Foot and Ankle Screw and Plating Range

Subtalar Implant, Forefoot Fixation Implant, Foot Plating System

Instructions for Use 191-07-0901 Rev. F Issue Date:09/2018

CE 0123

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.

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

1 General Instructions

The Signature Orthopaedics' range of foot and ankle screw and plating systems are intended for use in the correction of pathological conditions and deformities of the foot and ankle.

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 the implants, but must also be aware of their mechanical limitations. The device is intended to restrict the unwanted movement of bones within the foot/ankle joint, to help correct alignment. 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 Subtalar Implant

The R2 subtalar implant is a conical, threaded implant inserted into the sinus tarsi. It is intended to block the forward, downward, and medial displacement of the talus, thus allowing normal subtalar joint motion but limiting excessive pronation. The R2 implant is manufactured from implant grade Ti6Al4V titanium alloy and available in 6 sizes from 7-12mm in diameter. The implant has self-locking wedge design, with a cannulated centre and a hexagonal drive feature at the head for insertion. The implant is provided individually packaged sterile for single use only.

3 Forefoot Fixation System

Signature Orthopaedics' Forefoot Fixation System (FFS) is designed to be placed into the Metatarsals and Forefoot for small bone fixation. The devices in FFS are manufactured from implant grade Ti6Al4V. The FFS consists of SEC Screw, Twist-off and Staple that are described below:

- SEC Screw is available in long and short thread options and various length. It has self tapping feature, differential pitch and provides primary fixation and compression of metatarsal osteotomies
- Twist-off offers two options (Pin Loaded and Chuck Loaded) and various length for convenience of patients of different age and bone quality.
- Staple offers the options of Straight (90°) or oblique (26°) and various length. staples are used for simple and strong fixation of Akin osteotomies.

The implants in Forefoot Fixation System are individually packaged and provided sterile for single use only.

4 Foot Plating System (FPS)

Signature Orthopaedics' Foot Plating System (FPS) is designed for stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet. Signature Orthopaedics' FPS is manufactured from implant grade Ti6Al4V. Signature Orthopaedics' FPS is available in a range of sizes and shapes to compensate for the anatomical variation of different patients group.

5 Indications

Components of the Signature Orthopaedics' range of foot and ankle screw and plating systems are intended to correct deformities and pathological conditions of the foot and ankle. The indication for use of Signature Orthopaedics' Foot and Ankle Screws and Platings includes the following:

- Metatarsal fracture
- Lisfranc dislocation/fracture
- Cuboid fracture
- Navicular fracture
- Metatarsal osteotomies
- Calcaneal valgus deformity
- Lapidus MTP fusion
- TMT fusion
- Lateral column lengthening
- Medial column reconstruction
- Calcaneal fracture
- Naviculocuneiform fusion
- Talonaviculocuneiform fusion
- Talonavicular fusion
- Calcaneocuboid fusion
- Weil osteotomy
- Plantarflexed talus
- Severe pronation
- Congenital and painful flatfoot deformity
- Failed correction with long-term orthotic treatment
- Repair of tarsal coalitions
- Posterior tibial tendon dysfunction
- Paralytic flat foot deformity
- Subtalar instability

6 Contraindications

Components of the Signature Orthopaedics range of foot and ankle screw and plating systems are contraindicated for:

- Patients with superstructural alignment deformities.
- Patients with active, systemic infection.
- Patients with Sepsis
- Patients with Osteoporosis bone
- Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.
- Any condition not described in the indications for use

7 Warnings and Precautions ⚠

1) U.S Federal law restricts this device to sale by or on the order of a physician.
2) It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device. These instructions must be read in their entirety before use of the device.
3) Signature Orthopaedics' Foot and Ankle Screw and Plating Systems are supplied sterile. Resterilisation of these devices may alter devices' material properties including mechanical properties and/or biocompatibility, therefore resterilisation of these devices is strictly prohibited. Implanted components are intended for single use, and must be disposed following explantation. Reusing implanted components increases the likelihood of fatigue failure and may lead to cross-contamination between patients, and is strictly prohibited.
4) Instruments supplied with Signature Orthopaedics' Foot and Ankle Screw and Plating Systems are supplied non-sterile and are intended to be cleaned and sterilized prior to use in accordance with the procedure outlined in section 13 of this document. The instruments are intended to be used multiple times but they must be cleaned and sterilized between use.
5) Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful internal stabilization. Patients affected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations as long as the device remains implanted.
6) Correct handling of implants is extremely important. Do not modify implants. Do not notch implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage.
7) Prior to use, inspect the device to ensure it is not damaged. Do not use a device that is scratched, bent or damaged in any way.
8) Correct selection of the implant is extremely important. The potential for success in internal stabilization procedures is increased by the selection of the proper type of implant. An undersized implant may not seat firmly within the cavity and increase the risk of loosening. An oversized implant may fracture or excessively stress surrounding bone. The devices are designed to carry loading through the joint whilst correction occurs, however it is unreasonable to assume that any implant can withstand unsupported in-vivo loading indefinitely.
9) Prosthetic components from different manufacturers must not be combined. All devices should only be used according to the package directions in conjunction with the specified surgical technique and instructions for use. Additional warnings and precautions may be included in component literature.
10) Careful attention should be paid to asepsis and avoidance of anatomical hazards. Thorough debridement during the procedure is recommended to reduce the likelihood of infection.
11) Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
12) The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
13) Signature Orthopaedics' does not recommend MR imaging for any patients implanted with the foot and ankle screws and platings systems' components 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 Possible Adverse Events ⚠

The Signature Orthopaedics' range of foot and ankle screw and plating systems have the following possible adverse events:

- Fracture of the implants due to the excess loading
- Incomplete or inadequate healing
- Nerve damage resulting from surgical trauma
- Delayed correction in alignment
- Pain, discomfort or abnormal sensations due to presence of implant
- Decrease in bone density due to stress shielding
- Migration or loosening of the implant

- Foreign body reaction
- Infection
- Allergic reaction
- Bursitis

9 Preoperative Planning

A thorough clinical evaluation of the patient must occur prior to undertaking surgery. Radiological scans must be taken 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.

10 Postoperative Care and Mobilization

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. Assuming no adjunctive procedures were performed, post-operative care generally consists of protective weight bearing e.g. below the knee walking cast or walking boot, for 2 - 4 weeks. A gradual return to limited activity in 4 - 6 weeks may be permitted as tolerated, as per the physician's discretion. Patients who are at risk of non-compliance with post-operative activity limitations are contraindicated for this procedure.

11 Patient Information

In addition to the contraindications for use, precautions and possible adverse effects, it is critical that the patient is aware that activity increases the risk of device failure. The likelihood of clinical success is increased by appropriate postoperative care and the patient's ability and willingness to adhere to the surgeon's recommendations.

12 Packaging and Labeling

Components should only be used if the factory packaging and labeling are intact. If the product or its packaging are damaged please return the component to Signature Orthopaedics.

13 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The method of sterilization is noted on the package label. The Signature Orthopaedics' Foot and Ankle Screw and Plating System are sterilised by EO gas. Dispose of the implant if the packaging is damaged. Resterilization of the implants is strictly prohibited, as it may alter the mechanical integrity of the device.

Unless specifically labeled sterile, instruments are supplied non-sterile and must be sterilized prior to use. A complete guide for reprocessing unused implants and 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

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

14 Cleaning

Devices 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.

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 Sterilization

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 Storage and Handling

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

16 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 having received appropriate training in orthopaedic surgical techniques.

17 Manufacturer 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 Europe Ltd

Unit A, IDA Business & Technology Park, Garrycastle

Athlone, N37 DY26, Co. Westmeath, Ireland

Tel: +353 (0) 906400539

Signature Orthopaedics USA LLC

46 Chagrin Plaza, #118

Chagrin Falls, Ohio 44022

USA

Tel: 661 349 8502

Fax: 440 543 2174

Signature Orthopaedics Australia Pty Ltd

7 Sirius Rd

Lane Cove West NSW 2066

Sydney Australia

Tel +61 2 9248 5181

Fax +61 2 8456 6065