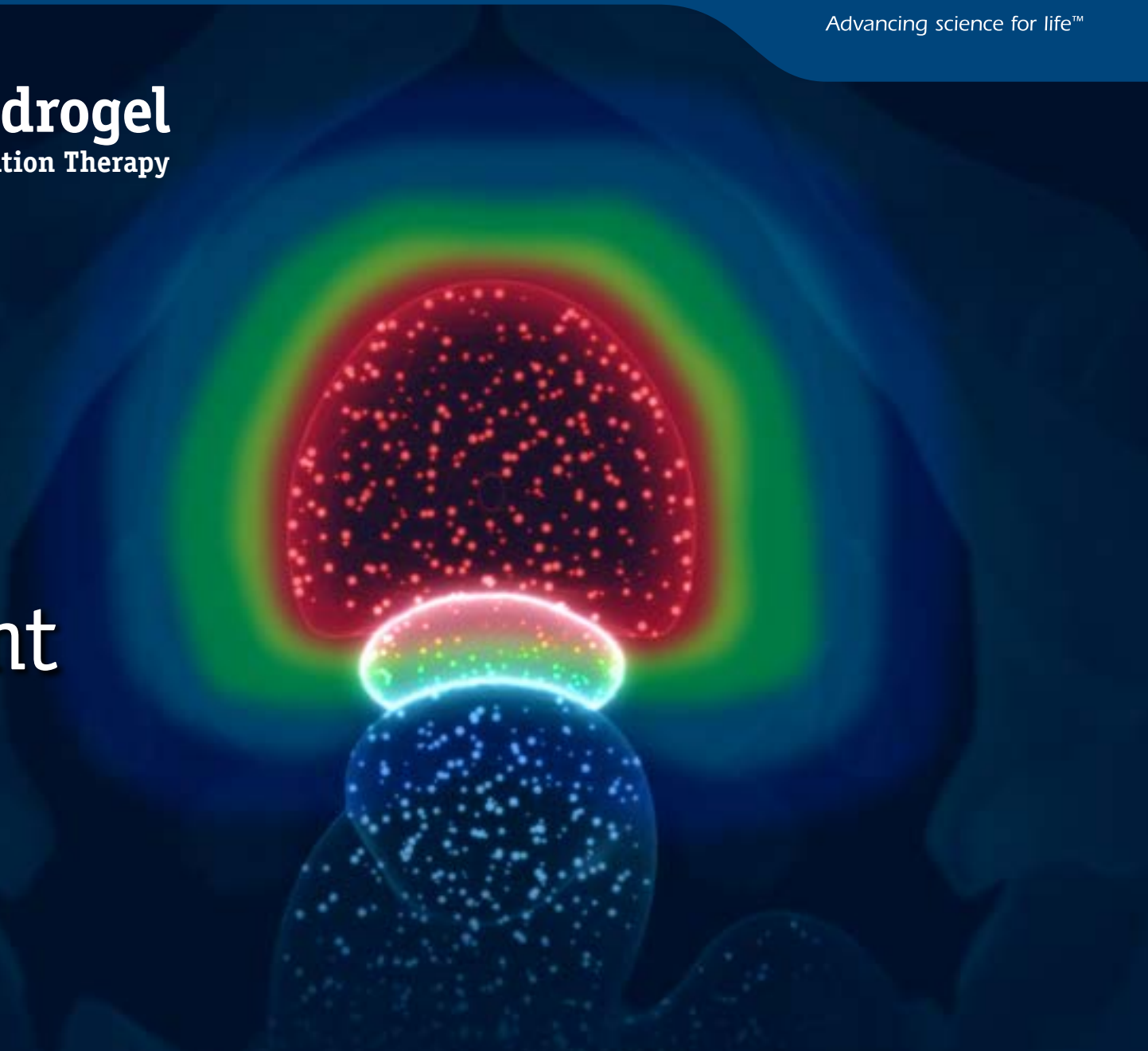


SpaceOAR Vue™ Hydrogel

Radiopaque Perirectal Spacer for Radiation Therapy

Visibly different

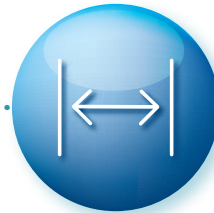




Boston
Scientific



Radiation
Therapy



Hydrogel
Spacing



SpaceOAR Vue
Hydrogel



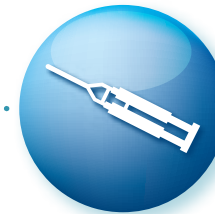
Clinical
Evidence



Procedure



MOA



Composition



Benefits



Training
and Support



Patient
Outcomes



References

Who is Boston Scientific?

As a medical technology leader for 40+ years, we advance science for life by providing a broad range of high performance solutions to address unmet patient needs and reduce the cost of healthcare¹.

We are dedicated to collaborating with healthcare professionals worldwide to develop a broad portfolio of meaningful innovations that improve patient outcomes, increase efficiencies and - most importantly - help more people in more places around the world live longer, healthier lives¹.

\$1 BILLION
INVESTED IN R&D

30M PATIENTS
TREATED EACH YEAR

120 COUNTRIES
AROUND THE WORLD

13K+ THERAPEUTIC
SOLUTIONS

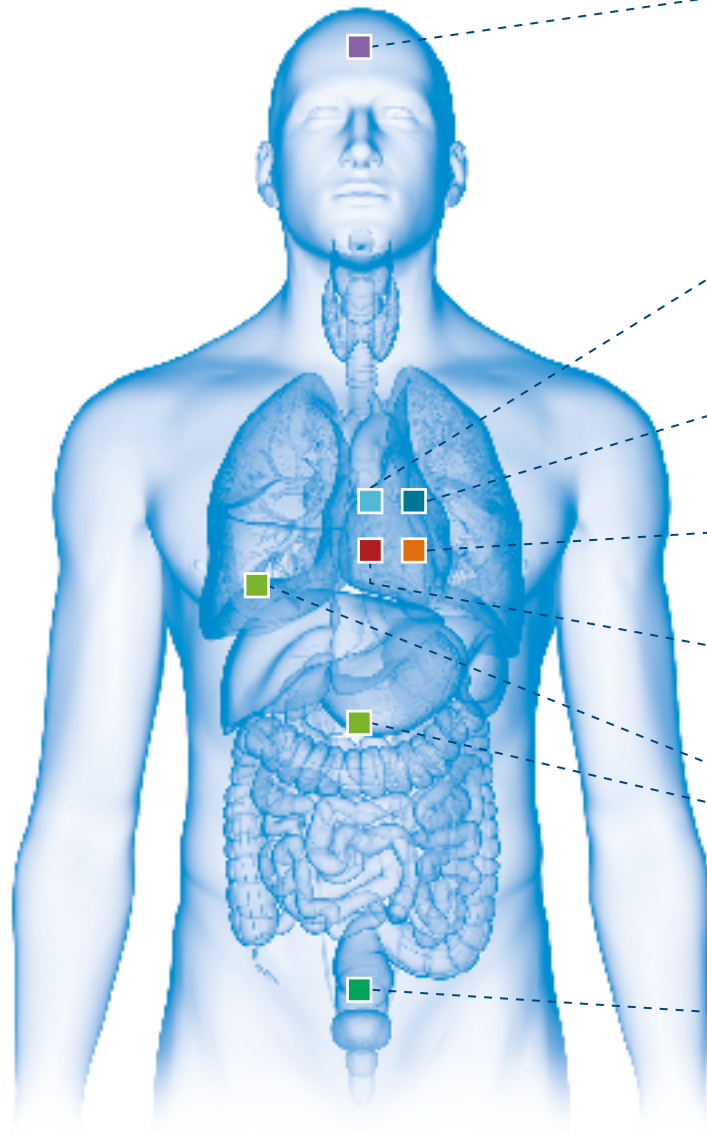
38 MANUFACTURING
CENTERS WORLDWIDE

36K EMPLOYEES

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What do we do?



■ NEUROMODULATION

Electronic implantable technologies that help patients manage debilitating chronic pain and neurological conditions

■ CARDIAC RHYTHM MANAGEMENT

Groundbreaking technologies that treat irregular heart rhythms and heart failure and help protect against sudden cardiac arrest

■ ELECTROPHYSIOLOGY

A broad range of mapping and treatment technologies for diagnosing and treating heart rhythm disorders

■ INTERVENTIONAL CARDIOLOGY

Minimally invasive innovations that help improve the lives of patients living with heart and vascular conditions

■ PERIPHERAL INTERVENTIONS

Leading devices for diagnosis and minimally invasive treatments of peripheral vascular disease and cancer

■ ENDOSCOPY

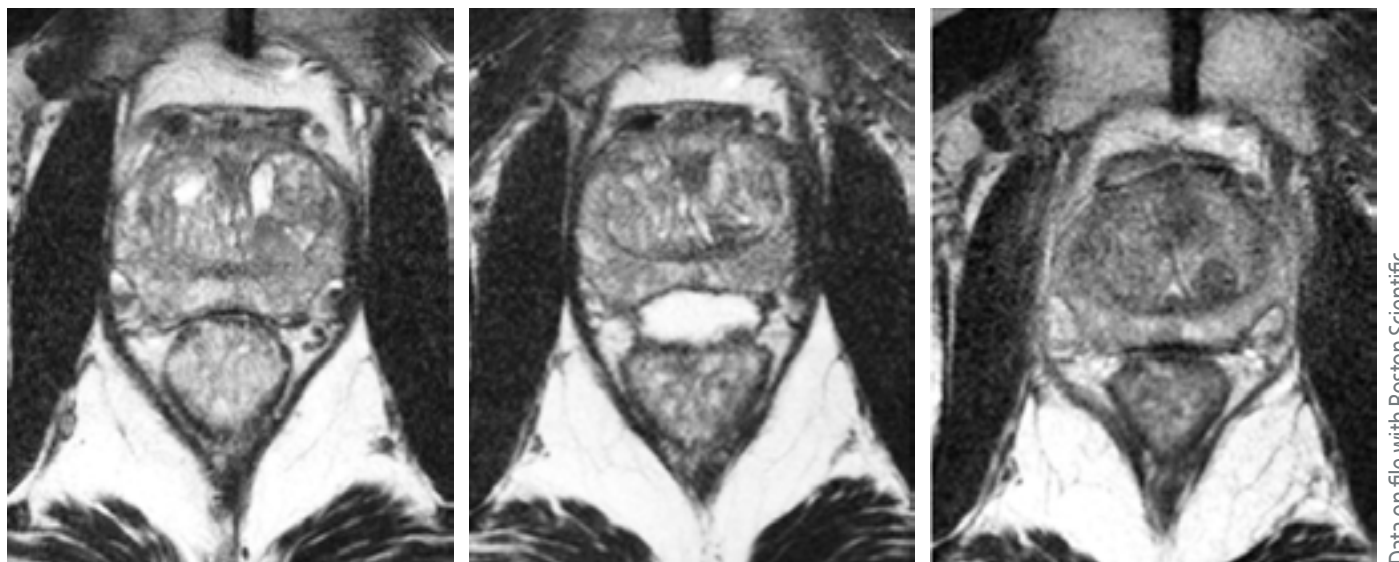
Minimally invasive devices for diagnosing and treating gastrointestinal and pulmonary conditions

■ UROLOGY AND PELVIC HEALTH

Solutions for urological and urogynecological diseases

What does Boston Scientific do in Urology and Pelvic Health?

T2-weighted magnetic resonance images of SpaceOAR Hydrogel patient¹



Pre-implant space

3-month persistence

Post-absorption

Data on file with Boston Scientific

Since the late 1980s, Boston Scientific has offered treatment options for patients suffering from urological and urogynecological diseases. Since 2018, Boston Scientific has offered a minimally invasive treatment for prostate cancer patients undergoing radiation therapy.

SpaceOAR™ Hydrogel is an absorbable hydrogel that temporarily creates space between the prostate and rectum, designed to reduce the radiation dose delivered to the rectum during prostate cancer radiation therapy².


In U.S. and European clinical trials, SpaceOAR Hydrogel has demonstrated its ability to reduce radiation delivered to organs surrounding the prostate, in particular the rectum³.

A decrease in radiation-induced toxicity has been shown to help minimise the negative impacts on urinary, sexual and bowel quality of life for prostate cancer patients undergoing prostate radiotherapy treatment¹.

What is Prostate Cancer Radiotherapy?

How does Prostate Radiation Therapy work?

One in 8 men will be diagnosed with prostate cancer in their lifetime¹. In Europe, **449,761** men are diagnosed with prostate cancer each year². Radiotherapy is a well-established and highly effective curative treatment for patients with prostate cancer³.

A prostate cancer patient who undergoes [radiotherapy](#)  will potentially suffer from side effects due to radiation³.

Due to its proximity to the prostate, the rectum is vulnerable due to ionated radiation, which can cause undesirable gastrointestinal complications⁴.

Symptoms include diarrhoea, incontinence, proctitis and ulceration of the rectal mucosa³.

Why is QoL important for prostate cancer survivors?

With more than **70%** of men surviving 10 years or longer⁵, long-term quality of life can be as important as the effectiveness of the treatment itself.

One in 10 men experienced a severe gastrointestinal complication after radical radiotherapy⁶.



What is Radiation Toxicity?

What is the Impact of Radiation Toxicity?

Randomised control trials show **11% - 25%** of men may suffer grade 2+ and above bowel complications following hypo-fractionated radiotherapy¹.

Grade 2+ rectal toxicity side effects include:

- Bowel movement >5 times a day
- Loose stools and diarrhoea
- Radiation proctitis/fistulas
- Excessive mucus discharge
- Intermittent rectal bleeding
- Urgency².



Damaged rectum after radiation therapy.



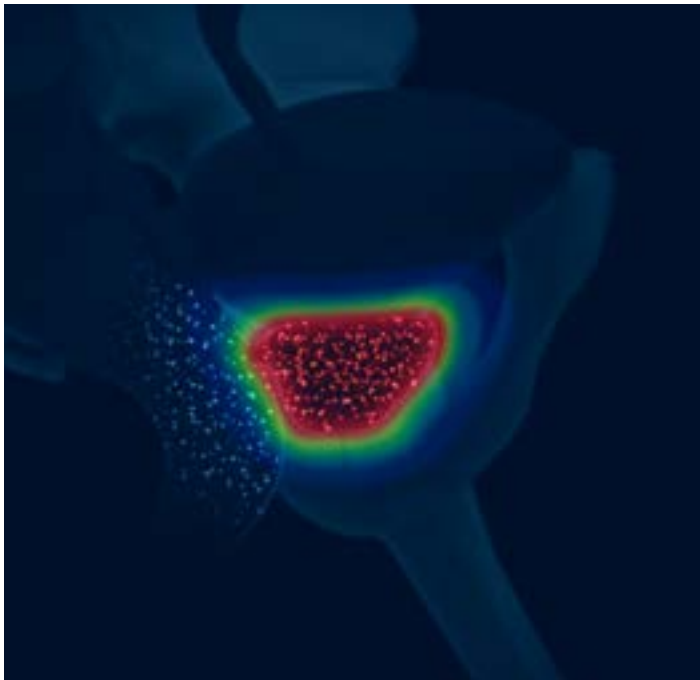
Images Data on file with Boston Scientific

What is Hydrogel Spacing?

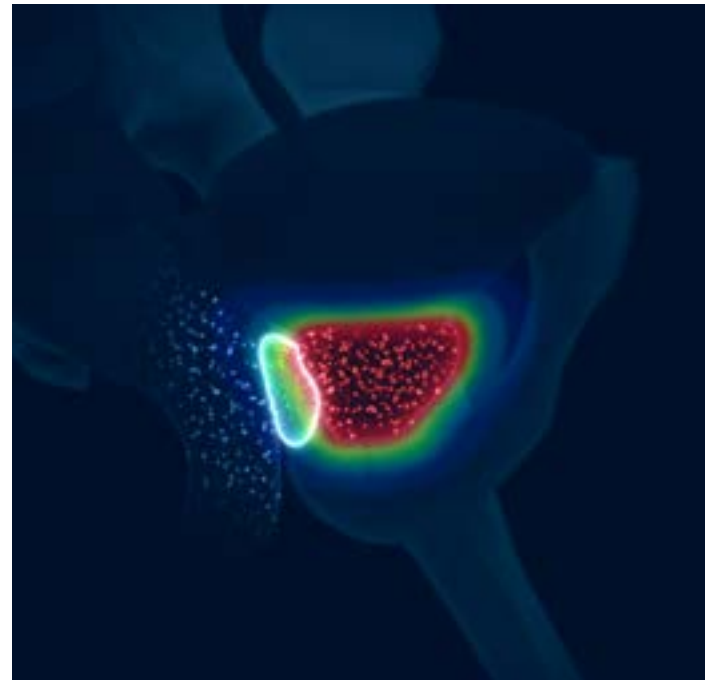
SpaceOAR Hydrogel is a hydrogel spacer intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy in prostate cancer patients¹.

In a randomised clinical study, SpaceOAR Hydrogel was shown to help minimise the impact on bowel, urinary and sexual quality of life for prostate cancer patients undergoing radiation therapy².

Anatomy without SpaceOAR System



With SpaceOAR System



What is SpaceOAR Vue Hydrogel?

SpaceOAR Vue Hydrogel is a new generation hydrogel spacer that offers enhanced visibility on CT scan and kV Cone beam¹. It is possible that clinicians obtain the same anatomical separation with SpaceOAR Vue as you are used to with SpaceOAR™ Hydrogel¹.

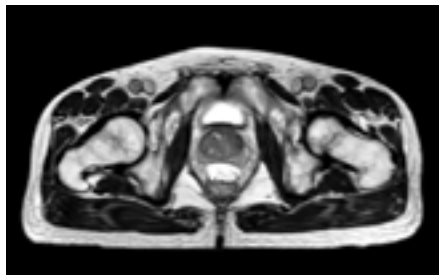
SpaceOAR Vue Hydrogel visibility on a CT scan is:

- intended to improve contouring accuracy of the prostate
- designed to help reduce under and over contouring of the prostate and rectum¹.

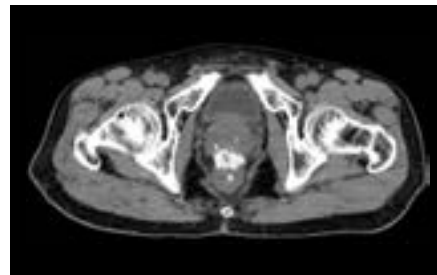
SpaceOAR Vue Hydrogel is designed to offer clinical benefits similar to SpaceOAR Hydrogel¹.

SpaceOAR Hydrogel and SpaceOAR Vue Hydrogel have been used in prostate radiation therapy, including [these types](#) 

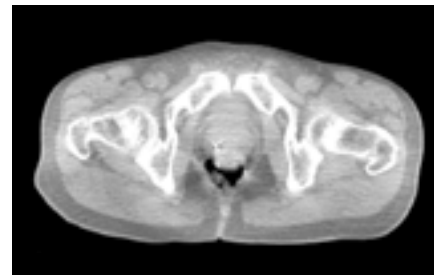
SpaceOAR Vue Hydrogel in different image modalities



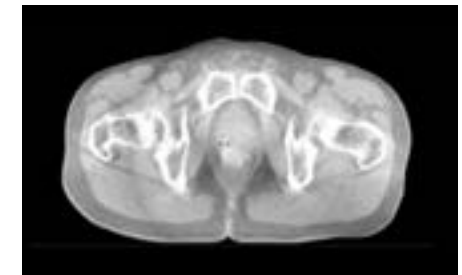
T2-weighted Magnetic Resonance image.



Computed Tomography image.



First Fraction



Last Fraction

Images courtesy of Jeff Michalski, MD (2020).
Permission granted by Washington University Imaging.

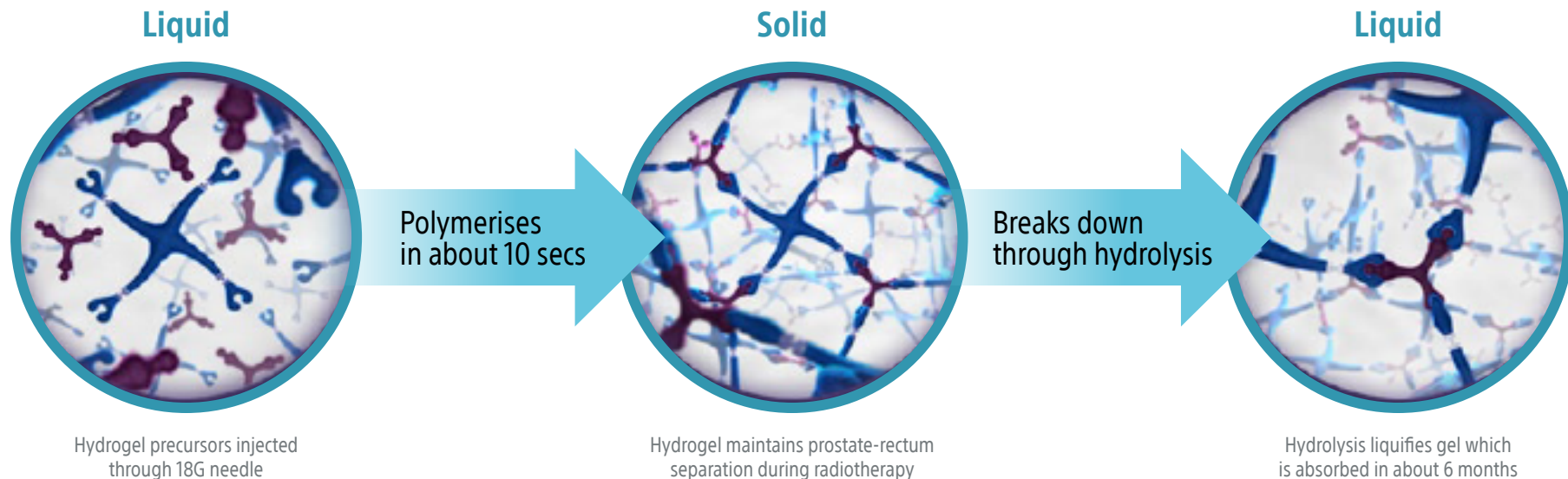
What is SpaceOAR Hydrogel Composed of?

SpaceOAR and SpaceOAR Vue Hydrogels consist of water and a Polyethylene Glycol (PEG) in a Trilysine buffer (7%) that polymerise to form a semi-solid gel material that is both highly biocompatible and biodegradable¹.

The hydrogels stay in place for about 3 months and then liquify and are naturally absorbed by the patient's body, then eliminated by the patient over 6 months¹.

In addition, SpaceOAR Vue features an iodinated polymer visible on CT scan.

Its total iodine content is <1% and its HU value is ~300.



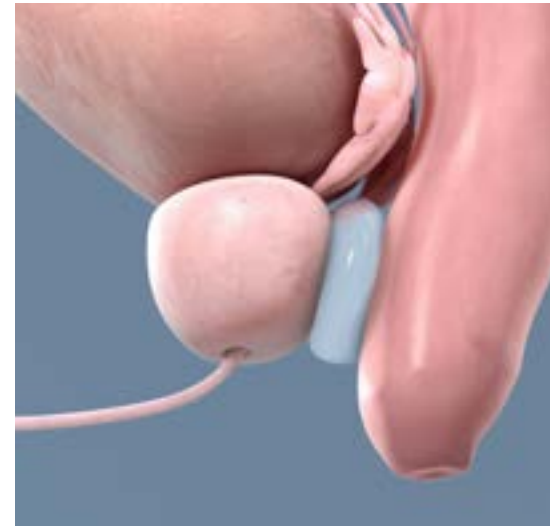
What is the Mechanism of Action of SpaceOAR Hydrogel?

SpaceOAR Vue Hydrogel, like SpaceOAR, is designed to temporarily position the anterior rectal wall 1.3 cm (half an inch) away from the prostate during radiotherapy for prostate cancer^{1,2}. In creating this space, the SpaceOAR system is intended to reduce the radiation dose delivered to the anterior rectum and the serious, radiation-induced side effects on your patient¹.



Anatomy without SpaceOAR Hydrogel

The anterior rectal wall is particularly vulnerable to radiation-induced toxic effects given its anatomical proximity to the prostate, with 2 to 3 mm of distance typically separating the organs. Thus, the rectum is the dose-limiting structure with prostate RT. Greater rectal irradiation during RT increases the risk of both early and late gastrointestinal complications³.



SpaceOAR Hydrogel with Radiation Therapy

The hydrogel spacer creates a temporary space between the rectum and prostate, decreasing the potential for rectal injury during radiation therapy¹. By creating space between prostate and rectum, the radiation dose delivered to the rectum is reduced, which may lessen damage to the rectum⁴.

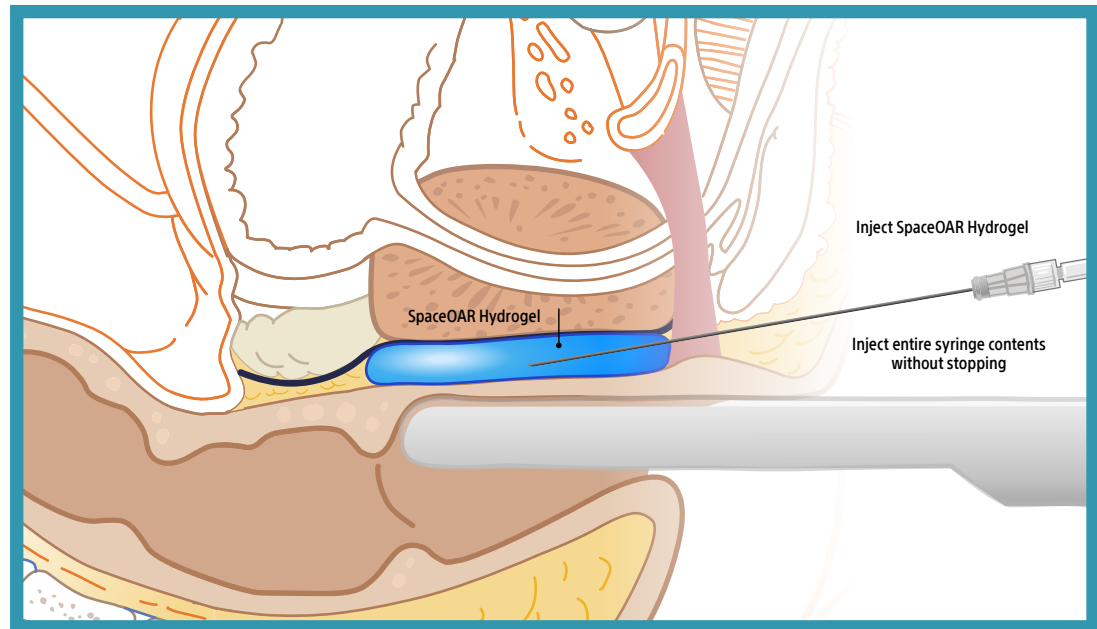
What is the Procedure?

SpaceOAR Hydrogel is injected as a liquid through an 18 G needle inserted between the rectum and the prostate.

Subsequent ultrasound imaging confirms correct placement.

The injection of SpaceOAR Hydrogel can be performed on its own or in combination with fiducial markers.

Following successful spacing, a CT scan of the prostate is made with the hydrogel spacer in position and then planning can proceed.



Is SpaceOAR Hydrogel Clinically Proven?

Lower rectal toxicity and improved bowel quality of life

To-date there are **75+** clinical publications¹ including a **222**-patient prospective multicentre randomised clinical study with 3-year follow-up data².

Clinical trials in the U.S. and Europe have demonstrated that SpaceOAR Hydrogel is safe and that the space created with hydrogel spacers significantly reduces the radiation delivered to the rectum³.

The randomised SpaceOAR Hydrogel U.S. clinical trial found statistically significant reduction in acute rectal pain in spacer patients as well as a significant reduction in late rectal toxicity severity in the spacer group⁴.

Summary

In a pooled analysis of **1,011** patients receiving radiotherapy from 7 clinical studies, SpaceOAR Hydrogel when compared to control demonstrates³:



66% less v70 rectal irradiation



77% reduction in the risk of rectal toxicity (grade ≥ 2) in late follow-up



70% reduction in the risk of rectal toxicity (grade ≥ 1) in late follow-up



Better patient bowel quality of life in late follow-up exceeding the threshold for a minimal clinically important difference (mean difference = 5.4)

Is SpaceOAR Hydrogel Clinically Studied in BRACHYTHERAPY?

Brachytherapy represents an **effective treatment** option to be considered for many men with prostate cancer. Both LDR and HDR treatments have demonstrated excellent outcomes confirmed by up to 15 years of follow-up for treating men in all risk groups of localized prostate cancer¹.

Combined with SpaceOAR Hydrogel patients could potentially experience minimised acute and long-term side-effects^{2,3}.

SpaceOAR is utilised worldwide for all types of radiation treatment. **Studies have shown the use of hydrogel spacing with all forms of Brachytherapy including Combination with EBRT significantly improves rectal and urethral dose sparring^{2,3}.**

0% Grade 2 toxicity shown with HDR-IMRT combination Brachytherapy and SpaceOAR Hydrogel vs. non-spacer group of 1.5³.

All rectal dosimetric parameters improved significantly for the cohort with spacer placement as compared with the non-spacer cohort ².

0% Acute rectal bleeding toxicity shown with LDR Brachytherapy and SpaceOAR Hydrogel vs. non-spacer group of 6.8%².

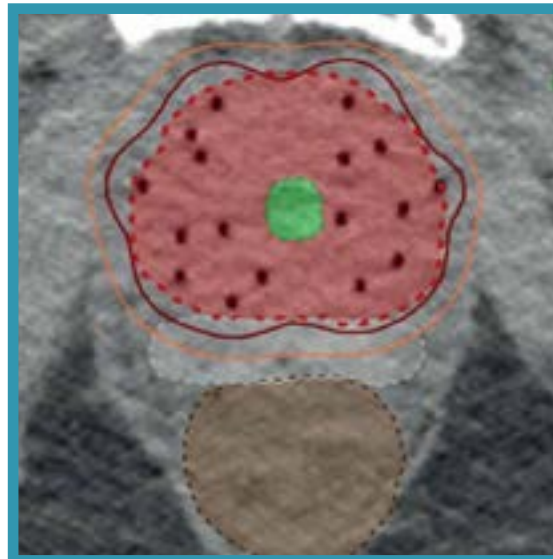


Image from Taggar AS, Charas T, Gil'ad NC, et al. Placement of an absorbable rectal hydrogel spacer in patients undergoing low-dose-rate brachytherapy with palladium-103. Brachytherapy. 2018 Mar-Apr;17(2):251-8.

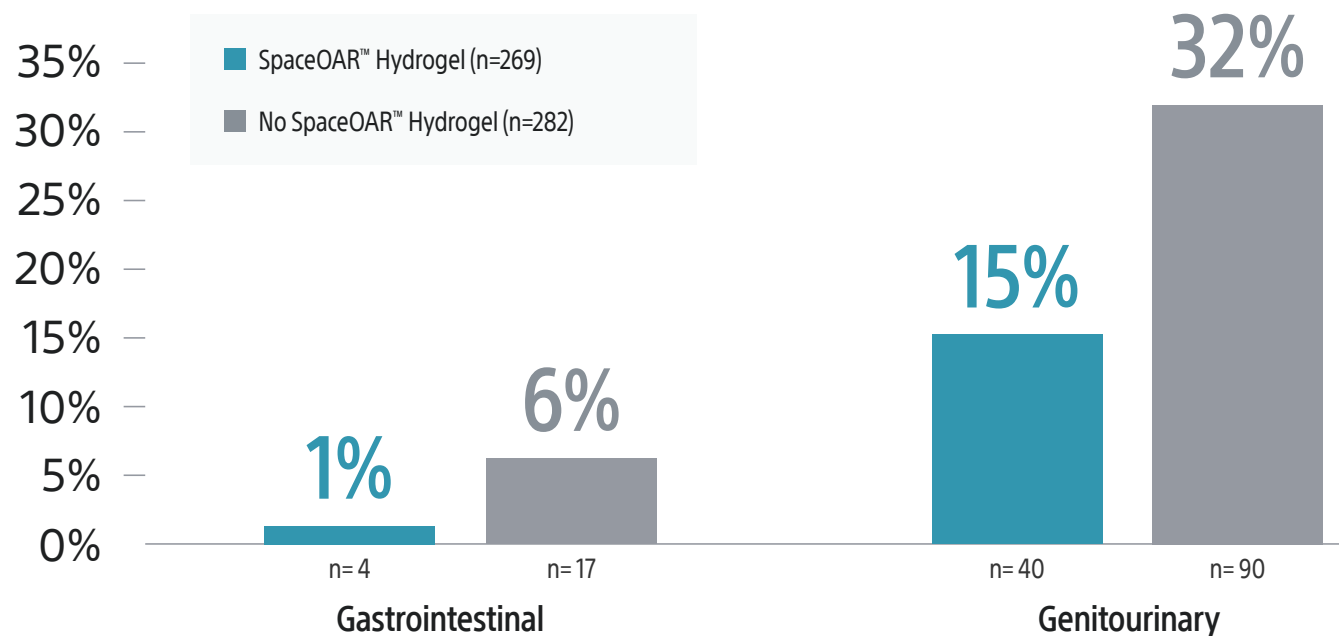
Is SpaceOAR Hydrogel Clinically Studied in SBRT?

During high-dose ultrahypofractionated radiation therapy for prostate cancer (SBRT), the use of a hydrogel rectal spacer was proven to be significantly associated with **reduced late GI toxicity and lower odds of developing late GU toxicity**¹.

The use of SpaceOAR may promote not only sparing of the rectum, but also result in **decreased dose to other organs at risk including the penile bulb and bladder**².

In a retrospective comparison study with 64 patients, the SpaceOAR application resulted in improved dosimetry for rectal endpoints pertinent to high radiation dose regions that are likely to confer long-term toxicity. In addition, penile bulb dosimetry was significantly improved with the use of SpaceOAR¹.

Percentage of Late Toxicities with and without SpaceOAR™ Hydrogel

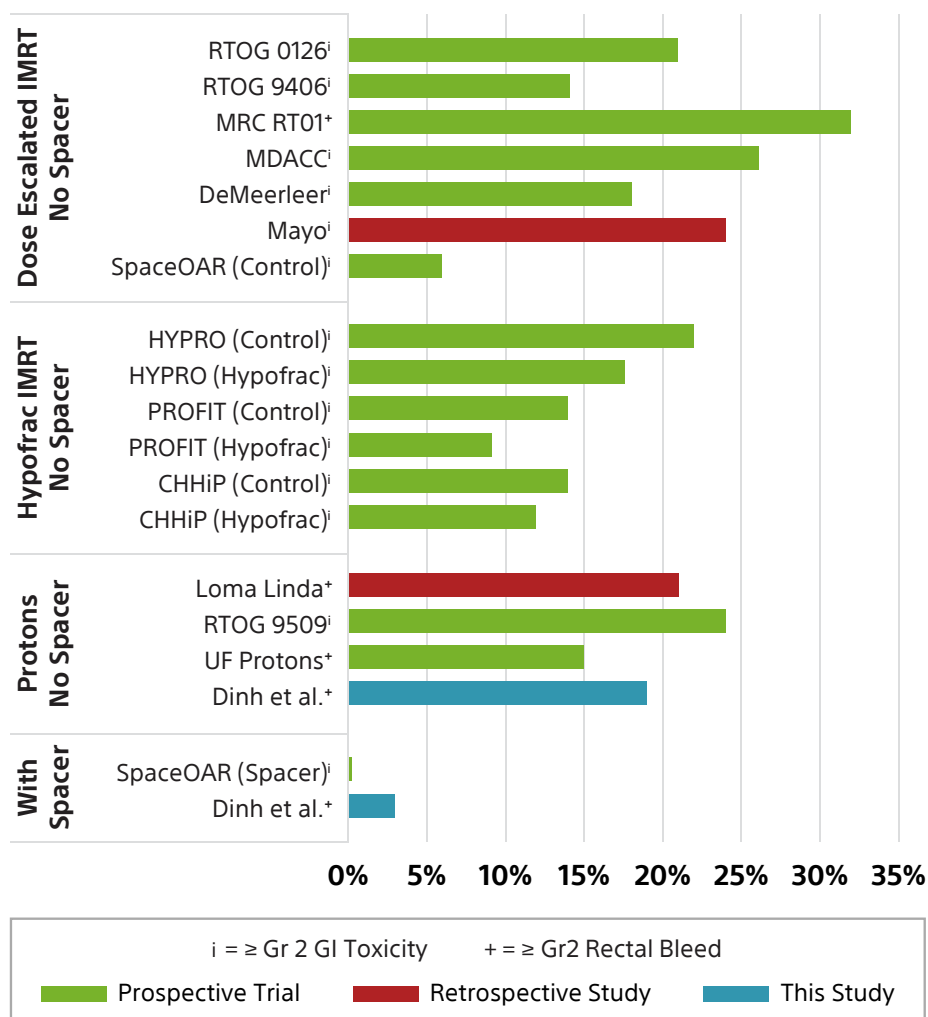


Median follow-up was 17 months

Is SpaceOAR Hydrogel Clinically Studied in PROTON THERAPY?

For patients treated with proton therapy, hydrogel spacer appears to provide a substantial reduction in the risk of rectal bleeding and toxicity¹.

Grade 2+ GI Toxicity or Rectal Bleeding Across Reported Trials



313 men were treated (75 with Hydrogel Spacer) with definitive proton RT (267 included in the final analysis) for prostate cancer in a single-institutional prospective registry between 2013 and 2018. Dose of 79.2 cobalt Gray equivalents in 44 fractions^{1,2}.

- **3%** 2+ rectal bleeding with spacer and proton versus **19%** without spacer^{1,2}.

- Without the use of a rectal spacer, there seems to be an increased rectal toxicity with proton therapy compared with intensity modulated radiation therapy (IMRT)^{1,2}.

- Rectal spacers seem to significantly **reduce both the dose of radiation to the rectum and the long-term rectal toxicity** associated with RT for prostate cancer^{1,2}.

What are the Benefits for the Radiation Oncologist?

The enhanced visibility on a CT scan is designed to help physicians improve contouring accuracy of the prostate and rectum, potentially leading to more accurate treatment plan creations when compared to SpaceOAR Hydrogel¹. Reducing the need for a post-implant MRI may reduce the overall treatment costs per patient, it reduces time required to fuse CT and MRI images, and the hospital staff's time spent in obtaining MRI reimbursement authorisation^{1,2}.

Potential Operational Benefits

With the improved visibility of SpaceOAR Vue Hydrogel on a CT scan, a department's clinical workflow may be improved as the patient will not need a post-procedural MRI for treatment planning¹.

Potential Clinical Benefits

For CT planning, physician-delineated prostate volume can be as much as 15% smaller (under contouring) or 30% larger (over contouring) than the "true" prostate volume. With SpaceOAR Vue Hydrogel, physicians may be able to contour the prostate and rectum with a greater degree of confidence without the need for an additional MRI. This may also reduce any contouring inaccuracies, potentially leading to more accurate treatment plan creations^{3,4}.

Accurate and consistent positioning of the patient from one fraction to the next is important to physicians, to ensure that treatment is delivered according to plan. The radiopacity provides a suitable imaging option to MRI for patients with implanted metallic devices.



Optimise dosing plan

Visibility of the gel on a CT scan may help to reduce under- or over-contouring of the prostate and rectum for improved accuracy and more precise treatment delivery¹.



Treat more patients

CT radiopacity may provide a suitable imaging option to MRI for patients with implanted metallic devices so you can care for a broader population of prostate cancer patients¹.



Streamline workflow

Can reduce the need for an MRI or an MRI-CT Fusion and improves visualization of the target area during patient positioning using kv cone-beam CT¹.

What are the Benefits for the Urologist?

SpaceOAR Hydrogel is an absorbable hydrogel that temporarily creates space between the prostate and rectum, designed to reduce the radiation dose delivered to the rectum during prostate cancer radiation therapy¹. SpaceOAR is naturally absorbed after 3 months and is excreted through the patient's urine leaving no implant behind after 6 months¹. In addition, SpaceOAR Vue offers enhanced visibility on CT scan designed to improve the contouring accuracy of the prostate and the rectum, potentially leading to more accurate treatment plan creations¹.



Minimally Invasive Outpatient Procedure

SpaceOAR Hydrogel can be injected with an 18G needle, under general or local anesthesia, facilitating ambulatory care without dependence on operating room availability².



Optimised and Safe Procedure

In a Pivotal Trial, there was a 99% placement success rate. Both the radiation oncologists and urologists who applied the spacer rated the device's ease of use as "easy" or "very easy" 98.7% of the time³.



Training and Support

Boston Scientific trains all new implanters through its mandated training pathway, providing support of procedures until the clinician is confident in injecting the gel independently.



Optimised Product Design

To facilitate assembly of the SpaceOAR Application system - 1x needle access, 1x SpaceOAR Hydrogel Injection, 1x seamless workflow.



Clinical Evidence

- 75+ studies¹.
- Meta analysis across 7 clinical studies including 1,011 patients⁴.
- 222-patient prospective multicentre randomised clinical study with 3-year follow-up data³.

Why Do We Offer Certification?

Over **100,000** applications have been performed since the first SpaceOAR treatment was performed in Germany in 2012¹. Boston Scientific accompanies the process from the first certification until additional training and support for urologists, physicists and radiation oncologists.

Thanks to the complete training support by Boston Scientific throughout the certification process and beyond, clinicians can quickly become proficient².

Slightly asymmetrical hydrogel distribution with a small overlap between planning target volume and rectum (A) and the 95% isodose in red color (B). Symmetrical hydrogel distribution without overlap between planning target volume and rectum (C) or the 95% isodose (D).

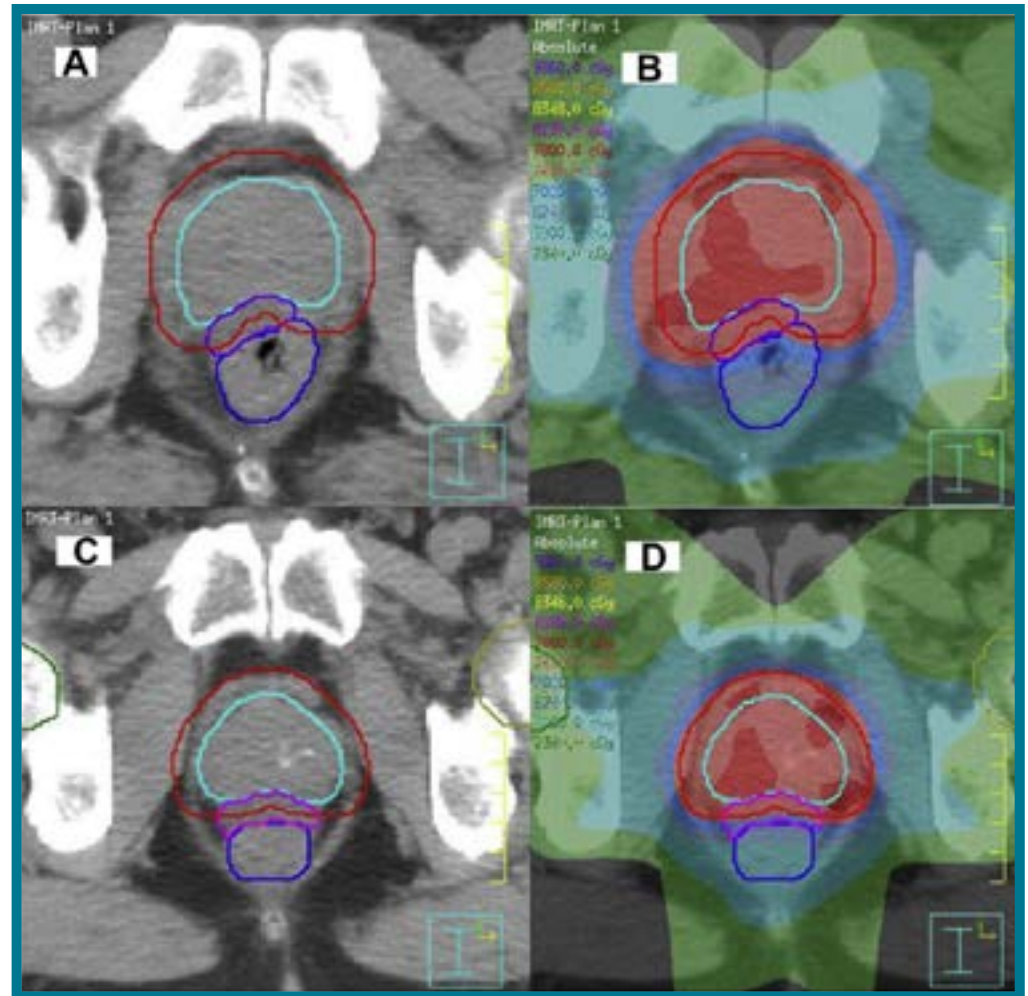


Image courtesy of Prof. Dr. med. Michael Pinkawa

What Does Our Training And Support Service Offer?

Required Training

To become certified in the application of SpaceOAR Hydrogel, physicians must complete the following necessary steps:



Hands-on desktop demonstration of product setup & application by a certified SpaceOAR Hydrogel representative



Review SpaceOAR Hydrogel System Application Physician Training Module with a certified SpaceOAR Hydrogel representative



Complete multiple cases under guidance of a certified SpaceOAR Hydrogel representative and demonstrate competency to successfully complete the SpaceOAR Hydrogel application independently

Additional Training Opportunities

In addition to the required training, Boston Scientific offers various additional training opportunities to enhance your SpaceOAR Hydrogel application technique:

Peer-to-Peer Training

- Preceptorships
- Proctorships
- Peer-to-Peer Calls

Webinars

Targeted topics led by our top healthcare experts

National Courses

Procedural & clinical education

Simulator



EDUCARE

Start your online learning experience at:
[EDUCARE.BostonScientific.com](https://www.boston-scientific.com/educare)

Marketing Support

Contact your local sales representative

What is the Benefit for the Patient?

SpaceOAR Vue treatment does mean patients have no need to undergo a control MRI and potentially need less hospital visits¹.

SpaceOAR is designed to reduce the radiation dose delivered to the patient's rectum, thus reducing potential side effects which can have a profoundly negative impact on your patient's quality of life, including:

- Rectal pain and bleeding
- Chronic diarrhea
- Urinary urgency and leakage
- Erectile dysfunction²

Patients receiving SpaceOAR Hydrogel reported significantly favorable outcomes relating to erection ability, orgasm ability, erection quality and frequency³.*



Fewer Bowel Complications

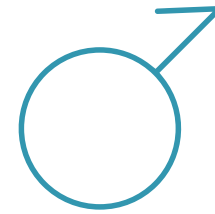
At median 3 years SpaceOAR Hydrogel reduced declines in bowel QOL by **70%**.



Fewer Urinary Complications

The use of the hydrogel spacer reduced the likelihood of either an MID or more ³ serious changes in urinary QOL by **>60%**.

The median 3-year incidence of grade 1 urinary incontinence was lower in the spacer arm (15% vs 4%; P=.046)³.



Fewer Sexual Complications

SpaceOAR Hydrogel patients who had erections sufficient for intercourse at baseline were **67%** more likely to retain sexual function at 3 years³.

*All 4 have statistical significance at median 3-year time point.

What do Patients Say?



SpaceOAR Vue Hydrogel may provide a suitable imaging option for patients with implanted metallic devices who cannot undergo an MRI.

"This was very straightforward, indeed. I had the SpaceOAR introduced, and by dinner the same day I was ready to come out - I came out, and within two days I was running again."

Alex Lamb, SpaceOAR patient, UK



Click here to view Alex Lamb's story:
[SpaceOAR Hydrogel.co.uk](https://SpaceOARHydrogel.co.uk)

One patient's experience is not predictive of other patients' experiences.

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Page 5 What does Boston Scientific do in Urology and Pelvic Health?

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Page 8 What is Hydrogel Spacing?

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Page 9 What is SpaceOAR Vue Hydrogel?

¹Data on file with Boston Scientific.

Page 10 What is SpaceOAR Hydrogel Composed of?

¹Data on file with Boston Scientific.

Page 11 What is the Mechanism of Action of SpaceOAR Hydrogel?

¹Data on file with Boston Scientific.

²Mariados 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.

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Page 13 Is SpaceOAR Hydrogel Clinically Proven?

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Page 14 Is SpaceOAR Hydrogel Clinically Studied in BRACHYTHERAPY?

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