BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

Non-Sterile Single Use K-wires Instructions for Use

For the most current instructions for use and symbol glossary visit www.bioproimplants.com/ifu. Instructions for Use should always be reviewed before using or implanting a device. To receive a printed IFU within 5 business days, please contact orders@bioproimplants.com

Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

Description
BioPro k-wires are designed for hand, foot, and small bone fragment repairs or fusions. Uses include fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants.

Material
Stainless Steel (ASTM F138) or Titanium (ASTM F67)

Indications for use:
BioPro k-wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeleton system.

Contra-indications:
1. Comminuted bone surface that would mitigate against k-wire placement.
2. Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the k-wire
3. Foreign body sensitivity to metals specifically stainless steel or titanium. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Precautions and Handling
- Devices must only be used by surgeons who are familiar with the k-wires provided.
- All k-wires should be carefully examined for damage by surgeons and staff in operating centers prior to surgery.
- Use care in handling and storage. K-wires are sharp and incorrect use or handling may result in puncture wounds.
- Improper use may result in deformation or breakage of the k-wire during operation.
- Post-surgical monitoring should be conducted to ensure k-wire migration is not occurring.

Potential Complications and Adverse Effects
- Allergic reactions to stainless steel or titanium
- Delayed or Non-union of bone
- Delayed Healing
- K-wire may bend or break
- K-wire may extrude or back out of the surgical site

MR Safety Information
Warning: k-wires have not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

℞ Only

Cleaning and Sterilization Introduction
These guidelines are intended to provide a better understanding of the care and handling of BioPro non-sterile k-wires. These guidelines are not intended for use with electrical, pneumatic or other powered surgical instruments. K-wires are shipped in a NON-STERILE condition and must be cleaned and sterilized prior to use.

General Care and Handling
Avoid undue stress or strain when handling or cleaning. Tap water can contain many minerals that may discolor and stain k-wires; therefore, it is recommended that deionized water be used for the final rinsing to prevent spotting.

Cleaning: Follow these steps to thoroughly clean all k-wires
1. Submerge k-wires in an enzymatic detergent. Prepare detergent according to the manufacturer's recommendations. Soak the k-wires for twenty (20) minutes in the protein solubilizing detergent.
2. Scrub the submerged k-wires with a soft sponge and agitate.

3. Rinse in warm (38-49 degree C) tap water for one (1) minute.
4. Ultrasonically clean the k-wires for ten (10) minutes in a neutral pH detergent (Neutrad or acceptable alternative). Prepare the detergent according to the manufacturer's recommendations.
5. Rinse the k-wires with deionized water for at least three (3) minutes.
6. Dry the k-wires thoroughly with a clean, lint free cloth.
7. Visually inspect k-wires for any damage or remaining contaminates. K-wires should be visually clean.
8. Repeat cleaning procedure if necessary if contamination remains.

Sterilization

Following the cleaning process, place a sterilization indicator with the k-wires. The k-wires are to be wrapped in a double layer of CSR wrap. Steam sterilization is required with the following parameters:

For pre-vacuum cycle:

Wrapped items: 4 minutes exposure at a minimum temperature of 132° C (270° F), maximum temperature of 143° C (290°F), 4 pulses, 30 minutes dry time.

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