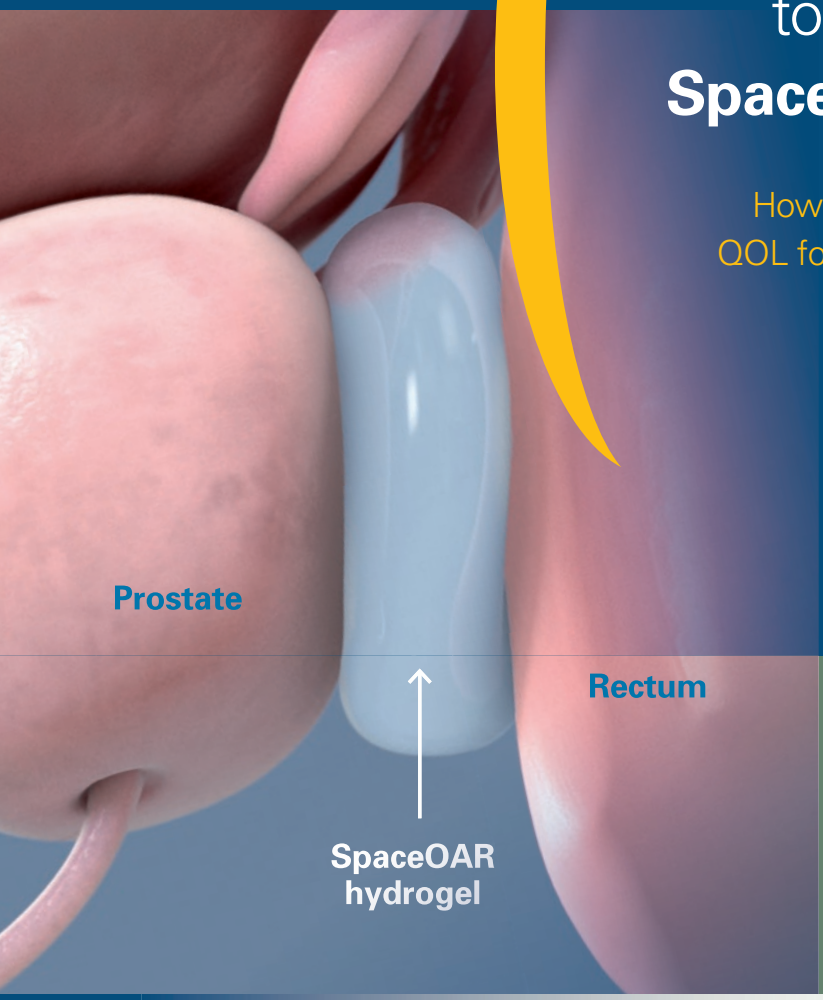
A PROMOTIONAL SUPPLEMENT TO

Urology Times®

What every urologist needs to know about **SpaceOAR® hydrogel**

How Augmenix is improving QOL for prostate cancer patients



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Introduction

Radiation therapy has been used to treat prostate cancer since the early 20th century. Relatively recent improvements, such as intensity-modulated radiotherapy (IMRT) and the more recent addition of image guidance, have improved the delivery accuracy and outcomes of treatment. Even with such advances in targeting like IMRT and image guidance, some patients still experience significant acute and long-term bowel, urinary, and sexual side effects.

The rectum mucosa is very sensitive to radiation injury. Its immediate proximity to the prostate makes the rectum the primary organ at risk (OAR) during prostate radiation therapy. Too much rectum radiation exposure can result in long-term abdominal pain, diarrhea, incontinence, bleeding, and mucus discharge. Three recent, prospective clinical trials found late grade 2+ gastrointestinal toxicity rates ranging from 14% to 25% in the 3 to 5 years following conventional prostate radiotherapy.[1–4]

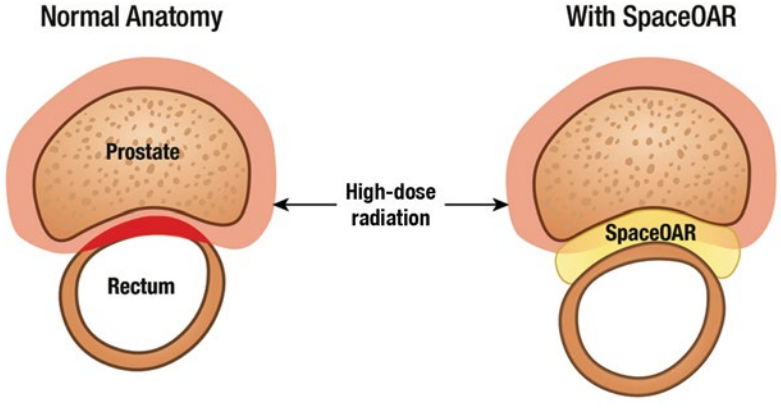


Figure 1. Normal prostate anatomy vs prostate anatomy with SpaceOAR

SpaceOAR® hydrogel (Augmenix, Bedford, MA) has been developed to address the issue of rectum proximity and minimize rectal radiation injury by displacing the rectum away from the prostate during radiation therapy (**Figure 1**). SpaceOAR hydrogel is an in situ curing polyethylene glycol (PEG)-based hydrogel that maintains space for 3 months and then completely absorbs within about 6 months. It is the first and only FDA-cleared absorbable spacer proven to significantly reduce rectum radiation dose during prostate radiation therapy, thereby improving the odds of preserved bowel and urinary quality of life (QOL) following radiotherapy.[5–8]

In a 3-year, multicenter, randomized, controlled clinical trial, SpaceOAR hydrogel safely created on average 1.3 cm of space to separate the prostate from the rectum.[5] This study also demonstrated that:[5–8]

- Relative to control patients without spacer placement, men with SpaceOAR hydrogel
  - Received significantly less radiation dose to the rectum and penile bulb; and
  - Had significantly improved patient-reported urinary and bowel QOL at 3 years;
  - From 3 months onward, no SpaceOAR patients experienced grade 2 or greater rectal toxicity (eg, proctitis, bleeding, fecal incontinence); and
  - Among baseline-potent men, the percentage of patients retaining erections sufficient for intercourse at 3 years was significantly higher in the SpaceOAR hydrogel group compared with controls (66.7% vs 37.5%; *P*=.046).

A recent, prospective, single-arm study of SpaceOAR hydrogel use was performed in urology group practices. A total of 99 patients were treated in 16 centers, either in the office or in the ambulatory surgical center (ASC) setting. Procedural and patient satisfaction data were collected at the time of procedure (data on file). Analysis showed that:

- 95% of cases were performed in an office setting, with the majority under local anesthesia;
- The average space created between the prostate and the rectum was 10.7 mm;
- 80% of investigators rated the procedure "very easy" or "easy," with the balance of investigators rating it "moderately easy";
- 94% of patients stated they would recommend the SpaceOAR hydrogel procedure to others; and
- 97% of patients said they were less anxious to receive radiation therapy knowing that they had SpaceOAR hydrogel implanted and present during treatment.

SpaceOAR hydrogel is currently being used in many leading cancer centers throughout the United States. It has also received CE mark approval in Europe, is approved in Australia and Japan, and is licensed in Canada. To date, over 25,000 patients worldwide have benefited from the SpaceOAR hydrogel procedure.

Recently, urologists using SpaceOAR hydrogel participated in a tele-roundtable discussion of their experiences that show how it can easily be implemented in an urologist's office, ASC, or a hospital-based practice. This *Urology Times* supplement presents highlights of their conversation and describes the current reimbursement landscape in the US.

ROUNDTABLE DISCUSSION:
Using SpaceOAR in your practice

Dr. Neal D. Shore: Our center was an investigational site for the SpaceOAR hydrogel premarketing clinical trial. Two radiation oncologists in our group had read about SpaceOAR and were very impressed with the treatment plan and patient tolerability after we did our first few cases. Now, they request its consideration for most of our prostate cancer patients undergoing radiotherapy.

How did you hear about SpaceOAR, and how did you get started with it in your practice?

Dr. Scott A. Montgomery: I am part of a large group urology practice that is committed to being a center of excellence for prostate cancer treatment. We have our own radiation center and contract with the radiation oncology group. Implementation of SpaceOAR was jointly spearheaded by our medical director and a radiation oncologist because they believed it could improve the safety of radiotherapy.

We only recently started performing the procedure, and between 1 of my partners and I, we have done 6 cases.

Dr. Shaun G. S. Grewal: My first introduction to SpaceOAR was at a LUGPA [Large Urology Group Practice Association] Prostate Cancer Academy meeting, and after I returned, several radiation oncologists who had been eager to have SpaceOAR for their patients asked me if I would start doing the application. Another radiation oncologist who I work with more frequently was less knowledgeable about SpaceOAR. I educated him about it, and he was excited to use it.

In our practice, we have always placed the fiducials regardless of where men are having their radiotherapy. It seemed it would be an easy transition to add the SpaceOAR application to those cases. I have done 30 cases.

Dr. Jared G. Heiner: I also heard about SpaceOAR at a LUGPA Prostate Cancer Academy meeting in the fall of 2017, and it interested me because it seemed to be the only viable option for minimizing radiation-related rectal toxicity.

The radiation oncologist I work with knew about SpaceOAR and was waiting for it to become commercially available and eligible for reimbursement. When I came back from the meeting, I told him it had a CPT code and was ready for prime time. I have done 7 cases.

Learning curve

Dr. Shore: What type of skillset and training is needed for SpaceOAR application, and what was the learning curve like?

Dr. Grewal: SpaceOAR placement involves a transperineal approach under transrectal ultrasound guidance. I felt I had that expertise from doing both thermocouple placement for cryotherapy and magnetic resonance imaging (MRI) ultrasound fusion biopsies. I was also comfortable using a stepper, which is required.

To get started with SpaceOAR, I reviewed the product literature and some demonstration videos. I felt very comfortable with the procedure after just a few cases. It took me a little longer to become efficient in setting up the kit.

Dr. Montgomery: I was 1 of 2 urologists in our group who were initially chosen for training, likely because we had the most experience with brachytherapy. We watched the videos, practiced using a model, and when we transitioned to patients, the learning curve was pretty quick.

Dr. Shore: I think it is fair to state that for anyone who has experience with transperineal procedures and transrectal ultrasound, placing the needle for SpaceOAR application is learned very quickly.

What would the learning curve be for someone who has never done transperineal needle placement but has experience with transrectal ultrasound-guided biopsy?

Dr. Grewal: There may be more of a learning curve, but it is very doable. Anyone who has not done transperineal needle placement might consider using more anesthesia for initial cases so that they can concentrate on the technique without concern about the patient being uncomfortable or moving.

FACULTY

Moderator

Neal D. Shore, MD, is the medical director of Carolina Urologic Research Center in Myrtle Beach, SC. He practices with Atlantic Urology Clinics in Myrtle Beach.

Panelists

Jared G. Heiner, MD, practices with Idaho Urologic Institute in Meridian, ID.

Scott A. Montgomery, MD, practices with Kansas City Urology Care in Merriam, KS.

Shaun G. S. Grewal, MD, practices with Urologic Specialists of Oklahoma in Tulsa.

DISCLOSURES

Dr. Shore is a consultant to and does research for Augmenix. Dr. Heiner, Dr. Montgomery, and Dr. Grewal have no financial relationships relevant to the subject matter discussed.

The SpaceOAR hydrogel procedure

Patients are placed in a lithotomy position and anesthetized (using general anesthesia, conscious sedation, or local anesthesia) (**Figure 2**). Using stepper-mounted side-fire transrectal ultrasound guidance, an 18-gauge needle is advanced through the perineum and into the perirectal fat posterior to Denonvilliers' fascia and anterior to the rectal wall. Saline is then injected through the needle at mid-gland to expand the perirectal space.

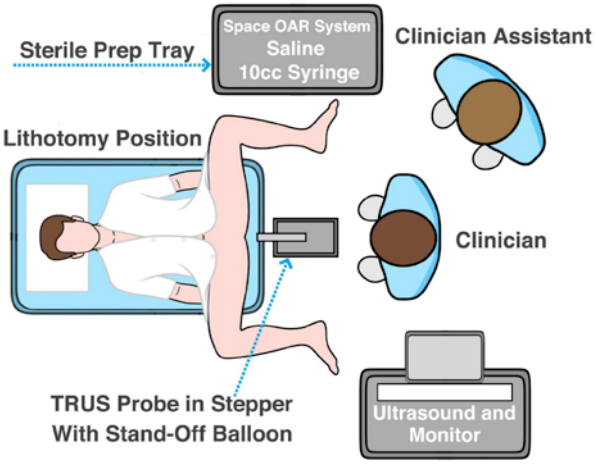


Figure 2. SpaceOAR procedure. TRUS, transrectal ultrasonography

Following confirmation of proper needle location via ultrasound, aspiration is performed to ensure the needle is not intravascular. The PEG hydrogel precursors are injected through the needle into the previously hydrodissected space (**Figure 3**). The precursors polymerize within 8 to 10 seconds to form a soft hydrogel spacer (**Figure 4**). The hydrogel is designed to remain dimensionally stable for 3 months during radiotherapy and then liquefy via hydrolysis within 6 months (**Figure 5**). The material is then absorbed and cleared via renal filtration.

Figure 3. SpaceOAR hydrogel kit

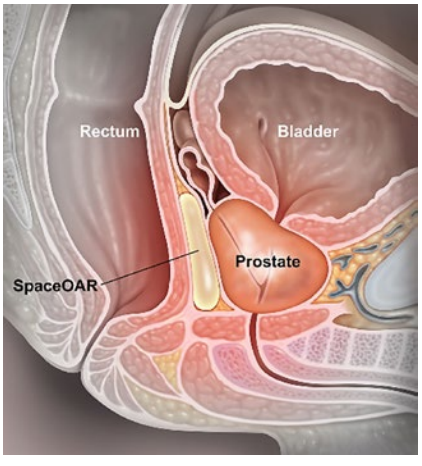
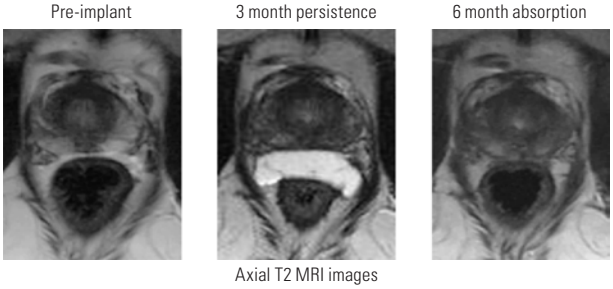


Figure 4. Anatomy with SpaceOAR



Axial T2 MRI images

Figure 5. Magnetic resonance imaging illustrating SpaceOAR absorption

Dr. Shore: I think the take-home message is to do everything you can at first to minimize your stress and optimize patient comfort and safety, but that the learning curve for SpaceOAR only involves a few cases.

Equipment needs

Dr. Shore: Dr. Grewal mentioned the stepper, which is required for SpaceOAR application. Is any other equipment necessary?

Dr. Heiner: A side-fire transrectal ultrasound probe is needed, and because we are doing the procedure in the clinic with the patient on a regular examination bed without rails, we needed a floor-mounted stepper.

Dr. Montgomery: We would like to have a floor-mounted stepper so that we can move it among the 3 rooms at our center where we do the SpaceOAR procedure.

Dr. Shore: For mobility, a floor-mounted stepper may be preferable over a model that attaches to the table or bed. However, as with most procedures we perform, individual surgeons will have preferences.

Is a template grid needed, or can SpaceOAR placement be done with a freehand technique?

Dr. Grewal: I have used a grid and done the procedure freehand. I think the grid is very helpful for placing the fiducial markers, but can be a hindrance when placing SpaceOAR.

Dr. Montgomery: We chose not to use a grid, but I can see how it could interfere with angling of the needle.

Incorporating SpaceOAR into clinical practice

Dr. Shore: In what setting are you performing the SpaceOAR procedure?

Dr. Montgomery: Our first cases were done at our procedure center where we have 2 fully functional operating rooms and a nurse anesthetist, and we used intravenous (IV) sedation.

Our plan is to transition to a procedure room and use local anesthesia with oral medication for sedation.

Dr. Grewal: I have done them under IV sedation in the hospital and under conscious sedation with oral diazepam 10 mg in the office.

Dr. Heiner: Our cases are done in the clinic on a regular examination bed. Initially, we gave men diazepam 10 mg and 2 tablets of acetaminophen 325 mg/hydrocodone 5 mg, but we adjusted our regimen because of some tolerability issues. Now, we are giving only diazepam 5 mg, which combined with local anesthetic in the perineum, has been enough to keep patients comfortable.

For urologists who are not experienced with the transperineal approach, however, I would recommend using IV sedation during the learning curve to avoid compromising patient confidence.

Dr. Shore: My clinical trial cases were done at our ASC under IV sedation. Post approval, all of my cases have been done in the clinic. We give all men an anxiolytic, but we individualize the dose and the decision to use a narcotic. It is important to wait 30 to 45 minutes after giving the premedication before injecting any perineal anesthetic.

Of course, we do a perineal prep and give various combinations of intramuscular antibiotics. You can argue, however, that there is minimal need for infection prophylaxis because the procedure is transperineal and does not involve urethral catheterization.

A periprostatic block is needed for cases not done under IV sedation. What is your technique for the block?

Dr. Heiner: I use 1% lidocaine buffered with bicarbonate. With a 22-gauge needle attached to a 10-cc syringe, I raise a subcuticular wheal in the perineum or on the midline, inject about 1-cm deep, and then fan out a little along the skin. Then I insert and position the transrectal ultrasound probe, put on sterile gloves, and drape the stepper. Using a longer, spinal-type needle and under ultrasound guidance, I inject the lidocaine up to the prostatic apex, to the left, the right, and posteriorly, sort of hydrodissecting along the SpaceOAR needle trajectory. I do not inject anesthetic transrectally or at the lateral aspects or base of the prostate.

Dr. Grewal: My technique is very similar, and I would point out that getting a good subcutaneous block of the perineum is very helpful for minimizing patient discomfort.

Dr. Shore: I also do the perineal subcutaneous block, fan out the anesthetic, and give a diffuse block around the apex. I do not go into the right or left lateral aspects because I don't want to create any ultrasound imaging artifact.

What do you do to keep the scrotum out of the way?

Dr. Montgomery: We place an unfolded wet blue towel under the scrotum and pull it up snug while tucking the ends into the inguinal creases.

Dr. Grewal: I do that too, and it works well in most cases. I have also used Tegaderm™.

Dr. Heiner: We create a sling using a long piece of silk tape.

Dr. Shore: What is the sequence of steps for patients having the SpaceOAR procedure?

Dr. Heiner: They are at the clinic for about 90 minutes. When men arrive, they take their medications and change clothes before having a simulation computed tomography (CT) scan. Then, patients come to the clinic, have counseling, and by the time they are positioned, 50 minutes have passed since they took their medication.

Patients go for another CT scan after the procedure. When preparing the SpaceOAR, our nurse shakes the precursor syringe vigorously before attaching it to the Y-connector to create air bubbles that enable visualization of the SpaceOAR on the CT image. We have not been charging for the second CT scan because it is something we are in the process of evaluating, but so far, the radiation oncologists feel it is helpful for future planning.

Dr. Shore: Is anyone else doing pre- or post-CT scans?

Dr. Grewal: Our radiologists are depending on MRI results to plan the radiation treatment because the SpaceOAR is clearly seen on the T2-weighted image.

Dr. Shore: SpaceOAR is inserted after the fiducials have been successfully placed. The needle is positioned within Denonvilliers' space at the prostate midline while monitoring in the sagittal view. It is critical to have clear imaging of Denonvilliers' space. Sector ultrasound imaging may distort the rectal–prostatic interface.

It is also critical not to perforate the rectum. If the needle enters the rectal lumen at any time, the procedure should be aborted.

Dr. Shore: Has doing the SpaceOAR cases affected your workflow efficiency?

Dr. Heiner: It has not, but we set aside half days for doing only 3 or 4 SpaceOAR procedures. Because it was something new, it seemed like a good idea to eliminate any other pressures and allow time for assessments after each step as a self-check and to see if we could identify ways to refine our procedures.

Dr. Montgomery: We also set aside an entire afternoon for our first patients and allowed 1 hour for each case.

In my weekly schedule, I have a half day when I schedule a lighter clinic load with just 8 to 10 patients and 2 to 4 patients having procedures done under IV sedation. I foresee doing the SpaceOAR cases in that time slot, but as I mentioned, I plan to do them with a local block and oral sedation.

Dr. Grewal: I also have been doing the SpaceOAR cases during a half day that is dedicated only to SpaceOAR. The time for each case has decreased progressively as everyone gained familiarity with the procedure.

Initial impressions

Dr. Shore: How satisfied have you been with the SpaceOAR placement?

Dr. Grewal: The size and location of the space created has been variable, and I believe that occurs because of various injection- and patient-related factors, including prostate size. Even in cases where the placement was not perfectly symmetric, however, the radiation oncologist felt the material was serving to distance the prostate from the rectum.

Dr. Montgomery: We saw apical asymmetry in 1 of our 6 patients, but overall, the SpaceOAR created significant space in all areas.

Dr. Shore: Have patients experienced issues tolerating the procedure or with delayed side effects?

Dr. Grewal: The procedure itself is well-tolerated, and side effects have been minimal.

Most often, men comment about feelings of constipation, having something in the rectum, or needing to have a bowel movement, but these are transient and not really bothersome.

Dr. Montgomery: Our patients also experience no more than an awareness of perineal pressure.

Dr. Heiner: One patient commented on feeling pressure in the rectum immediately after the procedure, but it abated within 10 minutes.

Dr. Shore: Data from longer-term follow-up of men enrolled in the phase 3 clinical trial demonstrate that SpaceOAR is associated with lower rates of late rectal toxicity and improvements in bowel as well as urinary and sexual QOL scores.6–8 Do you have any insights from your experience about the effect of SpaceOAR for mitigating rectal toxicity?

Dr. Grewal: We do not have sufficient follow-up to comment on late toxicity. Acutely, however, radiotherapy can be associated with rectal bleeding or urgency. None of our patients experienced those problems, although my series is still limited.

Informing patients

Dr. Shore: How are you talking to patients about SpaceOAR?

Dr. Grewal: About half of the 30 cases I have done involved patients sent to me from a radiation oncologist who had already discussed the procedure with them. I have also had a few patients who came to me from other practices because they had learned about SpaceOAR on their own, were interested in it, and their urologist was not doing the procedure.

I have been the only provider in our practice doing the procedure, and I talk to my own patients about it. My partners discuss it briefly with their patients who will be starting radiotherapy, and a nurse navigator in our group provides more thorough education, verbally and with some literature. I talk to all of the patients on the day of the procedure.

Men seem to easily understand the concept of how SpaceOAR provides protection by creating space and have been very eager to pursue it.

Dr. Shore: I am also seeing patients asking about SpaceOAR, perhaps through word-of-mouth referrals from other patients.

Dr. Montgomery: In our group, the conversation about SpaceOAR has mostly been initiated by our radiation oncologist, but I discussed it further with my own patients and explained that it is something we are evaluating to lower toxicity and complications from radiotherapy. It has been very well-received by patients based on that information.

Dr. Heiner: I send all of my patients for a radiation oncology consult to get a second opinion, but if I sense a man is really interested in radiation, I tell him about SpaceOAR first. The cases I have done who were my partners' patients came to me after seeing the radiation oncologist who recommended SpaceOAR to them.

We use a simple graphic that shows how SpaceOAR distances the rectum from the prostate, and men get a packet before the procedure that includes their medication prescriptions and information about what to expect. Because the concept is easily understood, there has not been a need to provide a lot of educational materials or in-depth explanation.

Financial issues

Dr. Shore: Is the cost of having to acquire equipment affecting your decision to incorporate SpaceOAR going forward?

Dr. Heiner: We have been using a loaner stepper and ultrasound unit but plan to purchase a new ultrasound system that will fit into the stepper and have a side-fire probe. My understanding is that the reimbursement for SpaceOAR application in the clinic setting is very favorable, and we anticipate getting a return on investment within a few months.

Dr. Montgomery: We estimate it will cost approximately $30,000 to get a side-fire probe and a floor stepper and that we will get to our breakeven point after about 40 cases.

Dr. Grewal: Our calculations show the same thing.

Concluding comments

Dr. Shore: What are your final thoughts about SpaceOAR?

Dr. Grewal: Because rectal toxicity is responsible for some of the most feared and grave complications of radiation treatment for prostate cancer, I consider SpaceOAR something very valuable that we can offer patients to help decrease the morbidity of their treatment.

Dr. Montgomery: The learning curve was very easy, and we are excited to be offering SpaceOAR in our practice.

Dr. Heiner: Augmenix provided great support and education for our entire staff. I think there is great benefit for SpaceOAR and no significant downsides considering that it is not associated with significant morbidity or infection risk, and I imagine that it will soon become a standard of care.

Dr. Shore: Gentlemen, thank you for sharing your experiences and pearls of wisdom regarding the SpaceOAR procedure. It appears that we all agree that SpaceOAR is a breakthrough in helping to improve the safety and tolerability of prostate radiotherapy. ()

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SpaceOAR reimbursement, coverage, and coding

MARK PAINTER is a managing partner of PRS Consulting, LLC, CEO of PRS Urology SC, and vice president of coding and reimbursement information for Physician Reimbursement Systems (PRS), Inc., in Denver, CO.

Mr. Painter is a consultant to Augmenix and a shareholder/founder/employee to PRS, Inc., a company contracted with Augmenix to provide reimbursement support.

Table. RVUs for SpaceOAR

Work	Nonfacility practice expense	Facility	Malpractice	Nonfacility total	Facility total	Global
3.03	102.06	1.39	0.39	105.48	4.81	000

Source: Adapted from Centers for Medicare & Medicaid Services data.

What is the latest situation with SpaceOAR reimbursement?

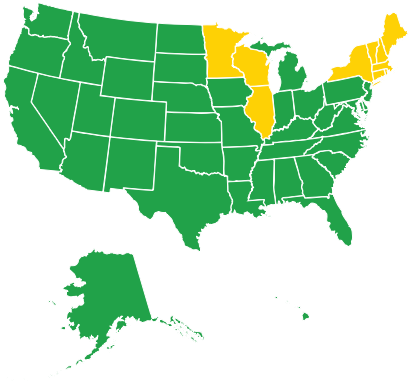
Reimbursement for SpaceOAR is expanding but not yet universal. As with many new technologies, there are 3 major issues that must be addressed for reimbursement in the healthcare system: coding, coverage, and payment.

The issues of coding and payment for SpaceOAR were solved with the release of the 2018 AMA CPT® Manual and subsequent RVU assignment in the 2018 final rules for Medicare. Below are the RVUs for SpaceOAR, which is typically billed using CPT code 55874 (transperineal placement of biodegradable material, periprostatic, single or multiple injection(s), including image guidance, when performed).

Coverage is slowly changing from commonly uncovered to covered by some plans.

Code 55874 was assigned to an APC (5375) to allow for facility payment in both the ASC and the outpatient hospital setting, which usually means that a carrier that will cover the service in the office setting will also allow coverage in the hospital outpatient department (HOPD) and ASC setting. If the service is provided in the HOPD or ASC, the payment system assumes the facility purchased the hydrogel and therefore payment to the facility will include payment for the supplies. Physician payments will be based on the facility practice expense and total RVUs as listed and adjusted for geographic place of service.

For Medicare, states currently reimbursing for SpaceOAR (as of April 12, 2018) are in dark green in the map provided here. Reimbursement is via the following Medicare Administrative Contractors: CGS Administrators, LLC, Noridian Health Care Solutions, LLC, Palmetto GBA, LLC, First Coast Service Options, Inc., Wisconsin Physicians Service Insurance Corporation, and Novitas Healthcare Solutions, Inc. National Government Services, Inc., does not typically reimburse the service at the time of this article's writing.



Among private payers, Aetna is reimbursing for SpaceOAR as the company has developed a positive national medical policy on SpaceOAR. The policy can be viewed at: www.spaceoar.com/aetna. Other private payers are beginning to cover it on a case-by-case basis.

It is wise to check with the payer regarding coverage for a patient prior to providing the service. Coverage reconsideration by a payer may be challenged based on medical necessity and increases in published peer-reviewed literature supporting effectiveness, safety, and appropriate use. The format and submission pathway for such reconsiderations varies among payers.

How can a physician learn more about local coverage and reimbursement rates?

Although the most accurate path to coverage and payment determination is to contact the payer, offices and hospital billing departments may keep track of payment policies for payers and plans and can serve as an additional resource.

Augmenix has established a reimbursement department and is working with industry partners, like PRS, to both track coverage and payment policies and assist with appeals for claims not paid.

Denied claims should always be appealed with medical records following formats and instructions provided by the payer denying the claim. Often a payer may not have a stated policy for new CPT codes, and coverage and payment rates are not known even after appropriate contact with the payer. In these cases, the patient should be made aware prior to provision of the service that the service may not be covered and he may be responsible for payment of the procedure. (Note: Some contractual arrangements with payers will not allow a practice to bill the patient for services considered medically unnecessary or noncovered. Understanding these contracts for those insurance companies that do not cover or may not cover the service is essential.)

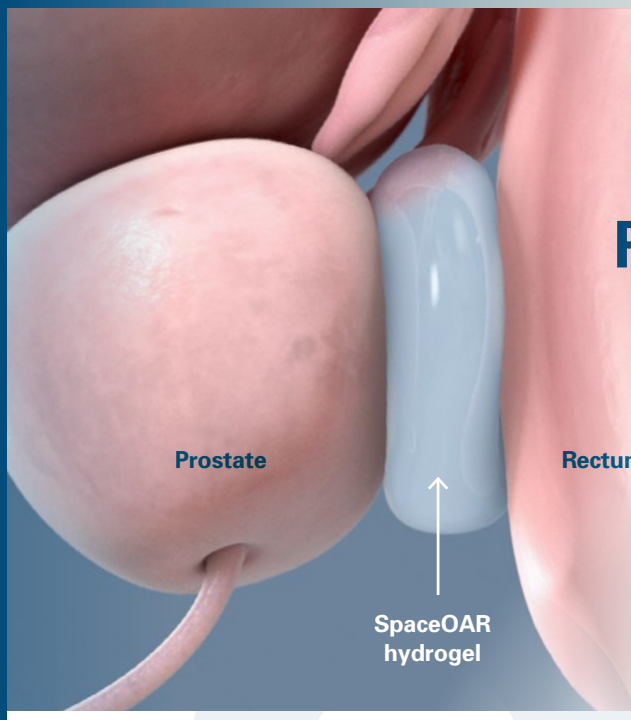
Is there any special coding guidance or tips on billing for SpaceOAR?

Under Medicare, SpaceOAR is reimbursed in a way that treats the biodegradable hydrogel as a surgical supply. This is slightly different from drug injection types that require reporting of the injectable under a separate code. Code 55874 reimbursement in the office setting includes reimbursement for the hydrogel.

Not all private payers follow Medicare reimbursement policies as these relate to supplies and drugs. As noted previously, checking with the payer is an important part of the reimbursement process. If a payer indicates that the hydrogel should be reported separately from the CPT code, J3490 unclassified drug or a separate supply code may be required in addition to the CPT code for proper reimbursement.

PROSTATE-RECTUM SPACING DURING RADIATION THERAPY

SpaceOAR® Hydrogel



Help Preserve Your Prostate Cancer Patients' Quality of Life with SpaceOAR Hydrogel.

- In the pivotal trial, SpaceOAR patients did not experience any Grade 2 or greater rectal toxicity (e.g. proctitis, rectal bleeding, or fecal incontinence).[1,2]
- In-office transperineal injection under local anesthesia
- New Category 1 CPT code - 55874 - effective January 1, 2018

To learn how you can integrate SpaceOAR hydrogel into your urology practice, go to **www.spaceoar.com/aua**

Augmenix®

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