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1. STATEMENT OF INTENDED USE

The K-BALL is a re-usable 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 a radiographic film by means of exposure to visible light. Shape and size of the device make it specifically adapted to spine X-rays.

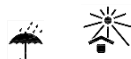
3. CONTRAINDICATIONS

In case of allergies, intolerances and/or hypersensitivity to the component materials of the instrument (see the K-BALL user guide*), 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.

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.
- The radio resolution must be between 96 ppi and 254ppi.
- Inspect the general condition of the device before use, do not use if the device is damaged.
- The K-BALL shall be used on an intact skin or over clothing.

7. INSTRUCTIONS FOR USE

Instructions for placement of the device are detailed in the user guide*.

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

8. 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.

9. GUARANTEE

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

10. VIGILANCE

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













11. MANUFACTURER CONTACT



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

12. MEANING OF SYMBOLS USED

Symbol	Title of symbol	Reference
	Manufacturer	ISO 15223-1, 5.1.1
	Date of manufacture Country of manufacture	ISO 15223-1, 5.1.3 ISO 15223-1, 5.1.11
	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