Signature ORTHOPAEDICS

Freedom and C-Zero Pedicle Screw System

Instructions for Use 131-13-0108 Rev. E Issue Date: Jul-23

CE 0123

Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. 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 on the performance of the system.

Federal law restricts this device to sale, distribution and use by or on the order of a physician.

Warning:

a) The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

b) The C-Zero and Freedom pedicle screw system have 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 C-Zero and Freedom pedicle screw systems in the MR environment are unknown. Scanning a patient who has these devices may result in patient injury.

1 Device Descriptions

All devices described herein are supplied individually sterile packed and are intend for single patient use only. Additionally, all devices described herein are available in a range of sizes to allow correct selection to match the patient's anatomy.

Material: Titanium 6-Aluminium 4-vanadium alloy per ASTM F136 and CoCr per ASTM-F1537

The Signature Orthopaedics' C-Zero and Freedom Pedicle Screw Systems are used to provide immobilization and stabilization of spinal segments in the treatment of acute and chronic instabilities or deformities of the lumbar, thoracic and sacral spine. These pedicle rod and screw systems surgically implanted from a posterior approach. The device subject to this file include polyaxial pedicle screws, rods, connectors and hooks.

2 Indications

The Signature Orthopaedic C-Zero Pedicle Screw and Freedom Pedicle Screw Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities and deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; and failed previous fusion (pseudarthrosis). In addition, the C-Zero Pedicle Screw and Freedom Pedicle Systems are intended for skeletally mature patients in the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra and degenerative spondylolisthesis with objective evidence of neurologic impairment.

3 Contraindications

The Signature Orthopaedics C-Zero and Freedom Pedicle Screw are contraindicated for use under the following conditions:

- Osteoporosis
- Tumor or trauma necessitating multiple vertebral segment stabilization
- Active systematic infection or infection localised 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

4 Patient Selection Precautions

The following factors may be relevant to the success of the procedure:

- The patient's body weight. An obese patient may place increased loads the device which can lead to premature failure of the device
- 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.
- Mental illness, or substance dependence which may tend to reduce the patients compliance with prescribed precautions and limitations on physical activities, which may cause implant failure or other complications
- Material sensitivity. Patients should be screened for potential sensitivity to the constituent materials composing the device. If sensitivity is suspected, Preoperative tests should be conducted

5 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

6 Patient Consent

As with all surgical procedures, the patient should be made aware of the risks and possible adverse effects. In particular the patient should be warned of limitations of the devices being implanted, including the limited expected service life of the device and the possible requirement for revision surgery to replace worn or damaged implant or to correct device malfunctioning.

7 Preoperative

Care should be taken when handling the C-Zero and Freedom Pedicle Screw Systems' components to avoid damaging the devices. Denting, notching or scratching can greatly reduce the compression strength, fatigue resistance or wear properties of the components potentially leading to fracture or failure of the devices. Surgical

technique information is available for the subject devices. The surgeon should familiarise themselves thoroughly with the technique prior to consideration of the use of the devices for any specific patient.

Implants are only to be used with approved Signature Orthopaedics instrumentation. The surgical instrumentation prescribed within the technique for the implantation of these devices should not be used for any other device or in a manner contrary to its intended use. Failure or breaking of instruments can occur. Instruments have a limited service life and should be examined for wear or damage and replaced prior to surgery if required.

Instrumentation should be sterilised according to the manufacturer's protocols. Do not resterilise component parts which have been assembled, or implants connected to surgical instruments. Do not cool hot components in cold water.

The Signature Orthopaedics pedicle screws have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. Signature Orthopaedic does not recommend MR imaging for any patients implanted with product 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.

8 Intraoperative

Correct implant selection is extremely important. The use of preoperative imaging and templating is recommended to facilitate the choice of an optimum size. The patients overall anatomical and medical condition should also be considered in conjunction with age, expected activity level, life expectancy and potential for future revision surgeries. The incorrect selection of implant size may result in failure of the device and/or bone.

Implants should be inspected before use. Do not use any implants that have visible damage such as chipping or bending. Do not use any implants that have been dropped on the floor.

Implants removed from the patient at revision surgery should never be reimplanted as the fatigue state of the implant cannot be determined by visual examination. Removed implants must be treated as biological hazards and are required to be treated or disposed of according to the country's waste regulations where the implant is removed.

The wound site should be thoroughly cleaned of bone and other debris before closure.

9 Postoperative Care

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.

10 Packaging and Labeling

Components should only be used if the factory packaging and labeling are intact. If the sterile barrier has been broken, return the component to Signature Orthopaedics.

11 Cleaning and Sterilization

A complete guide for reprocessing reusable instruments may be provided upon request.

12 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.

13 Limited Warranty / Liability

Signature Orthopaedics 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 with appropriate training in orthopaedic surgical techniques.

14 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 the appropriate Signature Orthopaedics location for current information. For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Signature Orthopaedics location as listed below.

Signature Orthopaedics Australia Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Sydney Australia
Tel +61 2 9428 5181
Fax +61 2 8456 6065

Signature Orthopaedics Europe Ltd
Unit A, IDA Business & Technology Park, Garrycastle
Athlone, N37 DY26, Co. Westmeath, Ireland
Tel: +353 (0) 906400539

Signature Orthopaedics USA Corp.
3150 Stage Post Drive, Suite 104
Bartlett TN 38133
USA
Tel: +1 844 762 9221
Fax: +1 855 630 9555

15 Glossary of Symbols

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD REFERENCE
REF	**Catalogue Number**	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1 Ref # 5.1.6 FDA Recognition #5-117
LOT	**Batch Code**	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Ref # 5.1.5 FDA Recognition #5-117
	**Consult instructions for use**	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Ref # 5.4.3 FDA Recognition #5-117
	**Do not resterilize**	Indicates a medical device that is not to be resterilized.	ISO 15223-1 Ref # 5.2.6 FDA Recognition #5-117
	**Do not re-use**	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Ref # 5.4.2 FDA Recognition #5-117
	**Do not use if package damaged**	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 Ref # 5.2.8 FDA Recognition #5-117
Rx Only	**Symbol for Prescription Device**	Caution: Federal law restricts this device to sale by or on the order of a physician.	Guidance for Industry and FDA on Alternative to certain Prescription Device Labelling Requirements
STERILE EO	**Sterilized by Ethylene Oxide**	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 Ref # 5.2.3 FDA Recognition #5-117

STERILE R	**Sterilized by irradiation**	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1 Ref # 5.2.4 FDA Recognition #5-117
	**Date of Manufacture**	Indicates the date when the medical device was manufactured.	ISO 15223-1 Ref# 5.1.3 FDA Recognition #5-117
	**Manufacturer**	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 89/79/EC	ISO 15223-1 Ref # 5.1.1 FDA Recognition #5-117
	**Use-by-date**	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Ref # 5.1.4 FDA Recognition #5-117
	**Caution**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Ref # 5.4.4 FDA Recognition #5-117
CE XXXX	**CE marking and notified body number**	Indicates a product have been assessed by a notified body (xxxx) to meet safety, health, and environmental protection requirements for the European Economic Area (EEA).	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [2023] OJ L117/1, art 20

Signature ORTHOPAEDICS