Signature ORTHOPAEDICS

Freedom Cervical Screw and Rod System

Instructions for Use 131-45-0110 Rev. B Issue Date: 15-May-25

Caution:

The latest version of this Instructions for Use document are provided on Signature Orthopaedics' eIFU website. It is highly recommended that the latest version is consulted to ensure the most current information is referenced. The latest version can be retrieved by following the directions on the eIFU website, signatureortho.com.au/eIFU.

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.

The Signature Orthopaedics' Freedom Cervical Screw and Rod System is used to provide immobilization and stabilization of spinal segments in the treatment of acute and chronic instabilities or deformities of the cervical spine (C1 to C7). This cervical rod and screw system is surgically implanted from a posterior approach. The device subject to this file include polyaxial cervical screws and bent, and straight longitudinal rods. The devices are used in accordance with the conditions detailed herein.

1 Indications

The Signature Orthopaedics Freedom Cervical Screw and Rod System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients (C1 to C7) as an adjunct to fusion in the treatment of the following acute and chronic instabilities and deformities of the cervical spine:

- traumatic spinal fractures and/or traumatic dislocations
- instability or deformity; failed previous fusions (e.g. pseudarthrosis)
- degenerative disease, including neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability, and
- short term stabilization of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom expectancy is of insufficient duration to permit achievement of fusion.

2 Contraindications

The Signature Orthopaedics Freedom Cervical Screw and Rod System is contraindicated for use under the following conditions:

- The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
- Biological factors such as smoking, use of non-steroidal anti-inflammatory agents, the use of anticoagulants etc all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
- Prior fusion at the level(s) to be treated.
- Any condition not described in the Indications for Use.

3 Material Composition

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.

4 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

- Non-union (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

5 Warnings and Precautions

The implantation of cervical spinal screw systems should be performed only by experienced spinal surgeons with specific training in the use of this cervical spinal screw 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.

Warning:

The safety and effectiveness of cervical screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation.

Precaution:

a) Pre-operative planning prior to implantation of posterior cervical lateral mass and pedicle screw spinal systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI imaging) to evaluate the patient's cervical anatomy including the transverse foramen and the course of the vertebral arteries. If any findings would compromise the placement of lateral mass or pedicle screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

b) Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity beyond what is required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.

5.1 MR Safety Information

The Freedom Cervical screw system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artefacts in the MR environment. The

safety of the Freedom cervical screw system in the MR environment are unknown. Scanning a patient who has these devices may result in patient injury.

6 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 patient's 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

7 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.

8 Preoperative

Care should be taken when handling the Freedom Cervical Screw and Rod 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 artefact 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.

9 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.

10 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.

11 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.

12 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The entirety of the implants listed hereby, included in the Signature Orthopaedics Freedom Cervical Screw and Rod System IFU, are EO (ethylene oxide) sterilized. The method of sterilization, sterile EO, is noted on the package label. Return the implant to Signature Orthopaedics if the packaging is damaged. Resterilisation of the implants is not recommended, as it may alter the mechanical integrity of the device. Do not sterilize implants using moist heat.

Unless specifically labelled sterile, instruments are supplied non-sterile and must be sterilized prior to use.

A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following sterilization method is recommended:

Method: Steam Autoclave
Cycle: Pre-vacuum
Temperature: 132°C (270° F)
Exposure time: 4 minutes
Drying time: 30 minutes

13 Cleaning

Implants are supplied sterile and intended for single use only. The implant should be returned back to Signature Orthopaedics if the packaging is damaged. Cleaning of the implants is not recommended.

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. Instruments should be returned to Signature Orthopaedics at the address provided below at least once every 2 years for review / repair / replacement. Instruments may be returned to Signature Orthopaedics for review / repair / replacement earlier if the user deems necessary.

14 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.

15 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.

16 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.

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Label Symbol Legend and Abbreviations

REF	Product code	STERILE EO	Sterilized by Ethylene Oxide
LOT	Batch number	STERILE R	Sterilized by radiation
	Consult instructions for use		Manufacture date
	Do not resterilise		Manufacturer
	Single Use		Expiration date
	Do not use if package damaged		Warning
Rx Only	Federal law restricts this device to sale, distribution and use by or on the order of a physician.		

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