Spinal Implant Product Range

Facet Fusion Cages
Interbody Fusion Cages
Pedicle Screw Systems
Vertebral Body Replacement Systems
Anterior Spinal Fixation Plates

Instructions for Use 131-111-001 Rev. U Issue Date: 05/2021

Caution:

Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use.

1 General Instructions

The Signature Orthopaedics' range of spinal implants are intended to immobilize and stabilize adjacent spinal segments to allow fusion in the cervical, thoracic, lumbar and/or sacral spine.

Prior to undertaking the procedure, patients must be evaluated according to the indications and contraindications of the particular system, as well as the patient selection criteria included in this document. Patients must also be informed of the precautions and possible adverse effects of the procedure, and of appropriate postoperative recovery procedures.

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of surgical implants, but must also be aware of the mechanical limitations of the implants. See the surgical technique manuals for each device as required.

The device is not intended to support in-vivo loading indefinitely.

Signature Orthopaedics implants and instruments should only be used with approved devices and accessories.

2 Facet Fusion Cages

Signature Orthopaedics' Facet Fusion Cage is an implant used to stabilise the triple joint complex in the thoracolumbar spine during the development of facet joint arthrodesis. The device is intended to be implanted by a posterior approach using the corresponding instrument set. Signature Orthopaedics' Facet Fusion Cages has been designed to be used in pairs at each level of the spine to be fused.

The cage consists of a tapered and hollowed cylindrical titanium cage that is threaded and grit blasted to promote stability. The cage is hollow through the center and has windows cut into the side to allow the loading and passage of bone graft to promote fusion. The cage is manufactured from implant grade titanium alloy in accordance with ISO 5832-3.

Signature Orthopaedics' Facet Fusion Cage is to be used with complimentary posterior support in the form of pedicle screws and rods and/or an anterior weight bearing structure to share loading prior to bony fusion. The cage is intended to be used with graft materials and/or BMP, or similar. Signature Orthopaedics' Facet Fusion Cages are indicated for use with both open and minimally invasive techniques (MIS).

3 Interbody Fusion Cages

Signature Orthopaedics' Interbody Fusion Cages are used to restore disc height and support loading during intervertebral body fusion. The devices are intended to be implanted by a posterior, anterior, lateral, or other approach, as specified in the device's surgical technique, using the corresponding instrument set.

Signature Orthopaedics' Interbody Fusion Cages are rectangular or pill-shaped in geometry, with a hollow center to accept bone graft to promote arthrodesis, and may be wedged to restore the patient's lordosis or kyphosis. The cage may have holes to allow the flow of bone graft into or out of the cage's hollow center. The cage may have a bulleted or rounded nose to ease insertion. The cage may include teeth on the inferior and superior surfaces, or incorporate screws to resist expulsion of the cage from the disc space. Signature Orthopaedics' Interbody Fusion Cages are manufactured from implant grade Polyether ether ketone (PEEK) in accordance with ASTM F2026, PEEK Optima HA enhanced (POHAe) in accordance with ASTM F2026 or implant grade titanium alloy per ISO 5832-3. Supplementary screws (if applicable) are manufactured from implant grade titanium alloy per ISO 5832-3.

Signature Orthopaedics' Interbody Fusion Cages are available in a range of sizes to match varying patient anatomy, and may be used in the cervical, thoracic, lumbar and/or sacral spine, as specified on the particular cage's product labeling. Interbody Fusion Cages are intended to be used with graft materials and/or BMP, or similar. Signature Orthopaedics' Interbody Fusion Cages may be used with open and/or minimally invasive techniques (MIS), as specified in the particular devices surgical technique.

4 Pedicle Screw Systems

Signature Orthopaedics' Pedicle Screw System is intended to provide immobilization and stabilisation of spinal segments in skeletally mature patients, as an adjunct to fusion in the cervical, thoracic, lumbar and sacral spine.

Signature Orthopaedics' Pedicle Screw System consists of polyaxial screws, hooks, longitudinal rods, tulips, cap screws, cross connectors, lateral connectors and screw retainers. The pedicle screw system is implanted from a posterior approach, and used bilaterally at the required spinal levels. The pedicle screw system components are manufactured from titanium alloy per ISO5832-3, or cobalt-chrome alloy per ISO5832-12.

Signature Orthopaedics Pedicle Screw System may be used in conjunction with the Signature Orthopaedics Facet Fusion Cage to provide stabilization during spinal fusion. The Signature Orthopaedics Pedicle Screw System is indicated for use only with open surgical techniques.

5 Anterior Spinal Fixation Plates

Signature Orthopaedics' Anterior Spinal Fixation Plates are used as an anteriorly placed supplemental fixation device to provide temporary biomechanical stability until fusion is achieved. Additionally, when used with an interbody fusion cage, the anterior spinal fixation plate serves to prevent anterior expulsion of the cage. The devices are intended to be implanted using an anterior or anterolateral approach using the corresponding instrument sets.

The plates consist of a main body which accommodate four variable angle bone screws to secure the plates into adjacent vertebrae. The plates are available in a range of sizes to match the patient's anatomy. The plates are contoured to better match the geometry of the anterior surface of the vertebral bodies. Screws are locked into position by an appropriate locking mechanism, to stabilise the vertebral segments. The subject plates and screw components are manufactured from titanium alloy per ISO5832-3.

Signature Orthopaedics' Anterior Spinal Fixation Plates should be used in conjunction with interbody fusion devices and/or posterior fixation constructs. Signature Orthopaedics' Anterior Spinal Fixation Plates are indicated for use with both open and minimally invasive techniques (MIS).

6 Indications for Use

The Signature Orthopaedics' spinal implant range (excluding vertebral body replacement systems) is indicated for use in skeletally mature patients with the following conditions:

- Arthrodesis required at any paired vertebral bodies in the cervical, thoracic, lumbar and/or sacral spine, as specified on the particular device's label
- Degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spinal stenosis
- Spinal deformities or curvatures
- Spondylolisthesis
- Trauma e.g. fracture or dislocation
- Pseudoarthrosis
- Previous failed fusion
- Tumour
- Can be used with osteobiological products such as OP1, BMP or similar

VERTEBRAL BODY REPLACEMENT SYSTEM INDICATIONS FOR USE:

The Signature Orthopaedics' Vertebral Body Replacement System is indicated for use in skeletally mature patients to:

- replace a collapsed, damaged or unstable vertebral body in the cervical spine
- replace a vertebral body in the cervical spine due to tumor or fracture

7 Contraindications for Use

The Signature Orthopaedics Spinal Implant Range is contraindicated for use under the following conditions:

- Osteoporosis
- Active systemic infection or infection localized to the site of the proposed implantation
- Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, osteopenia, obesity, or foreign body sensitivity.
- Patients whose activity, mental capacity, mental illness, or lifestyle may interfere with their ability to follow postoperative restrictions

ADDITIONAL FACET FUSION CAGE CONTRAINDICATION:

- Spinal fusion level associated with bilateral pars intra-articularis defects

8 Precautions

Following are specific precautions which should be understood by the surgeon and explained to the patient. These warnings do not include all precautions for surgery in general, but are important considerations particular to Signature Orthopaedics' Spinal Implant Range.

Bending, notching and/or scratching of the devices are not recommended. Alterations of the implant geometry or surface finish can have detrimental effects on the endurance properties or performance of the implant.

Facet Fusion Cages, Interbody Fusion Cages, and components of the Vertebral Body Replacement System are supplied sterile and intended for single use only. Resterilisation and re-use of these devices is strictly prohibited. Resterilisation of these devices may alter device material properties including reducing mechanical properties and/or biocompatibility.

Pedicle Screw System and Anterior Lumbar Fixation Plate components are supplied non-sterile, and intended for single use only. Re-use of any spinal implant may result in cross-contamination between patients and decreased mechanical performance. Explanted devices are to be disposed of immediately.

Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing.

The patient must be made aware of the limitations of the implant and follow post-operative care regimen as instructed by their physician.

Appropriate pre-operative planning and surgical technique can minimize complications. Proper patient selection and the patient's ability to comply with the post-operative prescribed treatment will greatly affect the clinical outcome. It is important to screen patients and select the optimal therapy given physical and / or mental activity limitations.

If fusion does not occur, spinal fixation devices cannot withstand activity levels placed on normal healthy bone. It is unreasonable to assume that any implant can withstand unsupported in-vivo loading indefinitely.

An explanted implant should never be re-used. Do not treat patients with implants that have been even momentarily placed in a different patient. If explanted, follow standard hospital procedures for disposing of biologically hazardous material.

Signature Orthopaedics does not recommend MR imaging for any patients implanted with products from their spinal implant range without prior consultation with an expert radiologist for assessment of potential adverse events such as device movement, localized burns, torsional or shear strain on the implanted device. Signature Orthopaedics' spinal implant range have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artefact in the MR environment. The safety of Signature Orthopaedics spinal implant range in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Do not alter or modify any implant or instrument. Repairs should only be performed at Signature Orthopaedics sites.

Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of these products.

Only approved Signature Orthopaedics instruments should be used in conjunction with the implants covered in this document.

9 Possible Adverse Effects

Following are specific adverse effects which should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that may occur in surgery, but are important considerations particular to the devices included in this document.

- Nonunion (pseudarthrosis)
- Bending or fracture of implant.
- Early or late loosening of the implant
- Metal sensitivity, or allergic reaction to the implant
- Early or late infection
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Various nerve and vascular damage due to the proximity of the implant to major structures
- Bursitis
- Paralysis
- Dural tears experienced during surgery could result in the need for further surgery, a chronic CSF leak or fistula and possible meningitis
- Death
- Damage to lymphatic vessels and/or lymphatic fluid
- Spinal cord impingement or damage
- Cessation of growth of the operated portion of the bone
- Fracture of bony structures, or penetration of the implant into the bone
- Bone formation around and through the implant making removal difficult
- Screw back out, possibly leading to implant loosening, and/or reoperation for device removal
- Post operative change in spinal curvature, loss of correction, height and / or reduction
- Degenerative changes or instability in segments adjacent to fused vertebral levels

10 Preoperative Planning

A thorough clinical evaluation of the patient must occur prior to undertaking surgery. Radiological scans must be taken to allow pre-operative templating and to allow assessment of the bony anatomy for possible deformities. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant.

At the time of the operation, the corresponding implantation instruments in addition to a complete set of implants must be available. It is important to determine pre-operatively whether the patient is allergic to any of the implant materials.

11 Postoperative Care and Mobilization

External immobilization is recommended until X-rays confirm the formation of the fusion mass. Instructions to the patient to reduce stress on the implants are an important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

12 Patient Information

In addition to the contraindications for use, precautions and possible adverse effects, it is critical that the patient is aware that activity, particularly but not exclusively prior to bony fusion, increases the risk of loosening, deforming, or breaking of the implant. The likelihood of successful bone healing is increased by appropriate postoperative care and the patient's ability and willingness to adhere to the surgeon's recommendations.

13 Patient Selection

The following factors should be considered in evaluating a candidate to undergo arthrodesis of a spinal segment.

- The patient's weight. Overweight patients can produce loads on the device which can lead to premature failure.
- The patient's occupation or activity. If the patient is involved in an occupation or activity that involves demanding loading or articulation of the operated spinal segment they should not return to these activities until bony fusion has occurred. Depending on the extent of the activity, or the quality of the bony fusion, the patient may not be able to return to such occupation or activity.
- Senility, mental illness, alcoholism, or drug abuse may cause the patient to ignore certain precautions, leading to implant failure or other complications.
- Smoking has been observed to increase the rate of pseudarthrosis.

14 Cleaning

Facet Fusion Cages, Interbody Fusion Cages, and components of the Vertebral Body Replacement System are supplied sterile and intended for single use only. Dispose of the implant if the packaging is damaged. Cleaning of the implants is not recommended.

Pedicle Screw System and Anterior Spinal Fixation Plate components are provided non-sterile and should be manually/mechanically cleaned prior to sterilisation.

Manual Cleaning

Implants are to be fully immersed in a solution of Enzol® detergent (1oz/gal) and lukewarm water, and allowed to soak for 5 minutes. While immersed, all movable parts should be actuated. Implants should then be thoroughly brushed using a soft bristle brush, pipe cleaner and syringe to clean hard to reach places, if required. Implants should be thoroughly rinsed under running cool tap water until all visible evidence of detergent is removed. While rinsing, all movable parts should be actuated.

Mechanical Cleaning

A solution of Enzol® detergent (1oz/gal) and lukewarm water is prepared in a sonication unit. Implants are fully immersed in the detergent and sonicated for 9 minutes. Implants are rinsed under reverse osmosis/deionized (RO/DI) water at ambient temperature until detergent residues are removed. While rinsing, all moveable parts should be actuated. Implants should be cleaned using a clean, soft cloth and filtered pressurized air (20 psi).

Re-usable instruments are delivered non-sterile. A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following cleaning method is recommended:

Manual Cleaning

Instruments are to be cleaned immediately after use with warm water and a mild detergent. Instruments consisting of multiple components must be disassembled prior to cleaning. After cleaning, the parts should be rinsed thoroughly with de-ionized water and dried.

Cleaning before Sterilisation

Instruments may be cleaned using a broad spectrum bactericide and fungicide agent in accordance with the instructions of the manufacturer of the agent.

Caution:

Do not clean instruments with products containing Sodium Hypochlorite (NaOCl) and Sodium Hydroxide (NaOH).

Corrosive products or abrasive instruments should not be used.

Instruments should be thoroughly inspected to ensure that they are in good condition and operating order.

15 Sterilisation

Facet Fusion Cages, Interbody Fusion Cages, and components of the Vertebral Body Replacement System are supplied sterile and intended for single use only. Dispose of the implant if the packaging is damaged. Resterilisation of the implants is not recommended.

Pedicle Screw System, Interbody Fusion Screws and Anterior Spinal Fixation Plate components may be provided sterile or non-sterile. The product labels should be consulted for sterility status of these devices. If a device is labeled as non-sterile, the device should be sterilised by the end-user before implanting. ISO 8828 and AORN recommended practices for in-hospital sterilisation should be followed for all components and ISO 17664:2004 "Sterilisation of medical devices – Information to be provided by the manufacturer for the re-sterilisable medical devices". In a properly functioning calibrated steam steriliser, effective sterilisation may be achieved using the following parameters:

METHOD:	STEAM AUTOCLAVE
CYCLE:	PRE-VACUUM
TEMPERATURE:	132°C (270° F)
EXPOSURE TIME:	4 MINUTES
MINIMUM DRYING TIME:	30 MINUTES

Re-usable instruments are delivered non-sterile. A complete guide for reprocessing reusable instruments may be provided upon request.

Note: Drying time is subject to variation depending on machine load.

16 Storage and Handling

Implants and instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilisation tray, respectively.

17 Limited Warranty / Liability

Signature Orthopaedics Europe Ltd. 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.

Signature Orthopaedics Europe Ltd. shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Signature Orthopaedics Europe Ltd. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Signature Orthopaedics Europe Ltd. intends that these instruments should be used only by physicians appropriately trained in orthopaedic surgical techniques.

18 Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Signature Orthopaedics Europe Ltd. for current information.

For further information or questions pertaining to sales and service, please contact your local sales representative or Signature Orthopaedics Europe Ltd. at the following:

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19 Abbreviations

S	Small
M	Medium
L	Large