



Needle fiducial -

Sensor IR

IFU

Instructions for use



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SUMMARY

1 Introduction 3

 1.1 Needle fiducial – Sensor IR description..... 3

 1.2 Safety precautions 3

2 Symbols 4

3 Labelling..... 4

4 Needle fiducial – Sensor IR connection..... 5

5 Disposal modes..... 6

6 Documentation Availability 6

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 IR description

Needle fiducial – Sensor IR 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 IR consists of two clips (proximal one and distal one).

Needle fiducial – Sensor IR is provided EtO sterile and single-use.

1.2 Safety precautions

 **Warning:** the use of Needle fiducial – Sensor IR 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 fiducial – Sensor IR 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 fiducial – Sensor IR under any circumstance. Failure to observe this precaution may result in serious harm or death of the patient.

 **Warning:** Needle fiducial – Sensor IR 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 IR before using it. In case of abnormalities, dispose Needle fiducial – Sensor IR and replaced 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 IR after the expiration date reported on the Needle fiducial – Sensor IR 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 resterilize |
|  | 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 fiducial – Sensor IR are provided with the following label on the packaging.

rev. 5.0

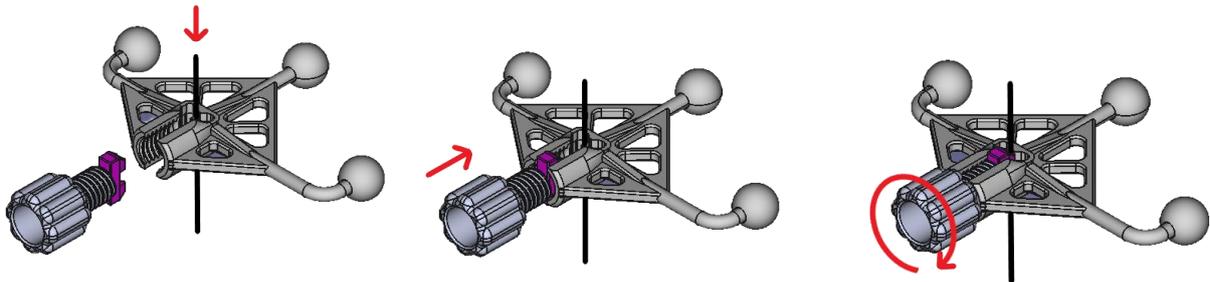
 Needle fiducial - Sensor IR

| | |
|--|---|
|  SIR000 |  (01)08052141890110 |
|  yyymmdd_jjSIR |  (17)yyymmdd |
|  yyyy-mm-dd |  (10)yyymmdd_jjSIR |
|  yyyy-mm-dd |  |
|  0°C - 40°C |  |
|  500hPa - 1080hPa |  |
|  10% - 85% |  |
|  R.A.W. S.r.l. Viale Premuda 46 20129 Milano - ITA info@endo-sight.it www.rawbiomed.com |  eIFU available by scanning the QR code inside the box and on company website |
| |  0051 |

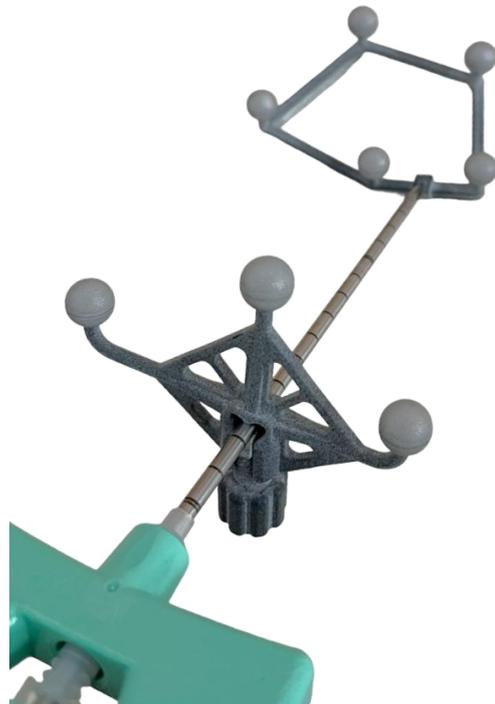
4 NEEDLE FIDUCIAL – SENSOR IR CONNECTION

⚠ Caution: always check the integrity of the sensor before using it.

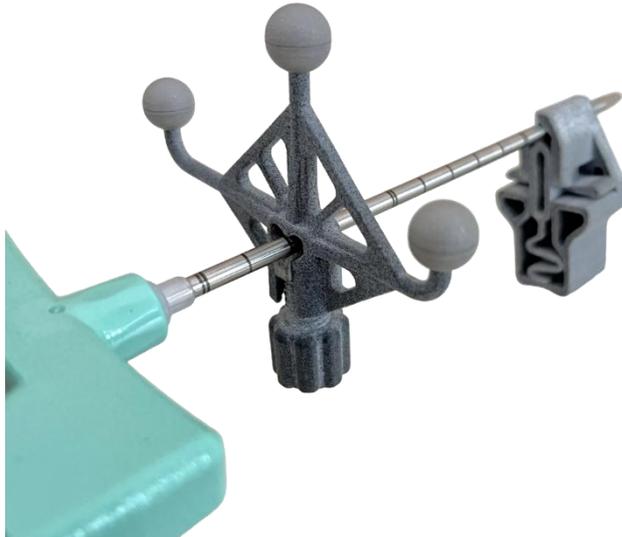
- **Caution:** Based on *Endosight* software configuration, it is important to pair correctly Needle fiducial – Sensor IR and Patient fiducial - Marker IR.
- Open Needle fiducial – Sensor IR packaging: remove the protective cover on the needle and open Needle fiducial – Sensor IR bags.
- Slide the entire needle shaft into proximal clip's housing and rotate the screw in order to close the proximal clip and fix the needle as shown below.



- The operator can proceed with the calibration of the needle, placing the tip of the needle in the cavity of Patient fiducial – Marker IR. Calibration of the needle is preceded by the fixation of Patient fiducial – Marker IR with medical tape on the body of the patient and by the use of disinfectant on the needle calibration cavity of Patient fiducial – Marker IR.



- Slide the needle in the Needle fiducial - Sensor IR distal clip until a small portion of the needle tip is visible on the bottom of the Needle fiducial - Sensor IR distal clip. It is recommended to place Needle fiducial - Sensor IR distal clip 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 IR to the needle.

5 DISPOSAL MODES

⚠ Warning: Treat Needle fiducial – Sensor IR 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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