Patient information leaflet for KHEIRON Spinal Fixation System

1. What is KHEIRON Spinal Fixation System used for

The KHEIRON Spinal Fixation System including the K-ROD patient-specific rod is a spinal fixation system intended to help provide immobilisation and stabilisation 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 confirmed by history and radiographic studies),
- 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),
- Tumour,
- 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

KHEIRON Spinal Fixation System includes pedicle screws, straight and curved rods of Ø5.5mm and Ø6mm, transverse systems, dominos connectors, sacral plates, sacral screws, iliac extension, iliac screws, hooks, claw hooks and connectors. Those components can be locked in various configurations, each assembly being tailor-made.

K-ROD rods are manufactured for a specific patient, each rod designed is identified by a patient code (ID KEOPS). The K-ROD patient specific rods are available in Ø5.5 and Ø6mm.

All implants are made of titanium alloy.

3. When KHEIRON Spinal Fixation System should not be used

Contraindications include, but are not limited to:

- The bony condition of the patient (e.g.: massive or severe osteoporosis) making the procedure risky in terms of mechanical securing of the implant
- Congenital spinal stenosis
- Comminuted (multiple) fractures involving several vertebrae
- Tumours involving several successive vertebrae
- Allergies, intolerance and/or hypersensitivity to the component material of the implant which is Ti-6Al-4V ELI, titanium alloys
- Primary or secondary infection
- Local inflammation
- Fever, leukocytosis
- Obesity
- PregnancyMental 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 decribed in section 1.

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:

- Displacement or expulsion of the implant before bone fusion requiring another surgical procedure
- Device malposition potentially requiring revision surgery
- Haematoma
- Infection at implantation site
- Failed bone fusion (pseudarthrosis)
- Neurological damage
- Bone damage
- Disassembly, deformation and/or rupture of one or more components of the system
- Risk of allergy to titanium alloy is rare, but must be considered
- Interference 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 KHEIRON Spinal Fixation System is a 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

Any adverse outcomes potentially attributable to KHEIRON Spinal Fixation System implants must be reported promptly to your doctor. You may also report it to S.MA.I.O at vigilance@smaio.com or directly to the Therapeutic Goods Administration at this link: http://www.tga.gov.au/reporting-problems

11. Manufacturer

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FRANCE
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Website: www.smaio.com

12. List of devices covered by this leaflet

24BR55XXX
24BR60XXX
24CR55XXX
24CR60XXX
24PW55600
24PW55700
24PW56XXX
24PW60600
24PWXXXXX
24SR55XXX
24SR60XXX
25SC55XXX
25SC60XXX
25SN55XXX
25SP55XXX
25SWXXXXX

26PH00001
26PH45XXX
26PH67XXX
26SL00XXX
26SP45XXX
26SP67XXX
26TC00001
26TC10XXX
26TC20XXX

27AC51000
27PC52XXX
27PC53XXX
27PC54XXX
27PC55XXX

28IE56XXX
28IS00001
28IWXXXXX

29TC55XXX
29TC60XXX

32KR55000
32KR60000

Where “XXX” and “XXXXX” can be any combination of numbers.