Instructions for use
for Raypilot® Viewcath™ 1005

Introduction

Please read these instructions carefully before using the device. The instructions contain important information for correct handling of the Raypilot® Viewcath™.

Limitations

The Raypilot® Viewcath™ is a Prescription Device (Rx only) and may only be inserted and removed by educated healthcare professionals.
Raypilot® Viewcath™ is intended for use with the Raypilot® System.

Manufacturer and identification

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Classification and compliance

CE 0402 The product complies with directive 93/42/EEC

Intended use and intended purpose of Raypilot® System including Raypilot® Viewcath™

The Raypilot® System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The Raypilot® System provides accurate, precise, and continuous localization of a treatment isocenter by using Raypilot® Hypocath®, a transmitter located within one lumen of a urinary catheter, for prostate localization and tracking, and for automatic patient identification.

The device is limited for use to patients who both have prostate cancer and that would also be reasonably expected to require a urinary catheter for the duration of the radiation treatment, for example due to bladder outlet obstruction or patients who require a chronic indwelling Foley catheter.

Device description

The Raypilot® Viewcath™ is a sterile single-use product. It is a three-lumen Foley catheter made of silicone with a marker inserted in one of the lumens. The Raypilot® Viewcath™ has a drainage lumen, which also permits reproducibility of the bladder filling, and balloon inflation channel. It has an integrated balloon towards the tip of the catheter and a funnel with an inflation valve at the bottom of the catheter.

The Raypilot® Viewcath™ with its integrated marker is a part of the Raypilot® System. The Raypilot® Viewcath is used for simulating the same situation during treatment planning as with the Raypilot® Hypocath® during treatment.

Product Specification

Balloon fill volumes are 10-40 ml and the shaft size is 16 French (Fr.), Charrière (Ch.), which is indicated on the funnel of each catheter. The length of the Raypilot® Viewcath™ is approximately 42 cm. The Raypilot® Viewcath™ contains a radioopaque barium line that permits identification of the urethra when inserted in a patient.

Raypilot® Viewcath™ has been sterilized by Ethylene Oxide (EtO). The expiry date can be found on the sterile pouch and the outer box. Each Raypilot® Viewcath™ is individually supplied in a sterile pouch.

Clinical benefit and clinical performance

The Raypilot® System including Raypilot® Hypocath® and Raypilot® Viewcath™ includes following clinical performance;

- accurate, precise, and continuous real-time localization of a target (prostate localization) during radiotherapy, the system display that the target stays within predefined tolerances and alert if the target moves outside the tolerances to let health care professionals stop the radiation and reposition the patient.
- the possibility to perform urethra sparing plans and minimize the dose to the urethra due to the radio-opaque barium line in the catheters,
- the possibility to repeat the bladder filling for a repeatable patient setup before treatment by being designed from an ordinary urinary catheter

The clinical benefits of using Raypilot® System with Raypilot® Hypocath® utilizing target monitoring, urethra outlining, and bladder filling repeatability is that the intended target receives treatment as planned as well as enabling the choice to plan with tighter margins and higher dosage.

Use

Catheter insertion

1. Raypilot® Viewcath™ insertion should always be carried out in accordance with local and national best practice policies. Specific attention must be paid to hand hygiene, aseptic techniques for site preparation, equipment and supplies.
2. Check that the package of Raypilot® Viewcath™ is intact before opening. Remove the Raypilot® Viewcath™ from its sterile package.
3. Prior to insertion, test the balloon inflation and use sterile water or solution of sterile water with glycerine 9:1 for inflation.
4. Lubricate the Raypilot® Viewcath™ with a suitable water-soluble lubricant.
5. Pass the deflated Raypilot® Viewcath™ through the urethra and into the bladder.
6. Guide the Raypilot® Viewcath™ gently 5-8 cm beyond the point at which urine begins to flow. The rationale for inserting the Raypilot® Viewcath™ further into the bladder ensures the balloon of the catheter is beyond the neck of the bladder before inflation to avoid the balloon being inflated in the urethra.
7. Connect a syringe containing sterile media to the Luer of the inflation lumen of the Raypilot® Viewcath™.
8. Use the syringe to fill the balloon.
9. Retract the Raypilot® Viewcath™ until you feel resistance of the balloon against the bladder wall. At imaging the Raypilot® Viewcath™ shall be fixed according to clinical procedure at the urethra opening, for example on the patient leg. This minimizes the occurrence of the Raypilot® Viewcath™ moving in the urethra independently from the prostate.
10. For final adaptions of the marker position, the filling of the balloon can be adjusted by inflating the balloon differently. This allows the user to position the marker more proximal to the bladder by inflating the balloon within the specified volumes.

11. Connect the funnel drainage lumen to a drainage bag and assure good drainage of the catheter.
12. The Raypilot® Viewcath™ is now ready to use.
13. For further information about the use of the Raypilot® System, and the Raypilot® Hypocath® see the IFU for the Raypilot® System and IFU for the Raypilot® Hypocath® respectively.

The Raypilot® Viewcath™ is intended for use up to 30 days.

Raypilot® Viewcath™ catheter maintenance

Hand hygiene shall be performed immediately before and after any manipulation of the Raypilot® Viewcath™.
Retract Raypilot® Viewcath™ to ensure the balloon against the bladder wall prior to imaging for treatment planning.
Replacement of urine collection system shall be performed according to local and national best practice policies.
Health care provider must ensure patient is instructed on the relevant content for catheter care, maintenance and potential complications according to section Complications and side effects in Instructions for use and in accordance with local and national best practice policies.

Check the Raypilot® Viewcath™ on a regular basis to ensure that the balloon volume is maintained.

1. Completely drain/aspirate the sterile medium from the balloon while the Raypilot® Viewcath™ is held in position in the bladder.
2. Replace the required volume with new sterile medium to the balloon lumen.
3. Remove the Raypilot® Viewcath™ immediately at the completion of the patient's imaging.

Catheter removal

1. The balloon must be completely deflated before Raypilot® Viewcath™ removal.
2. Do not cut the Raypilot® Viewcath™ or inflation channel to deflate the balloon.
3. Deflate the balloon by inserting the Luer tip of an empty syringe into the valve and aspiring the solution completely.
4. Remove the Raypilot® Viewcath™ following accepted medical techniques.
5. Discard the Raypilot® Viewcath™ according to hospital policy considering microbiological hazards.

Environmental conditions

Temperature
The device is considered safe at temperature, +10°C to +40°C.

Humidity
The device is considered safe at relative humidity level of 30% to 75%.

Pressure
The device is considered safe at an atmospheric pressure range of 70.00 kPa to 106.0 kPa.

Contraindications

The Raypilot® Viewcath™ should not be used for patients with known allergy to silicone.

Warnings

- Do not use the Raypilot® Viewcath™ if sterile packaging is breached or damaged.
- The Raypilot® Viewcath™ is single use only. Do not re-sterilize or reuse after removal. It could result in urinary tract infection.

Cautions

- The Raypilot® Viewcath™ is a Prescription device (Rx only) and must only be used by trained and experienced professionals.
- A medical doctor must evaluate the suitability for the patient to use the Raypilot® Viewcath™.
- The indwelling of the Raypilot® Viewcath™ shall be as short as possible in order to reduce the likelihood of infection or other events related to long term catheter usage.
- The Raypilot® Viewcath™ must be lubricated with a water-soluble lubricant prior to insertion using accepted medical techniques.
- Caution should be taken when the Raypilot® Viewcath™ is difficult to insert (e.g. patients with urethral stricture)
- A Luer syringe must be used to inflate the balloon.
- Do not overinflate the balloon.
- If the catheter is mechanically broken, make sure all material is removed. If patient is exposed to inner material a biochemical reaction can occur.
- Do not clamp the catheter shaft, this may damage the inflation lumen.
- Make sure to follow the instructions set out in this Instructions for use to minimizing risks related to catheter use.

Complications and side effects

The following complications and/or side effects have been reported for Raypilot® Hypocath® and/or Raypilot® Viewcath™:

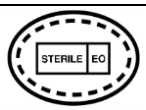
- Urinary tract infection
- Discomfort
- Pain
- Bladder discomfort
- Minor bleeding due to urethral injury
- Slight discomfort of bladder filling
- Balloon misplacement leading to urethral injury
- Dysuria and/or pollakiuria due to the catheter

Other complications and/or side effects reported from use of urinary catheters include:

- Obstruction
- Bladder stones
- Severe trauma such as vena cava air embolism or false passage

The use of Raypilot® System has not been shown to induce further adverse events than those related to the radiotherapy treatment or the use of the urinary catheter. The health care provider shall advise the patients of the potential side effects related with the radiotherapy treatment, such as genitourinary and gastrointestinal toxicity and urinary, sexual, bowel, and hormonal symptoms.

Symbols on the package

	Intended for single use
	Sterilized with ethylene oxide. Single sterile barrier system with protective packaging inside.
LOT	Manufacturing batch
	Expiration date
	Read the user instructions
	Manufacturer
	Country of manufacture. If date adjacent to symbol, it signifies date of manufacture.

	Item number
	Do not use this product, if the packaging is damaged
	Keep dry
	Keep away from sunlight
	Medical device
	Translation performed by Semantix: Adress: Box 10059, 100 55 Stockholm, Sweden
	Prescription use only (term applicable in US)
	Unique device identifier

Technical assistance

If you have any problems with the device please contact Micropos Medical at:
support@micropos.se

Electronic Instructions for Use (eIFU)

The electronic version of this Instructions for Use (eIFU) for the **Raypilot Viewcath** is available online.

- **Access Link:** https://micropos.se/ifu/
- **Device UDI:** 735000795RPCatheterU2
- **Format:** PDF (Viewable with Adobe Acrobat Reader or equivalent)

To access and view the eIFU, the following **minimum system requirements** are required:

- **Internet access:** Required to download/view the document.
- **Web browser:** Latest versions of Chrome, Firefox, Edge, or Safari.
- **Screen resolution:** 1024×768 pixels or higher is recommended.

Paper copy of this Instructions for Use will be provided free of charge within 7 days of request. Delivery times may vary depending on the customer's location.

To request a paper IFU, please contact:
Email: info@micropos.se
Phone: +46 31 760 80 05

Serious incident reporting

To report any patient incident when using the device please contact Micropos Medical at: support@micropos.se

If the incident is regarded a serious incident according to MDR 2017/745 it has also to be reported to the competent authority in your country.

Food and Drug Administration
10903 New Hampshire Ave Silver Spring, MD 20993 0002

www.fda.gov/about-fda/contact-fda