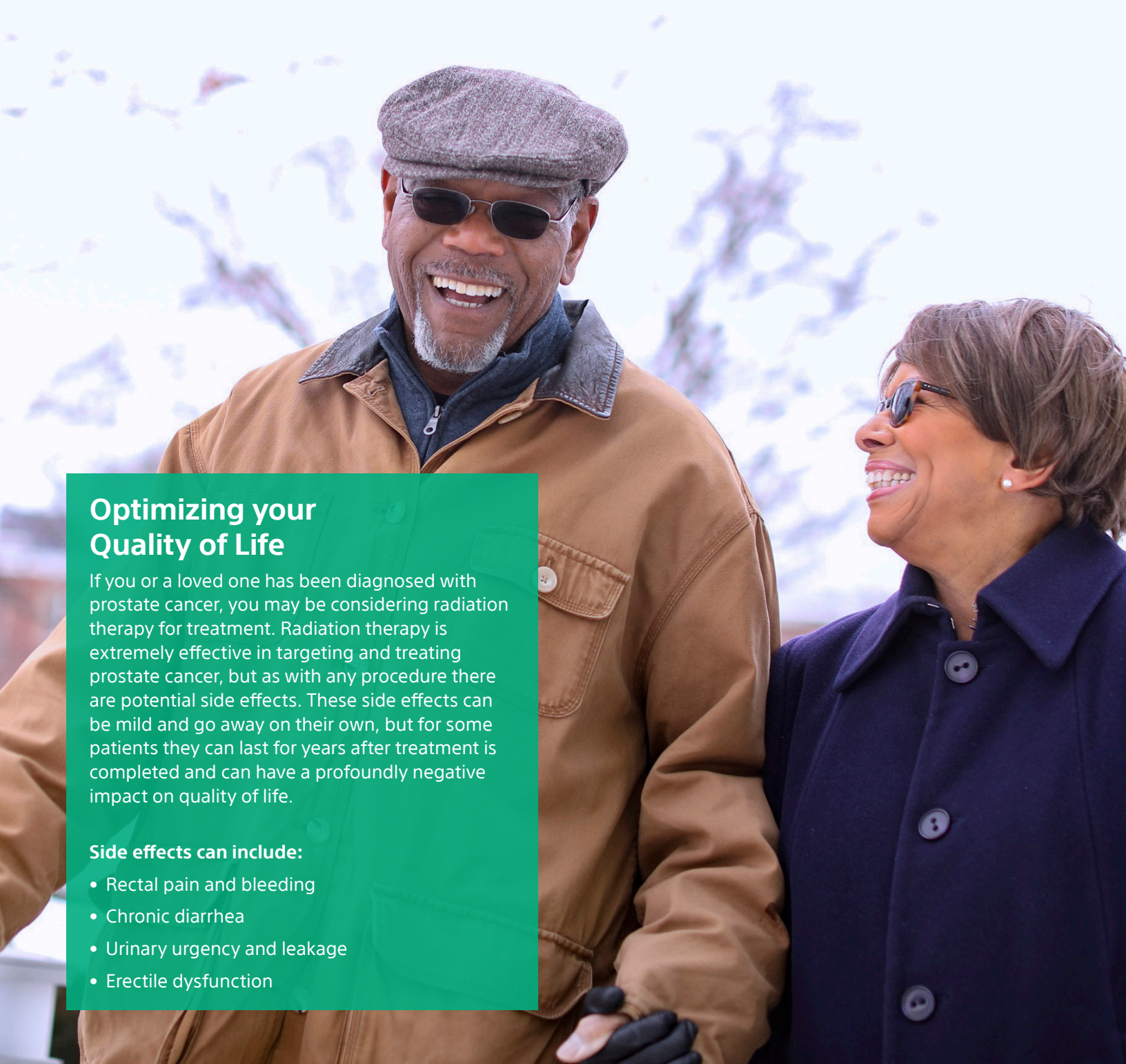


Space0AR™ Hydrogel

PATIENT INFORMATION ABOUT

**Minimizing potential side
effects of prostate cancer
radiation therapy**





Optimizing your Quality of Life

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. These side effects can be mild and go away on their own, but for some patients they can last for years after treatment is completed and can have a profoundly negative impact on quality of life.

Side effects can include:

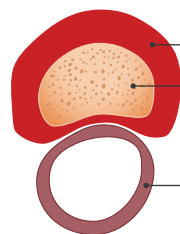
- Rectal pain and bleeding
- Chronic diarrhea
- Urinary urgency and leakage
- Erectile dysfunction



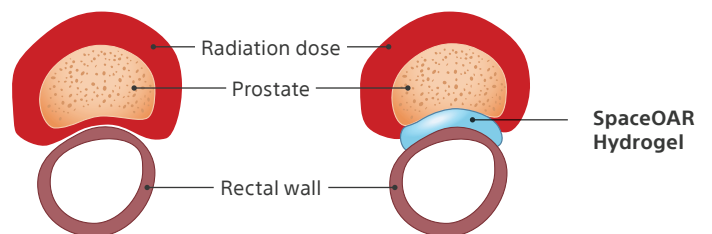
What is SpaceOAR™ Hydrogel?

SpaceOAR Hydrogel is an absorbable hydrogel that temporarily creates space between the prostate and the rectum, reducing the radiation dose delivered to the rectum during prostate radiation therapy.

Without SpaceOAR Hydrogel



With SpaceOAR Hydrogel



Frequently asked questions



Why should I have SpaceOAR™ Hydrogel?

When treating prostate cancer patients with radiation therapy, the goal is to kill the cancer cells while avoiding damage to surrounding healthy tissue. The prostate is next to the rectum and naturally separated by a small space. Due to the proximity, prostate radiation therapy can unintentionally cause damage to the rectum, which can lead to issues with bowel function. The “OAR” in SpaceOAR stands for “organ at risk,” and with radiation therapy to the prostate, this organ is the rectum.

How will SpaceOAR Hydrogel help me?

By acting as a spacer, the hydrogel temporarily moves the rectum a half inch (1.3 cm) away from the prostate.¹ By separating the prostate from the rectum, SpaceOAR Hydrogel reduces the radiation dose delivered to the rectum and may eliminate or decrease damage.

What is it made of?

SpaceOAR Hydrogel is made up of two liquids that when combined form a soft gel material that is mostly made of water. The material that the SpaceOAR Hydrogel is made from has been used in other implants such as surgical sealants used in the eye, brain and spine.

Where is the procedure done and how long does it take?

SpaceOAR Hydrogel can be implanted as an outpatient procedure in a hospital, surgery center, outpatient clinic or doctor’s office prior to the start of radiation treatment. It is typically not a lengthy procedure.

“ I would definitely recommend the SpaceOAR. For me it has had very little consequences, either the day of the treatments, the weeks and months afterward, several years afterward.”

Henry, a SpaceOAR Hydrogel patient

In what type of prostate cancer radiation treatment can SpaceOAR Hydrogel be used?

SpaceOAR Hydrogel can be used in all types of radiation therapy. Here are the four most common types:

External radiation (or external beam radiation therapy – EBRT) uses a machine that directs high-energy rays (or photons) from outside of the body into the tumor. Most patients get external radiation therapy over many weeks, during outpatient visits to a hospital or treatment center.

Internal radiation, also called brachytherapy, involves putting a radioactive source inside the body into or near the tumor.

Stereotactic body radiation therapy (SBRT) uses advanced imaging techniques to deliver extremely precise, very intense doses of radiation to the prostate (usually in up to five treatments over a period of days).

Proton beam therapy uses proton particles in lieu of x-rays or photons.

Frequently asked questions

How is SpaceOAR™ Hydrogel implanted (put into place)?

The SpaceOAR Hydrogel is injected as liquid through a small needle inserted between the rectum and the prostate. Your doctor will use ultrasound imaging to ensure correct placement.

What do I need to do to get ready before the procedure?

Your doctor will give you instructions on how to prepare for the procedure and information about any anesthesia you will receive.

Will I be awake or asleep during the procedure?

SpaceOAR Hydrogel can be implanted under local, regional or general anesthesia. You should discuss with your doctor which type of anesthesia will work best for you.

Will I feel any discomfort or pain during or after the procedure?

Your doctor will use a local, regional or general anesthesia and the injection site will be numbed, so you may feel a pinprick or pressure but should not feel any discomfort. Following the implantation, you may experience some temporary discomfort at the injection site. SpaceOAR Hydrogel patients typically report no prolonged discomfort from the implanted gel.

How soon after the procedure can I return to my normal activities?

You should be able to go back to your normal activities soon. Check with your doctor about anything you should avoid after the procedure and during your radiation treatments.

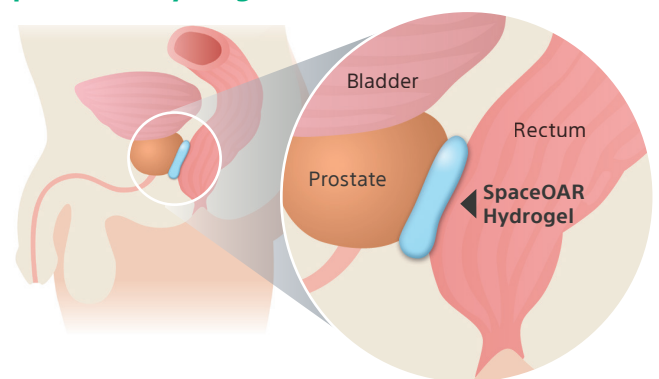
How long will SpaceOAR Hydrogel remain in my body?

SpaceOAR Hydrogel stays in place, separating your prostate and rectum, for about 3 months. After about 6 months, the hydrogel is naturally absorbed into the body and removed in your urine.

What are the risks associated with SpaceOAR Hydrogel?

As with any medical treatment, there are some risks involved with the use of SpaceOAR Hydrogel. 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.

SpaceOAR Hydrogel



Has SpaceOAR Hydrogel been clinically tested?

SpaceOAR Hydrogel has been evaluated in many clinical studies and shown to be effective in reducing radiation to organs at risk.

In the U.S., 222 prostate cancer patients participated in a multi-center, randomized, patient-blinded clinical study. Study results showed that the hydrogel was safe and effective. The average SpaceOAR Hydrogel study patient gained ½ inch (1.3 cm) of space between the prostate and rectum, and had significant reduction in radiation dose to the rectum resulting in significantly fewer rectal side effects.¹

Follow-up study

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, and showed significantly lower decline in patient-reported urinary and bowel quality of life.^{2,3}

To read the peer-reviewed clinical studies and other publications, please go to spaceoar.com/clinicals.

A little space makes a **big** difference™

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.



To find a doctor offering SpaceOAR Hydrogel visit spaceoar.com/find-a-doctor or if you have questions, please give us a call at **781-386-4682**.

1. Mariados N, Sylvester J, Shah D, et al. 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. *Int J Radiat Oncol Biol Phys*. 2015 Aug 1;92(5):971-7.
2. Hamstra DA, Mariados N, Sylvester J, et al. Continued benefit to rectal separation for prostate radiation therapy: Final results of a phase III trial. *Int J Radiat Oncol Biol Phys*. 2017 Apr 1;97(5):976-85.
3. Hamstra DA, Mariados N, Sylvester J, et al. Sexual quality of life following prostate intensity modulated radiation therapy (IMRT) with a rectal/prostate spacer: Secondary analysis of a phase 3 trial. *Pract Radiat Oncol*. 2018 Jan - Feb;8(1):e7-e15.

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Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

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Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

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