ORIO Intervertebral Body Fusion Cage System
INSTRUCTIONS FOR USE

CAUTION: USA law restricts this device to sale by or on the order of physician.

1. PRODUCT HANDLING

The implants and instruments used as a part of these systems are provided nonsterile and should be stored in their original packaging or placed within the aluminium sterilization container provided. Implants and instruments should be stored in such a manner when not in use, and until they are cleaned and sterilized according to the recommended guidelines listed below. Protect implants from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage.

2. PRODUCT DESCRIPTION AND IMPLANT MATERIALS

The ORIO intervertebral body fusion cage is a single component spinal device made from PEEK-Optima® polymer (polyetheretherketone). The implant is available in a range of sizes and lordotic angles to fit the patient's anatomical and physiological requirements. The implants have cavities to accept packing of bone graft. The entire structure is radiolucent so that healing can be assessed by normal radiographic methods. Additionally, radiotherapy can be performed immediately after surgery.

3. INDICATIONS

ORIO intervertebral body fusion cervical cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. ORIO intervertebral body fusion cervical cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. ORIO intervertebral body fusion cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The ORIO intervertebral body fusion lumbar cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). ORIO intervertebral body fusion lumbar cage implants are to be used with autogenous bone graft and implanted via a transforaminal, open posterior or lateral approach. The ORIO intervertebral body fusion lumbar cages are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage.

4. **PATIENT SELECTION**. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

A. **The patient's occupation or activity**. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

B. **A condition of senility, mental illness, alcoholism, or drug abuse**. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

C. **Certain degenerative diseases.** In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.

D. **Foreign body sensitivity**. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

E. **Smoking.** Patients who smoke have been observed to experience higher rates of pseudo-arthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

5. CONTRAINDICATIONS

- Active sepsis;
- Pregnancy;
- Muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- Conditions that place excessive demand on the implant (i.e. Charcot's joints, muscle deficiencies, refusal to modify post-operative physical activities, skeletal immaturity);
- Active infection in the area of proposed surgery;
- Severe osteoporosis;
- Paget's disease;
- Renal osteodystrophy;
- Advanced diabetes;
- Rheumatoid arthritis;
- Immunological suppression;
- Sustained trauma with instability;
- Fracture of the vertebra;
- Conditions requiring steroids in excess of usual doses;
- Obesity
- Signs of local inflammation,
- Fever or leukocytosis,
- Mental illness,
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count,
- Suspected or documented allergy or intolerance to composite materials,
- Any case not needing a fusion,
- Any case not described in the indications,
- Any patient unwilling to cooperate with postoperative instructions,
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery,
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1,
- Any case where the implant components selected for use would be too large or too small to achieve a successful result,
- Any case that requires the mixing of metals from two different components or systems,
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality,
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance,
- Prior fusion at the level to be treated

6. PRECAUTIONS

- **SURGICAL IMPLANTS MUST NEVER BE REUSED.** Although the device may appear undamaged, previous stresses could create imperfections that may lead to mechanical failure. Reusing an implant can potentially cause cross contamination. It is advised to utilize new implant of current design.

- **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT**. Familiarity with, and attention to the surgical technique recommended for this device is imperative for best results. The correct selection as well as the correct seating/placement of the implant is extremely important. SpineCraft instruments and implants should only be used in conjunction with other SpineCraft instruments and implants. The surgical technique may be obtained from the company or its representative.

  Care must be taken to protect surfaces from nicks and scratches that could become focal points for failure. An implant must not be tampered with, as tampering could adversely affect the performance of the implant.
  Surgical technique brochures are available upon request. Before the initial use of the ORIO System, the surgeon should review all available information and consult with other surgeons having experience with these type of devices. The surgeon should be thoroughly familiar with the assembly of the components.

  The implantation of two devices of the same size at each targeted level is recommended in case of posterior lumbar interbody fusion.

- **IMPLANTS FATIGUE**. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

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

7. PREOPERATIVE PLANNING AND POSTOPERATIVE CARE

Preoperative planning provides essential information regarding the appropriate implant and likely combinations of components. Use instrument trial components for fit verification (where applicable) and extra implants for backup.
Accepted surgical practices should be followed for postoperative care. Excessive physical activity and trauma affecting the implanted devices have been implicated in premature failure by fracture, migration and/or wear of the implants. The patient should be cautioned to govern his/her activities accordingly as the risk of implant failure increases with weight and activity levels of the patient.

8. ADVERSE EFFECTS

- Cracking or fracture of the implants or loss of fixation in bone; attributable to nonunion, osteoporosis, markedly unstable comminuted fractures.
- Loss of anatomic position with malunion.
- Implant dislodgement or subsidence.
- Infections, both deep and superficial.
- Vascular or visceral injuries.
- Allergies and other reactions to device materials.
- Cracking or fracture of the vertebrae.

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- Post-operative change in spinal curvature, loss of correction, and/or height reduction.
- Death.
- Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
- The risk of device expulsion and migration is higher without the use of supplemental fixation.

9. PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to SpineCraft.

10. CLEANING AND DECONTAMINATION

Unless just removed from an unopened SpineCraft package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to SpineCraft. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must 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 other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device. Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company.

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11. STERILIZATION

The PEEK-Optima® implants and instruments are provided nonsterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below. Implants are single-use devices, thus do not clean or resterilize an implant that has been in contact with or contaminated by blood or other infectious substances. The manufacturer and distributor assume no responsibility for the cleaning and resterilization of implants, components, or reusable instruments performed by the individual or hospital. SpineCraft instruments and instrument cases are generally composed of titanium, stainless steel, aluminum, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and listed below. Instrument cases do not provide a sterile barrier and must be used in conjunction with sterilization wrap to maintain sterility.

All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Instructions for cleaning and sterilization of ORIO instruments can be found in SpineCraft publication # RG-0010-5 and can be obtained by contacting the company. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the set of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	273° F (134° C)	18 min with Four Pulses	30 Minutes

Wrap: The wrap should be FDA cleared for the proposed cycle specifications.

Monitor every load with a PCD containing a BI and a Class 5 integrating indicator.

This Pre-Vacuum Steam sterilization is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

NOTE: SpineCraft does not recommend Flash Sterilization within instrument cases or Chemical Sterilization.

LIMITED WARRANTY AND DISCLAIMER: ORIO CAGE PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT SPINECRAFT FOR CURRENT INFORMATION at:
+1 630-920-7300.

SURGICAL TECHNIQUE MANUAL COULD BE OBTAINED BY CONTACTING SPINECRAFT CUSTOMER SERVICE at +1 630-920-7300. ALSO, IT COULD BE DOWNLOADED DIRECTLY FROM THE COMPANY WEBSITE USING THE SURGEON LOG-IN.

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