Choice Spine Lumbar Spacer System

Instruction for Use
Rx Only

General Description

The Choice Spine Lumbar Spacer System consists of interbody fusion devices (specifically, SABRE, SHARK™, HORNET™ & HARPOON™ Lumbar Spacers) comprised of polyetheretherketone (PEEK) with tantalum markers (ASTM F2026 and ASTM F560) or Ti 6AL4V ELI (ASTM F136).

The spacers have a basic rectangular shape, a hollow center for placement of bone graft and a smooth bullet-shaped anterior surface. They are available in an assortment of height, length and anteroposterior angulation combinations to accommodate many different anatomic requirements.

Indications for Use

When used as an intervertebral body fusion device, Choice Spine Lumbar Spacers are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

When used as a vertebral body replacement device, Choice Spine Lumbar Spacers are intended for use in the thoracic and lumbar spine, from T1 to L5, for the replacement of a collapsed or unstable vertebral body resulting from a tumor or traumatic injury. The device system is designed for use with supplemental fixation and with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

Contraindications

Contraindications for Choice Spine Lumbar Spacers are similar to those of other systems of similar design, and 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 and 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 post-operative instructions.
6. Pregnancy.

Warnings

1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
2. A satisfactory outcome is enhanced by the selection of the appropriate device size and angle.
3. This CS.Lumbar Spacer System has not been evaluated for safety and compatibility in MR environment. It has not been tested for heating and migration in the MR environment.

Precautions

1. Choice Spine Lumbar Spacers should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.
2. 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.
3. Choice Spine Lumbar Spacers are 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.
4. Refrain from handling Choice Spine Lumbar Spacers 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:

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 and displaced devices adjacent to large vessels could cause vessel erosion and catastrophic bleeding.
9. Loss or impairment of bowel, sexual, and/or bladder function and 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. Death

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

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.

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.

Cleaning and Decontamination

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants 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. Cleaning and disinfecting of instruments can be performed with alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners follow 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.

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 (M-16) 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.

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

Phase	Time (min)	Temperature	Detergent
Pre-wash 1	1:00	Cold tap water	N/A
Enzyme Wash	1:00	Hot Tap water	Enzol® @ 1 oz per 1 gal water
Wash 1	2:00	60°C	Prolystica™ 2x Concentrate

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			Neutral @ 1/8 oz per 1 gal water
Rinse 1	1:00	Hot tap water	N/A
Drying	7:00	115°C	N/A

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 (M-16) 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 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.

1. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
2. Fully immerse instrument(s) in the detergent for at least one (1) minute.
3. Use a soft bristle brush (M-16) as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
4. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
5. 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.
6. Dry instrument(s) using a clean, soft cloth & filtered, pressurized air (20 psi).
7. Visually inspect for soil. Repeat if necessary.

Care and Handling

1. Torque wrenches require service every 6 months, 3000 cycles or 200 autoclave cycles.
2. Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
3. Prior to us, 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.
4. 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

Choice Spine Lumbar Spacer System components are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Implants and 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

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 and procedures.

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

1. 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.
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 Lumbar Spacers should be verified prior to every surgical procedure.
3. The appropriate type and size of implant appropriate to the patient and 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 and to consider necessary action.

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. Furthermore, Choice Spine 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.

Surgical Technique Manual

The Choice Spine Lumbar Spacer System Surgical Technique Manual is available by contacting Choice Spine Customer Service.

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
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400 Erin Drive
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