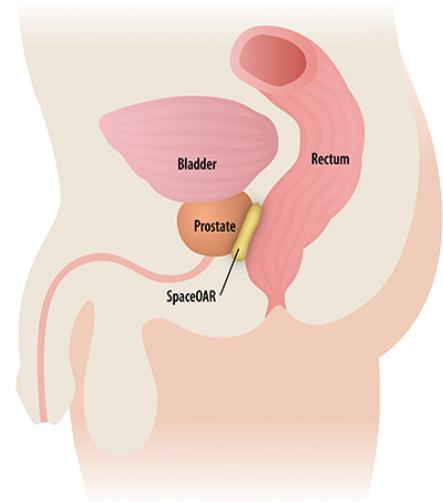


## What is SpaceOAR Hydrogel?

SpaceOAR hydrogel is an absorbable hydrogel that temporarily creates space between the prostate and the rectum, protecting the rectum from radiation exposure during prostate radiation therapy.

SpaceOAR® hydrogel **minimizes the side effects** of prostate cancer radiation therapy and **protects your quality of life**.



## Frequently Asked Patient 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.<sup>1</sup>

### Is It 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.

### What is the Procedure Like and How Long Will it Stay in My Body?

The procedure is commonly done in a hospital, surgery center, outpatient clinic or doctor's office. While there is no required special preparation for the SpaceOAR hydrogel procedure, your doctor may give you individual instructions on how to prepare for the procedure and for any anesthesia you will receive. Always ask your doctor what you should do in advance of the procedure. Your doctor will either use an anesthetic that will put you to sleep during the procedure or a local anesthetic that will numb the injection area. You may feel a pinprick or pressure but should not feel any major discomfort. After the procedure you may experience some temporary discomfort at the injection site. SpaceOAR hydrogel patients typically report no prolonged discomfort from the implanted hydrogel. You should be able to immediately resume your normal activities. Always be sure to check with your doctor for any restrictions associated with the procedure and your radiation treatment. SpaceOAR hydrogel separates your prostate and rectum for about 3 months providing protection during radiation treatment and is naturally absorbed in about six months – well after your last treatment.<sup>1</sup>

## 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.

---

**“During my eight weeks of radiation treatment and it’s now been over a year since, at no time did I experience any rectal side effects, no pain or discomfort, no bleeding, no incontinence - so very glad I decided to have SpaceOAR.”**

- Larry, a SpaceOAR patient

---

## SpaceOAR Hydrogel Can Help Ease the Side Effects of Prostate Cancer Radiation Therapy

If you or a loved one has been diagnosed with prostate cancer, you may be considering radiation therapy for treatment. Radiation therapy is extremely effective in targeting and treating prostate cancer, but as with any procedure there are potential side effects. Side effects can be mild and go away on their own, but for some patients they can last for years after treatment is completed & can have a profoundly negative impact on quality of life.

### Side Effects of Prostate Cancer Radiation Therapy Can Include:

- Rectal pain and bleeding
- Urinary urgency and leakage
- Chronic diarrhea
- Erectile dysfunction

## Follow-up Patient Result

Three years after treatment, patients from the study were asked to report on their Quality of Life for bowel, urinary and sexual functions. These patient-reported outcomes showed that SpaceOAR hydrogel patients experienced significantly fewer long-term rectal side effects, were more likely to maintain sexual function<sup>2</sup>, and had significantly higher patient reported scores for urinary and bowel Quality of Life<sup>3</sup>.

To learn more about SpaceOAR hydrogel please talk with your doctor. This guide is not intended to be a substitute for a thorough discussion with your doctor. Call us directly at **781-906-0325** to learn more.

1. Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. Mariados, Neil et al. International Journal of Radiation Oncology • Biology • Physics , Volume 92 , Issue 5 , 971 - 977
2. Sexual quality of life following prostate intensity modulated radiation therapy (IMRT) with a rectal/prostate spacer: Secondary analysis of a phase 3 trial. Hamstra, Daniel A. et al. Practical Radiation Oncology , Volume 8 , Issue 1 , e7 - e15
3. Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. Hamstra, Daniel A. et al. International Journal of Radiation Oncology • Biology • Physics , Volume 97 , Issue 5 , 976 - 985