Patient information leaflet for K-ROD custom-made rod

1. What is K-ROD custom-made rod used for

K-ROD custom-made rods are devices to be used in association with KHEIRON Spinal Fixation System, intended to help provide immobilization and stabilization of spinal segments as an adjunct to bone fusion of the thoracic, lumbar, and/or sacral spine.
These devices are indicated in skeletally mature patients when conservative treatments were not efficient or when the disease progression may represent a threat to patient safety, for all the following indications:

- Degenerative disc disease (defined as back pain with degeneration of the disc),
- Spondylolisthesis, i.e sliding of a vertebra forward and and downward in relation to the vertebrae just below it
- Trauma (i.e., fracture or dislocation),
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease),
- Tumor,
- Stenosis (i.e narrowing of the spinal canal)
- Pseudoarthrosis (i.e failed previous bone fusion).
- Treatment of severe spondylolisthesis of the L5-S1 vertebrae.

2. Product description

Rods are manufactured for a specific patient, each rod designed is identified by a patient code (ID KEOPS). The K-ROD custom-made devices are available in Ø5.5 and Ø6mm.
K-ROD custom-made devices are made of titanium alloy.

3. When K-ROD custom-made rods should not be used

Contraindications include, but are not limited to:

- The bony condition of the patient (e.g.: massive or severe osteoporosis)
- Congenital spinal stenosis
- Comminuted (multiple) fractures involving several vertebrae
- Tumours involving several successive vertebrae
- Allergies, intolerance and/or hypersensitivity to titanium alloys
- Infection
- Local inflammation
- Fever, leukocytosis
- Obesity
- Pregnancy
- Mental illness or patient not likely to follow the surgeon’s recommendations
- Congenital abnormal anatomy
- Rapidly progressive joint disease, severe osteoporosis
- Inappropriate anatomy
- Patient having inadequate tissue coverage over the operative site
- Any case not described in the indications.

4. Caution

The following information should be considered before the procedure in order to ensure success of the surgical implantation:

- Clinical data show that patients who smoke tend to have less optimum bony consolidation, as do patients who are undernourished or alcoholic.
- To aid bone healing, it is important to limit use of nicotine and non-steroidal medicinal products (e.g.: aspirin).
- The implanted device must not be exposed to unwanted forces such as mechanical vibrations. Consequently, the patient must limit his or her physical activity (athletic and occupational), especially in cases of lifting, twisting and crushing.
- Throughout the consolidation period, the patient must follow the surgeon's instructions and recommendations.

5. Adverse effects

The following adverse effects have been observed. This list may not include all complications caused by the surgical technique itself:

- Device malposition potentially requiring revision surgery
- Haematoma
- Infection at implantation site
- Failed bone fusion (pseudarthrosis)
- Neurological damage
- Bone damage
- Disassembly, deformation and/or rupture
- Risk of allergy to titanium alloy is rare, but must be considered
- Interferences with radiographic, CT scan, and/or MR imaging caused by the implants
- Complications due to surgery (haemorrhage, infection, complications due to the use of bone grafting, respiratory problems, reaction to anaesthesia, death).

6. MRI information

- These implants do not present any known risk of interference with other medical equipment.
- Device safety and compatibility in a magnetic resonance setting have not been evaluated. No thermal test or migration test has been performed on the device in this setting.

7. Symptoms that could be related to a dysfunction of the device

Fever, back pain and squeaks at the operated site may be the signs of a dysfunction of the device.

8. Lifetime

The K-ROD custom-made rods are devices to be used in association with KHEIRON Spinal Fixation System, intended to help provide immobilisation and stabilisation of spinal segments as an adjunct to bone fusion. Bone fusion may occur after a variable period depending on each

patient. After fusion occurs, the material can be removed (in this case the benefit/risk ratio of an additional surgery should be discussed with the practitioner).

9. Monitoring/maintenance of the implanted devices

No specific monitoring/maintenance of the implanted devices is necessary.
In case of adverse event your surgeon may request a radiographic check-up.

10. Vigilance

For a patient in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to S.M.A.I.O at vigilance@smaio.com and to your national authority.

11. Manufacturer

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12. List of devices covered by this leaflet

30KR55000
30KR60000