



Space  OAR[®]
Hydrogel

Agenda

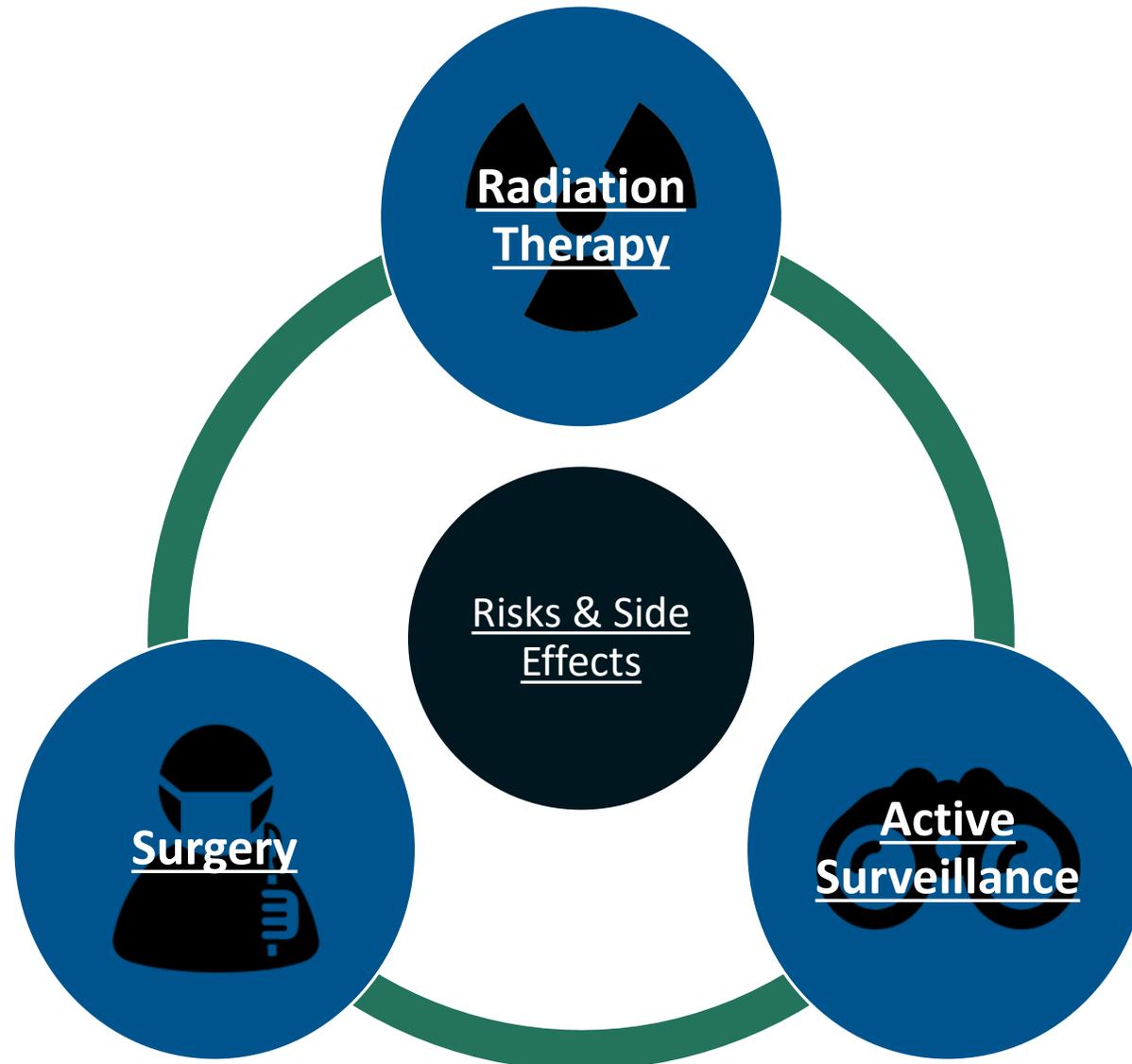
- Prostate cancer overview
- Why a prostate-rectum spacer is needed
- What is a SpaceOAR hydrogel
- Clinical Evidence

Prostate Cancer

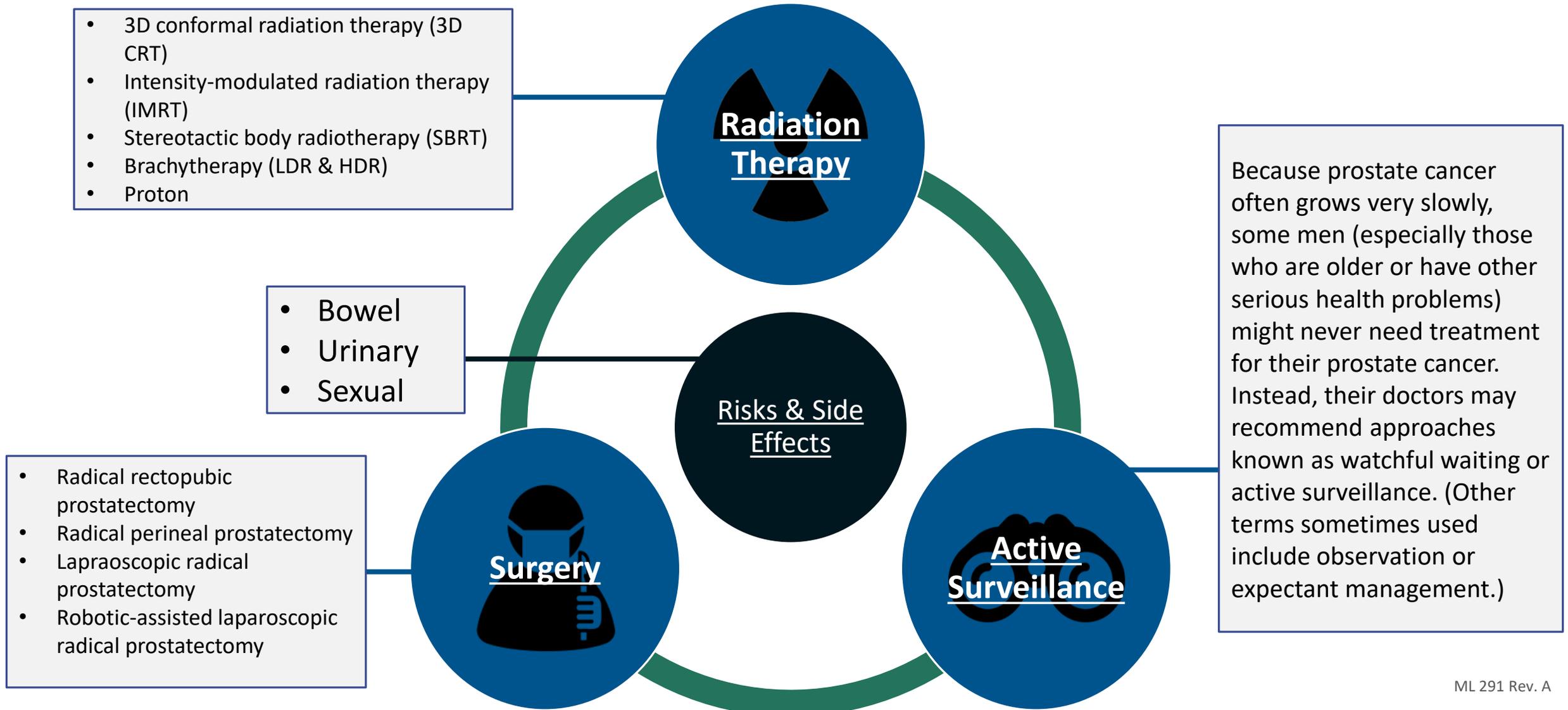
About 1 man in 9 will be diagnosed with prostate cancer during his lifetime¹

Prostate cancer is the second leading cause of cancer death in American men, behind lung cancer. About 1 man in 41 will die of prostate cancer.¹

Common Treatment Options

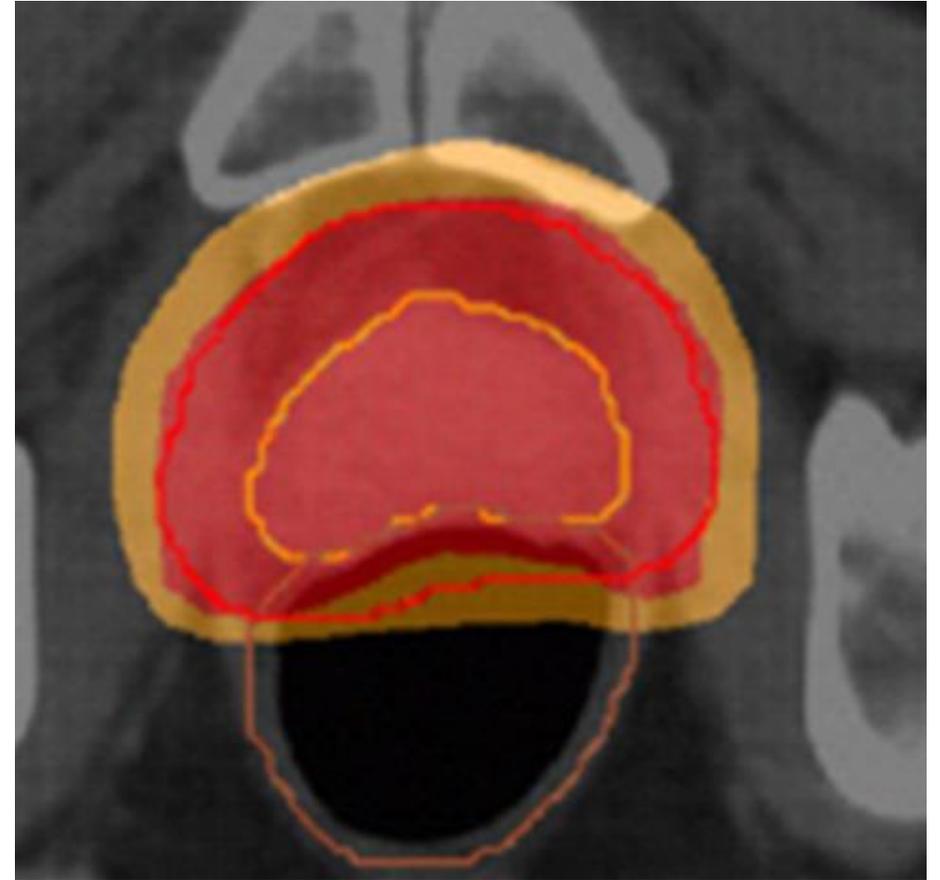


Common Treatment Options



OAR – Organ at Risk

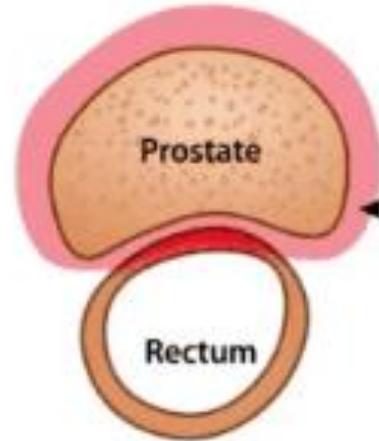
- The rectum has been the dose-limiting factor
- Rectal Toxicity / Rectal complications
 - Bleeding, frequency, urgency, pain, fistulas
- Loss of Quality of Life
 - Radiation injury can lead to bowel, urinary and sexual symptoms that can affect patient health and quality of life during RT and for years afterward



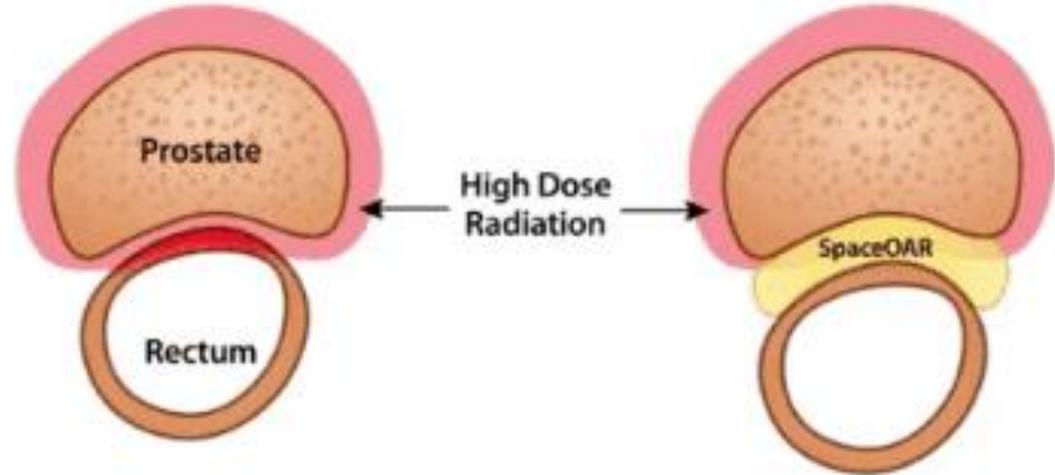
- Rectal radiation is currently unavoidable
- Close proximity to prostate
- Prostate movement between treatments
- Prostate movement during treatments

Rectum and Prostate Movement

Without SpaceOAR Hydrogel



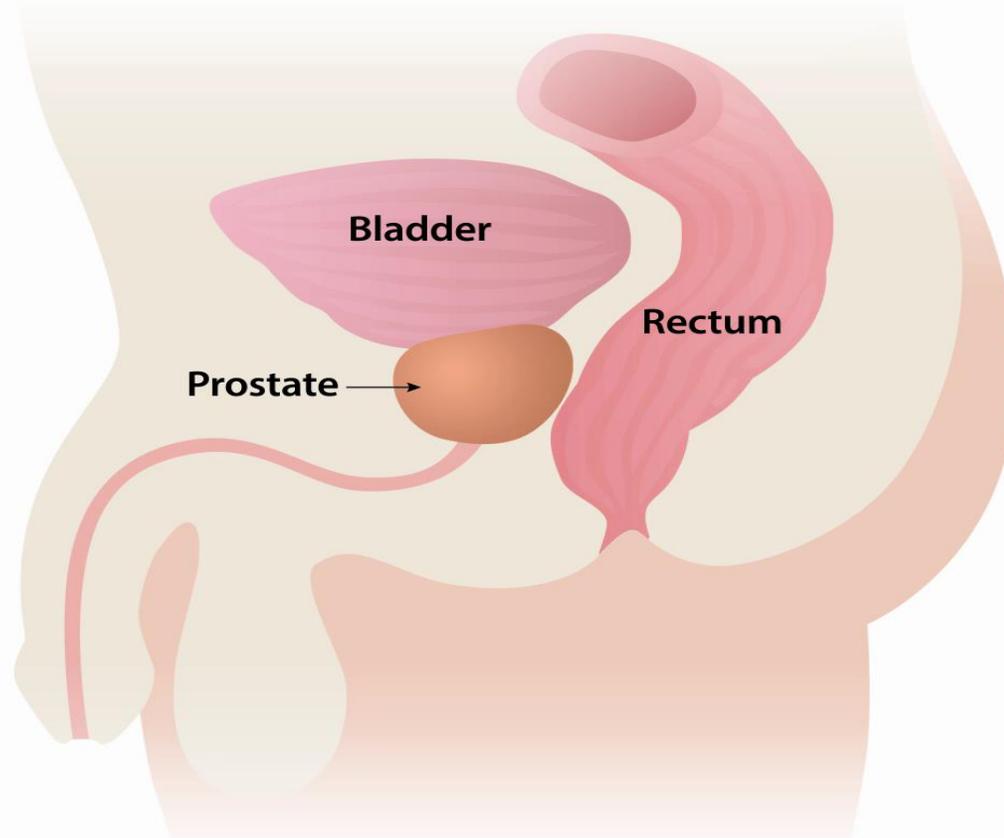
With SpaceOAR Hydrogel



High Dose
Radiation

What is SpaceOAR Hydrogel?

- Indication: SpaceOAR Hydrogel 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 SpaceOAR System to reduce the radiation dose delivered to the anterior rectum.
- Commercially available in the United States April 2015
- SpaceOAR hydrogel temporarily positions the anterior rectal wall away from the prostate creating a space of approximately 1 cm

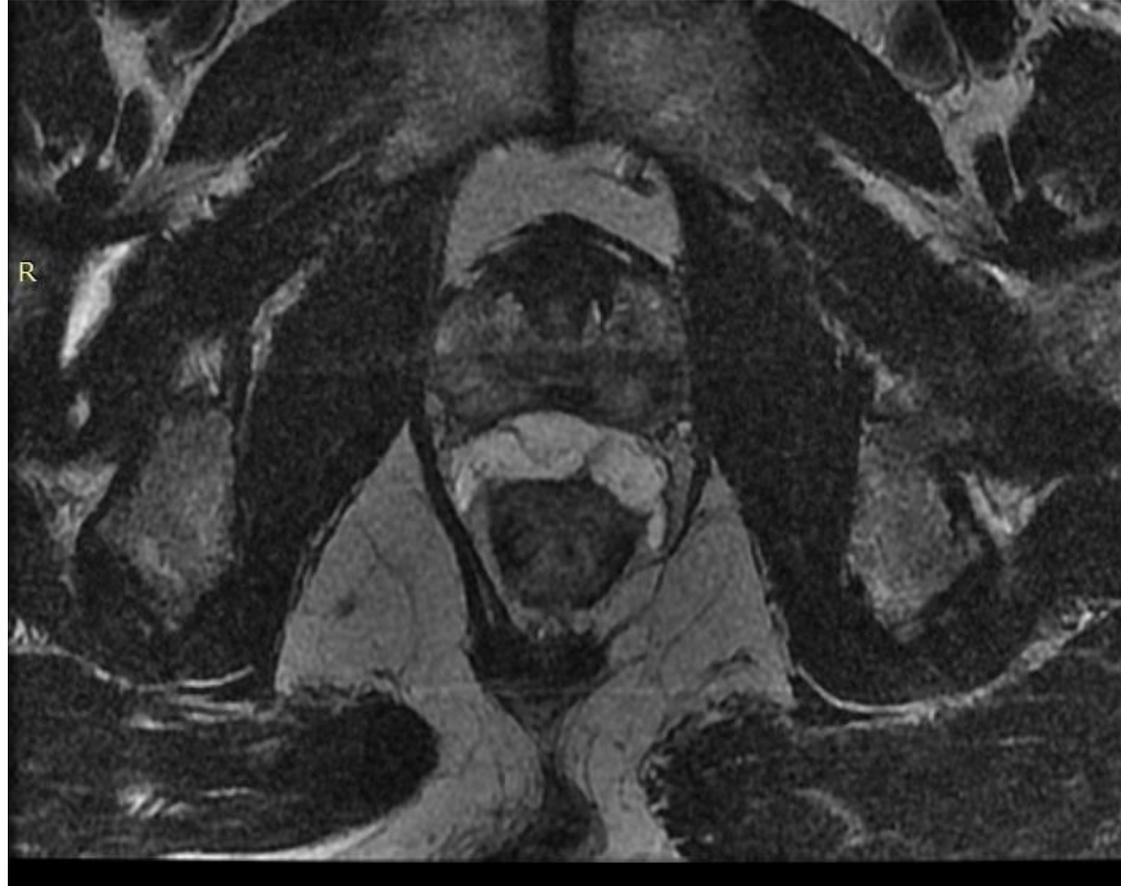


SpaceOAR hydrogel temporarily positions the rectum away from the prostate during prostate radiotherapy thereby reducing rectal wall/mucosa radiation exposure.

Anatomy Pre-Implant



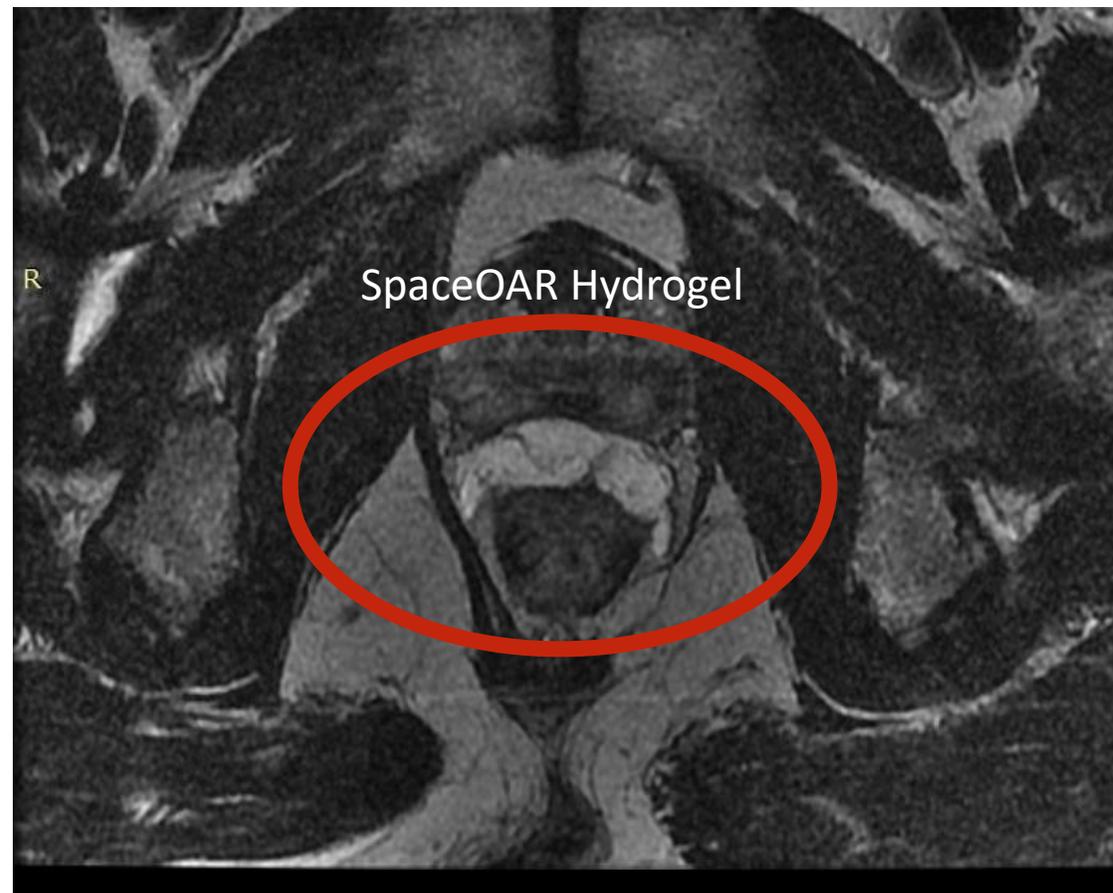
Anatomy Post-Implant



Anatomy Pre-Implant



Anatomy Post-Implant



Material

- Made of mostly water and polyethylene glycol (PEG)
- PEG is used in many medical products including artificial tears, prescription drugs, and medical implants
- Synthetic, biocompatible, non-toxic
- Absorbs in approximately 6 months

Procedure

- Outpatient procedure
- Local, regional or general anesthesia

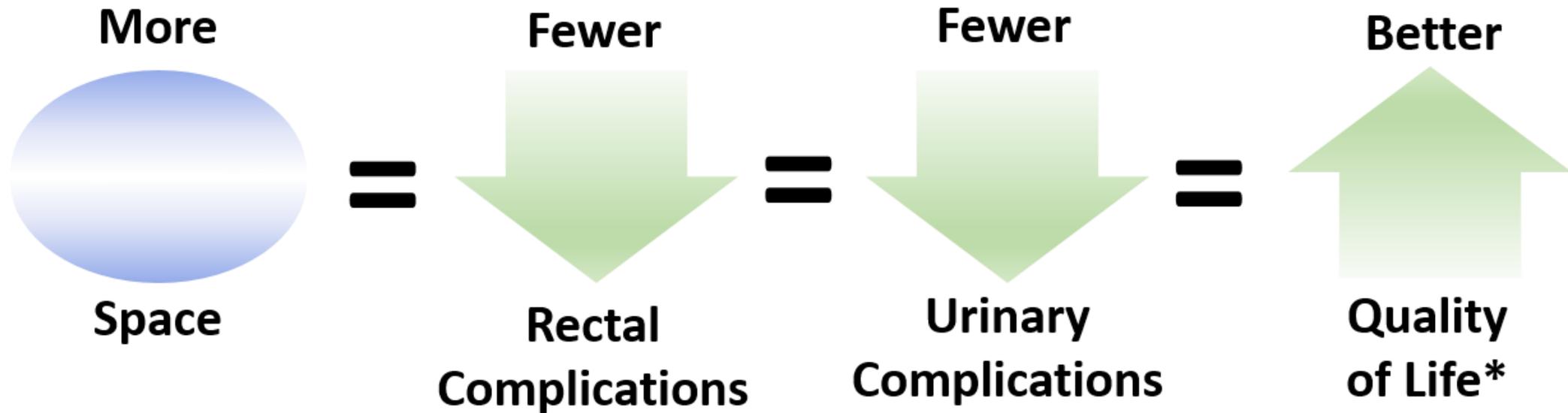
Clinically Proven

- SpaceOAR hydrogel provides space between the rectum and the prostate, reducing high dose radiation to the rectum.
- Control patients were: 8x more likely to have a decline in bowel, urinary and sexual quality of life when compared to SpaceOAR patients at median 3 years^{1,2}

1) Hamstra D, et al. Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial. Int J Radiation Oncol Biol Phys, Vol. 97, No. 5, pp. 976-985, 2017

2) Hamstra D, et al. Evaluation of sexual function on a randomized trial of a prostate rectal spacer. J Clin Oncol 35, 2017 (suppl 6S; abstract 69)

Clinical Results



*After radiotherapy was complete, control patients experienced a clinically significant (1X MID) decline in bowel, urinary and sexual QOL 8 times more often than SpaceOAR patients.^{1,2}

1) Hamstra D, et al. Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial. *Int J Radiation Oncol Biol Phys*, Vol. 97, No. 5, pp. 976-985, 2017

2) Hamstra D, et al. Evaluation of sexual function on a randomized trial of a prostate rectal spacer. *J Clin Oncol* 35, 2017 (suppl 6S; abstract 69)

SpaceOAR Hydrogel Facts



- 60+ Peer Reviewed Publications



- Used in many of the leading cancer centers in the United States



- Over **25,000** patients treated worldwide



- Reimbursed by Medicare in most States

Frequently Asked Questions

Why Should I Have SpaceOAR Hydrogel?

The goal of radiation therapy is to maximize radiation to the prostate and to avoid radiating surrounding normal tissue. The prostate and rectum are very close and are only naturally separated by a small space. Due to this closeness, prostate radiation therapy can accidentally cause damage to the rectum. SpaceOAR hydrogel is a gel-like material that temporarily moves the rectal wall away from the prostate during radiotherapy. By separating the prostate from the rectum, SpaceOAR hydrogel reduces radiation dose delivered to the rectum and may eliminate or reduce damage to the rectum. It may also allow your doctor to enhance radiation treatment to your prostate to better target the cancer or to reduce the total number of treatment sessions.

Is SpaceOAR Hydrogel Safe?

SpaceOAR hydrogel is made of two liquids that when combined form a soft gel-like synthetic material that is mostly made of water. Because of its water content it is called a hydrogel. The material that the SpaceOAR hydrogel is made from has been used in other implants such as surgical sealants used on the eye, brain and spine. Studies have shown that the material is biocompatible and can be used safely in the body. SpaceOAR hydrogel is commercially available in the United States and approved in countries outside the United States.

What Are the Risks?

SpaceOAR 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 SpaceOAR hydrogel to reduce the radiation dose delivered to the anterior rectum. The SpaceOAR hydrogel is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment. It is completely absorbed by the patient's body over time.

Clinical data comparing patients with and without SpaceOAR hydrogel demonstrated the benefits of SpaceOAR hydrogel to include reduction of rectal toxicity resulting in improved bowel function, improvements in urinary function, and a higher likelihood to maintain sexual function.

Potential complications associated with SpaceOAR hydrogel include but are not limited to pain associated with SpaceOAR hydrogel injection; pain or discomfort associated with SpaceOAR hydrogel, needle penetration of the bladder, prostate, rectal wall, rectum, or urethra; injection of SpaceOAR hydrogel into the bladder, prostate, rectal wall, rectum, or urethra; local inflammatory reactions; infection; injection of air, fluid or SpaceOAR hydrogel intravascularly; urinary retention; rectal mucosal damage, ulcers, necrosis; bleeding; constipation; and rectal urgency.

Visit [SpaceOAR.com](https://www.spaceoar.com) For More Information