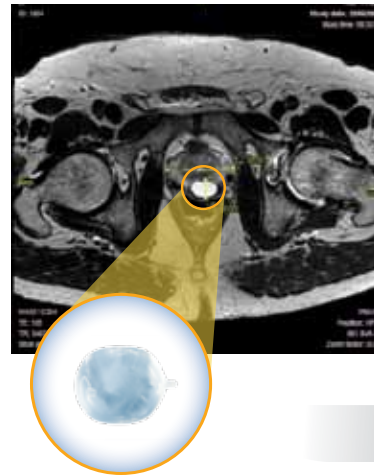


BioProtect Balloon Implant – Protecting Healthy Tissue During Prostate EBRT¹; Enabling Hypofractionation

The innovative biodegradable balloon implant separates the prostate and rectum allowing physicians to radiate prostate tumors while sparing healthy rectal tissue. With the balloon implant, hypofractionation and dose escalation are finally made possible, dramatically decreasing the chances of patient G2 rectal toxicity and improving biochemical tumor control.



EBRT Is the Treatment of Choice for Prostate Cancer, but It Has Drawbacks

Radiotherapy is considered a treatment of choice for patients with localized prostate cancer. However, despite its benefits, radiation therapy is complex to plan and deliver and involves the administration of low dose radiation delivered to the patient in 45 daily sessions (fractions). This is burdensome to patients and highly expensive to payers. Despite sufficient margins left around the prostate to compensate for intra- and inter-session movement of the prostate, parts of the ventral rectal wall are frequently exposed to high radiation doses. Excess radiation may result in complications, causing increased damage to the rectal tissue, with G2 acute rectal toxicity occurring in up to 35% of treated patients.²

Hypofractionation May Be the Solution, If Made Safe

Hypofractionation could profoundly alter the management of localized prostate cancer. It involves treating prostate cancer with fewer daily sessions (fractions) while administering larger doses of radiation in each fraction. Since prostate cancer is highly sensitive to fraction size (low α/β ratio), hypofractionation could become the standard of care in radiation therapy. However, the larger the daily dosage, the greater the risk to surrounding healthy tissue. The need for a separator that shifts the rectum away from harmful radiation is clear. With such a device, hypofractionation will be more widely adopted.

1. External Beam Radiation Therapy

2. Budiharto et al, External Beam Radiotherapy for Prostate Cancer, J Endourol 2010, 24(5): 781-789

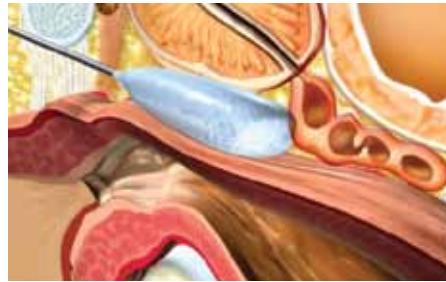
BioProtect – for Safer EBRT and Hypofractionation

The novel BioProtect Balloon Implant is indicated for prostate cancer patients undergoing EBRT. The balloon creates a safe distance between the prostate and the rectum. Balloon deployment into the prostate-rectum interspace is performed in a quick and minimally invasive transperineal technique using a proprietary insertion device under local or general anesthesia. Once the balloon is in situ, it is inflated with sterile saline to reach its final configuration as illustrated below. The balloon remains inflated during the entire treatment period and biodegrades in the body following treatment completion.

Balloon Implant Inserted



Balloon Implant Deployed



The Balloon Implant maintains its size and shape in the body during the radiation period and naturally biodegrades within 6 months post-implantation.

"The use of a biodegradable balloon spacer in prostate cancer patients offers an easy, safe and effective option for significant reduction of rectal radiation dose". (ASTRO 2010)

Clinically Proven

Data from a 2010 24-patient multicenter study of the balloon implant has shown a 70% average reduction in radiation of the prostate prescribed dose to the rectum and significant reduction in radiation parameters at the rectum with a reproducible separation throughout the radiation period and follow-up periods.

- No major adverse events
- Average radiation reduction of 70% (at D90)
- No patients had Acute Proctitis above Grade 1 (at 6-month follow-up)
- Stable separation throughout the XRT period in all subjects



www.bioprotect.co.il

The BioProtect Balloon Implant is not yet cleared for marketing in the U.S. © 2012 BioProtect, Inc. MRK101 Rev. 03

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