The market’s leading endorectal balloon just got better
Addresses Three Challenging Clinical Scenarios

Gaseous Patients
Removes rectal gas and reduces prostate motion

Low Bowel Patients
Repositions and lifts low lying bowel

Post Radical Patients
Defines anatomy for difficult planning scenarios

References:

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 therapy (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. • Do not transport patient from the treatment table with the immobilizer balloon inserted. • 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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