KHEIRON® Spinal Fixation System including patient specific K-ROD
Non-sterile IMPLANTS
Instructions For Use

This document is only valid on the date printed. If unsure of the print date, please re-print to ensure use of the latest revision of the IFU available on the website www.smaio.com/ifu.

Instruction for use only for the United States of America (USA).

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed health practitioner

Note:

- **This IFU should only be used when K-ROD rods are used with Orthofix Mariner® and Virata™ Systems. If the K-ROD rods are used with KHEIRON Spinal Fixation System, please refer to the KHEIRON Implants IFU on the SMAIO website. If the K-ROD rods are used with NuVasive Reline System, Highridge Medical Vital Spinal Fixation System, DePuy Synthes Expedium and TriALTIS Spine Systems or Silony Medical VERTICALE® System, please refer to the dedicated IFU on the SMAIO website.**
- **This IFU is dedicated to K-ROD rods, please refer to Orthofix Mariner® and Virata™ IFUs* for instructions specific to Orthofix Mariner® and Virata™ devices.**
- **K-ROD implants are compatible with screws from Ø4.5mm and length 25mm.**
- **Orthofix Mariner® and Virata™ systems are compatible with Ti-6Al-4V ELI or Co-28Cr-6Mo K-ROD implants.**

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.

Patient specific K-ROD devices are compatible with:

- NuVasive Reline System components that are only compatible with Ø5.5mm and/or Ø6.0mm rods as well as screws Ø4.5mm or larger and at least 25mm in length
- Orthofix Mariner® System components that are compatible with Ø5.5mm and/or Ø6.0mm rods as well as screws Ø4.5mm or larger and at least 25mm in length
- Orthofix Virata™ System components that are compatible with Ø5.5mm and/or Ø6.0mm rods as well as screws Ø4.0mm or larger and at least 20mm in length
- Highridge Medical Vital Spinal Fixation System components that are compatible with Ø5.5mm and/or Ø6.0mm rods as well as screws Ø4.0mm or larger and at least 20mm in length
- DePuy Synthes Expedium Spine system components that are compatible with Ø5.5mm and/or Ø6.0mm rods as well as screws Ø4.35mm or larger
- DePuy Synthes TriALTIS Spine system components that are compatible with Ø5.5mm and/or Ø6.0mm rods as well as fenestrated screws Ø4.50mm or larger
- Silony Medical VERTICALE® System components that are compatible with Ø5.5mm rods as well as screws Ø4.5mm or larger and at least 25mm in length

2. INDICATIONS FOR USE

KHEIRON® Spinal Fixation System including patient specific K-ROD is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal stenosis, spinal tumor, pseudarthrosis and failed previous fusion.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, KHEIRON® Spinal Fixation System including patient specific K-ROD is indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, KHEIRON® Spinal Fixation System including patient specific K-ROD is intended to treat pediatric patients diagnosed with spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion.

This system is intended to be used with autograft and/or allograft.

Pediatric pedicle screw fixation is limited to a posterior approach.

When connected to compatible pedicle screw systems, the patient specific K-ROD is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal stenosis, spinal tumor, pseudarthrosis and failed previous fusion.

Please refer to the additional information section of the most up-to-date Instructions for Use on compatible pedicle screw systems.

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 and/or Co-28Cr-6Mo
- 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

K-RODs are to be used in conjunction with the Orthofix Mariner® System and Virata™ System to reach intended use. The Orthofix Mariner® and Virata™ Systems are pedicle screw systems that consists of a variety of screws, hooks, rods, lock screws, transverse connectors, rod-to-rod connectors, iliac connectors and associated general instruments. Implant components are available in a variety of sizes and can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient.

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

Material: K-RODs are bent rods made of titanium alloys (Ti-6Al-4V ELI per ISO 5832-3 and ASTM F136) or cobalt-chromium alloys (Co-28Cr-6Mo per ISO 5832-12 and ASTM F1537), available in diameters 5.5mm and 6mm, which shape is a 3D spline designed to meet the need of specific correction of a patient.

Packaging: the K-ROD patient-specific rods are delivered in PE pouches. Packaging must be intact upon receipt. Damaged packages or products must not be used and must be returned to SMAIO.

5. EQUIPMENT REQUIRED FOR IMPLANT PLACEMENT

K-ROD placement technique being identical to Mariner® and Virata™ rod's, instruments provided in the Orthofix Mariner® and Virata™ Systems sets are compatible with K-ROD implants.
Furthermore, Orthofix Mariner® and Virata™ Systems surgical technique can be followed for the placement of the K-ROD implants.

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 sterilized according to the instructions given in §8.
- A K-ROD 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 between the shape of the implanted rods and the patient's anatomy is the responsibility of the surgeon.
- 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 nor 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.
- Never use stainless steel and cobalt chromium implant components in the same construct.
- The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity, requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- 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 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 implants do not present any known risk of interference with other medical equipment.
- Based on the fatigue testing results, the physician/ surgeon should consider the levels of implantation, patient weight patient, activity level, other patient conditions, etc. which may impact on the performance of the system.
- **MRI Safety information**

  K-ROD used with the Orthofix Mariner® and Virata™ Systems has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of K-ROD used with the Orthofix Mariner® and Virata™ System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

8. CLEANING/STERILIZATION

- Unless they come directly from their original SMAIO packaging, implants must be cleaned following the parameters mentioned in the tables below.
- Before use, this product 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 washer disinfector which complies with standard EN ISO 15883-1, used with 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 sterilized in the corresponding box. Any other configuration used would jeopardize the manufacturer's validation.
- The instructions provided below have been validated by SMAIO as being capable of preparing a medical device for reuse. The processor remains responsible for ensuring that the processing, as actually performed using 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**: KHEIRON Spinal Fixation System including K-ROD rods	
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 step.

INSTRUCTIONS	
Initial treatment at point use	Place the implants on a tray or in a suitable basket for the cleaning step.
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 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 rough or hard-to-reach area, cavity, etc.
Cleaning: Automated	Place the implants in a suitable basket for the cleaning step. **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)
Neutralization	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 FDA cleared Pasteur wrap. The K-ROD patient-specific rods can be placed in a wire basket and packed in a double FDA cleared Pasteur wrap.
Sterilization	The sterilization cycle is the following:

Method: steam	Yes
Pre-vacuum	Yes
Temperature	132°C (-0/+3°C) 269.6 °F (-0/+5.4°F)
Time	4 min
Drying time	60 min

Storage	Not applicable
Additional information	Look for any signs of visual contamination of the implant 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	See §14

9. INSTRUCTIONS FOR USE

K-RODs should be placed according to Orthofix Mariner® and Virata™ Systems 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 or its certified distributor.

a) Before the operation

- Read the surgical technique carefully*.
- Always plan to have an additional Orthofix Mariner® or Virata™ Systems compatible rod for each of the rod required to be able to replace it in the event of accidental contamination during the procedure.

b) During the operation

- The procedure should be performed by a surgeon who has received the necessary spinal surgery training.
- 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 straightenings is prohibited.

c) After the operation

- Radiological examinations must be performed regurlaly to check on postoperative progress and thus prevent possible complications.
- The patient specific K-ROD 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 orthopedic implants, K-ROD 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:

- Displacement of the implant before bone fusion requiring another surgical procedure.
- Device malposition potentially requiring revision surgery.
- Hematoma.
- 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.
- System fragility during growth in a young patient.
- Risk of allergy to Ti-6Al-4V ELI and/or Co-28Cr-6Mo 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** is sent with products returned to SMAIO.
For disposal of a product following 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

For patient specific K-ROD rod only, in the event the implant is not used for any reason, contact the SMAIO customer service department, and return the device accompanied by the liaison form**.

13. VIGILANCE

Any adverse events linked to the use of the device must be reported to SMAIO at usvigilance@smaio.com and to the FDA.

14. MANUFACTURER CONTACT

S.M.A.I.O
2, Place Berthe Morisot – Parc Technologique
69800 SAINT-PRIEST
France

Customer service contact: contact@smaio.com
Web site: www.smaio.com

* Documentation available upon request on the Orthofix website.
**Documentation available upon request at contact@smaio.com.

15. GLOSSARY OF SYMBOLS USED IN ALL KHEIRON LABELING

Symbol	Meaning 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	CE Marking of conformity
	Federal Law (USA) restricts this device to sale by or on the order of a physician	21 CFR 801.109