



Needle fiducial - Sensor U

IFU

Instructions for use

CE
0051



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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 Needle fiducial – Sensor U description

Needle fiducial – Sensor U is used in combination with *endosight* to plot the spatial position of straight rigid instruments (needles and probes) during image guided procedures.

Needle fiducial – Sensor U consists of a cube together with a clip that allows to fit the sensor itself on third party instruments. Needle fiducial – Sensor U, through the markers printed on its cube, enables to track the position of the instrument on which it is fixed.

Needle fiducials are provided EtO sterile and single-use.

1.2 Safety precautions

 **Warning:** the use of Needle fiducial – Sensor U connected with devices other than those indicated by the manufacturer, R.A.W. S.r.l., may result in a wrong visualization provided by the guidance hence in a wrong patient treatment.

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

 **Warning:** Needle fiducials – Sensor U are provided EtO sterile and individually packed. Carefully check the packaging before opening it. If the packaging is damaged, do not use the contained Needle fiducials – Sensor U under any circumstance. Failure to observe this precaution may result in serious harm or death of the patient.

 **Warning:** Needle fiducials – Sensor U are intended for single use only. Failure to observe this precaution may result in serious harm or death of the patient.

 **Warning:** carefully check each Needle fiducial – Sensor U before using it. In case of abnormalities, dispose Needle fiducial – Sensor U and replace it with a new one. Failure to observe this precaution may result in serious harm to the patient.

 **Warning:** do not use Needle fiducial – Sensor U after the expiration date reported on the Needle fiducials – Sensor U label. Failure to observe this precaution may result in serious harm or death the patient.

2 SYMBOLS

	Manufacturer		CE mark
	Date of manufacture		Expiration date
	Lot number		Unique Device Identification
	Do not re-use		e-IFU indicator
	Sterilized using ethylene oxide		Do not re-sterilize
	Single sterile barrier and external packaging		Do not use if package is damaged
	Atmospheric pressure limitation		Humidity limitation
	Temperature limit		Caution, Consult instructions for use
	Warning		Catalogue number
	Medical device		

3 LABELLING

Needle fiducials – Sensor U are provided with the following label on the packaging.

rev. 5.0

 Needle fiducial - Sensor U

 SU000	 (01)08052141890103
 yyymmdd_jjSU	 (17)yyymmdd
 yyyy-mm-dd	 (10)yyymmdd_jjSU
 yyyy-mm-dd	
 40°C	
 500hPa	
 1060hPa	
 10%	
 85%	
	
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eIFU available by scanning the QR code inside the box and on company website

4 NEEDLE FIDUCIAL – SENSOR U CONNECTION

⚠ Caution: always check the integrity of Needle fiducial – Sensor U before using it.

⚠ Caution: Based on *endosight* software configuration, it is important to pair correctly Needle fiducial – Sensor U and Patient fiducial - Marker kit.

Once the patient is ready to be treated, he/she lies on the operatory bed and *endosight* has already and successfully performed Patient fiducial - Marker kit coregistration step, Needle fiducial – Sensor U shall be connected with its specific instrument.

- Open Needle fiducial – Sensor U packaging: remove the protective cover on the needle, open Needle fiducial – Sensor U clip and slide the needle in it until a small portion of the needle tip is visible on the bottom of Needle fiducial – Sensor U. It is recommended to place Needle fiducial – Sensor U on the patient in order to identify the best entry trajectory and to use rigid needles (introducers) in order to avoid needle bending during the insertion.
- Check the correct attachment of Needle fiducial – Sensor U to the needle.

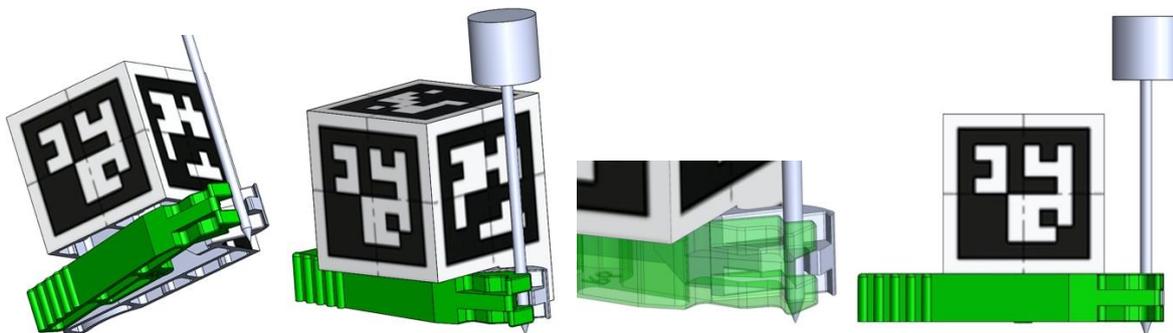


Figure 1: *endosight* Needle fiducial – Sensor U connection on an example needle

5 DISPOSAL MODES

⚠ Warning: Treat Needle fiducial – Sensor U 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.

6 DOCUMENTATION AVAILABILITY

The electronic version of the Instructions for Use for all *endosight* accessories is available by scanning the QR code inside the box or on the manufacturer's website.

A paper version of the Instructions for Use for *endosight* accessories can be provided by R.A.W. S.r.l. by sending a request via email to info@endo-sight.it. The paper version of the Instructions for Use will be sent within 7 calendar days of receiving the request.

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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