# Patient fiducial - Marker kit
# IFU
# Instructions for use

CE

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# 1  INTRODUCTION

Before proceeding with the installation and use, carefully read this IFU. Always keep this manual within reach. The information and illustrations contained in this IFU are updated to the date of publication indicated in the page footer.

**IMPORTANT**: to prevent harm to person or damages to things carefully read this manual. Safety prescriptions are classified, based on their severity level, according to the subsequent indications:

⚠️ **Warning**: referred to precaution that, if ignored, can cause death or serious injury.

⚠️ **Caution**: referred to precaution that, if ignored, may cause minor or moderate injury.

## 1.1  Patient fiducial – Marker kit description

Patient fiducial – Marker kit is intended to be positioned on the patient intact skin before performing the pre-treatment CT scan and it shall be removed from the patient after the intervention. Patient fiducial – Marker kit is used in combination with *endosight* to plot the spatial position of patient's anatomical structures, reconstructed from radiological images, during image guided procedures, allowing their superposition onto the real-time image of the patient acquired by *endosight*

Patient fiducial – Marker kit includes 20 square patient's markers, working as fiducial markers for patient's anatomical structures tracking, and one QR code sticker, used to uniquely identify the patient. The QR code can be simply distinguished from the other markers since it is larger than the patient's markers. The QR code allows to associate each patient to a unique code, the *endosight* kit code, which corresponds to the Patient fiducial – Marker kit's serial number provided on the label of the box. *endosight* software requires the user to insert the Patient fiducial – Marker kit code during case creation phase and it matches the inserted kit code with the QR code found during marker coregistration phase (see *endosight* user manual for further details) in order to match the patient's 3D reconstructions from radiological images with the AR/VR visualization.

Patient fiducial – Marker kit is provided single use.

## 1.2  Safety precautions

⚠️ **Warning**: only use original R.A.W s.r.l. accessories.

⚠️ **Warning**: Patient fiducial – Marker kit is intended for single use only. Failure to observe this precaution may result in serious harm or death to the patient.

⚠️ **Caution**: do not use any substances or disinfectant on Patient fiducial – Marker kit. Failure to observe this precaution may cause the impossibility to detect Patient fiducial – Marker kit by *endosight*, hence the impossibility to correctly represent the patient's anatomical structures during navigation.

# 2  SYMBOLS

| Symbol | Description | Symbol | Description |
|---|---|---|---|
| ▲▲▲ | Manufacturer | CE | CE mark |
| (factory) | Date of manufacture | (hourglass) | Expiration date |
| SN | Serial number | UDI | Unique Device Identification |
| (book i) | e-IFU indicator | ⚠️ | Caution, consult instructions for use |

| | | | |
|---|---|---|---|
| ⚠ NON STERILE | Not sterile | ② | Do not re-use |
| % | Humidity limitation | 🌡 | Temperature limit |
| ⇨•⇦ | Atmospheric pressure limitation | ⚠ | Warning |
| REF | Catalogue number | ⊠ | Do not use if package is damaged |
| MD | Medical device | | |

## 3    LABELLING

Patient fiducial – Marker kit is provided with the following label.



## 4    PATIENT FIDUCIAL – MARKER KIT USE

Patient fiducial – Marker kit shall be positioned on the patient's abdomen skin before performing the pre-treatment CT (computed tomography) scan according to the following instructions.

- Identify and mark the area that presumably will include the needle entry point in order to not position Patient fiducial – Marker kit on it.

⚠ **Caution**: always overestimate the area on which Patient fiducial – Marker kit is not positioned in order to subsequently decide the exact entry point.

⚠ **Caution**: check that the patient's skin is dry before placing Patient fiducial – Marker kit. Always place Patient fiducial – Marker kit on patient's dry skin.

- Place the 20 markers of Patient fiducial – Marker kit on the patient's abdomen skin around the previously identified area with a distance of around 3 cm from each other, as shown in the figure below.
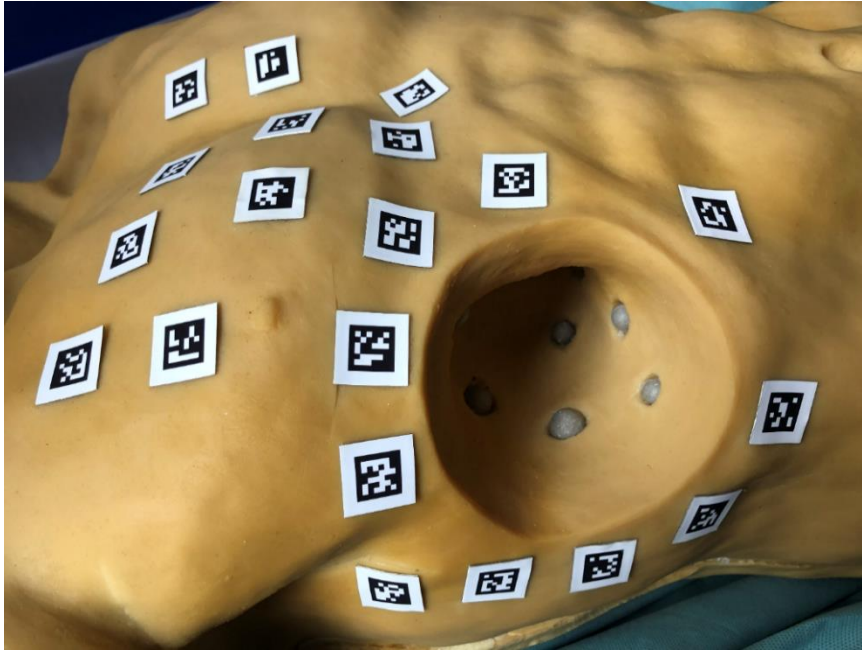
Figure 1: example of Patient fiducial – Marker kit positioning on a phantom model. The hole represents the area that presumably will include the needle entry point

QR code: also the QR code shall be positioned on the patient's abdomen skin before performing the pre-treatment CT (computed tomography) scan according to the following instructions.

- Attach the QR code sticker on the patient's abdomen skin even far from the other already attached markers.

**Note:** the QR code sticker may not be close to the treatment area.

- Keep the Patient fiducial – Marker kit package label, provided on the packaging. This label includes the kit code string to be inserted in *endosight* software during case creation.
- *endosight* kit code to be inserted in *endosight* software is the serial number provided on the box.

⚠ **Caution**: do not throw away Patient fiducial – Marker kit box with the label since it includes the *endosight* kit code required by *endosight* software and needed to correctly match patient's CT images with AR/VR visualization.

## 5    DISPOSAL MODES

⚠ **Warning**: Treat Patient fiducial – Marker kit as hospital waste at the end of each treatment.

Single-use components and materials that entail a biological risk shall be disposed according to the local regulations in force concerning hospital wastes.