# K-BALL

## Calibration ball

## Instructions For Use

www.smaio.com/ifu

**This document is valid only 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.**

### 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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2, Place Berthe Morisot – Parc Technologique
69800 SAINT-PRIEST – France
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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 |
|---|---|---|
| | Manufacturer | ISO 15223-1, 5.1.1 |
| CC | Date of manufacture Country of manufacture | ISO 15223-1, 5.1.3 ISO 15223-1, 5.1.11 |
| LOT | Batch number | ISO 15223-1, 5.1.5 |
| REF | Catalogue number | ISO 15223-1, 5.1.6 |
| SN | Serial number | ISO 15223-1, 5.1.7 |
| NON STERILE | Non-sterile | ISO 15223-1, 5.2.7 |
| | Do not use if package isdamaged | ISO 15223-1, 5.2.8 |
| | Keep away from sunlight | ISO 15223-1, 5.3.2 |
| | Keep dry | ISO 15223-1, 5.3.4 |
| www.smaio.com/ifu | Consult instructions for use | ISO 15223-1, 5.4.3 |
| | Caution (see instructions for use) | ISO 15223-1, 5.4.4 |
| MD | Medical Device | ISO 15223-1, 5.7.7 |



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