RectalPro™75 Endo Rectal Balloon Instructions for Use

REF 105.1014

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Device Description

The RectalPro™75 Endo Rectal Balloon (ERB) is intended to be used during all the phases of radiation therapy, including treatment planning, image verification, and radiotherapy delivery.

Figure 1: Endorectal Balloon (ERB), inflated

The RectalPro™75 ERB is designed as an immobilizer to assist in positioning the prostate in a more predictable and reproducible location during Computed Tomography (CT) exam and X-ray, when these imaging techniques are used for Radiation Therapy (RT) planning. The ERB is inserted into the rectum and inflated prior to the start of a CT scan or RT therapy procedure. The device stabilizes the prostate once the device is inflated. The ERB is deflated and removed after each individual scan or therapy procedure is complete, and a new balloon is used in the next therapy session.

QLRAD's device is designed for single use, is provided non-sterile to the end user, is not intended to be sterilized by the end user, and is packaged in a kit configuration.

Materials

The RectalPro™75 Endorectal Balloon is manufactured from biocompatible polyvinylchloride (PVC) and silicone.

Indications for Use

The RectalPro™75 Endo Rectal Balloon device is a single-use disposable, inflatable, non-powered positioning device intended for us in the temporary positioning of the rectal wall and adjacent structure in the male human anatomies. The purpose of the device is to stabilize the prostate during Computed Tomography (CT-exam, and X-Ray when these imaging techniques are used for Radiation Therapy (RT) planning.

Contraindications

- Severe hemorrhoids
- Peri-rectal / Peri-anal abscess
- Anal Fissure
- Prior low anterior resection
- Rectal Fistula
- Rectal Fissure
- Rectal Ulcer
- Anal Canal Stricture
- Diverticulitis
- Surgery of the prostate, rectum or surrounding area within the last eight weeks
- Radiation of the rectum or surrounding area within the last eight weeks
- Any standard exclusionary criteria recognized for endo-rectal / intra-rectal devices

Warnings

- The placement/insertion of the RectalPro™75 Endorectal Balloon should only be performed by a licensed physician or trained professional.
- Failure to perform the standard imaging position verification protocol may cause the device to not perform as intended.
- The RectalPro™75 Endorectal Balloon is provided non-sterile. Do not sterilize any portion of the device. Sterilization will damage the device and may result in patient injury.
- The RectalPro™75 Endorectal Balloon is intended for single use only. Never re-use a device, even if it appears undamaged. Re-use of the device presents a risk of contamination to the patient and personnel.
- Do not use if the package is opened or damaged.
- Do not transport the patient with the RectalPro™75 endorectal balloon inserted. The balloon should be removed prior to transport.
- Reduce the rectal balloon fill volume if the patient experiences discomfort due to the rectal balloon inflation.
- Do not apply excessive pressure/force on the shaft or tubing of the rectal balloon.
- The RectalPro™75 Endorectal Balloon should not be used after the Use By date on the product label.
- These devices are only intended to help position/fixate/immobilize the prostate for radiation treatment and to reduce the radiation on surrounding organs and anatomical structures.

- Care must be taken during insertion of the ERB device into the patient to prevent too much pressure on the rectal wall, which can lead to vasovagal reactions and syncopal episodes. When filling the balloon, one should not exceed the above-advised volume of 100 cc of air / 100 mL water.
- Forceful or deep insertion may also cause tearing or perforation of the anal canal or rectum. Make sure there is no obstruction noticed during insertion.
- Patients with pre-existing anorectal disease (e.g. hemorrhoids and severe proctitis) are at higher risk of developing acute anorectal toxicity with the use of an endorectal balloon.

RectalPro™75 Endorectal Balloon Package Contents:

The RectalPro™75 ERB package contains the following items:

Description	Quantity	Material
RectalPro™75 Endorectal Balloon Assembly	1 piece	-
Locking ERB Stopper	1 piece	Propylene Ethylene Copolymer
Small Clamp	1 piece	Polyoxymethylene Acetal Copolymer (PC)
Shaft (Blue)	1 piece	Polyvinylchloride (PVC) with Medical Grade Blue
Tube	1 piece	Polyvinylchloride (PVC)
Female Luer Lock	1 piece	Methyl Methacrylate Acrylonitrile Butadiene Styrene MABS)
Protective Sleeve	1 piece	Polyethylene
Single Balloon	1 piece	Silicone
100 mL Syringe	1 piece	Polypropylene-Silicone

Figure 2: Endorectal Balloon components

Protective Sleeve, PS01

RectalPro™75 Endorectal Balloon Technical Information:

The RectalPro™75 Endorectal Balloon consists of an angled (42 degree) 22.5-cm long flexible shaft made of polyvinylchloride (PVC) that is connected to a 75-mm long silicon balloon. The device is equipped with a stopper. The RectalPro™75 Endorectal Balloon has depth markings along its shaft to aid in reproducible positioning over the course of multiple treatments. The balloon may be inflated with 80 mL of water or 100 mL of air, and has a diameter of aprox. 4,5 cm when inflated.

Reference Inflation Volumes versus Diameter

Distal to Proximal Balloon Diameters	Liquid	Air
75 mm	60-100 mL	60-100 cc

CAUTION: The Balloon is not recommended for volumes greater than 100mL of Liquid or greater than 150cc of air.

Device Preparation

Device Preparation Using Liquid

1. Fill the 100-mL syringe with approximately 50 mL of the desired inflation media.
2. Connect the syringe to the female luer lock.
3. In an elevated position with respect to the balloon, withdraw the syringe plunger to evacuate the air from the device. It may be necessary to cycle the syringe multiple times by pulling the syringe plunger and allowing the liquid to backfill the balloon until few or no air bubbles can be observed in the syringe when drawing a vacuum.
4. *Close the white clamp on the tubing and remove the syringe.*

Device Preparation Using Air

1. Fill the 100mL syringe with approximately 100 mL of the desired inflation media.
2. Connect the syringe to the female luer lock.
3. Fill the ERB with air slowly

Check if balloon performs well before use at patient and is not deflating

Directions for Use

Before Each Treatment Session:

Preparation of the Balloon before Insertion

1. Ensure all the required equipment is present prior to use. Additional equipment required is: Kidney bowl containing an RectalPro™75 Endorectal Balloon ERB, locking ERB stopper, the air / water valve, a 100-mL syringe, aqueous-based lubricant (e.g., K-Y Jelly, Surgilube, etc.), and gloves.
2. The stopper is used to stabilize the balloon and to decrease shifting. Place the ERB stopper onto the shaft. The flat side of the stopper should be facing the end of the ERB containing the balloon (towards the body). The stopper's four prongs should be facing the opposite direction of the balloon (or the end of the ERB with the attached air / water tube). The ERB stopper is placed onto the shaft on the standard setting of digit 4 for the Curved ERB as indicated on the shaft. These stopper positions are the most commonly used, but they can be adjusted individually as needed by the professional. The stopper position is anatomically determined by the licensed physician or trained professional, depending on the thickness of the buttocks.
3. Using an air / water filled syringe, inflate the ERB with 100 mL's of air or 80 mL's water. Checks for leakage of air / water from the balloon and for asymmetric filling of the balloon around the ERB shaft. If leakage or asymmetric filling of the balloon is noted, discard that specific ERB device, and use a new RectalPro™75 Endorectal Balloon ERB, and repeat the ERB checks until it is determined that there is no leakage, nor asymmetric filling of the balloon. Deflate the balloon.

Instructions to the Patient Prior to ERB Insertion

1. Have the patient undress from the waist down.
2. Explain the procedure to the patient. The procedure is not meant to be painful, but the inflated balloon when placed in the rectum will give a sensation of the need to evacuate the bowel. Tell the patient that this sensation should disappear within 10 seconds. Have the patient relax his pelvic muscles and concentrate on breathing to facilitate a smooth introduction of the ERB.

Insertion and Inflation of the ERB

Caution: It is important to proceed with caution as forceful or deep insertion may cause tearing or perforation of the anal canal or rectum.

1. Place the patient in back position or a left lateral position. Patient can also be treated supine if required.
2. Place the tip of the curved ERB towards the patient's sacrum, to ensure a correct and anatomically proper ERB positioning. Ensure that the numbers on the shaft are visible to check for proper positioning of the curved ERB, prior to the insertion.
3. Make sure that the ERB Stopper is on the ERB shaft.
4. Pre-fill the ERB with air water to see if it performs well before use on the patient.

5. Make sure the air / water valve is in the air / water tube.
6. The lubricant is applied to the top 2 cm of the deflated ERB shaft. This should take approximately 5-10 seconds.
7. The air / water -filled syringe is connected to the ERB's female luer receptor.

WARNING: DO NOT INSERT THE ERB WITHOUT THE STOPPER.

8. The deflated ERB's balloon is gently inserted into the patient's anal canal. The operator should check for any obstruction or difficulty during insertion. If any obstruction or difficulty is detected, then retract the ERB and resolve the obstruction.
9. For comfortable insertion, the ERB should not be fully inserted.

WARNING: IF ONE INSERTS THE ERB FULLY, IT MAY HIT THE RECTAL WALL WHICH CAN BE PAINFUL TO THE PATIENT.

10. Ensure that 2-3 mL of the ERB shaft is visible in front of the stopper at this point. This will hold the insertion position.
11. Fill the ERB balloon with 100 mL of air or 100 mLof water via the air / water filled syringe.
1. As the balloon fills with air / water, the remaining section of the ERB shaft is automatically drawn into the patient's rectum. Once the ERB has reached its definitive position and depth, the stopper should press firmly against the patient's buttocks. If the ERB is too loose, then the ERB can shift up and down resulting in less precision.
2. Make a note in patients file the digit number of the stopper position for this patient after 1st time setting. This stopper postion needs to be used at future use during other fractions to prevent pain or damage to rectum.
3. Close the air / water valve straight and firmly and remove the syringe from the RectalPro™75 Endorectal Balloon.

After the ERB has been inflated Inside the Patient's Rectal Canal

1. Check the position of the RectalPro™75 Endorectal Balloon. Ensure that the position of the RectalPro™75 Endorectal Balloon is not too tight nor too loose against the patient's buttocks, to ensure a proper reproducible ERB positioning and depth.
2. Record the position of the stopper and the amount of air / water added to the balloon on the patient's record.
3. Carefully help the patient move to the treatment position (if they are not already in treatment position).
4. If required, help stabilize the patient's position with additional positioning supports during his treatment. For example, a pillow or knee support device can be placed under the patient's knees for stability.
5. The patient is now ready for irradiation treatment.

After Each Treatment Session

Removal of the Balloon

1. Patient stays on his back or the patient is asked to turn on his/her left side and adopt the left lateral or supine position again.
2. The ERB's air / water valve is released, deflating the balloon. The ERB can then be carefully and slowly removed.
3. The ERB is immediately deposited into a hospital biomedical waste bin.

DO NOT RE-USE THE ERB AFTER IT HAS BEEN INSERTED INTO A PATIENT'S RECTAL CANAL.

Disposal Procedure

The device and components that require disposal should be considered a biohazard and disposed of in accordance with local regulations and hospital guidelines.

Imaging Methods

The Endorectal Balloon has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Endorectal Balloon in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The Endorectal Balloon is safe for use with CT and X-ray Imaging.

Packaging and Storage

Packages for each of the components should be intact upon receipt. All kits should be carefully checked for completeness, and all components to ensure there is no damage prior to use. Damaged packages or products should never be used and should be returned to the manufacturer.

Handling and Storage

- The ERB is not supplied sterile. All packaging and labeling must be removed prior to use.
- Store in a cool dry environment. The ERB must be stored with care to maintain package integrity.
- Packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.
- Before use, inspect the device for proper function, possible damage, wear or non-function. Damaged or defective endorectal balloons should not be used. Contact the manufacturer for replacement instructions.

Product Complaints

Communicate suspected defects in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to QLRAD. Email: info@QLRAD.com; Tel: For North America and European Union, +1-888 596 8010. When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint, and patient case number. Place all returned

component(s) in a biohazard bag, and return to your local QLRAD representative. Notify QLRAD immediately of an incident resulting in patient death or serious injury.

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Further information

If further directions for use of this system are needed, contact QLRAD Customer Service, email: info@QLRAD.com • Tel: +1 888 596 8010.

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