## **BioProtect**

BioProtect specializes in the design, development and commercialization of its innovative balloon systems based on BioProtect's proprietary technology. The patented technology allows for the design and manufacture of implantable biodegradable balloon products that support a wide range of clinical applications in oncology and surgery.

The BioProtect Balloon Implant, indicated for prostate cancer patients undergoing radiation therapy, is now commercially available in Europe. BioProtect has already licensed its technology to OrthoSpace Ltd., which markets a biodegradable balloon system for rotator-cuff tear repair.



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**Biodegradable Balloons** for Oncology and Surgery

#### **Biodegradable Solutions for Optimizing Treatment Outcome**

**BioProtect's** core technology makes possible the design, development and manufacturing of implantable biodegradable balloon products, in virtually any shape and form. The balloons degrade at a predetermined rate, depending on the type of application, and are completely absorbed in the patient's body. The balloons are implanted through a proprietary and quick insertion technique and support a wide range of clinical applications in oncology and general surgery.



## The BioProtect Balloon Implant

BioProtect's Balloon Implant, indicated for prostate cancer, protects the rectum from powerful radiation used in cancer treatment. It achieves this by creating a separation between the prostate and rectum, allowing physicians to radiate the tumors while sparing healthy rectal tissue.

#### Why Prostate Cancer?

Prostate cancer is the most common cancer in men in the U.S. Prostate cancer increases substantially with age and is prevalent in 80% of men in their 70s.

#### Radiation Therapy Causes Rectal Toxicity in as Many as 35% of Patients

External beam radiation therapy (EBRT) is the treatment of choice for patients with prostate cancer. More than 200,000 EBRT sessions are performed in the U.S. each year. Up to 35%\* of patients experience radiation-related side effects, including G2 rectal toxicity, despite advanced techniques to mitigate the problems associated with radiation therapy. These methods include treating patients with lower doses of radiation at more patient visits—sometimes as many as 45 separate sessions.

A growing body of evidence supports the use of higher EBRT doses for achieving better long-term biochemical control. However, high dose EBRT increases the risk to healthy tissue. A need exists, therefore, for a product that provides a separation between the rectal wall and the prostate, enabling fewer, shorter and more efficient radiation therapy treatments.



Balloon Implant Post Deployment

#### A Bridge to High Dose EBRT

BioProtect has developed a biodegradable implantable balloon that protects the rectum from the potential risk of rectal toxicity in patients undergoing EBRT for prostate cancer. The Balloon Implant is deployed percutaneously in a quick, minimally invasive procedure. The inflated balloon separates the rectal wall from the prostate, considerably reducing the risk of radiation to healthy tissue while enabling more efficient radiation of the prostate. The balloon dissolves completely in the patient's body 3-6 months following radiation therapy.

# A Wide Range of Clinical Applications in the Pipeline

Using the same proprietary technology, BioProtect has been developing additional applications in oncology and general surgery.

### **Oncology Applications**

**Radiation therapy or radiosurgery with reduced complications** – An intraperitoneal spacer will be implanted to protect organs during radiation therapy in a wide range of applications. Potential areas include cervical cancer, vaginal cancer and more.

**Radical prostatectomy made shorter and safer** – A balloon will be inserted to dissect and separate the prostate from the rectum during robotic or laparoscopic radical prostatectomy procedures, protecting the rectum and neurovascular bundles while reducing procedure time and complications.

## **General Surgery Applications**

Treating Pelvic Organ Prolapse – ProFix, a biodegradable mesh placement and anchoring balloon, will be used to treat recurring pelvic organ prolapse, which affects an estimated 50% of women between 50 and 79.

Hernia Repair – Hernia repair is a commonly performed surgery. ProFix technology is being leveraged to develop a balloon system that will shorten hernia surgery procedures, reduce complications and improve outcomes.

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

