

# SpaceOAR™ Hydrogel



## What is SpaceOAR Hydrogel?

SpaceOAR Hydrogel is an absorbable gel that is designed to create a temporary space between the prostate and the rectum, reducing the radiation dose delivered to the rectum during prostate cancer radiation treatments.<sup>1</sup>

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.

SpaceOAR Hydrogel is inserted during a minimally invasive procedure and remains in place until radiation therapy is complete, then is naturally absorbed and cleared from the body in the patient's urine.

## Why is it important for patients?

By pushing the prostate further from the rectum, the radiation dose delivered to the rectum is reduced, which may lessen damage to the rectum. With SpaceOAR Hydrogel in place, a doctor can complement the patient's radiation treatment to better target their cancer while preserving healthy tissue to help maintain quality of life.<sup>1-3</sup>

## How many patients have received the SpaceOAR Hydrogel?

More than 50,000 patients worldwide have been treated with SpaceOAR Hydrogel.

## What research has been done?

A clinical study demonstrated the benefits of SpaceOAR Hydrogel, including a reduction of radiation dose to the rectum resulting in maintained bowel function.<sup>1</sup>

In the study, men who underwent radiation therapy without SpaceOAR Hydrogel were eight times more likely to experience a decline in bowel, urinary and sexual function when compared to men who underwent radiation therapy with SpaceOAR Hydrogel at a median follow-up of three years.<sup>2</sup>



## How prevalent is prostate cancer?



Prostate cancer is the most common cancer among American men, with **more than 183,000 new cases diagnosed each year.**<sup>4</sup>

More than

# 60,000

American men opt to treat their prostate cancer with radiation every year.<sup>3</sup>



## What is the procedure like and where can it be done?

SpaceOAR Hydrogel is injected as a liquid through a needle inserted between the rectum and the prostate. It can be implanted via a local anesthetic that will numb the injection area or under general anesthesia that will put a patient to sleep during the procedure. SpaceOAR Hydrogel stays in place for about three months and is naturally absorbed into the body and removed through urine in about 6 months.

SpaceOAR Hydrogel can be implanted during 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 – usually about 30 minutes.

## What is the hydrogel made of?

SpaceOAR Hydrogel is made up of two liquids that, when combined, form a soft gel material mostly made of water. Studies have shown that the material is biocompatible, that it can be used in the body without causing injury or a reaction, and it can also be safely absorbed by the body. 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.

## For more information, visit [SpaceOAR.com](http://SpaceOAR.com)

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

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 imageguided 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 D, Shah D, Kurtzman S, et al. Evaluation of sexual function on a randomized trial of a prostate rectal spacer. *J Clin Oncol.* 2017 February 20;35(Suppl 6):69.

4. Key Statistics for Prostate Cancer. American Cancer Society. <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>. Accessed February 13, 2019.

5. Treatment for Prostate Cancer: External-Beam Radiation Therapy. Prostate Cancer Foundation. <https://www.pcf.org/c/treatment-for-prostate-cancer-external-beam-radiation-therapy/>. Accessed February 13, 2019.

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