INSTRUCTIONS FOR USE

FOCUS Interbody System

Important Information — Please Read Prior to Use

CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

Description:

The FOCUS Interbody System includes interbody fusion devices for lumbar implantation. The FOCUS-T and FOCUS-TO implants are designed as structural columns to provide surgical stabilization of the lumbar spine. Each interbody has a central cavity to be packed with bone graft material and inferior/superior teeth to resist expulsion. Lateral windows provide for radiographic visualization on most implant sizes. The implants are available with and without the xCELLerate surface coating and in a variety of height, length, width and lordotic angulation combinations to accommodate the patient specific anatomy and clinical circumstances. The devices are manufactured from titanium alloy (Ti6Al4V ELI per ASTM F136). The xCELLerate layered coating is manufactured from titanium powder (ASTM F1580) and calcium phosphate (hydroxyapatite per ASTM F1185 and ASTM F1609). The instrumentation for implantation is manufactured from medical grade stainless steel per ASTM F899 some of which feature Radel handles. The implants are provided sterile.

Indications:

The FOCUS Interbody System is intended to be used as a lumbar intervertebral fusion device at one or two adjacent levels from L2 to S1. This system should be limited to skeletally mature patients who have had six months of non-operative care for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. In addition, the FOCUS Interbody System can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The FOCUS Interbody System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate. These implants are intended for use with supplemental fixation indicated for lumbar spinal fusion procedures such as the OrthoCircle Spine Pedicle Screw System.

Contraindications:

Absolute contraindications include, but are not limited to:

1. Active systemic infection or infection localized to the site of the proposed implantation
2. Prior fusion at the level(s) to be treated
3. Any condition not described in the Indications for Use

Any entity or condition that totally precludes the possibility of fusion is a relative contraindication. In addition, the patient's occupation, activity level, or mental capacity may be relative contraindications to this surgery. Relative contraindications include, but are not limited to: cancer, kidney dialysis, osteopenia, obesity, pregnancy, certain degenerative diseases, foreign body sensitivity, mental illness, alcoholism, drug abuse.

Warnings and Precautions

1. The FOCUS Interbody System should only be implanted by surgeons experienced in the use of these implants and the associated spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for the implantation of these devices.
2. 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. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
3. These FOCUS Interbody System implants are provided as single use only and are not to be reused or reimplanted regardless of an apparent undamaged condition. Any retrieved devices must never be reused under any circumstances.

4. These FOCUS Interbody System implants are provided sterile. Do not clean and/or resterilize sterile implants. Do not use if package is opened or damaged or if expiration date has passed.
5. The FOCUS Interbody System cages 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.
6. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Sterile implants must be stored in a dry area away from radiation and extreme temperatures and environments such as moisture, air, etc.
7. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Components of this system should not be used with components of any other system or manufacturer.
9. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.
10. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.
11. As with all orthopedic implants, none of the FOCUS System components should ever be reused under any circumstances

Preoperative:

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken, loose or migrating implant components. The patient must be made aware that implant components may bend, break, loosen or migrate even though restrictions in activity are followed.

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. Implants should be used only if received with packaging and labeling intact. Instruments must be inspected, cleaned and sterilized prior to use in the operative field.

Intraoperative:

Breakage, slippage, misuse, or mishandling of the instruments or implant components, such as on sharp edges, may cause injury to the patient or operative personnel. The implants must be handled and contoured carefully so as to avoid damage to the surface. Before closing the soft tissues, all of the set screws should be tightened firmly according to the operative surgical technique. The tightness of all set screws must be rechecked before wound closure to ensure that no loosening occurred during tightening or manipulation of the other implants. Explanted implants must never be reused.

Postoperative:

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 limit those 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.

Possible 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: Bending, fracture or loosening of implant component(s), nonunion or delayed union, fracture of the vertebra, neurological, vascular or visceral injury, metal sensitivity or allergic reaction to a foreign body, infection, decrease in bone density due to stress shielding, pain, discomfort or abnormal sensations due to the presence of the device, nerve damage due to surgical trauma, bursitis, dural Leak, paralysis and death.

MRI Safety Information:

The FOCUS Interbody System 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 the FOCUS Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

How Supplied:

All FOCUS Interbody System implants are sterilized via gamma irradiation and are delivered sterile. These implants are for single use only and must not be processed or sterilized again. Do not use if package is opened or damaged or if expiration date has passed. FOCUS Interbody System instruments are delivered nonsterile and therefore must be reprocessed - thoroughly cleaned and sterilized - prior to surgical use.

Cleaning:

Cleaning reduces the population of microorganisms and facilitates subsequent sterilization. Strict compliance with these validated instructions pertaining to cleaning, and sterilization is mandatory. All instruments must first be thoroughly cleaned using the following method:

- Prior to cleaning, disassemble the Prep Tool Inserter by unthreading the retention rod from the instrument head and removing the rod from the cannulated prep tool handle.
- Clean devices immediately after use to prevent drying of debris or body fluids
- Remove any debris with a water moistened gauze pad. Substitute a fresh pad if it becomes soiled.
- Cleaning, soak in neutral PH enzymatic cleaner or detergent solution for a minimum of 5 minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. Rinse device thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes.
- Clean disassembled instrument using a pipe cleaner or nylon brush on the accessible surfaces until all visible debris is removed.
- Thoroughly rinse the device using free-flowing warm tap water for a minimum of 15 seconds. Repeat this step using purified water.
- Drain and wipe dry using a sterile gauze pad.
- Place the cleaned instruments back into the appropriate location within the instrument trays

Visually inspect all instruments to assure there is no visual contamination. If any visual contamination is detected, repeat the cleaning process prior to sterilization.

Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage, particularly instruments; these solutions should not be used. All products should be treated with care; improper use or handling may lead to damage and possible improper functioning of the device

Sterilization:

AORN recommended practices for in hospital sterilization should be followed. The use of a double layer of FDA cleared sterilization wrap is recommended. Sterilization testing of components has shown the following recommendations for steam sterilization are effective to an SAL of 10^{-6}. It is imperative to steam sterilize the instrument kits under these following operating conditions:

Method	Cycle	Exposure duration	Temperature	Dry Time
Steam	Pre-vacuum	4 minutes	132˚C (270˚F)	40 minutes

NOTE: Sterilization does not replace cleaning. Only a clean product can be correctly sterilized.

NOTE: Do not stack trays – sterilize trays as a single layer/individually

Only sterile implants and instruments may be used for surgery.

Useful life of instruments

Routinely inspect devices for wear and tear. If evidence of wear such as corrosion, pitting, or discoloration is observed, dispose of the instrument and obtain a new instrument from the manufacturer. If any cutting instruments become dull and do not function properly, obtain a new instrument from the manufacturer.

Surgical Technique Manual

The FOCUS System Surgical Technique is available by contacting Customer Service at *888.463.5803*.

Product Complaints:

Any healthcare professional (e.g., a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any FOCUS spinal implants should notify OC Medical Devices, or, where applicable, their distributor. In the event of serious incident, or risk of serious incident, having resulted in, or may potentially result in, the death or severe deterioration in the state of health of a patient or user, OC Medical Devices or the distributor must be notified as soon as possible. When filing a complaint, please provide the component(s) reference number, manufacturing lot number(s), your name and address, and the nature of the complaint in full detail, as well as notification of whether a written report is requested.

Symbols and Definitions

REF	Catalog Number		Consult Instructions for Use.
LOT	Batch code		Do not use if package is damaged.
	Date of Manufacture (YYYY-MM-DD)		Single use only. Do not reuse.
	Manufacturer	Rx Only	Prescription use only
	Use by date (YYYY-MM-DD)	UDI	Unique Device Identification
STERILE R	Sterilized using irradiation	NON STERILE	Nonsterile
QTY	Quantity		

For Product Complaints or for additional product information please contact:
OC Medical Devices, 888-463-5803, 15 East Montgomery Crossroads, Suite 3, Savannah, GA 31406