

The BioProtect Balloon Spacer:

From Reducing Toxicity to Preserving Life Quality

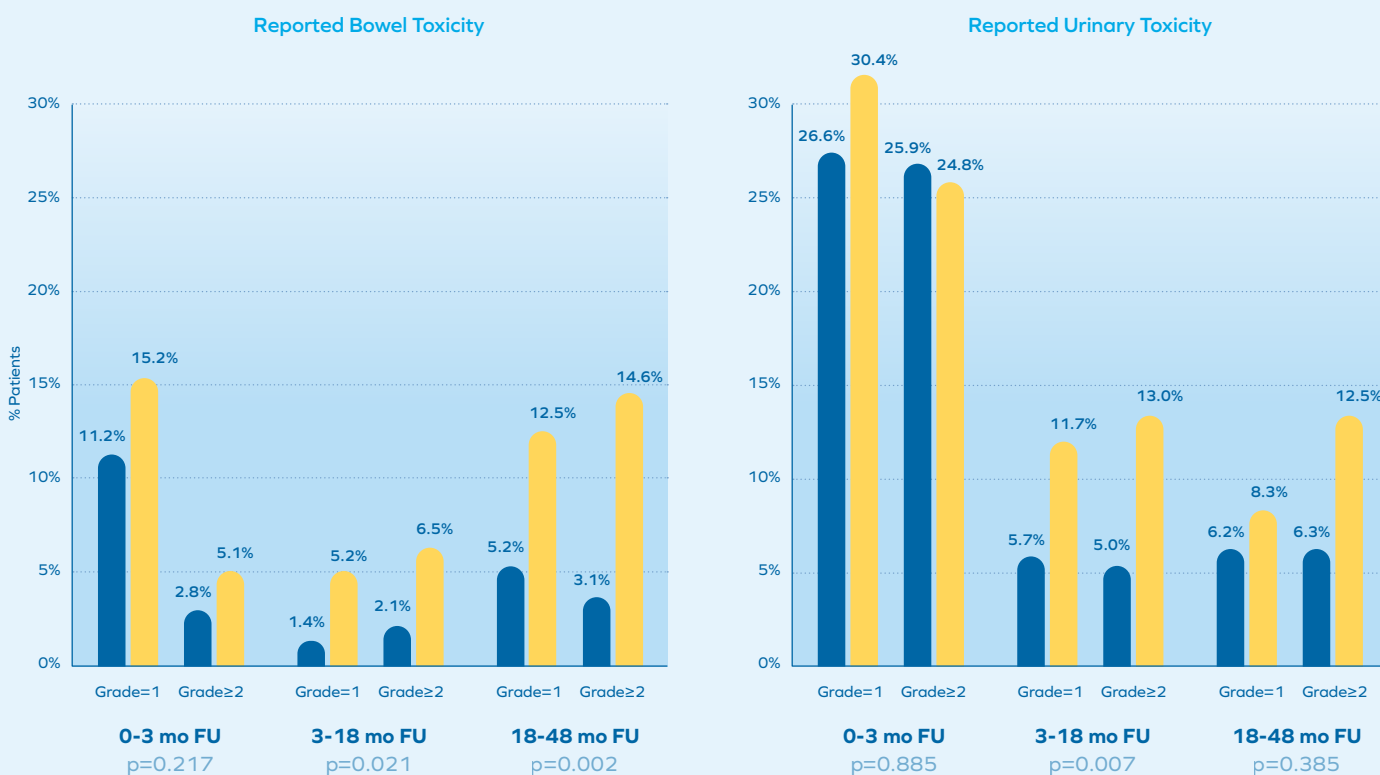
BIOPROTECT

In a pivotal randomized trial, the BioProtect Balloon Spacer significantly reduced rectal V70 and was associated with fewer rectal and procedure-related adverse events.¹ Extended follow-up over 48 months demonstrated preserved patient-reported bowel, urinary, and sexual quality of life, along with lower rates of rectal and urinary toxicities.^{2*}



Physician-Reported Toxicity Over 48 Months^{2*}

CHART 1: INCIDENCE TO 48 MONTHS



BioProtect Control

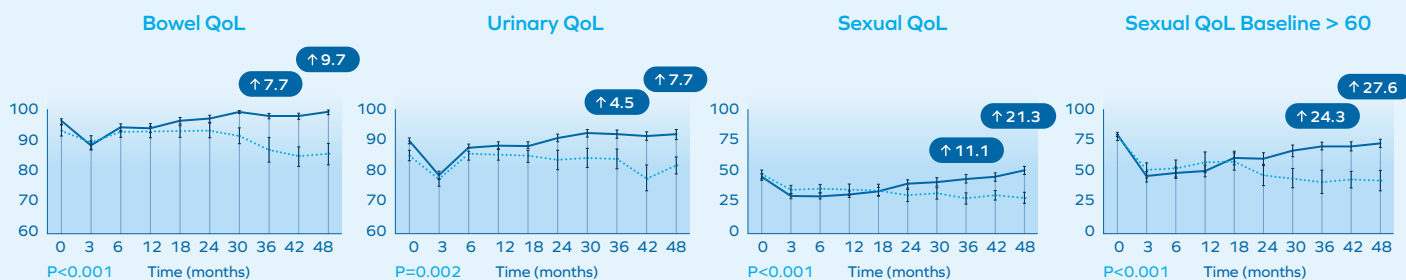
* Preliminary data are from a conference abstract; not yet peer-reviewed; values and follow-up may change upon publication.

Patient-Reported Quality of Life[†]

CHART 2: BIOPROTECT VS. SPACEOAR QOL

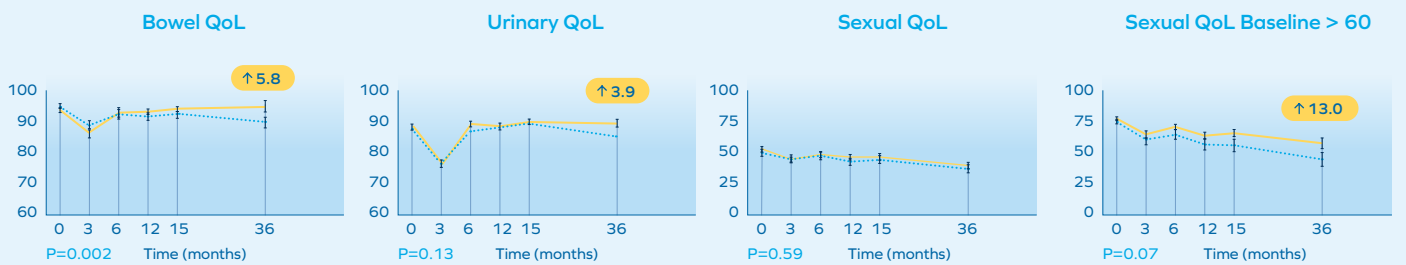
BioProtect Balloon Spacer
(2025)^{2*}

Controlled, randomized, prospective, multi-center clinical trial.
48 month follow-up



SpaceOAR
(2017-2018)^{3,4}

Controlled, randomized, prospective, multi-center clinical trial.
36 month follow-up



[†]QoL data are from separate long-term trials. No head-to-head QoL comparison has been conducted.

Balloon Spacer **Gel Spacer** **Control**

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. 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.
3. Hamstra, Daniel et al. "Continued benefit to rectal separation for prostate radiation therapy: final results of a phase III trial." *International journal of radiation oncology, biology, physics*. 2017;97(5):976-985. doi:10.1016/j.ijrobp.2016.12.024
4. Hamstra, Daniel et al. "Sexual quality of life following prostate intensity-modulated radiation therapy with a rectal/prostate spacer: secondary analysis of a phase 3 trial." *Practical radiation oncology*. 2018;8(1):e7-e15. doi:10.1016/j.pro.2017.07.008

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