Allegra ORTHOPAEDICS
Human Movement Technology

K-Wires and Steinmann Pins

Allegra Orthopaedics K-Wires and Steinmann Pins are available in a range of types including double-ended, single-ended and threaded, in various lengths and diameters.

All Allegra Orthopaedics K-Wires are supplied in easy to use, single use packaging and manufactured in an ISO 13485:2003 accredited facility, located in Sydney, Australia.

Indications for Use

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 implant. 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.

Allegra 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.

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 accurate 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.

Warnings and Precautionary Information

Before using Allegra Orthopaedics products, the surgeon and ancillary staff should study the safety information in these instructions, as well as any product-specific information in the product description, surgical procedures and/or brochures.

Allegra Orthopaedics K-Wires and Steinmann Pins are made from surgical grade 316L Stainless Steel and are designed, constructed and produced with utmost care. These quality K-Wires and Steinmann Pins assure best working results provided they are used in the proper manner. Therefore, the following instructions for use and safety recommendations must be observed.

Improper use of this instrument can lead to damage to the tissue, premature wear, destruction of the instruments and injury to the operator, patients or other persons.

It is vital for the operating surgeon to take an active role in the medical management of their patients. The surgeon should thoroughly understand all aspects of the surgical procedure and instruments including their limitations. Care in appropriate selection and proper use of surgical instruments is the responsibility of the surgeon and the surgical team. Adequate surgical training should be completed before use of Allegra Orthopaedics K-Wires and Steinmann Pins.

The patient's attention should be drawn to the contents of this IFU as well as to any factors that may impair the results of the operation and to possible complications that may arise through use of these K-Wires and Steinmann Pins. The patient should also be informed about the measures which the surgeon will use to minimise the possible effects of these factors.

Factors which could impair the success of the operation:

- Allergies to implanted materials.
- Localised bone tumours.
- Osteoporosis or osteomalacia.
- System disease and metabolic disturbances.
- Alcohol and drug abuse.
- Physical activities involving excessive shocks, whereby the implant is exposed to blows and/or excessive loading.
- Patients who are mentally unable to understand and comply with the doctor's instructions.
- Poor general health.

Possible Adverse Effects

The following adverse effects are the most common resulting from implantation:

- Loosening of the implant, which may result from cyclic loading of the fixation site and/or tissue reaction of the implant.
- Early and late infection.
- Further bone fracture resulting from unusual stress or weakened bone substance.
- Temporary or chronic neural damage resulting from pressure or haematomata.
- Wound haematoma and delayed wound healing.
- Vascular disease including venal thrombosis, pulmonary embolism and cardiac arrest.
- Heterotopic ossification.

- Pain and discomfort due to presence of the implant.
- Mechanical failure of the implant, including bending, loosening or breakage.
- Migration of implant resulting in injury.

Preoperative Planning

The operating planning is carried out following a thorough clinical evaluation of the patient, Also, x-rays must be taken to allow a clear indication of the bony anatomy and associated deformities. At the time of the operation, the corresponding Allegra Orthopaedics implantation instruments in addition to a complete set of implants must be available.

The clinician should discuss with the patient the possible risks and complications associated with the use of K-Wires and Steinmann Pins. It is important to determine pre-operatively whether the patient is allergic to any of the implant materials. Also, the patient needs to be informed that the performance of the device cannot be guaranteed as complications can affect the life expectancy of the device.

Safety and Liability

The user is responsible for checking the product prior to use to ascertain whether it is suitable for the intended purpose.

In the case of contributory negligence by the user, Allegra Orthopaedics Ltd partially or totally declines liability for the resulting damages, particularly if these are due to non-observance of our recommendations for use or warnings as well as inadvertent misuse by the user.

Sterilisation

All K-Wires and Steinman Pins are supplied sterile in protective packaging to a Sterility Assurance Level (SAL) of 10^{-6}. K-Wires and Steinmann Pins have been sterilised using a minimum dose of 25 kGy of gamma irradiation (ISO 11137) and bear a red dot indicator. All K-Wires and Steinmann Pins are for single use only and must not be resterilised.

Packaging and Labelling

The dual tube/pouch packaging system protects the wires and pins during transportation and storage, and allows for aseptic handling within the surgical environment.

Packaging should be inspected for signs of damage or tampering prior to using the instrument. Any Wires/Pins with damaged packaging where the sterile barrier may have been compromised should not be used.

The expiry date for the instrument should also be confirmed prior to use. Damaged or out of date stock should be returned to the distributor or manufacturer.

Key symbols on the packaging labels:

REF	Catalogue Number
2	Single Use - Do not Reuse
LOT	Lot Number
	Date of Manufacture
	Expiry Date
Qty.	Quantity of Items in Package
	See 'Instructions for Use'
Rx Only	Federal Law (USA) restricts these devices to sale by, or on the order of, a physician.

Handling and Storage

Always handle K-Wires and Steinmann Pins with sterile powder-free gloves. Prior to use, K-Wires and Steinmann Pins should be stored in clean, dry conditions and should not be exposed to direct sunlight, ionising radiation, and extremes of temperature or contamination.

Additional Information

Further information on Allegra Orthopaedics products is available at www.allegraorthopaedics.com or by contacting us via email at sales@allegraorthopaedics.com

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