INSTRUCTIONS FOR USE

BioProtect Balloon Implant™ System

OPL-10000 Rev.01

INSTRUCTIONS FOR USE

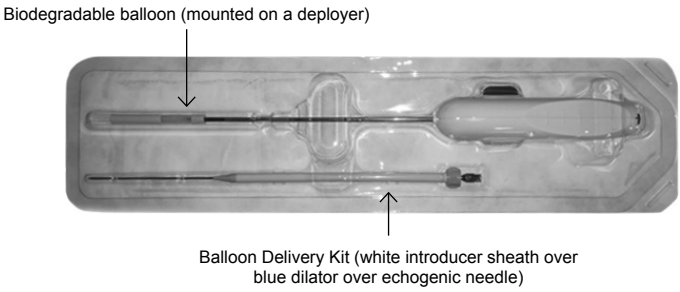
BioProtect Balloon Implant™ System

⚠ The Instructions for Use provides instructions for use and recommended guidelines specifically dedicated to the BioProtect Balloon Implant™ System. Read carefully and entirely before using the system.

DEVICE DESCRIPTION

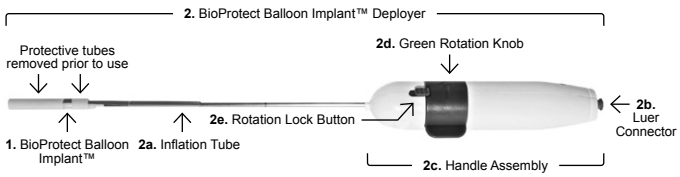
The BioProtect Balloon Implant™ System is a single use, biodegradable, inflatable balloon implant, designed to act as a spacer between the prostate and the rectum. The BioProtect Balloon Implant System is supplied sterile (sterilized by EO). When removed from the sterile package, the system is ready to use.

The BioProtect Balloon Implant System is packed in a sterile blister and Tyvek and comprised of:



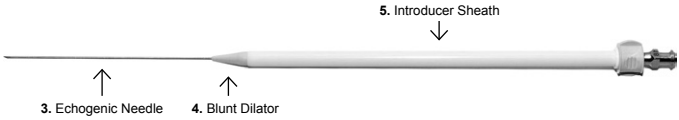
› Biodegradable, inflatable balloon (mounted on a deployer) that includes

	Component	Material
1	BioProtect Balloon Implant	Poly L-Lactide-co-e-Caprolactone, max weight: 1gr
2	BioProtect Balloon Implant Deployer	See below
A	Inflation Tube assembly	Stainless steel + PET
B	Luer Connector	Polyoxymethylene (POM) – Acetal
C	Handle Assembly	Polycarbonate
D	Green Rotation Knob	
E	Rotation Lock Button	



› Balloon Delivery Kit (echogenic needle, blunt dilator and introducer sheath)

	Component	Material
3	Echogenic Needle	Stainless steel
4	Blunt Dilator	HDPE tubing compound
5	Introducer Sheath	



The Balloon (implant) is Biodegradable, inflatable balloon made of Poly L-Lactide-co-e Caprolactone.

PACKAGE CONTENTS:

› BioProtect Balloon Implant™ System
› Instructions for Use
› Patient Implant Card and Instructions for Completion
› 4 Patient Labels
› Humidity indicator
› Desiccant

In addition to the devices listed in the package contents section, the following items (not provided) are required for the procedure and should be readily available prior to commencing the procedure:

› Saline solution (0.9%)
› 20 ml Sterile, disposable luer-lock syringe
› Scalpel
› 10 ml tapered/slip tip syringe (for hydrodissection)
› Suturing kit

INTENDED USE/INTENDED PURPOSE

The BioProtect Balloon Implant™ System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of the BioProtect Balloon Implant System to reduce the radiation dose delivered to the anterior rectum.

The BioProtect Balloon Implant System is composed of 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.

INDICATIONS

› The BioProtect Balloon Implant™ System is indicated for patients undergoing prostate radiation.

CONTRAINDICATIONS

› The BioProtect Balloon Implant System should not be implanted into areas with active or latent infection or signs of tissue necrosis.
› The BioProtect Balloon Implant System should not be used if the patient has any disorder which would create an unacceptable risk of post-operative complications such as an uncontrolled bleeding tendency, immuno-suppression or severe chronic diseases.
› Do not use if the patient has a known allergy to any of the device components.

IMPLANT MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

The BioProtect Balloon Implant System is MR safe and poses no known hazards resulting from exposure to any MR environment.

All other BioProtect Balloon Implant System delivery components are MR unsafe.

WARNINGS AND PRECAUTIONS

BEFORE USE

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed health care professional.

› BioProtect Balloon Implant System should be used by physicians experienced with performing trans-perineal procedures under transrectal ultrasound guidance.

› User should be trained by a BioProtect representative.

› Do not use the BioProtect Balloon Implant System if the package was opened, broken or damaged, as sterility may have been compromised.

› Do not inflate prior to insertion.

› Do not use the BioProtect Balloon Implant System if the humidity indicator inside the package shows 40% or above (the 40% indicator is lavender color).

› Do not re-sterilize or reuse the BioProtect Balloon Implant System or any of its components.

› Do not use any part of the BioProtect Balloon Implant System after the indicated expiration date.

› If placing fiducials, do so with a transperineal approach prior to BioProtect Balloon Implant placement. Do not use the BioProtect Balloon Implant System if fiducials that were implanted with transrectal approach are in place.

› BioProtect pivotal clinical trial demonstrated that the balloon is typically resorbed within 6 months, and residual risk of incomplete resorption showed no potential late complications or side effects. This residual risk is also supported by biological risk assessment and biocompatibility tests.

DURING PROCEDURE

› Special care must be taken during dissection and balloon insertion to avoid perforation of adjacent organs and vessels or nerve damage. Pay attention to the UltraSound (US) monitor during insertion of the needle and dilator.

› Do not fill the balloon before it is located at the desired position.

› The saline solution should be 35-40°C (95-104°F) when filling the balloon.

› Do not overfill the balloon - the maximal amount of saline solution required to fill the balloon is 17ml.

› If you encounter difficulty filling the balloon in the proper space due to fibrosis, leave the balloon empty in situ.

POST PROCEDURE

› If subsequent infection, signs or symptoms of damage to adjacent organs is detected, the patient should be inspected and treated accordingly using modalities such as: patient reassurance, antibiotics, rectal examination, or balloon needle aspiration.

› Ensure safe disposal of needle and any used components and packaging materials utilizing standard hospital safety regulations and procedures and universal precautions for bio-hazard waste.

The Summary of Safety and Clinical Performance (SSCP) of the BioProtect Balloon Implant System (for products sold in European union only) is available in the European database on medical devices (Eudamed) https://ec.europa.eu/tools/eudamed .Use the following Basic UDI-DI to search: 7290014878BP0135V3.

DIRECTIONS FOR USE

PATIENT PREPARATION

› Prior to the procedure the patient may receive medication to relieve anxiety. Various anesthesia methods may be used (local, epidural, general) with or without sedation.

› The patient should receive broad spectrum antibiotics for a total of 5 days, starting two (2) days before the procedure and for two (2) consecutive days after, or per treating institution's standard practice.

› Make sure that the patient had bowel preparation per the treating institution's standard practice.

› Position the patient in lithotomy position per local practice.

› Introduction of a urethral catheter at the beginning of the session is optional and may aid in visualization of the urethra. At the end of the procedure (or per standard practice) the catheter should be removed.

› Position the US probe in the patient's rectum and ensure optimal visibility.

› If placing fiducials, do so with a transperineal approach prior to the implantation of the balloon.

OPENING THE STERILE PACK

› Check the carton pack for expiration date to ensure that the pack is not damaged.

› Open the carton pack and remove the foil pack.

› ⚠ The outer surface of the sterile blister pack is non-sterile.

› Inspect the humidity indicator, make sure there is no change in color, then discard. At 40% humidity the indicator should show blue. If colored pink, the device should be discarded.

› Holding the blister pack in one hand, and working from the end with the straight edge, peel back the cover to expose the inner sterile blister pack.

› Present the external blister pack for aseptic removal of the inner sterile blister pack.

› Remove the lid from the inner blister pack, by pulling upwards (where indicated by Pull mark).

BLUNT DISSECTION

› Insert the needle approximately 1-2 cm anterior to the anal opening, using a finger's width as guide.

› Push the echogenic needle forward on the midline under US vision towards the top of the rectourethralis muscle (visible mound proximal to the prostate).

› Perform a 6mm deep and 6mm long incision at the point of entry and advance the beveled tip dilator over the echogenic needle up to the rectourethralis muscle, and remove the echogenic needle.

› Once below prostate apex, ensure dilator is at midline.

› Slowly advance the dilator, gliding between the prostate and the rectal wall towards the prostate base at the seminal vesicles level. If tissue resistance is noticed, hydrodissection is optional using a slim tip syringe.

› Using axial view, raise and gently wiggle the dilator to ensure that there is no rectal wall involvement. Upon reaching the prostate base, maintain the dilator in place.

› Once the desired location at midline is confirmed, withdraw the blue dilator while holding the white introducer sheath in place.

BALLOON INSERTION

› Remove (push away) the upper (blue) protecting tube from the balloon while holding the balloon base to prevent balloon movement.

› Remove (pull it toward the handle) the lower (blue) protecting tube.

› Ensure that the balloon deployer's red knob is facing up and introduce the balloon through the white introducer sheath.

› Advance the deployer through the white introducer sheath up to the designated mark on the deployer and hold the deployer in place.

› Fill a 20 ml luer lock syringe with 17ml of warm, bubble-free saline solution and connect it to the balloon deployer.

› Fully uncover the folded balloon by pulling the white introducer sheath all the way back until it reaches the deployer handle.

› Under sagittal view, slowly fill the balloon, ensuring optimal prostate-apex through to base separation. Halfway through inflation volume, stop filling and check the balloon's position using sagittal and axial views.

  › If balloon repositioning is desired, ensure full deflation of the balloon before repositioning. Once the balloon is repositioned, follow the instructions above to fill the balloon again.

  › Once desired balloon position is confirmed, lower the US probe slightly while maintaining sufficient visibility, and slowly deflate the balloon until you reach a balloon height of ~18 mm and rectal wall thickness is >1mm.

  › Release (push forward) the red safety lock button and rotate the green knob on the balloon deployer 180° to the right. This will seal the balloon, detach the deployer from the balloon and leave the balloon sealed in situ.

› Pull out the introducer sheath and deployer.

› Verify the balloon is in correct location and is intact.

CLOSING OF INCISION

› Suture the incision.

› Perform digital rectal examination to confirm rectal mucosa integrity.

RISKS RELATED TO BIOPROTECT BALLOON IMPLANT™ SYSTEM PROCEDURE:

Risks associated with the fiducial marker and/or balloon implantation procedure include, but are not limited to:

› Fever greater than 100°F/37.7°C;
› Site bleeding - mild to moderate;
› Site hematoma - temporary, self-terminated;
› Site infection and related symptoms - Infection along the trajectory of the insertion of surgical tools, including the site of implantation;
› Rectal wall puncture / perforation;
› Abdominal tenderness;
› Burning with urination;
› Dysuria;
› Hematuria;
› Hemospermia;
› Fatigue;
› Pain;
› Nausea and vomiting;
› Constipation.

Risks specifically associated with the BioProtect Balloon Implant System include:

› Erosion through a hollow organ wall such as bowels, urinary bladder, etc.;
› Inflammatory reaction;
› Migration of the device from the desired location;
› Needle penetration into bloodstream, bladder, prostate, rectal wall, rectum or urethra or seminal vesicles;
› Premature balloon deflation;
› Urinary retention;
› Rectal urgency, tenesmus;
› Tissue necrosis;
› Abdominal tenderness;
› Burning with urination;
› Dysuria;
› Constipation;
› Defecation reflex while urinating.

The risks and benefits of implanting the BioProtect Balloon Implant System in patients with blood coagulation disorders, compromised immune systems or any other conditions that would compromise healing should be carefully considered.

Note: adverse events related to radiation are not discussed here.

STORAGE

› Until use, the BioProtect Balloon Implant System should be stored in a clean and dry area, out of direct sunlight. Maintain in ambient room temperature (typically below 25˚C/77˚F).

SHELF LIFE

› The expiry date is indicated on the package.

USE OF ORIGINAL PRODUCTS

The components of the BioProtect Balloon Implant System are designed for a specific use and complement each other. No system components may be replaced by a product from another manufacturer even if the other product or part is comparable or identical to the original product in appearance and dimensions. Any material used from other manufacturers, any structural alterations resulting from use of products from another source and/or impurities of the material as well as minor adjustments of the BioProtect Balloon Implant System or any of its components, might introduce unforeseen risks to both patient and user.

INSTRUCTIONS HOW TO COMPLETE THE IMPLANT CARD

1. Remove the Implant Card from inside the Implant Card Instructions folder which includes patient label.
2. Complete in handwriting lines and on the other side of the Implant Card
3. Hand out the Implant Card to the patient

In case of serious incident that has occurred in relation to this device report to the manufacturer and in European Union to the competent authority of the Member State in which the incident occurred.

BioProtect Ltd.

8 Tsor St.
Tzur Yigal 4486200
Israel

Mail: info@bioprotect.com

EC REP

CEpartner4U

Esdoornlaan 13, 3951 DB Maarn
The Netherlands

MedEnvoy Global B.V

Prinses Margrietplantsoen
33 Suite - 123
AM The Hague 2595
The Netherlands

CH REP

MedEnvoy Switzerland

Gotthardstrasse 28 Zug 6302
Switzerland

CE 0344

SYMBOLS ON THE PACKAGING

	Catalog Number
	Serial Number
	Date of Manufacture
	Use-by Date
	Volume
	Caution
	Consult Instructions for Use
	Sterilized using Ethylene Oxide
	Do Not Re-sterilize
	Do Not Re-use
	Fragile, Handle with Care
	Keep Dry

	Keep away from sunlight
	Do not use if package is damaged and consult instruction for use
	Manufacturer
EC REP	Authorized representative in the European Community
	Single sterile barrier system with protective packaging outside
UDI	Unique Device Identifier
MD	Medical Device
	Importer
MR	MR Safe
Rx only	“Caution: Federal law restricts this device to sale by or on the order of a physician”
CH REP	Authorized representative in the Switzerland

NOTES