to be present during the case, even if the implant is not being used for that particular patient state. Any implant that has been used, twisted, bent, implanted and/or sterilized should not be used.

The TiGER SHARK™ Interbody Fusion System is used to augment the development of a spinal fusion by providing additional stability. This implant may not be intended to be the sole means of spinal stabilization. A 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 intraoperative and postoperative activity, as this may compound the implant limitations. The patient should be instructed to limit postoperative activity, as this may reduce the risk of infection, break, or loosen implants through restrictions in activity are followed.

Additional Cleaning: All instruments should be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments that have been previously taken into a sterile field should be reprocessed in an autoclave or other sterilization method. All instruments in single use packages must be reprocessed in an autoclave, dry heat, or other sterilization method. All instruments that have been opened, damaged, or otherwise compromised should be reprocessed. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

Cleaning and Decontamination: All implants should be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments that have been previously taken into a sterile field should be reprocessed in an autoclave or other sterilization method. All instruments in single use packages must be reprocessed in an autoclave, dry heat, or other sterilization method. All instruments that have been opened, damaged, or otherwise compromised should be reprocessed. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

Care and Handling:

All implants should be used with care. Improper use and handling may lead to damage and possible improper functioning of the device. Refer to the Technique Manual for proper sterilization and decontamination. Preoperative and postoperative postoperative activity, as this may reduce the risk of infection, break, or loosen implants through restrictions in activity are followed.

Potentially 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
- Migration of any or all of the components
- Foreign body (allergic) reaction to the implants
- Loss of nuclear function, including paralysis, spinal cord impingement or damage
- Dehiscence of the endplate or meniscom
- Bone graft donor complications including pain, fracture or wound infection
- Vascular damage resulting in excessive bleeding and displaced devices adjacent to large vessels that could cause vessel erosion and fragmentation
- Bone loss due to reoperation or stress shielding
- Death

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

How Supplied:

STERILE™ TiGER SHARK™ Interbody Fusion System implants are supplied with STERILE™ Ethylene oxide (ETO) sterilization of a 5A level and intended for single use only. The sterility can only be ensured if the packaging is intact. Do not use this device if the sterile packaging has been opened or removed. Contact your STERIS representative for replacement. Remove all packaging material prior to use. Only sterile implants should be used in surgery.

The TiGER SHARK™ Interbody Fusion System instruments are provided non-sterile and must be sterilized prior to use. Instruments can be reprocessed using the recommended cleaning instructions.

Single Use Only:

Meant for single use implant. Any implant that has been twisted, bent, or implanted, even if it appears intact, must be discarded and utilized as single use only.

Storage and Handling:

Implants should be stored in their original, sealed packaging in clean, dry storage. These implants should not be directed toward germs, radiation, extreme temperatures, or particulate contamination. In order to ensure sterility, implants must be stored before the end of the expiration date, which is also indicated on the label to use, in an approved container. To maintain sterility, the packaging and labeling for integrity. If the device has been opened, damaged, or otherwise compromised, it should be reprocessed. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

Reused sterilization after these instructions has a minimal effect on the system's sterilization. Sterilization should be performed using the recommended cleaning instructions.

Cleaning and Decontamination:

All implants and instruments should be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments that have been previously taken into a sterile field should be reprocessed in an autoclave or other sterilization method. All instruments in single use packages must be reprocessed in an autoclave, dry heat, or other sterilization method. Additionally, all instruments in single use packages must be reprocessed in an autoclave, dry heat, or other sterilization method. All instruments that have been opened, damaged, or otherwise compromised should be reprocessed. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

Note: Certain cleaning solutions such as those containing formula, glacial acetic acid, halloysates, or detergents can damage some devices, particularly instruments; these solutions should not be used. Also, certain instruments may require dismantling before cleaning. Any instruments that are to be reprocessed should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

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

The system instruments are packaged in a convenience caddy/case. All devices must be removed from the case, checked for completeness, and counted to ensure they are one of the appropriate methods below. All instruments must be placed back into the caddy and case prior to steam sterilization.

Automated Cleaning:

The Steris™ 444, PrOlytix™, and Enzol™ are trademarks of ultrasonic equipment and ultrasonic devices utilized in the recommended cleaning instructions. Any other solutions can be utilized when in accordance to the manufacturer’s instructions.

Automated Cleaning:

1. Rinse instrument(s) under cool running tap water (≤ 35°C) to remove gross soil. Use a sterile syringe to flush detergent 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. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.

4. Rinse instrument(s) from washer & visually inspect for soil. Repeat if necessary.

5. Dry instrument(s) using a clean, soft towel & filtered, pressurized air.

6. Visually inspect for soil. Repeat if necessary.

Steam Sterilizer Types: Pre-vacuum

Temperature: 132°C

Duration: 4 minutes

Dry instrument(s) must be removed, cleaned, and the implant must be sterilized. If the implant has not been evaluated by the manufacturer for use in a steam sterilization process, I.

If the implant has not been evaluated by the manufacturer for use in a steam sterilization process, I.

Stabilization:

Choice Spine TiGER SHARK™ Interbody Fusion System instruments are provided non-sterile and must be used in surgery. Use of these instruments is recommended to be used in surgery using the following process parameters:

Sterilization:

Choice Spine TiGER SHARK™ 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 Types: Pre-vacuum

Temperature: 132°C

Duration: 4 minutes

Dry instrument(s)

Steam sterilization is the end user's responsibility to use only sterilizers and accessories (such as sterilization wrappings or pouches, chemical biological indicators, and/or chemical indicators) and appropriate sterilization cycle for the device. The manufacturer has no responsibility to provide the FDA for the sterilization cycle specification.

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

Postoperative:

Patients must be informed of the precautions to be taken in their event of the surgery. Regular post-operative follow-up is recommended to detect early signs of implant failure and to consider necessary action.

Postoperative:

Patients must be informed of the precautions to be taken in their event of the surgery. Regular post-operative follow-up is recommended to detect early signs of implant failure and to consider necessary action.

Caution:

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

Product Complaints:

Any dissatisfaction with the product quality, labeling, or performance should be reported to Choice Spine immediately by the customer or health care provider. Further, Choice Spine should be notified immediately of an implant malfunction by telephone, fax, or written correspondence. When filing a complaint, the name, number, and
Lot number of the part should be provided along with the name and address of the person filing the complaint.

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:
Choice Spine, LP
Customer Service Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; fax: 865-588-4045
customerservice@choicespine.com

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