

BIOPROTECT



BIOPROTECT
BALLOON
SPACER

The Apex of Spacing

Whole-gland spacing for prostate radiation therapies

Innovation in Space Creation

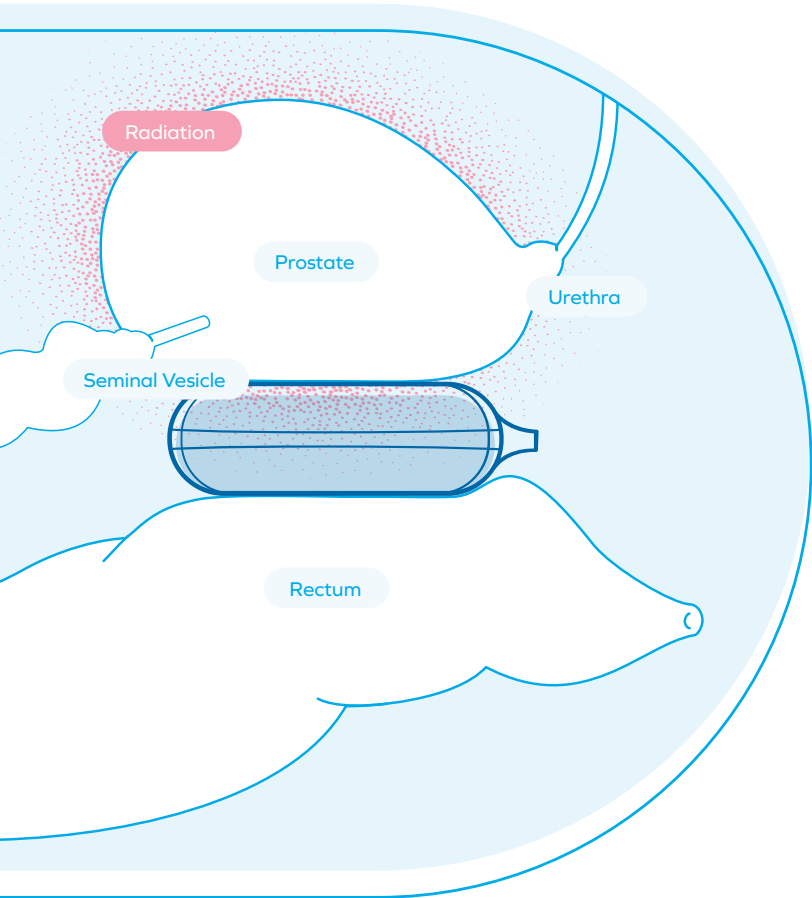
The BioProtect Balloon Spacer represents an advancement in rectal spacing. Designed for precision and reproducibility, BioProtect has been shown to provide **consistent separation from base to apex**, supporting stable anatomy for radiation planning.^{1,2} Clinical studies demonstrate **significant rectal dose reduction** and support use in advanced planning, including **hypofractionation and SBRT**.^{1,2}



Consistent Space with Apical Coverage

The predefined shape of the BioProtect Balloon Spacer creates **consistent, symmetric spacing** with minimal variability. Comparative data show that **balloon spacers reliably create measurable apex separation**, while gel spacers may not always do so,³ and an SBRT abstract analysis linked **greater apical separation** to lower rectal dose.^{4*} In the pivotal trial and long-term studies, BioProtect achieved **consistent spacing with significant rectal dose reduction** and sustained quality-of-life benefits.^{1,5*}

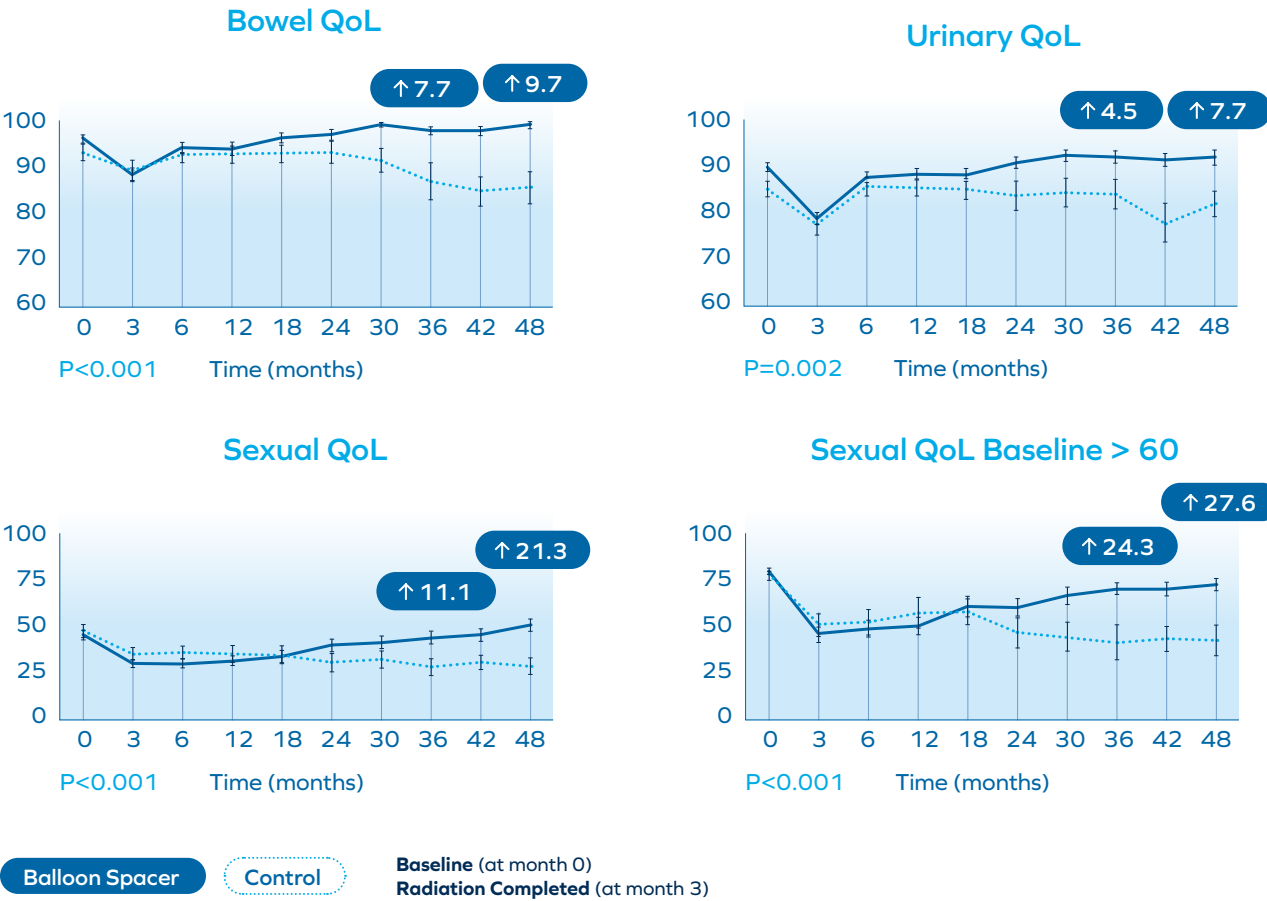
- ✓ Significant rectal dose differences vs. hydrogel²
- ✓ Preshaped balloon visible on imaging⁶
- ✓ Low rectal and procedure-related adverse events¹
- ✓ Preserved quality of life in preliminary data^{5*}



For Life After Treatment

Rectal protection is vital for post-treatment care, and preliminary abstract data suggest the BioProtect Balloon Spacer is associated with reduced long-term Grade 1 and ≥ 2 rectal toxicity.^{5*} Patients also reported improved quality of life, with significant benefits across bowel, urinary, and sexual domains over 48 months.^{5*}

Patient-Reported Quality of Life^{5*}



Physician-Reported Toxicity^{5*}

Rectal Toxicity 18-48 Month Follow-Up
Grade ≥ 2 : 3.1% balloon vs. 14.6% control

Urinary and Sexual Side Effects 18-48 Month Follow-Up
Urinary Toxicity Grade ≥ 2 : 6.3% vs. 12.5%
Sexual Dysfunction Grade ≥ 2 : 8.3% vs. 14.6%

References

1. Song, Daniel et al. "Prospective, Randomized Controlled Pivotal Trial of Biodegradable Balloon Rectal Spacer for Prostate Radiation Therapy." *International journal of radiation oncology, biology, physics* vol. 120,5 (2024): 1410-1420. doi:10.1016/j.ijrobp.2024.07.2145
2. Kos, Michael et al. "Multicenter, dual fractionation scheme, single core lab comparison of rectal volume dose reduction following injection of two biodegradable perirectal spacers." *Journal of applied clinical medical physics* vol. 24,10 (2023): e14086. doi:10.1002/acm2.14086
3. Ben-Dor, Yossi et al. "Comparative Evaluation of Symmetry, Dosimetry, and Toxicity in Prostate Cancer EBRT with Spacing Techniques." *Frontiers in Oncology*. 2025;15:1668726. doi:10.3389/fonc.2025.1668726
4. Ng, Victor C et al. "Separation Effect of Biodegradable Balloon Spacer on Rectal Dose from Apex to Base in Prostate Cancer SBRT". Abstract presented at: American Society for Radiation Oncology (ASTRO) 67th Annual Meeting; 2025; San Francisco, CA.
5. Song, Daniel et al. "Long-term toxicity and patient-reported quality of life after prostate IMRT with or without biodegradable balloon rectal spacer: analysis of a pivotal randomized trial." Abstract presented at: American Society for Radiation Oncology (ASTRO) 67th Annual Meeting; 2025; San Francisco, CA.
6. BioProtect Balloon Implant™ System 510(k) K222972, August 2023.

* Preliminary data are from a conference abstract; not yet peer-reviewed; values and follow-up may change upon publication.

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Prepackaged Easy-Use Kit

Includes sterile BioProtect Balloon Spacer, balloon implant deployer, echogenic needle, blunt dilator, and introducer sheath.



Item Number: 5135

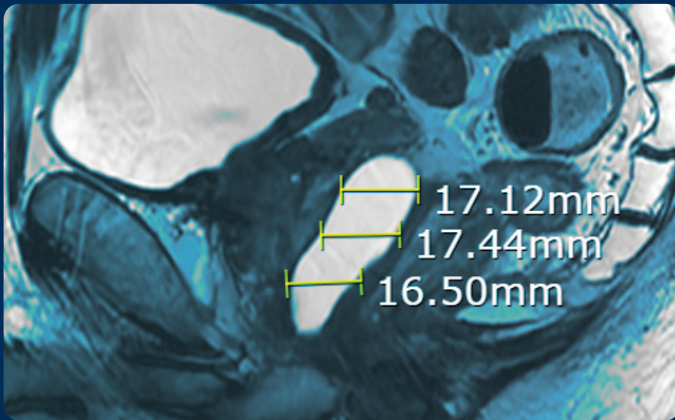


Image courtesy of Dr. Vishesh Agarwal, Radiation Oncologist.

Symmetric Whole-Gland Spacing

The BioProtect Balloon Spacer creates visibly symmetric apex-to-base spacing.

Reach **The Apex** of Spacing

BIOPROTECT

See how you can lift your patients
to the apex of care.

Contact a BioProtect representative.

BioProtect.com