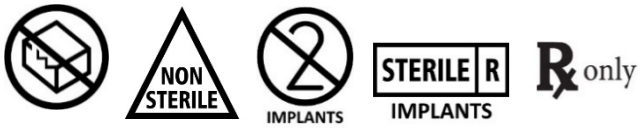
ChoiceSpine®
Propelling Spinal Surgery

HARRIER™-SA Lumbar Interbody System
Instruction for Use



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USA

Important Note to Operating Surgeon:
The HARRIER-SA Lumbar Interbody System is designed to provide biomechanical stabilization as an adjunct to fusion. Spinal fixation should only be undertaken after the surgeon has had hands-on training in this method of spinal fixation and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A surgical technique is available for instructions on the important aspects of this surgical procedure.

Preoperative:
Preoperative instructions to the patient are essential. Only patients who meet the criteria described in the Indications for Use section should be selected for implantation. Patient conditions and/or predispositions such as those addressed in the Contraindications section should be avoided. Care should be used in the handling and storage of the implant components. The implants should not be damaged. Implants should be protected from corrosive elements during storage. The type of construct required for the surgery should be determined prior to beginning the surgery. Non-sterile implants and instruments must be inspected, cleaned and sterilized prior to use in the operative field.

Intraoperative:
Caution should be used around the spinal cord and nerve roots, particularly when using screws. Damage to the nerves may cause loss of neurological functions. Breakage, slippage, misuse, or mishandling of the instruments or implant components may cause injury to the patient or operative personnel. The implants must be handled carefully so as to avoid notching or scratching the surface. Explanted implants must never be reused.

Post-Operative:
The risks and benefits of a second surgery must be carefully evaluated. The patient must be adequately instructed regarding the risks and limitations of the implant, as well as postoperative care and rehabilitation. The patient should be instructed in the proper use of crutches, canes, external braces or any other weight bearing or assist devices that may be required, and physical activities which would place excessive stresses on the implants or cause delay of the healing process. The patient should also be instructed in the proper methods to ambulate, climb stairs, get in and out of bed and perform activities of daily living, while minimizing rotational and bending stresses.

Description:
The ChoiceSpine HARRIER-SA Lumbar Interbody System is available in various sizes to accommodate individual patient anatomy. The ChoiceSpine HARRIER-SA Lumbar Interbody System is a stand-alone device intended to be used with (4) bone screws.

The implant spacer components are made from multiple materials: Invibio PEEK OPTIMA™ HA Enhanced with Tantalum markers per ASTM F560 or Ti-6Al-4V ELI Titanium per ASTM F3001, Class C. Plates, coverplates, and screws are made from Ti-6Al-4V ELI Titanium per ASTM F136.

Indications for Use:
The ChoiceSpine HARRIER-SA Lumbar Interbody System is 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.

This 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. This device is designed to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The ChoiceSpine HARRIER-SA Lumbar Interbody System is a stand-alone device intended to be used with four bone screws. Supplemental fixation, cleared by the FDA for use in the lumbosacral spine, must be used with spacers ≥20°. Supplemental fixation must also be used whenever fewer than four bone screws are used.

Contraindications:
Contraindications include, but are not limited to:
- Infection, systemic or localized
- Signs of local inflammation
- Morbid obesity
- Fever or leukocytosis
- Mental illness
- Alcoholism or drug abuse
- Pregnancy
- Severe osteopenia
- Suspected or documented sensitivity allergies to the implant materials
- Presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device
- Any condition having inadequate tissue coverage over the operative site
- Any circumstances not described under Indications for Use
- Patients unwilling or unable to follow post- operative instructions
- 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)

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.
- Do not use components of the HARRIER-SA Lumbar Interbody System with components from any other system.
- As with all orthopedic implants, none of the HARRIER-SA Lumbar Interbody System implants should ever be reused under any circumstances.

Precautions:
- Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.
- The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case. The physician should consider patient weight and patient activity.

Warnings:
- Patient compliance to postoperative pre-cautions will greatly affect surgical outcomes.
- The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. All implants should be examined before use and discarded if damaged.
- The HARRIER-SA Lumbar Interbody System spacers with lordotic angles greater than or equal to 20 degrees are required to be used with supplemental fixation to reduce the risk of implant expulsion.
- The HARRIER-SA Lumbar Interbody System has not been evaluated for safety and compatibility in the MR environment. The HARRIER-SA Lumbar Interbody System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the HARRIER-SA Lumbar Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Possible Adverse Effects:
Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects:

- Early or late loosening of the components
- Disassembly, bending, loosening, and/or breakage
- Foreign body reaction to the implants including possible tumor migration
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- Pressure on the skin from components where there is inadequate tissue coverage over the implant
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Bone graft, intervertebral body and/or sacral fracture at, above, and/or below the level of surgery
- Non-union or delayed union
- Loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- Gastrointestinal and/or reproductive system compromise, including sterility
- Cessation of growth of the fused portion of the spine
- Death
- Neurovascular compromise including paralysis or other types of serious injuries

How Supplied:

STERILE R The HARRIER-SA Lumbar Interbody System spacers and plates 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 HARRIER-SA Lumbar Interbody System instruments, screws and coverplates are provided clean but non-sterile and must be sterilized prior to use. Instruments can be reprocessed using the recommended cleaning and steam sterilization instructions. The instrumentation is made from 455 and 465 SS per ASTM A564 and 17-4 SS per ASTM F899.

Cleaning and Decontamination:
All screws, coverplates, and instruments are supplied to the health care facility clean but non-sterile. Implants are single use. 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 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 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 (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.

Sterilization:
All ChoiceSpine screws, coverplates, and instruments are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments and non-sterile screw(s) and coverplate implants 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, screws, and coverplates. 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 HARRIER-SA Lumbar Interbody 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. The patient 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 HARRIER-SA Lumbar Interbody 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
salessupport@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