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1. STATEMENT OF INTENDED USE

The K-BALL is a reusable radiopaque sphere used during a radiographic procedure to be displayed on radiographies and to calibrate a 2D X-ray.

2. INDICATIONS FOR USE

The K-BALL is a device intended for medical purposes to calibrate an X-ray.

Shape and size of the device make it specifically adapted to spine X-rays.

3. CONTRAINDICATIONS

In case of allergies, intolerances and/or hypersensitivity to the component materials of the instrument, do not use the device in direct contact with the skin.

4. DESCRIPTION OF THE EQUIPMENT PROVIDED

The K-BALL is a truncated 35mm diameter calibration sphere made of stainless steel used to add a radiographic marker onto images after exposure to X-rays.

5. STORAGE CONDITIONS



Store the devices in a clean place, at room temperature, in their original packaging.

6. PRECAUTIONS AND WARNINGS

- Do not use a device outside of its intended scope of application.
- Inspect the general condition of the device before use, do not use if the device or the package is damaged.
- The K-BALL shall be used on an intact skin or over clothing and is intended for temporary external contact only during radiographic procedures. The device shall be removed immediately after completion of the examination.
- The K-BALL is for use during a radiographic (X-ray) Imaging examination only. Under no circumstances shall the device be used during medical Imaging examination requiring exposure to electromagnetic fields.

7. INSTRUCTIONS FOR USE

The K-BALL is intended for use by trained healthcare professionals (e.g., X-ray operators) and hospital logistics agents and is intended for patients who are able to stand and require spinal X-ray imaging. Instructions for placement and for measurements of the device are detailed in the user guide*.

Disinfection: The K-BALL is cleaned prior shipping to the healthcare center. The K-BALL is a multiple patient multiple use device. The device must be disinfected with a solution of Isopropyl Alcohol 70%

In case of doubt concerning use or discarding of the device, contact the SMAIO customer service department.

8. ADVERSE EFFECTS

Other than skin reaction or allergy to the device material, no foreseeable adverse effects posed by the use of the device is known.

9. PRODUCT DISPOSAL

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

10. GUARANTEE

In the event of a defect, contact SMAIO at usvigilance@smaio.com and return the defective device.

11. VIGILANCE

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













12. MANUFACTURER CONTACT



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* Documentation available upon request at contact@smaio.com

13. MEANING OF SYMBOLS USED

Symbol	Title of symbol	Reference
	Manufacturer	ISO 15223-1, 5.1.1
	Date of manufacture	ISO 15223-1, 5.1.3
	Batch number	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
 <small>www.smaio.com/ifu</small>	Consult instructions for use	ISO 15223-1, 5.4.3
	Caution (see instructions for use)	ISO 15223-1, 5.4.4
	Medical Device	ISO 15223-1, 5.7.7