

ENGLISH**Implants for Osteosynthesis****Specific product information**

For detailed information concerning individual products (such as product code, description and lot number) please refer to the labelling on the package.

Intended Use

KellMed Wires/ Pins are designed to offer temporary transfixion of bone particles during surgery or to provide guide wire facility to be used in conjunction with other instruments.

Indications for Use

KellMed Wires/ Pins are implants for use in orthopaedic surgery for the fixation, reparation, revision, and alignment of bones and bone fragments. Some wires may be used for longer term transfixion of bone fragments while fusion and healing takes place after which they are removed.

General Advice

Ensure that you are familiar with the recommended uses, compatibility, and correct handling of the implant. Product should be handled with care as it may have sharp edges. Stick injury can cause damage to user and cross contamination of the implant. This implant should be used once, on a single patient, and then discarded. A reused device may cause cross contamination and have small surface defects or internal stress concentrations that could lead to failure. Handle this device with care both prior to and during implantation, to minimise the risk of surface damage. Unnecessary bending forces should be avoided. If contouring of implants is necessary it should be



performed without generating sharp bends, notching, or scratching. Any metallic device used in conjunction with this implant should be manufactured from metal of a similar composition. 'Mixing' materials may lead to metallic interactions such as galvanic corrosion, which will weaken the implant and increase the risk of failure and consequent revision surgery.

Sterile Packed Product

The packaging of sterile packed product should be inspected for flaws before opening. If a flaw is detected, the product must be assumed non-sterile. Once the sterile packaging has been opened, care should be taken to prevent contamination of the device. Note that sterile-packed product has a defined shelf life (see label) beyond which sterility is not guaranteed.

Warning and contraindications

This product contains nickel. A nickel allergy test is recommended if there is any doubt regarding patient sensitivity. Contraindications for this product should include active or recent sepsis and marked atrophy or deformity of the bone to be fixed. Patients who are overweight, or who are physically very active, will place relatively heavy demands on the implant. Such patients should be instructed on the limitations of the device to minimise the risk of premature failure. Implants supplied with this leaflet are not approved for attachment or fixation to the pedicles of the cervical, thoracic or lumbar spine. When using wires as guides for cannulated screw systems, it is particularly important to continuously screen with an image intensifier during guide wire insertion, and whenever cannulated instruments are inserted over a guide wire. For each patient, the benefit of fluoroscopy should be weighed against the risk from radiation exposure.

