BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

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 sterile 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.

Warnings and Precautions
- 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.

MR Safety Information
Warning: k-wires have not been evaluated for safety and compatibility in the MR environment and have 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.

Sterile:

Sterilized with ethylene oxide gas. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.
time.

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