K-Wires and Steinmann Pins

Instructions for Use 192-340-001 Rev. C Issue Date:06/2021

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.

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

1 General Instructions

Signature Orthopaedics' K-Wires and Steinmann Pins are indicated for use in the fixation of bone fractures, bone reconstruction, and as guide pins for insertion of other implants.

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.

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

2 K-wires and Steinmann Pins

Signature Orthopaedics' K-Wires and Steinmann Pins are available in various lengths and diameters. All components are made from implant grade, cold worked 316LVM Stainless Steel to meet ISO 5832-1.

Only supplied Signature Orthopaedics instruments are to be used with Signature Orthopaedics' K-wires and Steinmann Pins. Any misuse may result in damage.

3 Indications

Signature Orthopaedics' K-Wires and Steinmann Pins are indicated for use in the fixation of bone fractures, bone reconstruction, and as guide pins for insertion of other implants. The size of the K-Wire/Pin chosen should be adapted to the specific indication. Surgeon judgement is required to ensure a K-Wire or Steinmann Pin is appropriate for the indication. There is a potential risk of K-Wire migration in some fracture fixation applications such as the clavicle.
Signature Orthopaedics' K-Wires and Steinmann Pins are indicated for use only in the following conditions:

- Bone trauma requiring internal fixation for healing.
- Fixation of soft tissue to bone where K-Wires or Pins are able to so do safely.
- Bone lengthening and shortening procedures.
- Osteotomies and other realignment procedures.

4 Contraindications

Contraindications may be qualified or total, and need to be taken into consideration when evaluating the prognosis in each case. Alternative management techniques may need to be considered under the following conditions:

- Acute or chronic infections, either local or systemic.
- Local or systemic acute or chronic inflammation.
- Serve muscular, nervous or vascular disease endangering the affected area.
- Defective bone structures, which would impede adequate anchoring of the implant.
- All associated diseases which could endanger the function and success of the implant

5 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) Implanted components are intended for single use, and must be disposed of following explantation. Reusing implanted components increases the likelihood of fatigue failure and may lead to cross-contamination between patients, and is strictly prohibited. Instruments supplied are also reusable, and are to be cleaned and sterilized between use.
4) 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 fracture management. 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.
5) 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.
6) 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.
7) Correct selection of the implant is extremely important. The potential for success in open reduction internal fixation procedures is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the devices are not designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
8) 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.
9) 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.
10) Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or fractured bone. Sufficient bone quantity and quality are important for 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.
11) Do not attempt to implant this device within cartilage epiphyseal growth plates or nonosseous tissue.
12) The implants can loosen or fail when subjected to increased loading associated with nonunion or delayed union. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant.
13) The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
14) Signature Orthopaedics does not recommend MR imaging for any patients implanted with the K-wires and Steinmann Pins 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.

6 Possible Adverse Events

Signature Orthopaedics' K-wires and Steinmann Pins has the following possible adverse events:

- Delayed union, non-union or pseudoarthrosis of the fracture
- Shortening of the limb
- Reduced function or range of motion of the operated limb
- Soft tissue irritation
- Mild inflammatory reaction
- Foreign body reaction
- Early and late Infection
- Allergic reaction
- Loosening of the implant, which may result from cyclic loading of the fixation site and/or tissue reaction of the implant
- Vascular disease including venal thrombosis, pulmonary embolism and cardiac arrest
- Heterotopic ossification
- Mechanical failure of the implant, including bending, loosening or breakage
- Migration of implant resulting in injury

7 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.

8 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. Patients who are at risk of non-compliance with post-operative activity limitations are contraindicated for this procedure. Immobilization of the fracture site may also be necessary following removal of the implant to reduce the likelihood of refracture.

9 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.

10 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.

11 Cleaning and Sterilization

Implants are supplied sterile and have been double sterile packaged. The method of sterilisation is noted on the package label. Dispose of the implant if the packaging is damaged. Resterilisation of the implants is not recommended, as it may alter the mechanical integrity of the device.

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

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

As a guideline, the following cleaning 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.

12 Cleaning

Implants 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 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.

13 Storage and Handling

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

14 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.

15 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:

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