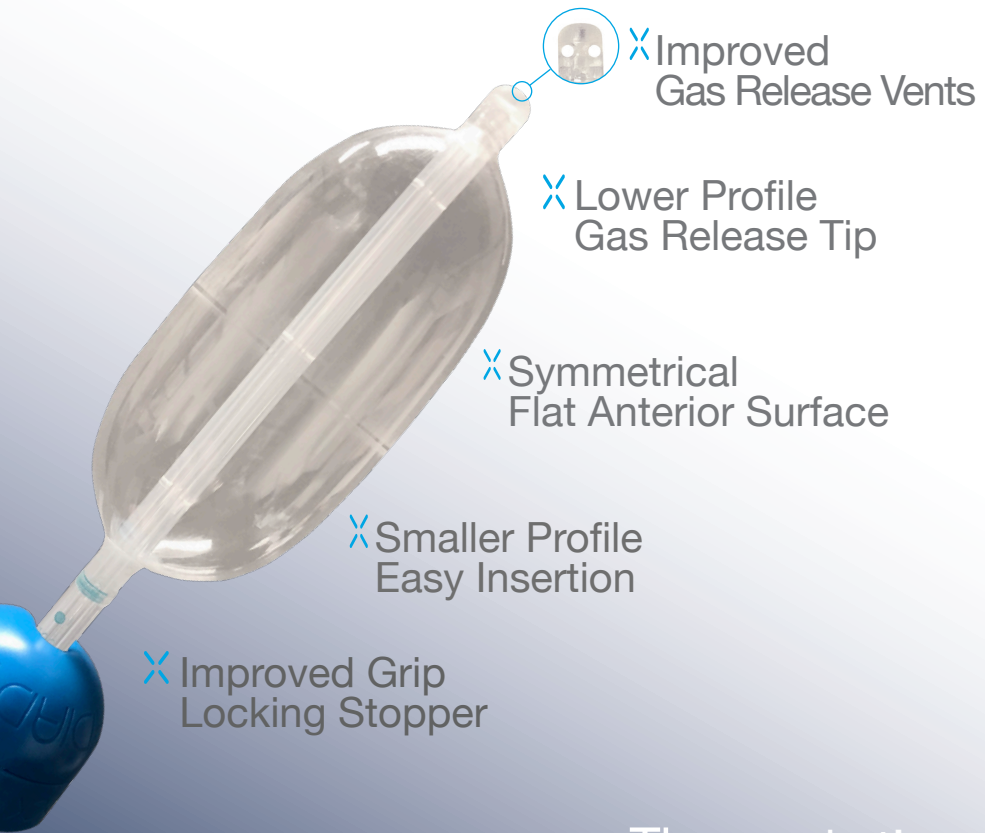
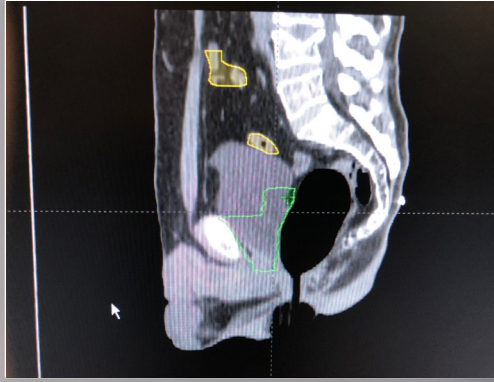


ISOLOC

Gas-Release Endorectal Balloon



The market's
leading endorectal balloon
just got better



Addresses Three Challenging Clinical Scenarios

Gaseous Patients

Removes rectal gas and reduces prostate motion¹

Low Bowel Patients

Repositions and lifts low lying bowel³

Post Radical Patients

Defines anatomy for difficult planning scenarios²

References:

- 1- Reduction Of Prostate Intrafraction Motion Using Gas-Release Rectal BalloonsZ. Su, T. Zhao, Z. Li, B. Hoppe, R. Henderson, W. Mendenhall, C. Nichols, R. Marcus, N. Mendenhall et al. University of Florida Proton Therapy Institute, Jacksonville, FL. Int. J. Radiat Oncol. Bio Phys, Vol 81 Issue 2; Supplement PS780, October 2011
- 2- Endorectal Balloon In Post-Operative Radiation Therapy For Prostate CancerL. K. Morikawa, R. Kudchadker, J. Kanke, M. Oyerivides, S. Frank, A. K. Lee, K. Hoffman, S. Choi, Q. Nguyen, D. Kuban et al., MDACC, TX, Int. J. Radiat Oncol Biol Phys, 2010; Vol 78 Issue 3; Supplement PS395
- 3- Dosimetric Impacts of Endorectal Balloon in CyberKnife Stereotactic Body Radiation Therapy (SBRT) for Early-Stage Prostate CancerHong F. Xiang, Hsiao-Ming Lu, Jason A. Efstathiou, Anthony L. Zietman, Ricardo De Armas, Kathryn Harris, B. Nicolas Bloch, Muhammad Mustafa Qureshi, Sean Keohan, Ariel E. Hirsch, International Journal Appl. Clin. Med. Phys. 2017 May; 18 Vol 3:37-43.

Intended Use and Product Information:

The IsoLoc Endorectal Balloon Immobilization Treatment Device is designed as an immobilizer to assist in positioning the prostate in a more predictable and reproducible location during the computed tomography (CT) exam and radiation treatment (RT) therapy.

Indications For Use:

The IsoLoc Endorectal Balloon Immobilization Treatment Device is a single use, disposable, flexible, inflatable, non-powered positioning device, intended to be used on a daily treatment basis for the temporary positioning of the rectal wall and adjacent structural anatomies of patients who require radiation therapy for Cancer Treatment. The purpose of the device is to stabilize the rectum during computed tomography (CT) exam, X-ray, or radiation treatments (RT). The placement of the balloon requires a Physician or a Physician directed health care professional, and it is performed as a separate procedure outside of the standard (CT) exam and (RT) treatment.

Caution: Please read and comprehend all warnings before operating this device.

• Do not use if there are any outward signs of physical damage to the device. • The device is for Single Patient Use, and is a Single Use Device (SUD) only. • The device cannot be sufficiently cleaned or sterilized to insure product performance or patient safety. • Patient injury may result from tampering with the device. Upon suspicion, please contact RadiaDyne immediately. • The immobilizer device is not sterilized, nor is it compatible with sterilization procedures. • Do not apply excessive pressure/force on the shaft or tubing of the rectal balloon. • Do not transport patient from the treatment table with the immobilizer balloon inserted. • The balloon should be removed from the patient prior to transporting from the treatment table. • The RadiaDyne balloon should not remain inserted into the patient for any time longer than required for actual treatment. • Reduce the rectal balloon fill volume if the patient experiences discomfort due to the rectal balloon inflation. • If the patient cannot tolerate the rectal balloon during treatment, stop and remove the balloon as described in the Instructions for Use section. Therapist should promptly notify the treating Physician. • A new CT Scan and/or Treatment Plan may be required after stoppage of the balloon per Physician's orders. • Failure to perform the standard imaging position verification protocol may cause the device to not perform as intended. Refer to Directions for Use provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications.

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

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