KHEIRON Spinal Fixation System
INSTRUMENTS
Instructions For Use

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

1. INTENDED USE

This instrument, herein referred to as "device", is part of a kit dedicated to placement of a specific product in the KHEIRON range of implants.
This device is re-usable, re-sterilizable 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

This device belongs 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 can be used only with the KHEIRON range of implants.

3. CONTRAINDICATIONS

- Do not use this device if it is no longer functional.
- Do not use this device outside of its planned 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.

 Keep dry  Keep away from sunlight

5. PRECAUTIONS AND WARNINGS

- Delivered instruments are NON-STERILE and are intended to be cleaned and sterilized according to the instructions given in §6.

  Knowledge and experience in spinal surgery are prerequisites.
- These implants do not present any known risk of interference with other medical equipment.

6. CLEANING / STERILIZATION

- 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 sterilization.
- Before use, these products must be sterilized by steam autoclaving in appropriate containers in accordance 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 (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 process monitoring.
- Clean the device until there is no visual contamination of the instruments directly after application (within a maximum of 2 h of use).

Manufacturer: SMAIO **Method**: Steam autoclaving **Devices**: KHEIRON Spinal Fixation System	
WARNINGS	• Devices made of stainless steel, silicone, and POM (Polyacetal) must NOT BE processed 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.
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 and decontamination steps.
Preparation before cleaning	Disassemble the devices when possible (see 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] [68 °F; 77 °F] ; 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] [68 °F; 77 °F] 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" 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 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 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.

<table>
<tr><td>Sterilization</td><td>Assembled devices must NOT be re-assembled before the sterilization cycle.
The sterilization cycles are the following, depending on the geographic area:
<table><tr><th></th><th>European Union</th><th>United Kingdom</th><th>United States</th></tr><tr><td>Method: steam</td><td>Yes</td><td>Yes</td><td>Yes</td></tr><tr><td>Pre-vacuum</td><td>Yes</td><td>Yes</td><td>Yes</td></tr><tr><td>Temperature</td><td>134 °C
273.2 °F</td><td>134 °C
273.2 °F</td><td>132 °C
269.6 °F</td></tr><tr><td>Time</td><td>18 min</td><td>3 min</td><td>4 min</td></tr><tr><td>Drying time</td><td>45 min</td><td>45 min</td><td>45 min</td></tr></table>Wrap tray with a towel placed between tray and FDA cleared wrap.</td></tr>
<tr><td>Storage</td><td>Not applicable</td></tr>
<tr><td>Additional information</td><td>Look for any signs of premature implant wear after sterilization. If such is the case, DO NOT use them and inform SMAIO (see §11).</td></tr>
<tr><td>Manufacturer contact</td><td>See §11</td></tr>
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7. 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 qualified distributor.

a) Before the operation

- Carefully read the instructions for use of the KHEIRON implants 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 implants and instruments required for the procedure and ensure that nothing is missing.
- Check their cleanliness, integrity and functionality.
- Only SMAIO implant placement instruments, designed and provided by SMAIO, should be used with the implants.
- 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*.
- Do not use this device for purposes other than those for which it is intended (see 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*.

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 sterilize 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 pathway for removal of hospital waste products 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 available on SMAIO website.

10. VIGILANCE

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

11. 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 on request on the www.smaio.com website.

12. GLOSSARY OF SYMBOLS USED IN ALL KHEIRON LABELING

Symbol	Title of symbol	Reference
	Medical Device	MedTech Guidance Annex 1
	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
	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, 5.1.3
	Catalogue number	ISO 15223-1, 5.1.6
	Batch code	ISO 15223-1, 5.1.5
	Serial number	ISO 15223-1, 5.1.7