K-ROD – Custom-made Rods
Instructions For Use

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1. STATEMENT OF INTENDED USE

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

2. INDICATIONS

K-ROD custom-made rods 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),
- Tumor,
- Stenosis,
- Failed previous fusion (pseudoarthrosis).

In addition, the rod, used as a component of 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
- Tumors 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

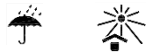
Rods are manufactured for a specific patient, each rod designed is identified by a patient code (ID KEOPS). The K-ROD custom-made devices are available in Ø5.5 and Ø6mm.

Materials: K-ROD custom-made devices are made of Ti-6Al-4V ELI titanium alloy in accordance with medical standards ISO 5832-3 and ASTM F136.

Packaging: the rods are delivered in PE pouches. Packaging for each component must be intact upon receipt. 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

The equipment with KHEIRON instruments required to implant the K-ROD custom-made rods is referenced in SMAIO's product catalogue*. Some instruments can be specific to a given rod diameter. Before surgery, check the availability of instruments corresponding to the diameter (s) of the rods to be implanted.



6. STORAGE CONDITIONS

The rods 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 conditions

- K-ROD custom-made devices are single-use
- The rods are delivered NON-STERILE and are intended to be cleaned and sterilized according to the instructions given in §8.
- A rod is specific for a given patient, under no circumstances should it be implanted in a patient other than the one for whom this rod was developed.
- The adequacy with the shape of the implanted rods and the patient's anatomy is the responsibility of the surgeon
- Never use a damaged, explanted rod, or one which has been used erroneously when it has come into contact with tissues, even after cleaning. The rod 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 the rods are important factors in the successful use of the system by the surgeon.

  Knowledge and experience in spinal surgery are prerequisites.
- Furthermore, appropriate patient selection, as well as the patient's cooperation, will greatly affect results.

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 rods 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, the rods must be cleaned and decontaminated in accordance with the legislation in force prior to sterilization.
- The implants must not be cleaned and sterilized more than once before the implantation.
- Before use, the rods must be sterilized 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 instructions provided below have been validated by SMAIO as being capable of preparing a medical device for 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.I.O. **Method**: Steam autoclaving **Devices**: K-ROD custom-made rods	
WARNINGS	• The rods 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	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). Brush for at least 2 minutes. Remove the devices 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.
Cleaning: automated	Place the implants in a suitable basket for the cleaning/decontaminating equipment. **Recommended parameters with the cleaning/disinfector HAMO ECOLINE LM-25 and the "VARIO TD LIQUID" program**

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 (2mL per liter)
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 a suitable container.
Sterilization	The sterilization cycles must respect the applicable standards, according to the approved regulations.
Storage	Non applicable
Additional information	Look for any signs of premature implant wear after sterilization. If such is the case, DO NOT use them and inform SMAIO (see §14). After a cleaning and sterilization cycle, check that laser marked information are still legible, for each device.
Manufacturer contact	Cf §14

9. INSTRUCTIONS FOR USE

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

If in doubt concerning use, cleaning, decontamination, sterilization or discarding of an implant, do not hesitate to 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).
- Always provide an additional standard straight rod for each of the rods required to be able to replace it in the event of accidental contamination during the intervention.
- 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.
- Rod straightening is prohibited.

c) After the operation

- Radiological examinations must be performed regularly to check on postoperative progress and thus prevent possible complications.
- K-ROD custom-made rods 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, K-ROD custom-made rods 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:

- Device malposition potentially requiring revision surgery
- Hematoma
- Infection at implantation site
- Pseudarthrosis
- Neurological damage (breach of the dura mater, lesion of spinal root)
- Bone fracture
- Disassembly, deformation and/or rupture
- 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 (hemorrhage, infection, complications due to the use of bone grafting, respiratory problems, reaction to anesthesia, 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 **before** deconditioning, contact the SMAIO customer service department and return the defective implant together with the Customer return form* PAD-F-018.
In the event of a defect **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 to vigilance@smaio.com 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
Phone: +33 (0)4 69 84 23 02
Web site: www.smaio.com

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

15. MEANING OF SYMBOLS USED

Symbol	Title of symbol	Reference
	Medical Device	ISO 15223-1, 5.7.7
	Do not re-use	ISO 15223-1, 5.4.2
	Non-sterile	ISO 15223-1, 5.2.7
	Caution (See Instruction for use)	ISO 15223-1, 5.4.4
	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
	Consult instructions for use on the web	ISO 15223-1, 5.4.3
	Manufacturer	ISO 15223-1, 5.1.1
	Date of manufacture Country of manufacture	ISO 15223-1, 5.1.3 5.1.11
	Catalogue number	ISO 15223-1, 5.1.6
	Batch code	ISO 15223-1, 5.1.5
	Serial number	ISO 15223-1, 5.1.7
	Patient information website	ISO 15223-1, 5.7.4