KHEIRON - Spinal Fixation System Implants
Instructions For Use

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1. INTENDED USE

The KHEIRON 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 fusion of the thoracic, lumbar, and/or sacral spine.

2. INDICATIONS

These devices are indicated as an adjunct to fusion 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 discogenic back pain with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation),
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease),
- Tumour,
- Stenosis,
- Failed previous fusion (pseudoarthrosis).

In addition, the pedicle screw system is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after attainment of a solid fusion.

3. CONTRAINDICATIONS

Contraindications include, but are not limited to:

- The bony condition of a patient (e.g.: massive osteoporosis) making the procedure risky in terms of mechanical securing of the implant
- Congenital spinal stenosis
- Comminuted fractures involving several vertebrae
- Tumours involving several successive vertebrae
- Allergies, intolerance and/or hypersensitivity to the component material of the implant Ti-6Al-4V ELI
- Primary or secondary 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. DESCRIPTION OF THE EQUIPMENT PROVIDED

KHEIRON Spinal Fixation System includes screws, anchoring and connecting components in a wide variety of sizes and shapes, which can be locked in various configurations, each assembly being tailor-made. KHEIRON pedicular screws must be used with straight, curved or patient specific rods of Ø 5.5mm and Ø 6mm.

Materials: all implants are made of Ti-6Al-4V ELI titanium alloy in accordance with medical standard ISO 5832-3 and ASTM F136.

Packaging: the K-ROD patient-specific rods are delivered in PE pouches.

For replenishment of other devices pertaining to KHEIRON system the implants are delivered in PE pouches.

Packaging for each component must be intact upon receipt. If a loan or consignment system is used, the complete set must be carefully checked for completeness. Integrity of each device, including the instruments, must be carefully checked prior to use. Damaged packages or products must not be used and must be returned to SMAIO.

5. EQUIPMENT REQUIRED FOR IMPLANT PLACEMENT

All the equipment required to perform the surgery is referenced in SMAIO's product catalogue*.

Some instruments may be specific to a given rod diameter. Before the operation, check the availability of the instruments corresponding to the diameter(s) of the rods to be inserted.

6. STORAGE CONDITIONS

Implants must be stored in a clean place, at room temperature in their original packaging, or in the box provided for this purpose by SMAIO.

7. PRECAUTIONS AND WARNINGS

a) General considerations

- Implants are for single use only.
- Delivered implants are NON-STERILE and are intended to be cleaned and sterilised according to the instructions given in §8.
- Never use a damaged, explanted implant, or one which has been used erroneously when it has come into contact with tissues, even after cleaning. The implant must be discarded. Re-use of a single-use device makes it impossible to ensure structural integrity or achievement of the assigned performances over time and may result in premature rupture. Such re-use may also result in infection in the patient.
- Never use stainless steel and titanium implant components in the same construct.
- Compliance with pre-operative and perioperative procedures, including knowledge of the surgical technique, as well as the proper selection, adequate reduction and correct selection and positioning of implants are important factors in the successful use of the system by the surgeon.

  Knowledge and experience in spinal surgery are pre-requisites.
- Furthermore, appropriate patient selection, as well as the patient's cooperation, will greatly affect results.
- The surgeon is responsible for ensuring that the shape of the K-ROD patient-specific rods implanted matches the patient's anatomy. Any change in the patient's anatomy since the radiograph which was used for the surgery planning should be assessed to ensure that the rod is compatible with the patient's anatomy.

b) Warning for surgeon and medical staff

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 be informed of limiting 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.
- 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.

8. CLEANING/STERILISATION

- Whether they come directly from their original packaging or from the tray of use, implants must be cleaned and decontaminated in accordance with the legislation in force prior to sterilisation.
- Before use, this product must be sterilised by steam autoclaving in compliance with ISO standard ISO 17665-1.
- SMAIO recommends cleaning the non-sterile devices by combined manual and automatic cleaning, using a heat disinfector which complies with standard EN ISO 15883-1, used with an alkaline cleaning product with pH ≤ 10,8 as per the validated method described in the tables below.
- The aforementioned parameters are valid only for devices in the product range sterilised in the corresponding box. Any other configuration used would jeopardise the manufacturer's validation.
- The instructions provided below have been validated by SMAIO as being capable of preparing a medical device for its use. The processor remains responsible for ensuring that the processing actually performed using the equipment, materials and personnel at the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

Manufacturer: S.M.A.IO **Method**: Steam autoclaving **Devices**: KHEIRON Spinal Fixation System	
WARNINGS	• Implants must NOT be processed with NaOH but can be processed without damage with a sodium hypochlorite solution (6 chlorometric degrees) for 60 min at 20 °C. • Do not use a wire brush or an abrasive, and handle products with gloves throughout the various processes and uses, during which they must be arranged on appropriate trays for cleaning and decontamination steps.
Limitations on processing	Non applicable

INSTRUCTIONS FOR CLEANING/DECONTAMINATION AND STERILISATION	
Initial treatment at point use	Place the implants on a tray or in a suitable basket for the cleaning and decontamination steps.
Preparation before cleaning	Disassemble the devices when possible (see the disassembly instructions). Open the devices, when possible. Fully immerse the devices in an enzymatic solution for the time recommended by the cleaning agent manufacturer. Validated parameters are: "Neodisher® MediClean Forte" 0.5% cleaning agent; room temperature [20 °C; 25 °C]; for 10 minutes.
Pre-cleaning: manual	Remove any visible residues with a soft brush (non-wire) or a long-neck brush capable of reaching the cavities. Brush for at least 2 minutes. Carefully clean each cavity. Remove the device from the enzymatic solution. Abundantly rinse the devices with tap water, at room temperature [20 °C; 25 °C] for 1 minute and repeat the operation at least 3 times. Carefully rinse each lumen, rough or hard-to-reach area, cavity, etc.
Cleaning: Automated	Place the implants in an opened position in a suitable basket for the cleaning and decontamination step. **Parameters validated with the cleaning/disinfector HAMO ECOLINE LM-25 and the "VARIO TD LIQUID" programme**

Steps	Time (min)	Temperature	Cleaning agent
Pre-cleaning	2 :00	< 45 °C – 113°F	Tap water
Cleaning	5 :00	55 °C – 131°F	Neodisher® MediClean Forte (2 mL per litre)
Neutralisation	2:00	< 45 °C – 113°F	Tap water
Rinsing	2:00	< 45 °C – 113°F	Tap water
Disinfection	5:00	90 °C – 194°F	Osmosis water
Drying	22:00	80 °C – 176°F	N/A

Maintenance, inspection and Testing	After the cleaning cycle, check each device for any visible residue. If residue is found, repeat each cleaning step until there is no visible residue left.
Packaging	The devices are placed in the SMAIO kit. The kit is packaged in a double Pasteur wrap. The K-ROD patient-specific rods are placed in a wire basket and packed in a double Pasteur wrap.
Sterilization	Devices that have been dismantled must be reassembled before the sterilisation cycle.Assembled devices must NOT be re-assembled before the sterilisation cycle. The sterilisation cycles are the following, depending on the geographic area:

	European Union	United-Kingdom
Method	Steam	Steam
Cycle	Pre-vacuum	Pre-vacuum
Temperature	273.2 °F – 134 °C	273.2 °F – 134 °C
Time	18 minutes	3 minutes
Drying	45 minutes	45 minutes

Storage	Not applicable
Additional information	Look for any signs of premature implant wear after sterilisation. If such is the case, DO NOT use them and inform SMAIO (see §15). After a cleaning and sterilization cycle, check the legibility of the laser marked information.
Manufacturer contact	See §14

9. INSTRUCTIONS FOR USE

Instructions for placement of implants are detailed in the surgical technique.*

If in doubt concerning use, cleaning, decontamination, sterilisation or discarding of an implant, contact the SMAIO customer service department.

a) Before the operation

- Read the surgical technique carefully*.
- Prepare all bone implants and instruments necessary for the procedure and check their integrity.
- Only SMAIO implant placement instruments, designed and provided by SMAIO, should be used with the implant.
- Handle implants with care to prevent deep scratches (risk of incipient rupture).
- Assess the height and number of implants to install based on a preoperative radiograph.
- After taking the measurement, ensure the availability of implants in the different sizes considered in order to have a sufficient choice during the surgical procedure.
- Always plan to have an extra implant in each required size to allow replacement in the event of accidental contamination during the procedure.
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- Before a first implantation, the surgeon and his/her surgical team should practice handling the instruments to become familiar with the equipment.

b) During the operation

- The procedure should be performed by a surgeon who has received the necessary spinal surgery training.
- Observe the different phases described in the KHEIRON surgical technique*.
- The implantation must be performed solely with the instruments provided for this purpose and according to the indications of the surgical technique*.
- SMAIO ensures the performance of the aforementioned implants if they are used together and not alongside implants from other manufacturers.
- SMAIO declines all responsibility in the event of implantation of a device previously altered by the user (dimensions, surface condition, etc.)
- Use an image intensifier to check the position of the implants.
- After the final tightening, count both the loose parts removed from the nuts and the screws to make sure that no nut has been left in the implantation site.
- **Rod straightening is prohibited.**

c) After the operation

- Radiological examinations must be performed regurlaly to check on postoperative progress and thus prevent possible complications.
- The KHEIRON Spinal Fixation System implants are temporary fixation devices. The internal fixation devices are intended to stabilize the implantation site during the normal healing process. Once the spine bony fusion has occured, these devices have no functionality and can be removed.
- All explanted implants must be treated in such a way that they cannot be re-used for any other surgical procedure. As for all orthopaedic implants, KHEIRON spinal fixation system implants must not be re-used under any circumstances.

10. 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
- Pseudarthrosis
- Neurological damage (breach of the dura mater, lesion of a spinal root)
- Bone damage
- Disassembly, deformation and/or rupture of one or more components of the system
- Risk of allergy to Ti-6Al-4V ELI is rare, but must be considered
- Interference with radiographic, CT, 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).

11. PRODUCT DISPOSAL

To discard products which have been implanted, these must firstly be disinfected and decontaminated. This information, which is mentioned on the accompanying liaison form* PAD-F-036, is sent with products returned to SMAIO.

For disposal of a product following an error in storage or improper use of the product, implants must follow the pathway for removal of hospital waste products in compliance with the procedures in force within the institution.

12. GUARANTEE

In the event of a defect detected **before** deconditioning, contact the SMAIO customer service department and return the defective implant, cleaned, decontaminated and together with the liaison form.* (PAD-F-018 for the K-ROD patient specific rod)
In the event of a defect detected **after** deconditioning, contact the SMAIO customer service department and return the defective implant, cleaned, decontaminated and together with the liaison form.* PAD-F-036.

13. VIGILANCE

Any adverse events linked to the use of the device must be reported to SMAIO at vigilance@smaio.com email address and to the competent authority of the Member State in which the user and/or patient is established.

14. MANUFACTURER CONTACT

S.M.A.I.O
2, Place Berthe Morisot – Parc Technologique
69800 SAINT-PRIEST
France
Tel.: +33 (0)4 69 84 23 02
Website: www.smaio.com

* Documentation available upon request on the www.smaio.com website.

15. MEANING OF SYMBOLS USED

Symbol	Title of symbol	Reference
	Manufacturer	ISO 15223-1, 5.1.1
	Date of manufacture	ISO 15223-1, 5.1.3
	Batch code	ISO 15223-1, 5.1.5
	Catalogue number	ISO 15223-1, 5.1.6
	Serial number	ISO 15223-1, 5.1.7
	Non-sterile	ISO 15223-1, 5.2.7
	Do not use if package is damaged	ISO 15223-1, 5.2.8
	Keep away from sunlight	ISO 15223-1, 5.3.2
	Keep dry	ISO 15223-1, 5.3.4
	Do not re-use	ISO 15223-1, 5.4.2
	Consult instructions for use	ISO 15223-1, 5.4.3
	Caution	ISO 15223-1, 5.4.4
	Medical Device	ISO 15223-1, 5.7.7
	Unique device identifier	ISO 15223-1, 5.7.10
	CE marking of conformity	MDD 93/42/EEC Annex XII
	Federal Law (USA) restricts this device to sale by or on the order of a physician	21 CFR 801.109