VEO® Lateral Access & Interbody Fusion System
Instruction for Use

Rx only

CE 2797

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USA

General Description:
The VEO Lateral Access & Interbody Fusion System is a multi-component system including instrumentation made of biocompatible materials such as Stainless Steel, Aluminum, and Radel R and implants made of Tantalum (ASTM F560) and PEEK (ASTM F2026).

Additional Resources:
A light source is required that is compatible with an ACMI connection to be used with the Light Cable for the Stadium Mount Light

Indications for Use:
The VEO® Lateral Access & Interbody Fusion System is indicated for spinal fusion 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 had six months of non-operative treatment. The VEO Lateral Access & Interbody Fusion System is designed to be used with autogenous and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and supplemental spinal fixation that is cleared for use in the lumbar spine.

Contraindications:
Contraindications include, but are not limited to, active systemic infection, localized or spinal infection; morbid obesity; signs of local inflammation; fever or leukocytosis; demonstrated allergy or foreign body sensitivity to any implant materials; any medical or surgical condition which would preclude or impede the potential benefit of spinal implant and/or spinal fusion surgery, which could include, but not be exclusive to, elevated erythrocyte sedimentation rate, unexplained inflammatory/disease processes, elevation of white blood cell count (WBC), marked left shift in the white blood cell count differential; distorted anatomy due to congenital or remote posttraumatic/post infectious abnormalities; conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication as this condition may limit the degree of obtainable correction and/or height restoration, the amount of mechanical fixation, and/or the quality of the bone graft); any case in which a bone graft and fusion technique or where fracture fixation is not performed or required; any operative case utilizing the mixing of dissimilar metals from different components; patients having inadequate soft 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; patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, smoking, occupation, or lifestyle may interfere with their ability to follow postoperative instructions and/or activity restriction guidelines and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

Warnings:
The following warnings apply to components of the VEO Lateral Access & Interbody Fusion System.

- Refer to the Surgical Technique Guide to choose the correct size of implant. Correct selection of the implant is important. The potential for satisfactory anterior column support is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
- Patients must follow post-operative instructions as listed in the Precautions section below. Not following post- op instructions can result in delayed union or non-union. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. The implant should be handled with care during the surgery. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

MR Magnetic Resonance Environment
MR Conditional: (implants only)
Non-clinical testing has demonstrated that the VEO Lateral Access & Interbody Fusion System devices are MR conditional. A patient with these devices made of only PEEK and tantalum markers 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 2°C after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends radially up to 0.5cm and 0.7cm (respectively) from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system and a gradient echo pulse sequence in a 3.0T MR system.

Precautions
The following precautions apply to components of the VEO Lateral Access & Interbody Fusion System. Physicians using this device should have significant experience in spinal surgery, including spinal fusion procedures. Physicians should not independently use this device prior to participation in specific training on its use.

- Surgical implants must never be reused. An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
- Correct handling of the implant is extremely important, and it should always be handled with care during surgery. Contouring of this implant should not be done. The operating surgeon should avoid notching, scratching, or reverse bending of the implants. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
- Postoperative instructions: Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration to the devices and damage to nerves or blood vessels.
- Postoperative external immobilization, i.e., bracing and/or casting is recommended, at the surgeon's discretion, as is a comprehensive postoperative core stabilization physical therapy program. Instructions to the patient to reduce stress on the implant(s) are an equally important component of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure and delayed/non-union.
- Based upon surgeon preference, neuromonitoring may optionally be used to map the psoas muscle (XL Pedicle Screw Probe). Refer to the VEO Lateral Access & Interbody Fusion System Surgical Technique Manual and the XL Pedicle Screw Probe manufacturer's instructions for usage details and instructions. Direct visualization is intended to allow neural monitoring to be optional.

Possible Adverse Effects:
This list may not be inclusive of all possible complications caused by the surgical procedure itself.

1. Bending or fracture of implant
2. Loosening and/or collapse of the implant
3. Implant material sensitivity, or allergic reaction to a foreign body
4. Infection, early or late
5. Decrease in bone density due to stress shielding
6. Pain, discomfort, or abnormal sensations due to the presence of the device
7. Nerve damage due to surgical trauma or presence of the device

8. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia
9. Vascular damage could result in catastrophic or fatal bleeding. Malposition implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
10. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
11. Bursitis
12. Paralysis
13. Death
14. Spinal cord impingement or damage
15. Fracture of bony structures
16. Reflex sympathetic dystrophy/Complex Regional Pain Syndrome, Types I and II, including dyesthesias/hypesthesias
17. If a pseudarthrosis occurs, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis.
18. Degenerative changes or instability in segments adjacent to fused vertebral levels

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

How Supplied:

The VEO Lateral Access & Interbody Fusion System devices are provided non-sterile and must be sterilized prior to use. Implants are intended for single use only. Instruments can be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination:

All instruments must first be cleaned using methods recommended in this document or established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using methods recommended in this document or established hospital methods before sterilization and reintroduction into a sterile surgical field. 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 in 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 & 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. 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 instruments and inspect for soil, repeat cleaning 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:

The implants should be inspected after processing, prior to sterilization. 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-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.

Storage and Handling:
Implants should be stored in the implant sterilization case in clean, dry, well-ventilated conditions away from floors, ceilings, and outside walls. Store and transport sterile implants in such a way as to maintain sterility and functional integrity. Do not use implants if the sterilization wrap is opened, damaged or wet. Implants should remain covered until needed to avoid contamination. Only those to be implanted should be handled.

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 implants and instruments. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

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.

Device Retrieval Efforts:
Should it become necessary to remove any or all of the VEO Lateral Access & Interbody Fusion System 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 ChoiceSpine VEO Lateral Access and Interbody Fusion System 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.

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.

Information:
See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

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

For product complaints please contact:
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EC REP

Emergo Europe
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The Netherlands

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