

Hygienic Safety

In order to maintain hygiene, the device should be cleaned and sterilised as described. It should be handled with care to avoid injury as it may have sharp edges.

If in a sterile state, in order to remain in this state, it must be kept in a sterile environment and handled with sterile rubber gloves and other necessary clothing. It must be used in a sterile operating theatre.

All necessary precautions should be taken to avoid contamination, and for the device to remain in a sterile state.

Cleaning and Sterilisation

These products are supplied non-sterile.

The temporary implant should be decontaminated using machines that comply to HTM 01-01. Sterilisation will be via steriliser which confirms to HTM 01-01 on a cycle of 134°-137° C for 3 minutes.

Surgical Holdings

Parkside Centre, Temple Farm
Industrial Estate, Southend-on-Sea,
Essex SS2 5SJ

T. +44 (0)1702 602050

E. info@surgicalholdings.co.uk

www.surgicalholdings.co.uk



Kirschner Arthrodesis Wires

Product Instructions

The following instructions should be followed in order for your Class IIB medical device to remain safe.



0120

**If the pack is damaged
do not use**



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Attention Operating Surgeon

- These products are only to be implanted by a qualified medical practitioner using compatible CE Marked instruments.
- Skeletal wires should only be used for fusion, skeletal traction, and fixation (to fixate bones while they are healing) in the areas of the body for which they were intended, namely hands and feet.
- Pins and wires are non-permanent implants: they should be removed after 120 days, and **SHOULD NEVER BE RE-USED**. The skeletal wires should never be misused in any way.

Possible Adverse Effects

This product contains Nickel. It is recommended that hospitals perform nickel allergy tests if there is any doubt regarding patient sensitivity.

Infection, subclinical nerve damage, arterial puncture, tendon risk, metal sensitivity, loosening, migration, bending, or fracture of the device and/or bone.

Warnings and Precautions

The surgeon should:

- Discuss all physical and psychological limitations inherent in the use of these devices with the patient.
- Select the correct size and type of implant.
- Warn the patient against premature weight-bearing activity levels, and the necessity of periodic medical follow up and cleaning of the wound around the wires.
- The patient should be instructed to report any unusual changes around the operated site to his physician, eg: sign of infection.
- Surgical Holdings Kirschner wires are non magnetic. However, they have not been evaluated for safety and compatibility in Magnetic Resonance (MR) environment and have not been tested for heating or migration in the MR environment, unless otherwise specified on the product labels.

Disposal

Products should be disposed in clinical waste as per hospital protocol.

Product Range

REF

Kirschner and Arthrodesis Wires are prefixed with codes KWHSxxxx and SHxxxx where xxxx = catalogue number. Kirschner wires typically have one trocar point/one plain end and Arthrodesis wires two trocar points.