



**Patient fiducial -
Marker IR
IFU
Instructions for use**



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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 IR description


Patient fiducial – Marker IR 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. Item 1 of Patient fiducial – Marker IR is mandatory and 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*. Item 2 of Patient fiducial – Marker IR is optional since it is used for respiratory gating tool and it helps to determine how close you are to the respiratory phase of the CT scan.

Patient fiducial – Marker IR is a 3D printed structure. Five reflective spheres are mounted before the beginning of the procedure on item 1 of Patient fiducial – Marker IR, working as fiducial marker for patient's anatomical structures tracking, and one reflective sphere is mounted on item 2 of Patient fiducial – Marker IR, which is mandatory since it is used for respiratory gating tool.

Patient fiducial – Marker IR is re-usable.

1.2 Safety precautions

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

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

2 SYMBOLS



Manufacturer



CE mark



Date of manufacture



Unique Device Identification



e-IFU indicator



Caution, consult instructions for use



Not sterile



Warning



Humidity limitation



Temperature limit



Atmospheric pressure limitation



Do not use if package is damaged



Catalogue number



Lot number




Medical device











3 LABELLING

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

rev. 4.0



Patient fiducial - Marker IR

REF MIR000	UDI DataMatrix (01)08052141890097 (17)yyymmdd (10)yyymmdd_jjMIR
LOT yyymmdd_jjMIR	
 yyyy-mm-dd	
 yyyy-mm-dd	
 0°C 40°C	 500hPa 1060hPa
	 10% 85%
	  
	MD 
 R.A.W. S.r.l. Viale Premuda 46 20129 Milano - ITA info@endo-sight.it www.rawbiomed.com/it	CE

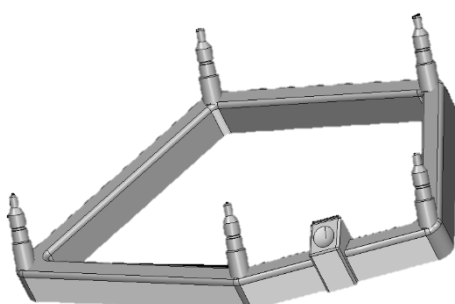
4 PATIENT FIDUCIAL – MARKER IR USE

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

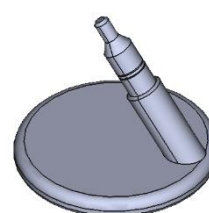
- Identify the area that presumably will include the needle entry point.

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

- Place Patient fiducial – Marker IR (the positioning of item 1 is mandatory, while item 2 is optional, since it is used for respiratory gating tool) on the patient's abdomen skin at a distance between 5 cm and 15 cm from the needle entry point, preferably on a flat item of the patient body.

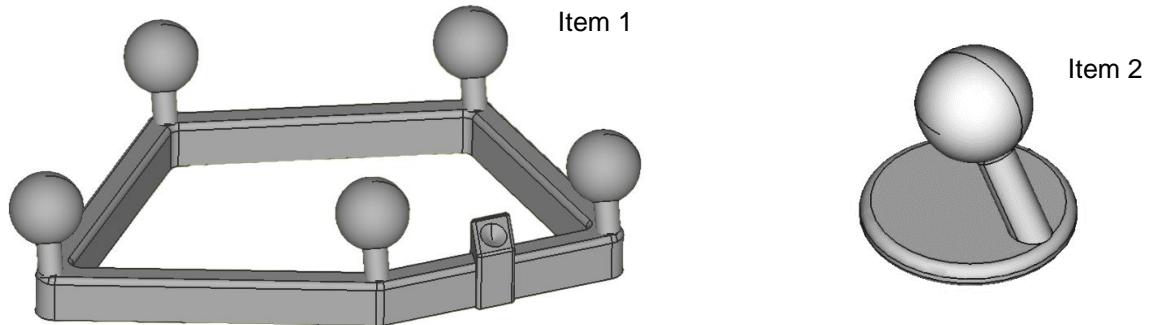


Item 1

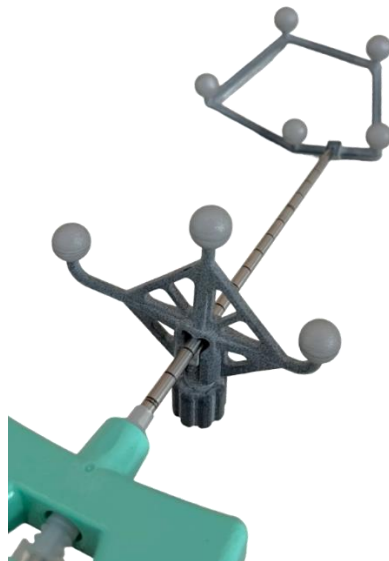


Item 2

- Secure Patient fiducial – Marker IR on the patient’s body by using medical tape so that Patient fiducial – Marker IR is firmly fixed on the patient’s body.
- Fit the five reflective spheres on item 1 of Patient fiducial – Marker IR and one reflective sphere on item 2 of Patient fiducial – Marker IR, as indicated below.



- Use disinfectant on the needle calibration cavity of item 1 of Patient fiducial – Marker IR.
- ⚠ Caution:** do not use any disinfectant on the reflective spheres of Patient fiducial – Marker IR. Failure to observe this precaution may cause the impossibility to detect Patient fiducial – Marker IR by *endosight*, hence the impossibility to correctly represent the patient’s anatomical structures during navigation.
- The operator can proceed with the calibration of the needle, placing the tip of the needle in the cavity of Patient fiducial – Marker IR.



5 DISPOSAL MODES

⚠ Warning: Treat Patient fiducial – Marker IR as hospital waste at the end of its lifetime.

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

The English version of this instruction for use is the original document from which all the translations have been obtained. In case of any inconsistencies, the English version matter.

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