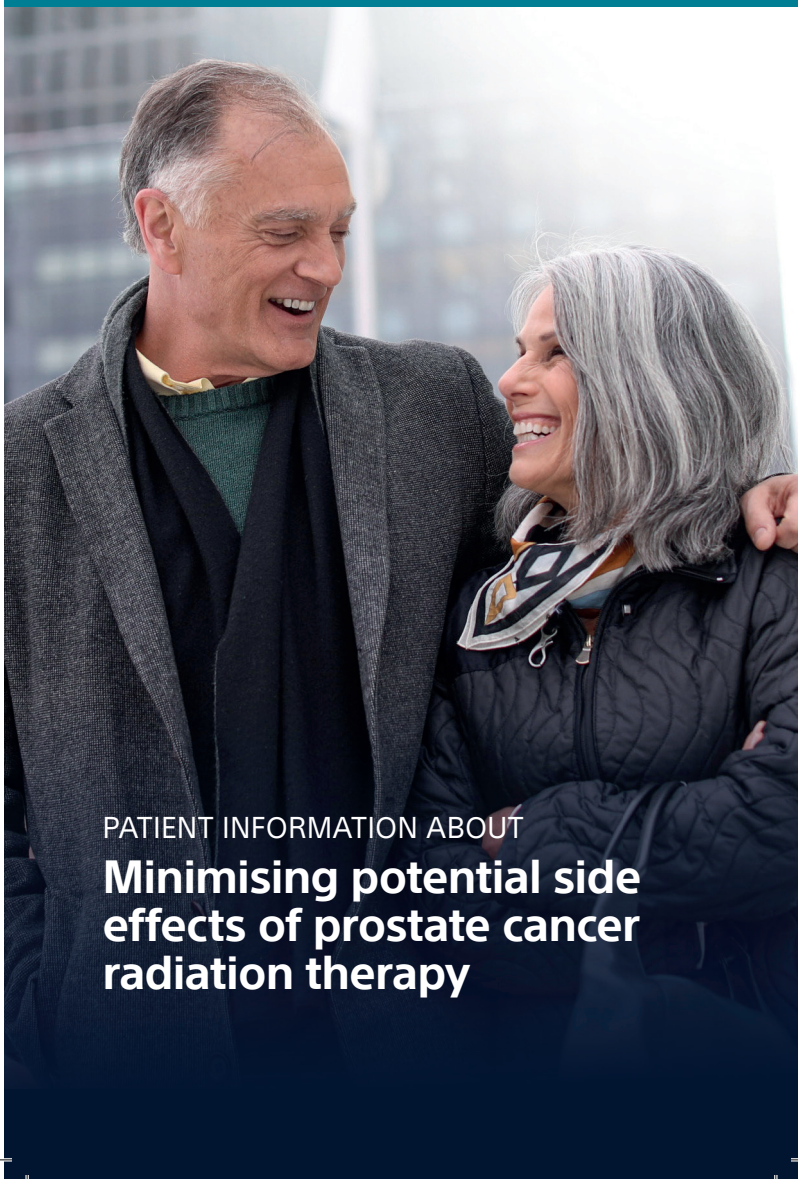


Space0AR™ Hydrogel

*'A little space makes a **BIG** difference'*



PATIENT INFORMATION ABOUT

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

Optimising 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.¹ 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:

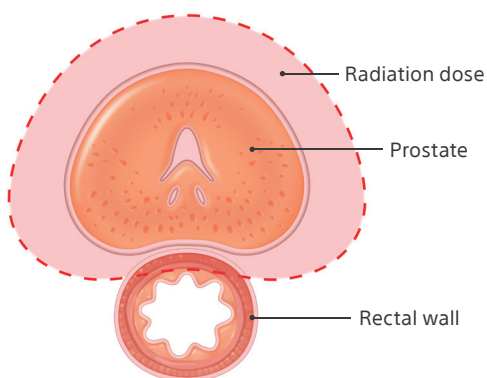
- Rectal pain and bleeding
- Chronic diarrhoea
- Urinary urgency and leakage
- Erectile dysfunction



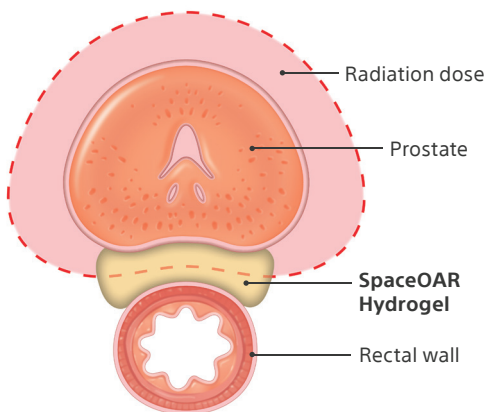
What is SpaceOAR™ Hydrogel?

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.² **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 centre, 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 or several years afterward.”

Henry, a SpaceOAR Hydrogel patient

Frequently asked questions

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

SpaceOAR Hydrogel can be used in all types of radiation therapy including external radiation, brachytherapy, stereotactic body radiation and proton beam.

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 anaesthesia you will receive.

Clinical Benefits of Hydrogel Spacing

SpaceOAR Hydrogel study patients: 67% maintained sexual potency compared to 38% in control group (at a median 3-year follow-up).^{3**}

***Of men who had erections sufficient for intercourse at baseline.*

SpaceOAR Hydrogel study patients: Experienced significantly less decline in bowel quality of life compared to control patients (at a median 3-year follow-up).²

Frequently asked questions

Will I be awake or asleep during the procedure?

SpaceOAR™ Hydrogel can be implanted under local, regional or general anaesthesia. You should discuss with your doctor which type of anaesthesia 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 anaesthesia 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.⁴

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.

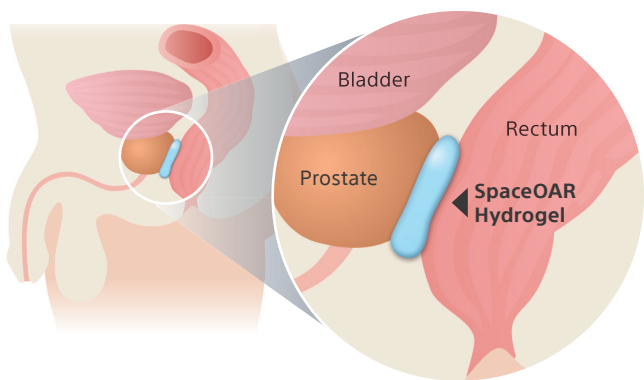
How long will SpaceOAR Hydrogel remain in my body?

SpaceOAR Hydrogel stays in place, separating your prostate and rectum, for about three months. After about six months, the hydrogel is naturally absorbed into the body and removed in your urine.²

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.⁴

SpaceOAR Hydrogel



Frequently asked questions

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-centre, randomised, 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.²

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.^{3,5}



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 centre offering SpaceOAR
Hydrogel visit **www.spaceoar.co.uk**

1. Hamdy, F.C. et.al (2016). 10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer. *New England Journal of Medicine*, 375(15), pp.1415–1424.
2. 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.
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.
4. SpaceOAR IFU, LCN 80-1010-001-en Rev L_SpaceOAR System 10mL IFU
5. 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.

The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. This material is not intended for use in France.

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