KHEIRON Spinal Fixation System
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

1. INTENDED USE

The KHEIRON Fixation System is a 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 FOR USE

The KHEIRON Spinal Fixation System 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, the KHEIRON Spinal Fixation System implants are 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, the KHEIRON Spinal Fixation System 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.

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

KHEIRON Spinal Fixation System includes screws 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 and curved rods of Ø 5.5mm and Ø 6mm.

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

Packaging: for replenishment, the implants are delivered in single 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

The kit containing the KHEIRON instruments required for implant placement is referenced in the SMAIO surgical technique*.

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.

The implants can be used until the date mentioned on the label only if the packaging is undamaged, and if the storage conditions are observed.


Keep dry


Keep away from sunlight

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.
- 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.
- 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.

- 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**

  The KHEIRON Spinal Fixation System has not been evaluated for safety and compatibility in the MR environment. It has bot been tested for heating, migration, or image artifact in the MR environment. The safety of KHEIRON Spinal Fixation 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 appropriate containers 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 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.
- Clean the device until there is no visual contamination of the implants directly after application (within a maximum of 2 h of use).

Manufacturer: S.M.A.I.O **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 step.
Limitations on processing	Non applicable

INSTRUCTIONS	
Initial treatment at point use	Place the implants on a tray or in a suitable basket for the cleaning step.
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 rough or hard-to-reach area, cavity, etc.
Cleaning : Automated	Place the implants in an opened position in a suitable basket for the cleaning step. **Parameters validated 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 oil 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.
Sterilization	Assembled devices must NOT be re-assembled before the sterilization cycle. The sterilization cycles are the following, depending on the geographic area:

	European Union	United-Kingdom	United States
Method: steam	Yes	Yes	Yes
Pre-vacuum	Yes	Yes	Yes
Temperature	134 °C 273.2 °F	134 °C 273.2 °F	132°C 269.6 °F
Time	18 min	3 min	4 min
Drying time	45 min	45 min	45 min

	Wrap tray with a towel placed between tray and FDA cleared wrap.
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).
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, 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*.
- 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.
- Before a first implantation, the surgeon and their 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 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.
- of blocking screws must be performed with the adequate dynamometric module provided to ensure rigidity of the assembly.
- 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 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 orthopedic implants, KHEIRON pedicular 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
- Hematoma
- Infection at implantation site
- Pseudarthrosis
- Neurological damage (breach of the dura mater, lesion of a spinal root)
- Vertebral fracture
- 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 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 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, contact the SMAIO customer service department and return the defective implant, cleaned, decontaminated and together with the liaison form available on SMAIO website.

13. VIGILANCE

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

14. MANUFACTURER CONTACT

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2, Place Berthe Morisot – Parc Technologique
69800 SAINT-PRIEST
France
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Website: www.smaio.com

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

15. GLOSSARY OF SYMBOLS USED IN ALL KHEIRON LABELING

Symbol	Meaning of symbol	Reference
	Medical Device	MedTech Guidance Annex 1
	Do not re-use	ISO 15223-1, 5.4.2
	Non-sterile	ISO 15223-1, 5.2.7
	Caution	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	ISO 15223-1, 5.4.3 (UE) 207/2012
	Manufacturer	ISO 15223-1, 5.1.1
	CE Marking of conformity	MDD 93/42/CE Annex XII
	Date of manufacture	ISO 15223-1, 5.1.43
	Catalogue number	ISO 15223-1, 5.1.46
	Batch code	ISO 15223-1, 5.1.54
	Federal Law (USA) restricts this device to sale by or on the order of a physician	21 CFR 801.109