KHEIRON – Spinal Fixation System Instruments

Instructions For Use

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1. STATEMENT OF INTENDED USE

These instruments, herein referred to as “devices”, are parts of a kit dedicated to placement of specific products in the KHEIRON range of implants and K-ROD rods.
These devices are re-usable, re-sterilisable and must be handled by healthcare professionals trained in its conditions for use. It must be handled with care at all stages of use, storage and maintenance.

2. INDICATIONS

1hese devices belong to the KHEIRON product range defined by a nomenclature described in the surgical technique* provided with the implants and/or instruments of the product range.
These devices allow the implantation of KHEIRON Spinal Fixation System implants and K-ROD rods. They can be used only with the KHEIRON range of implants and K-ROD rods.

3. CONTRAINDICATIONS

- Do not use a device if it is no longer functional
- Do not use a device outside of its intended scope of application
- Allergies, intolerances and/or hypersensitivity to the component materials of the instrument (see the KHEIRON surgical technique).

4. STORAGE CONDITIONS

Store the devices in a clean place, at room temperature in their original packaging or in the box provided for this purpose by SMAIO.

5. PRECAUTIONS AND WARNINGS

- Instruments are delivered NON-STERILE and are intended to be cleaned and sterilised according to the instructions given in §6.
- Knowledge of and experience in spinal surgery are prerequisites.
- These implants do not present any known risk of interference with other medical equipment.

6. CLEANING / STERILISATION

- Whether they come directly from their original packaging or from the tray of use, each device must be cleaned and decontaminated in conformity with legislation in force prior to sterilisation.
- Before use, these products must be sterilised by steam autoclaving in accordance with standard ISO 17665-1.
- SMAIO recommends cleaning the non-sterile devices by combined manual and automatic cleaning, using a heat disinfector which conforms to standard EN ISO 15883-1, used with an alkaline cleaning product (pH ≤ 10,8) following 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 validation by the manufacturer.
- The instructions provided below have been validated by SMAIO as allowing preparation of a medical device for reuse. The operator remains responsible for ensuring that the treatment, as actually performed using equipment, materials and personnel at the treatment facility, achieves the desired result. This requires verification and/or validation and routine process monitoring.

Manufacturer: S.M.A.I.O **Method**: Steam autoclaving **Devices**: KHEIRON instruments	
WARNINGS	• Devices made of stainless steel, silicone, and POM (Polyacetal) must NOT BE treated with chlorinated products but can safely be immersed in NaOH (NaOH – 1 mol/L) for 1h. • Devices made of radel or propylux can safely be immersed in NaOH or sodium hypochlorite. • In all cases, do not use a wire brush or abrasive, and handle these devices with gloves throughout the various processes and uses, during which they should be placed on trays suitable for the various cleaning and decontamination steps.
Treatment limitations	Not applicable

CLEANING/DECONTAMINATION AND STERILISATION INSTRUCTIONS	
Initial treatment at point of use	Place the implants on a tray or in a suitable basket for the cleaning and decontamination steps.
Preparation before cleaning	When possible, disassemble the devices (see disassembly instructions). When possible, open the devices. 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. Rinse abundantly 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 HAMO ECOLINE LM-25 washercleaning/disinfector 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 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.
Sterilisation / re-sterilisation	Assembled devices must NOT be re-assembled before the sterilisation cycle. The sterilisation cycles are as follows, depending on the geographical area:

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

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 §11). After a cleaning and sterilization cycle, check that the laser marked information are still legible, for each device.
Manufacturer contact	See §11

7. 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, do not hesitate to contact the SMAIO customer service department.

a) Before the operation

- Carefully read the instructions for use of the KHEIRON implants and K-ROD rods to be used in association with the KHEIRON instruments, along with the surgical technique*.
- Carefully read the documents provided with the instrumentation kit.
- Prepare all KHEIRON implants and instruments required for the procedure and ensure that nothing is missing.
- Only SMAIO implant placement instruments, designed and provided by SMAIO, should be used with the KHEIRON implants and K-ROD rods.
- Check their cleanliness, integrity and functionality.
- Before initial 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 surgical technique*.
- Do not use this device for purposes other than those for which it is intended.
- The implantation must be performed solely with the instruments provided for this purpose and according to the indications of the surgical technique*.

c) After the operation

- All materials must be cleaned and decontaminated immediately before transport (see §6)
- Discard any products which have not functioned properly and ask for a replacement.
- Disasemble this product if necessary according to the assembly/disassembly instructions*, scrupulously clean and decontaminate it, then sterilise it before returning it or putting it back into service (see §6).

8. PRODUCT DISPOSAL

To discard a product following an error in product storage or use, the implants must follow the hospital waste collection channel in compliance with procedures in force within the institution.

9. 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*.

10. VIGILANCE

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

11. MANUFACTURER CONTACT

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2, Place Berthe Morisot – Parc Technologique
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Site Internet : www.smaio.com

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

12. MEANING OF SYMBOLS USED

Symbol	Title of symbol	Reference
	Medical Device	ISO 15223-1, 5.7.7
	Non-sterile	ISO 15223-1, 5.2.7
	Caution (see instructions 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	ISO 15223-1, 5.4.3
	Manufacturer	ISO 15223-1, 5.1.1
	CE marking of conformity	MDD 93/42/CE Annex XII
	Date of manufacture Country of manufacture	ISO 15223-1, 5.1.3 ISO 15223-1, 5.1.11
	Catalogue number	ISO 15223-1, 5.1.6
	Batch number	ISO 15223-1, 5.1.5
	Serial number	ISO 15223-1, 5.1.7