PROTECTING THE RECTUM IN PROSTATE CANCER RADIOTHERAPY

“I would say that the device provides capability to significantly reduce the dose to the rectum, which should provide an added margin of safety beyond what can be achieved by even the most sophisticated radiation delivery techniques.”

Mitchell S. Anscher, MD, FACR, FACRO

Professor and Chair Department of Radiation Oncology, MD Anderson, TX, USA

“The unique blunt dissection procedure dramatically reduces the risk for rectal wall perforation. I performed over 100 implantations, and it is safe and simple to perform.”

Paulo S. Costa, MD

Instituto CUF Porto, Portugal

Ultrasound | CT | MRI

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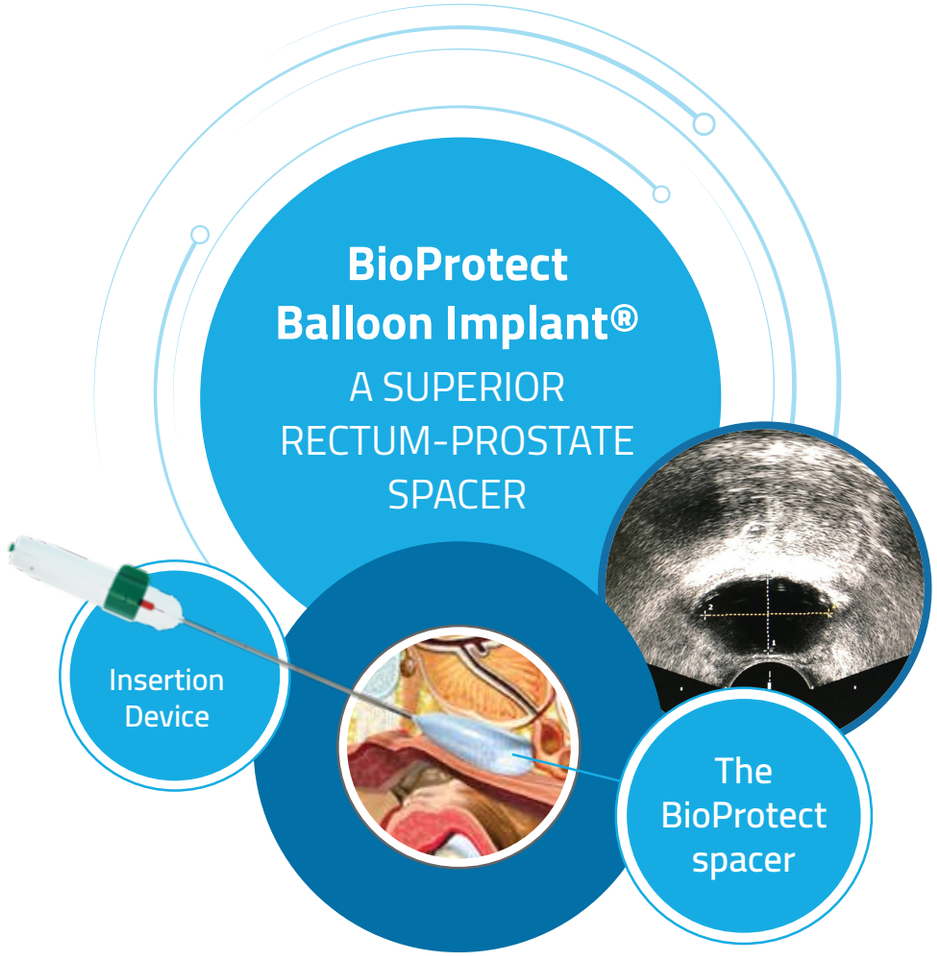
ProSpace Balloon Spacer is considered an investigational device in the U.S.A and is not available for sale in the U.S.A.

CE 0344

BIO PROTECT Space for your life

BioProtect Balloon Implant®

A SUPERIOR RECTUM-PROSTATE SPACER



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THE CHALLENGE: GI TOXICITY

TISSUE SPACERS ARE BECOMING STANDARD-OF-CARE IN PROSTATE RADIOTHERAPY

- Spacers reimbursement established in the US, Germany and spreading
- UK NICE evidence-based recommendation supporting biodegradable spacers[1]
- Published clinical data demonstrating safety and efficacy[1-6]

Spacers been clinically proven to reduce GI toxicity
Long-term clinical follow up data shows significant reduction in chronic GI toxicity, improved QoL.[6]

SPACERS ARE USED IN ALL RADIATION MODALITIES[1,2]

Including 3D-CRT, EBRT, SBRT, IMRT, Hypofractionation, proton* and brachytherapy.

*20% bowel toxicity risk shown in proton therapy[5]

Pelvic Radiation Disease (PRD) Under the Spotlight

With advanced technologies, cancer survivorship is on the rise, along with long-term chronic side effects of radiation, mainly due to the proximity of the rectum to the prostate

1. Chronic proctitis has been reported in 5% to 40% of patients[3,4]
2. Recent patient-reported outcomes, suggest 50% incidence[3,4]
3. Pelvic Radiation Disease adversely affects patient QoL [4]

THE BIOPROTECT BALLOON SPACER

A SUPERIOR RECTAL SPACING SOLUTION

Significantly reduce rectal radiation dose[7] by implanting a tissue spacer between the prostate and the anterior rectal wall

EFFICACY

- **Largest separation (1.8cm)**[7-9]
- **Reproducible and consistent shape**[7,8]
- **Lowest rectal dose**[9]
- **Visible borders** under CT, Ultrasound and MRI[7-9]

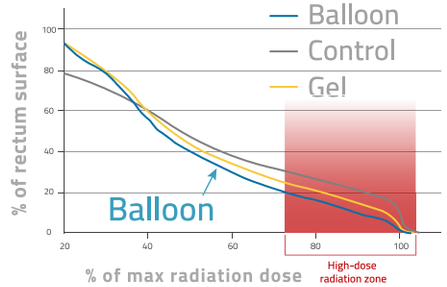
SAFETY

- **Unique blunt dissection**
- No time pressure – correct position[9,10]
- Excellent ultrasound visibility[9,10]

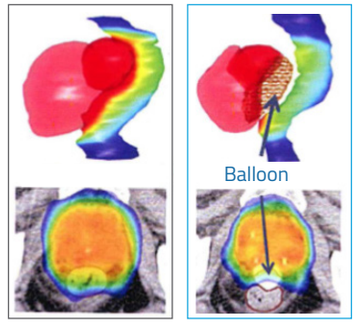
USABILITY AND CONTROL

- **Simple** transperineal deployment (5-10 min)[10]
- **Predictable position and shape**[9,10]
- Placement correction possibility[9,10]
- **Biodegradable** – absorbed within 6 months[7-10]

Absolute dose surface histogram of the rectum for balloon, gel and control[9]



Without Balloon **With Balloon[10]**



1. NICE interventional procedure guidance, August 2017 IPG590
2. Serrano, Kalman, Anscher, Cancer Management and Research 2017; 9: 339–350
3. Andreyev, J. (2007). Lancet Oncology 8: 10071017
4. M.T.W. Teo et al. / Clinical Oncology 27 (2015) 656e667
5. Pan et al, J Clin Oncol. 2018 Mar 21:JCO2017755371
6. Karsh et al. J Urology 2017.11.016
7. Gez et al. Radiation Oncology 2013, 8:96
8. Ben-Yosef et al. Red journal Oct 1, 2013 Volume 87
9. Wolf, Sedlmayer et al., Radiother Oncol. 2015 Aug;116(2):221-5.
10. Vanneste et al, Int Braz J Urol. 2017 Nov-Dec;43(6):1033-1042.