

BioProtect Balloon

Category:

Best Medical Technology

Company Name:

BioProtect

Product/Solution Name:

BioProtect Balloon

Compound/Tech Name:

Absorbable Perirectal Spacer

Trade Name:

BioProtect Balloon Implant System

Corporate Name:

BioProtect Balloon

Date of Approval:

2023-08-25

Indications:

The BioProtect Balloon Implant™ System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer. In creating this space, the BioProtect Balloon Implant™ System intends to reduce the radiation dose delivered to the anterior rectum. The BioProtect Balloon Implant™ System is a balloon made of a biodegradable material that maintains that space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

Therapeutic Areas:

Urology and radiation oncology for prostate cancer.

General Information File Document upload:

[**BioProtect_Logo_2021.jpg**](#)

Background information and need for drug / device:

The BioProtect Balloon Implant System is composed of a single use, biodegradable, inflatable balloon implant, designed to act as a spacer between the prostate and the rectum. The balloon is implanted transperineally using transrectal ultrasound (TRUS) guidance and remains stable throughout the radiation treatment and gradually degrades over time.

The BioProtect Balloon Implant System consists of single use components:

- Balloon: biodegradable, inflatable balloon acts as a spacer between the prostate and rectal wall
- Balloon Deployer: delivery system, the balloon is mounted and folded on the deployer
- Delivery Kit: an applicator system is used to position and deploy the balloon in the intended location. It includes an 18-gauge echogenic needle, blunt-tipped tissue dilator, and a balloon introducer sheath

The balloon is a biodegradable material and maintains space for the entire course of prostate radiotherapy treatment, approximately 3 months and is completely absorbed by the body over time, approximately 6 months.

There are two competitor spacers that were launched prior to the BioProtect Balloon. The difference is the balloon is a device that is manufactured as a preformed device making it reproducible each time where the competitor's spacers are made of gel, making it less predictable.

The balloon is implanted between the anterior rectal wall and prostate prior to radiotherapy. This creates space between the anterior rectal wall and prostate during radiotherapy for prostate cancer.

Implanted transperineally in a minimally invasive procedure in the space between the prostate and rectum under transrectal ultrasound guidance.

Additionally, the gels are inserted and where the placement ends are as is, with the balloon, it's adjustable so it can be repositioned as needed to ensure the best possible placement.

The balloon contains 17 ml of injected saline providing 10-18 mm space height, creating a larger space than the comparative gel spacer which creates 10 ml of space.

The implantation procedure includes establishing a working channel along the plane from the prostate apex to base using a beveled tip dilator dissection and then inserting the balloon through the working channel and slowly filling it with the saline. The inflated

balloon is then sealed using a plug sealing made of the same material as the balloon, detach the deployer and the inflated balloon is left in situ.

Background File Document upload:

[MKD10629 Rev01 BioProtect Balloon Product Booklet for print.pdf](#)

History of the development of the solution/product:

A prospective, multicenter, randomized, double-arm, single blind, concurrently controlled study was conducted to demonstrate that the subject device's balloon would temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer, and in creating this space reduce the radiation dose delivered to the anterior rectum. 222 subjects were enrolled in this clinical study. 2:1 ratio to the treatment group (fiducial markers and balloon) or control group (fiducial markers only). All subjects were diagnosed with T1-T3 prostate cancer, with a planned treatment of radiotherapy by means of IMRT.

This study had co-primary endpoints for safety and efficacy. The primary efficacy endpoint was defined as reduction of at least 25% of the volume of the rectum receiving greater or equal to 70 Gy when compared to pre-implantation values, in 75% of the subjects assigned to the balloon group. The primary safety endpoint was based on the proportion of the subjects with Grade 1 or greater rectal adverse events and implantation procedure related to adverse events with a duration of at least 2 days through the first 6 months.

The balloon placement was successful in a balloon group subjects. The primary efficacy endpoint was successfully met with 97.9% of subjects gaining rectal dose reduction >25% in rV70 post-implantation, with a relative mean dose reduction of 84% of the volume of the rectum receiving 70 Gy. Moreover, the rectal radiation dose was consistently and significantly reduced in all radiation levels (from 40 Gy to 80Gy), compared to pre-implantation values, with increasing relative reductions at higher doses.

There were no serious adverse events during the study. The complete balloon degradation at 6 months was demonstrated in 98.5% of the subjects, and with no potential late complications or side effects due to partially resorbed balloon.

Development File Document upload:

[BioProtect Development Clinical Evidence.png](#)
[BioProtect Development Clinical Evidence_competitor comparison.png](#)

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

The BioProtect Balloon is revolutionizing rectal protection from radiation toxicity. Prostate spacing is only 10 years old. The first spacer, SpaceOar, a gel, was approved in 2015, in 2022 another gel spacer, Barrigel was approved. In 2023, the BioProtect Balloon was approved.

Unlike the gel spacers, BioProtect innovated and created a manufactured balloon that produces a consistent size for protection every time it's used. The gel spacers offer a fixed placement once inserted you get what you get. The balloon is innovative because it's a device not a liquid gel, it allows for adjustable positioning, ensuring optimal placement for the intended placement.

The balloon helps prevent radiation beams from reaching surrounding non-cancerous tissues, minimizing treatment side effects such as frequent urination, incontinence, diarrhea, rectal bleeding, bowel movement discomfort, and erectile dysfunction.

In the randomized, 220 patients, multi-center, prospective, clinical study demonstrated significant dose reduction to the rectum in 97.9% of the patients, while maintaining very low rates of rectal toxicity compared to the control arm.

With 1 in 8 men being diagnosed with prostate cancer with the common treatment being radiation therapy, BioProtect does what the other two competitors couldn't—creating a reproducible, adjustable, and safe device.

The device is 18mm H x 48mm L x 35mm W and inflates to 17ml volume, creating a safe distance between the prostate and rectum. Additionally, you can see the balloon under imaging include CT, ultrasound, and MRI, allowing physicians to see the balloon as it's being inserted and making sure it's in the right space.

Innovation File Document upload:

[**Balloon drawing.jpg**](#)

[**Anatomy.png**](#)

[**Product Image BioProtect 2.png**](#)

Please provide appropriate references (PubMed, Abstract, Website):

BioProtect Balloon trial data was published in the Red Journal Dec 2024, PubMed link: Prospective, Randomized Controlled Pivotal Trial of Biodegradable Balloon Rectal Spacer for Prostate Radiation Therapy - PubMed

4 abstracts were presented in 2024, files attached.

ABS abstract feasibility of balloon rectal spacer implementation in HDR and LDR brachytherapy for prostate cancer treatment. Conclusion: the use of rectal balloon spacer in both salvage HDR and LDR brachytherapy is feasible and safe. The balloon insertion is done in a controlled manner, allowing placement adjustments with no time limitations, and providing rectal protection from high radiation doses.

ABS abstract dosimetric comparison of saline-filled biodegradable balloon (BB) and hydrogel spacer (HS) for high-dose-rate CT/MR-based prostate brachytherapy. Conclusion: the use of saline-filled biodegradable BS has greater reduction in rectal dose compared to HS while providing the same target dose coverage.

ASTRO abstract comparison of perirectal spacer height, quality, and symmetry during the learning curve for 3 FDA-approved products. Conclusion the balloon spacer achieved superior volume and separation near the prostate midgland, and apex, and a higher proportion of ideal spacer quality scores than the polyethylene glycol or hyaluronic acid spacers.

ASTRO abstract optimizing rectal dose and minimizing toxicity in prostate radiotherapy in a randomized pivotal trial, assessment of rectal spacer placement effect on rectal dosimetry and toxicity. Conclusion the rectal spacer spatial distribution significantly impacts rectal dosimetry and degree of rectal sparing. Symmetrical rectal spacing using a pre-formed saline-filled degradable balloon was associated with a trend to lower rates of acute rectal toxicity.

References File Document upload:

[ABS Abstract_Jul 2024_Charas_Feasibility of Balloon Rectal Spacer Implementation in HDR and LDR Brachytherapy for Prostate Cancer Treatment.pdf](#)

[ABS Abstract_Jul 2024_UCLA Dr Chang_Dosimetric Comparison of SalineFilled Biodegradable Balloon and Hydrogel Spacer.pdf](#)

[ASTRO Abstract_2024_Zimberg_Optimizing Rectal DOse and Minimizing Toxicity in Prostate Radiotherapy in a Randomized Pivotal Trial.pdf](#)

[ASTRO Abstract_2024_Tward_Comparision of Perirectal Spacer Height Quality and Symmetry During the Learning Curve for 3 FDAApproved Products.pdf](#)