English

Skeletal Dynamics K-Wires

INSTRUCTIONS FOR USE FOR THE UNITED KINGDOM AND THE EUROPEAN UNION

To ensure use of the most up-to-date revision, refer to www.skeletaldynamics.com/resources/

R_x: For use by physicians only. Caution: Federal Law restricts this device to sale by or on the order of a physician.

This package insert is designed to provide Instructions for Use of the Skeletal Dynamics K-Wire instrumentation. **Failure to follow instructions may lead to patient injury.**

Description

The Skeletal Dynamics K-Wire instrumentation is purposefully designed for orthopaedic procedures, including small bone fragment repairs or fusions. These wires support fracture fixation and bone reconstruction and act as guide pins for placing other Skeletal Dynamics implants, delivering reliable results in complex orthopedic procedures. They are also referred to as wires or temporary K-wires. Skeletal Dynamics K-Wires are not implantable devices.

The K-Wires are available in various sizes and are made of Stainless Steel (SST 316LVM). They shall be sterilized at the user facility.

Intended Use

The K-Wires are non-implantable devices intended to be drilled into the bone to assist in positioning an implantable device and/or surgical instrument (e.g., a fixation plate or drill guide) during an orthopaedic procedure.

Indication

The Skeletal Dynamics K-Wires devices are intended to be used with Skeletal Dynamics Implants according to each Implant System's indications for use.

Contraindications

Prior to using the K-Wires, ensure that none of the following patient conditions are present: active or latent infection, insufficient quantity or quality of bone and/or soft tissue, or material sensitivity.

Intended Patient Population

The Implant System and its associated instrumentation are intended for use in skeletally mature patients to treat acute, chronic, and degenerative orthopedic conditions.

Intended User

The implant system and its associated instrumentation should only be used by surgeons who are familiar with this system and facility processing staff trained to handle, clean, and re-sterilize surgical devices. Each surgeon must evaluate the appropriateness for the use of The Implant System and its associated instrumentation based on their clinical experiences.

Expected Clinical Benefits

The expected clinical benefit of the Skeletal Dynamics K-Wire, when used according to the instructions for use and the recommended technique, is the proper installation of the implant devices.

Material

Basic UDI Code	Basic UDI #	Device Component	Material	Standard
KWIR-FAM	0841506140055D	K-Wires	SST 316LVM	ASTM F138-19

*Nickel, classified as skin sensitizer 1: sensitization or allergic reactions to users and/or patients. Classification based on EU CLP Regulation (EC No 1272/2008) for chemical substances

Warnings and Precautions:

- DO NOT reuse any of the K-Wires. Reuse may compromise the structural integrity of the construct and/or lead to failure or infection, which may result in patient injury.
- Handle the K-Wire with extra caution to avoid user injury. K-Wires have sharp tips on one or both ends.

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- Assess patient-specific material sensitivities prior to use.
- Protect the K-Wires against scratching or nicking. Such stress concentration can lead to failure.
- Inspect K-Wires for any signs of wear, disfiguration, or physical damage. DO NOT use if any defects are observed.
- DO NOT permanently implant the K-Wires; they are intended to be used during provisional fixation of the Skeletal Dynamics Systems.
- The Skeletal Dynamics K-Wires are to be used only with Skeletal Dynamics instruments, implants, and accessories; consult the instructions for use of the relevant system (www.skeletaldynamics.com/resources).
- Dispose of contaminated K-Wires per established facility guidelines and protocols.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drill power sources.
- Do not overbend the K-Wire, as this may compromise its structural integrity.
- If a standard drill is used, it must be run as slowly as possible to avoid a thermal effect.

Potential Adverse Events:

Potential risks associated with orthopaedic surgery include infection, nonunion, persistent pain, allergic reactions to stainless steel, nerve or soft tissue damage. The K-Wires may bend or break, extrude, or back out of the surgical site. Serious incidents should be reported to Skeletal Dynamics Inc., or an in-country representative, and to the health authority where the incident occurred.

Directions for Use:

Please refer to Skeletal Dynamics' Surgical Technique Guides to review the surgical approach described by Jorge L. Orbay, M.D., of the Miami Hand and Upper Extremity Institute in Miami, Florida, USA.

Basic Surgical Technique:

- Based on the patient's anatomy, select the appropriately sized Skeletal Dynamics K-Wire.
- Use the accompanying instrumentation when suitable (refer to the surgical technique guides).
- Attach the K-Wire to a drill power source, then drill into the bone to place the K-Wire.
- Ensure the K-Wire is inserted in the correct direction and confirm accurate placement using fluoroscopy.
- Remove the K-Wire before completing the procedure.

The steps above outline a general approach to K-Wire use. For specific product applications, please refer to the corresponding surgical technique guides at www.skeletaldynamics.com/resources.

Cleaning, Sterilization, and Inspection

For instructions on cleaning, disinfecting, and sterilizing the K-Wires, please refer to the Reprocessing (cleaning, disinfection, and sterilization) Instructions for use (IFU-04056-00). Please refer to the system-specific surgical techniques for proper kitted-tray arrangements.

Resources

The latest version of the Instructions for Use may be requested in a physical format by email (orders@skeletaldynamics.com) or by phone (+1-877-753-5396). The physical copy will be provided within 7 calendar days of receiving the user's request, or, if requested at the time of order, at the time of device delivery.

For the most current instructions for use and symbol glossary, visit www.skeletaldynamics.com/resources. Instructions for Use should always be reviewed before using or implanting a device.

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