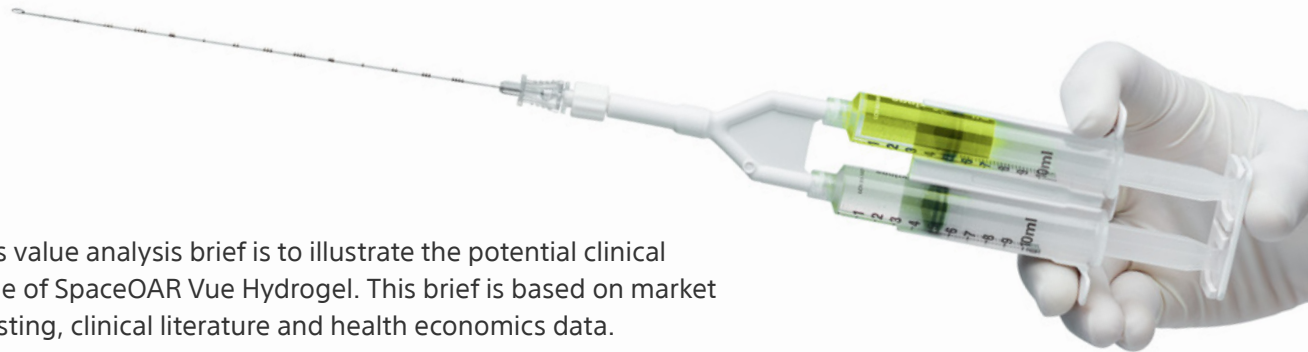




# SpaceOAR Vue™ Hydrogel

Scan. See. Plan. Treat. **All via CT.**



## Introduction

The purpose of this value analysis brief is to illustrate the potential clinical and economic value of SpaceOAR Vue Hydrogel. This brief is based on market research, bench testing, clinical literature and health economics data.

## Background

SpaceOAR Vue Hydrogel is the next-generation version of SpaceOAR™ Hydrogel, and has been designed to provide clinicians, practices and patients with the added benefit of enhanced visibility under CT imaging.<sup>1</sup> SpaceOAR Vue Hydrogel is intended to create a space between the prostate gland and the rectum (the Organ At Risk, OAR), helping to reduce the radiation dose delivered to the rectum during prostate cancer radiation therapy.<sup>1</sup> SpaceOAR Vue Hydrogel can be visualized under CT imaging offering a wide range of benefits:

- ▶ 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 Hydrogel.<sup>1</sup>
- ▶ The continuous visibility on kV CBCT for the visualization of the target region enables consistent positioning of patients receiving prostate cancer radiation, through intrafraction assessment of the anatomic geometry to ensure treatment is delivered to plan.<sup>1</sup>
- ▶ It may remove the need for a post-implant MRI scan for institutions that perform CT only planning.
- ▶ It may provide a suitable imaging option for patients with implanted metallic devices who cannot undergo an MRI.



### **Delivers potential clinical benefit and enhanced experience for patients**

- ▶ SpaceOAR Vue™ Hydrogel is designed to reduce the radiation dose to the rectum that can cause side effects, such as bleeding, leakage, diarrhea, chronic discomfort and irritation, and fecal incontinence.<sup>2-4</sup>
- ▶ May remove the need for the patient to obtain additional MRI scans, decreasing the number of visits to the hospital and the financial burden to patients (deductible, co-insurance).



### **Delivers potential operational benefits to providers and staff**

- ▶ One-time minimally invasive procedure remains in place for the duration of radiation.<sup>1</sup>
- ▶ Integrates into existing practice patterns, fiducial markers can be implanted via the transperineal approach prior to SpaceOAR™ Hydrogel injection.<sup>1</sup>
- ▶ Streamlines workflow as
  - Staff may not have to spend time on getting a preauthorization for an MRI approved.
  - May eliminate the need for MRI fusion verification or special techniques to visualize the hydrogel.



### **Delivers potential financial benefits to institutions**

- ▶ Covered procedure for patients with Medicare coverage, reimbursement is approved under CPT® code 55874 (transperineal placement of biodegradable material, peri-prostatic single or multiple injections, including image guidance) when performed.<sup>4,5</sup>
- ▶ Reimbursement<sup>1,5,6</sup>
  - Hospital outpatient department (HOPD) Medicare national average 2020 facility reimbursement is \$4,232. On average, the HOPD Medicare reimbursement has increased 7% year-over-year for the past 3 years.
  - Physician Medicare national average 2020 reimbursement in the office setting is \$3,143; physician facility reimbursement is \$172 or 3.03 work RVUs.
  - A Boston Scientific analysis of the 2018 Truven MarketScan dataset identified 67 paid commercial payer claims for SpaceOAR Hydrogel (CPT® code 55874) in the office setting. On average, commercial payers reimbursed the office \$4,755 or \$958 more than the Medicare national average in-office rate in 2018; a +125% premium. On the high end of the market, commercial payers reimbursed at \$6,355 (+167% premium) and a maximum reimbursement of \$10,200 (+268% premium).
- ▶ SpaceOAR Vue Hydrogel may reduce overall treatment costs by reducing the need for a post-implant MRI.
  - Some healthcare institutions have reported that payers do not reimburse for the post SpaceOAR Hydrogel procedure MRI.
- ▶ Costs associated with treating biochemical recurrence or side effects
  - 30-50% of patients undergoing RT will experience biochemical recurrence within 10 years.<sup>7</sup> The average annual cost of treating prostate cancer with radiation therapy, including recurrence or side effects, is \$10,810.<sup>8</sup> Creating accurate treatment plans may reduce both the side effects of radiation treatment and recurrence.



## Conclusion

**SpaceOAR Vue™ Hydrogel is the next-generation hydrogel spacer that provides physicians enhanced visibility on a CT scan that improves contouring accuracy and facilitates consistent patient positioning, while improving the patient experience by reducing the need for an MRI for treatment planning and improving their quality of life.**

1. Data on file with Boston Scientific.
2. Serrano NA, Kalman NS, Anscher MS. Reducing rectal injury in men receiving prostate cancer radiation therapy: Current perspectives. *Cancer Manag Res.* 2017 Jul;9:339-50.
3. 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.
4. 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.
5. Centers for Medicare and Medicaid Services, Revisions to Payment Policies under the Medicare Physician Fee Schedule, available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F.html>.
6. Centers for Medicare and Medicaid Services, Hospital Outpatient Prospective Payment, available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-FC.html>.
7. Paller CJ, Antonarakis ES. Management of biochemically recurrent prostate cancer after local therapy: evolving standards of care and new directions. *Clin Adv Hematol Oncol.* 2013 Jan;11(1):14-23.
8. Wilson LS, Tesoro R, Elkin EP, et al. Cumulative cost pattern comparison of prostate cancer treatments [published correction appears in *Cancer.* 2007 May 15;109(10):2155]. *Cancer.* 2007 Feb 1;109(3):518-527.

This information is intended solely to alert customers to potential economic opportunities. It is not meant to influence decisions regarding clinical care; decisions regarding the medical care of patients should only be made by licensed healthcare professionals and in the best interest of each individual patient. Nor is this information meant to be representative of the performance of any individual healthcare facility; individual results will vary.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered. It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters. Boston Scientific does not promote the use of its products outside their FDA-approved label. Information included herein is current as of November 2019 but is subject to change without notice. Rates for services are effective January 1, 2020.

### CPT® Disclaimer

Current Procedural Terminology (CPT) Copyright 2019 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions apply to government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

SpaceOAR Vue Hydrogel is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR Vue Hydrogel to reduce the radiation dose delivered to the anterior rectum.

SpaceOAR Vue Hydrogel contains polyethylene glycol (PEG) and iodine.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

As with any medical treatment, there are some risks involved with the use of SpaceOAR Vue Hydrogel. Potential complications associated with SpaceOAR Vue Hydrogel include, but are not limited to: pain associated with SpaceOAR Vue Hydrogel injection, pain or discomfort associated with SpaceOAR Vue Hydrogel, local inflammatory reactions, infection (including abscess), urinary retention, urgency, constipation (acute, chronic, or secondary to outlet perforation), rectal tenesmus/muscle spasm, mucosal damage, ulcers, fistula, perforation (including prostate, bladder, urethra, rectum), necrosis, allergic reaction (localized or more severe reaction, such as anaphylaxis) embolism (venous or arterial embolism is possible and may present outside of the pelvis, potentially impacting vital organs or extremities), syncope and bleeding. The occurrence of one or more of these complications may require treatment or surgical intervention. URO-989810-AB

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: 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 or at [www.IFU-BSCI.com](http://www.IFU-BSCI.com). Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

All images are the property of Boston Scientific. All trademarks are the property of their respective owners.

**Boston  
Scientific**  
Advancing science for life™

Boston Scientific Corporation  
300 Boston Scientific Way  
Marlborough, MA 01752-1234  
[www.BostonScientific.com](http://www.BostonScientific.com)

©2020 Boston Scientific Corporation  
or its affiliates. All rights reserved.

URO-851506-AA OCT 2020