Instructions for use
for Raypilot® Hypocath® 1004

Introduction

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

Limitations

The Raypilot® Hypocath® is a Prescription Device (Rx only) and may only be inserted and removed by educated healthcare professionals.
Raypilot® Hypocath® is only intended for use with the Raypilot® System.
Raypilot® Hypocath® 1004 can be connected to the Raypilot® System 2020.

Manufacturer and identification

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Classification and compliance

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

IP57 — The product is IP classed according to IEC 60601

Intended use and Intended purpose

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 target localization and tracking, and for automatic patient identification.

Indications for use

To use as adjunct in treatment planning and radiation therapy for adult prostate cancer patients, for real-time target localization and tracking, and automatic patient identification.

Device description

The Raypilot® Hypocath® is a sterile single-use product. It is a three-lumen Foley catheter made of silicone with a transmitter inserted in one of the lumens. The Raypilot® Hypocath® has a drainage lumen, which also permits reproducibility of the bladder filling, and a 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® Hypocath® with its integrated transmitter is an essential part of the Raypilot® System. The transmitter in Raypilot® Hypocath® transmits a signal to the Raypilot® Receiver. The position of the transmitter is determined and displayed in the user interface of the Raypilot® Software. The Raypilot® Hypocath® is equipped with an electrical jack that connects to the Raypilot® Receiver. The jack contains an ID chip that provides a unique ID number to be assigned to one patient for every Raypilot Hypocath®. This jack must not be connected to anything else.

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® Hypocath® is approximately 42 cm. The Raypilot® Hypocath® contains a radiopaque barium line that permits identification of the urethra when inserted in a patient.

Raypilot® Hypocath® has been sterilized by Ethylene Oxide (EtO). The expiry date can be found on the sterile pouch and on the outer box. Each Raypilot® Hypocath® 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 the 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® Hypocath® 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® Hypocath® is intact before opening. Open the Raypilot® Hypocath® package at the end of the connector without removing the whole Raypilot® Hypocath® from its sterile package.
3. Check the function of the Raypilot® transmitter with the transmitter tester. Note that the transmitter tester cannot be sterilized. Protection of the sterile Raypilot® Hypocath® must be taken in consideration prior to the insertion.
4. Prior to insertion, test the balloon inflation and use sterile water or solution of sterile water with glycerine 9:1 for inflation.
5. Lubricate the Raypilot® Hypocath® with a suitable water-soluble lubricant.
6. Pass the deflated catheter (with care) through the urethra and into the bladder. The Raypilot® Hypocath® should be inserted with care due to the transmitter placed in one of the catheter lumens being delicate.
7. Guide the catheter gently 5-8 cm beyond the point at which urine begins to flow. The rationale for inserting the Raypilot® Hypocath® further into the bladder ensures the balloon of the Raypilot® Hypocath® is beyond the neck of the bladder before inflation to avoid the balloon being inflated in the urethra.
8. Connect a syringe containing sterile media to the Luer of the inflation lumen of the Raypilot® Hypocath®.
9. Use the syringe to fill the balloon.
10. Retract the catheter until you feel resistance of the balloon against the bladder wall. During treatment the Raypilot® Hypocath® shall be fixed according to clinical procedure at the urethra opening, for example on the patient leg. This minimizes the occurence of the Hypocath moving in the urethra independently from the prostate.

11. For final adaptions of the transmitter position the filling of the balloon can be adjusted by inflating the balloon differently. This allows the user to position the transmitter more proximal to the bladder by inflating the balloon within the specified volumes.
12. Connect the funnel drainage lumen to a drainage bag and assure good drainage of the catheter.
13. The Raypilot® Hypocath® is now ready to use.
14. For further information about the use of the Raypilot® System, see the IFU for the Raypilot® System.

The Raypilot® Hypocath® is indended for use up to 30 days.

Raypilot® Hypocath® catheter maintenance throughout treatment

The health care provider shall check for signs and symptoms of infection regularly, at least every radiation therapy fraction.
The connector in the Raypilot® Hypocath® contains gold and brass. If a patient has a known sensitization to gold or brass or shows symptoms of skin irritation, use a paper or gauge to avoid direct skin contact with the connector.
Hand hygiene shall be performed immediately before and after any manipulation of the Raypilot® Hypocath®.
Retract Raypilot® Hypocath® to ensure the balloon against the bladder wall prior to each treatment.
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 this Instructions for use and in accordance with local and national best practice policies.

Check the Raypilot® Hypocath® at all treatment sessions to ensure that the balloon volume is maintained.

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

The Raypilot® Hypocath® is MR Unsafe. Please note that MRI scans during use of the Raypilot® Hypocath® may introduce local artefacts.

Reproducibility of bladder filling during treatment

During treatment the bladder can be filled with specified amount of liquid in order to reproduce the bladder filling that was present at the time of the planning CT. This is performed by first emptying the bladder, and thereafter filling with sterile water. The flow rate should be 100 - 150 ml/min. The filling volume before the urge of emptying occurs, varies a lot between patients and depending on patient age. The filling volume should not exceed 300 ml. In case of the patient experiencing bladder filling discomfort consider extending the duration of the filling and reducing the filling volume.

Catheter removal

1. The balloon must be completely deflated before Raypilot® Hypocath® removal.
2. Do not cut the Raypilot® Hypocath® 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® Hypocath® following accepted medical techniques.
5. Discard the Raypilot® Hypocath® according to hospital policy considering microbiological hazards.

The length of time of the Raypilot® Hypocath® patient indwelling should be limited by the treatment protocol and it should be removed as soon as the treatment with Raypilot® System is finalized.

Environmental conditions

The environmental conditions are only relevant for use and storage since the Raypilot® Hypocath® function is tested after transport, before use.

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.

If the conditions are not met it could influence the measurement precision, and the Raypilot® System would give a measurement quality warning.

Contraindications

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

Warnings

- Do not use the Raypilot® Hypocath® if sterile packaging is breached or damaged.

- The Raypilot® Hypocath® is single use only. Do not re-sterilize or reuse after removal. It could result in urinary tract infection.

Cautions

- The Raypilot® Hypocath® 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 be treated with radiation and the use of the Raypilot® System and Raypilot® Hypocath®.
- The indwelling of the Raypilot® Hypocath® shall be as short as permitted by the radiation therapy treatment protocol in order to reduce the likelihood of infection or other events related to long term catheter usage.
- The Raypilot® Hypocath® must be lubricated with a water-soluble lubricant prior to insertion using accepted medical techniques.
- Caution should be taken when the Raypilot® Hypocath® 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 or transmitter 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.
- The Raypilot® Hypocath® is MR Unsafe. Keep it outside the MRI scanner room.
- 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™:

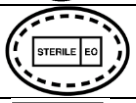
- Urinary tract infection
- Discomfort
- Pain
- Bladder discomfort
- Minor bleeding due to urethral injury
- Slight discomfort of bladder filling
- Balloon misplacement leading to urethral injury
- Dysuria and/or pollakiuria due to the catheter

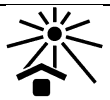
Other complications and/or side effects reported from use of urinary catheters include:

- 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.
	Manufacturing batch
	Expiry date (YYYY-MM-DD)
	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
	This product complies with the WEEE directive. The Raypilot® Hypocath® must not be disposed as unsorted municipal waste.
	Keep dry
	Keep away from sunlight
	Applied part type CF
	The Raypilot® Hypocath® is MR Unsafe. Keep it outside the MRI scanner room.
	Unique device identifier
	Medical device
	Translation performed by Semantix: Adress: Box 10059, 100 55 Stockholm, Sweden
	Prescription use only (term applicable in US)

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 Hypocath** 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.

Health products regulatory authority (HPRA)
Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace,
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