

Space0AR Vue™ Hydrogel

Product Review for the Value Analysis Committee



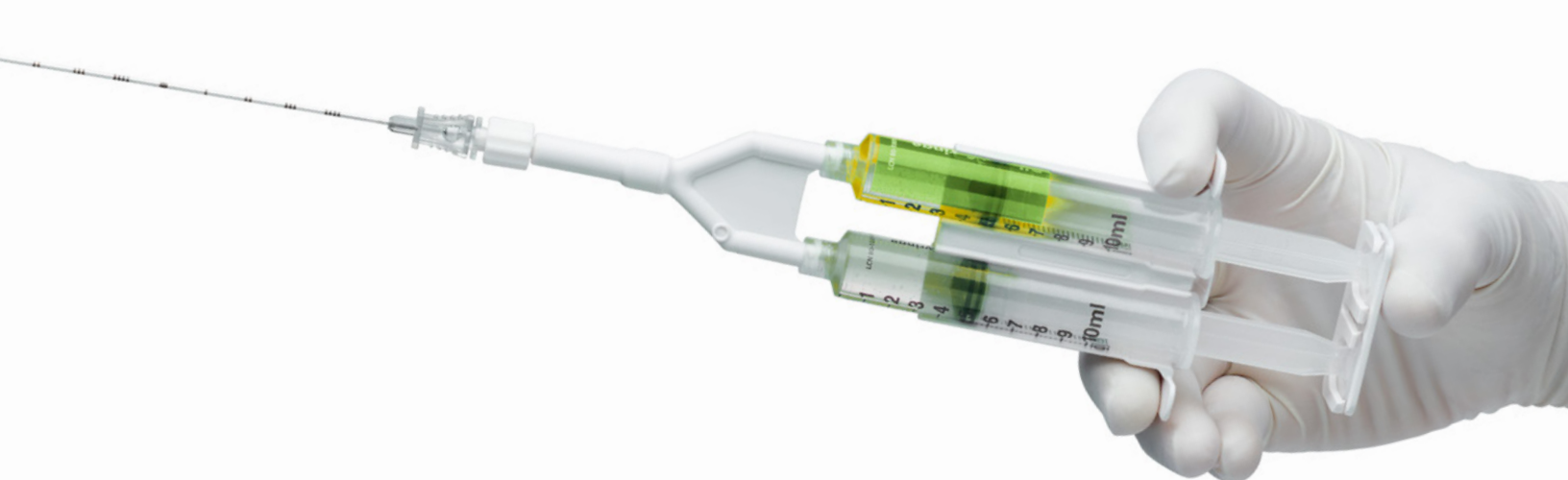
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Product overview

SpaceOAR Vue Hydrogel

Built off the clinical success of SpaceOAR™ Hydrogel, SpaceOAR Vue Hydrogel is the next-generation hydrogel spacer that offers enhanced visibility via CT scan. SpaceOAR Vue Hydrogel is designed to help physicians improve contouring accuracy and consistently position patients receiving prostate cancer radiation as compared to SpaceOAR Hydrogel.

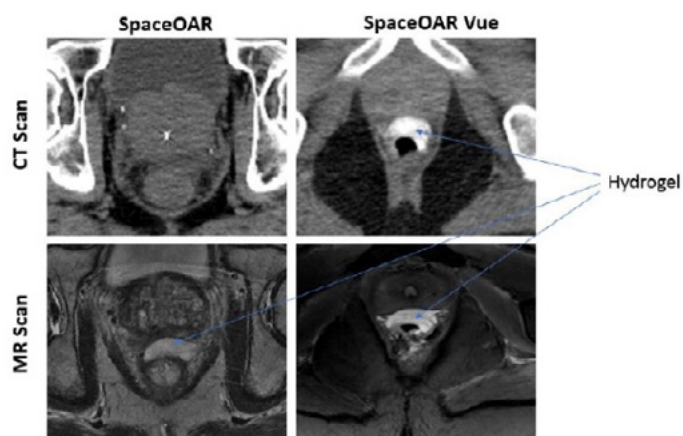


- ▶ The enhanced visibility on a CT scan is designed to help physicians improve contouring accuracy of the prostate and rectum, potentially leading to more accurate treatment plan creations when compared to SpaceOAR Hydrogel.
- ▶ It may remove the need for a post-implant MRI scan for institutions that perform CT only planning. This reduces the overall treatment costs per patient, reduces time required to fuse CT and MRI images, and the hospital staff's time spent in obtaining MRI reimbursement authorization.
- ▶ It may provide a suitable imaging option for patients with implanted metallic devices who cannot undergo an MRI.
- ▶ The persistent 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.

For more information on SpaceOAR Hydrogel, go to section on Clinical data.

Product value analysis

In addition to the value that SpaceOAR™ Hydrogel brings to Radiation Oncologists and patients, SpaceOAR Vue Hydrogel also provides the following values:



Delivers potential clinical benefits for physicians and patients

For CT planning, physician-delineated prostate volume can be on average 15%¹ smaller (under contouring) or 30% larger¹ (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. 30-50%² of patients undergoing RT will experience biochemical recurrence within 10 years. The average annual cost of treating prostate cancer with radiation therapy, including recurrence or side effects, is \$10,810.³ Creating accurate treatment plans may have an effect on both the side effects of radiation treatment and recurrence.

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 visibility of SpaceOAR Vue Hydrogel on kV cone-beam CT aids in the visualization of the target region for patient positioning prior to each treatment.

CT radiopacity may provide an effective imaging option to MRI for men with implanted metallic devices so physicians can care for a broader population of prostate cancer patients.



Delivers potential operational benefits to institutions

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 planning. Staff will not have to spend time on getting a preauthorization for an MRI approved. Treatment planning teams may not need to use special techniques to visualize the hydrogel.



Delivers potential economic benefits to institutions

SpaceOAR Vue Hydrogel reduces the overall treatment costs by reducing the need for a post-implant MRI.

Prostate cancer guidelines

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

In the U.S., the evidence-based clinical recommendations from the NCCN Guidelines® are considered the standard policy for the management of cancer. The NCCN Guidelines for Prostate Cancer recommend the use of a perirectal spacer in certain patients in its “Principles of Radiation Therapy” section and includes the following statements.⁴

“The disadvantages of EBRT include a treatment course of 8 to 9 weeks. Up to 50% of patients have some temporary bladder or bowel symptoms during treatment. There is a low but definite risk of protracted rectal symptoms from radiation proctitis, and the risk of erectile dysfunction increases over time.^{5,6} The risk of late rectal complications following RT is related to the volume of the rectum receiving doses of radiation close to or exceeding the radiation dose required to control the primary tumor.

Biomaterials have been developed, tested, and FDA approved to serve as spacer materials when inserted between the rectum and prostate. In a randomized phase 3 multicenter clinical trial of patients undergoing image-guided intensity-modulated RT (IG-IMRT), with the risk of late (3-year) common terminology criteria for adverse events (CTCAE) grade 2 or higher, physician-recorded rectal complications declined from 5.7% to 0% in the control versus hydrogel spacer group. The hydrogel spacer group had a significant reduction in bowel QOL decline. No significant differences in adverse events were noted in those receiving hydrogel placement versus controls. Results of a secondary analysis of this trial suggest that use of a spacer may decrease the sexual side effects of radiation.”⁷

Please refer to the full pdf of the NCCN Guidelines for complete details: <http://NCCN.org>

Regulatory information

What is the intended use?

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 is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

What is the FDA classification of the device?

SpaceOAR Vue Hydrogel is marketed in the U.S. in accordance with US 21 Code of Federal Regulations 892.5725 as an Absorbable Perirectal Spacer. These devices are Class II devices and are subject to the premarket notification 510(k) process.

The 510(k) clearance under which SpaceOAR Vue Hydrogel was cleared in the U.S. is attached.



July 19, 2019

Augmenix, Inc.
% Mr. Marcus Garcia
Principal Regulatory Affairs Specialist
201 Burlington Road, North Building
BEDFORD MA 01730

Re: K182971

Trade/Device Name: SpaceOAR Vue Hydrogel
Regulation Number: 21 CFR 892.5725
Regulation Name: Absorbable Perirectal Spacer
Regulatory Class: Class II
Product Code: OVB
Dated: June 13, 2019
Received: June 14, 2019

Dear Mr. Garcia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

K182971 – Mr. Marcus Garcia

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801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read 'Thalia T. Mills', is written over a large, light blue, semi-transparent 'FDA' watermark.

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Technical comparison

	SpaceOAR™ Hydrogel	SpaceOAR Vue Hydrogel
Chemistry	PEG Hydrogel	PEG Hydrogel
Hydrogel water content	~90%	~90%
Visibility	Ultrasound, limited CT visibility, and MRI	Ultrasound, Enhanced CT visibility, kV CBCT, and MRI
Iodine content	0%	~1%
Degradation	Via hydrolysis	Via hydrolysis
In vivo stability	3 months	3 months
Absorption profile	~6 months	~6 months
Hydrogel color	Clear	Tan
Application	Dual injection	Dual injection

Is this item/technology on a DAPA agreement or Department of Defense contract? Yes

Ship unit: Each

Mode of transportation: FedEx™ Delivery

Lead time in working days? None

What are the dimensions of the package?

6.00" x 1.50" x 15.25" (L x W x H)

Method of purchase: Direct purchase or bill upon use

Does this item require special storage considerations?

Per the DFU, store in a clean, dry, dark area at room temperature.

Is this a dated product?

Product contains expiration date on package label.

What specific departments/clinical areas will use the product/procedure?

Physician's office, Ambulatory Surgery Center, Hospital Outpatient Department

What department(s) will use and/or be affected by this product?

Radiation Oncology, Urology OR and Purchasing

Is there a requirement for staff training? Yes

Material / environment

Will there be additional implementation costs, such as installation, cost of education, impact on equipment or additional space?

Ultrasound equipment with a real-time bi-plane probe and a stepper stabilizer are required for the injection of SpaceOAR Vue Hydrogel; a stand-off balloon is recommended.

Does the product/procedure require a company representative to be present to operate equipment or to provide assistance to the physicians?

Yes, the physicians will need to go through a training process in the presence of a company representative, before they can perform procedures independently.

Is there any other equipment involved with the use of this product that will need to be leased, purchased, consigned or rented?

Ultrasound equipment with a real-time bi-plane probe and a stepper stabilizer are required for the injection of SpaceOAR Vue Hydrogel; a stand-off balloon is recommended.

What is the average length of procedure time to use this product/perform this procedure (surgery minutes)? 30 minutes

Will this equipment interface with any other equipment/supplies currently utilized at this facility?

Yes, a saline syringe

Does this product contain metal substances that may affect tests and or procedures performed on patients? No

If yes, is this product MRI safe? Yes

Is this considered an implantable device? Yes

Does this item and its packaging contain latex? No

Is this a pharmaceutical or contain any pharmaceutical product? No

Is SpaceOAR Vue Hydrogel contraindicated for patients with iodine allergies or risks?

The product is not contraindicated for patients with iodine sensitivity or risks. This is because the iodine is covalently bound to the PEG molecule and does not present in the body in the same way as free-flowing iodine contrast that is typically used in imaging. Boston Scientific has not conducted studies with SpaceOAR Vue Hydrogel in patients with iodine sensitivity or risks, so the decision to use the product in patients is left to the physician's discretion.

Does the product require a Material Safety Data Sheet? No

Is this product reusable? No

What additional waste or recycle costs are anticipated?

After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

Does the product contain Mercury?

No

Does this product contain PVC?

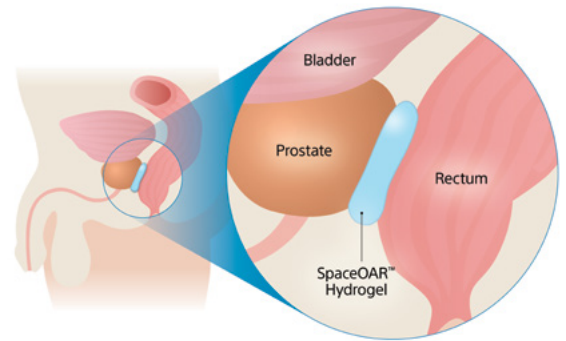
No

Does this product contain PVC halogenated flame retardants/halogenated organic chemicals (HOCs)?

No

Clinical data

The first generation 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. SpaceOAR Hydrogel is clinically proven to help minimize the impact on urinary, sexual and bowel quality of life for prostate cancer patients undergoing radiation therapy.⁸⁻¹⁰ Currently, there are 100,000 patients to date and growing.^{11,*}



Minimize prostate cancer radiation therapy side effects with SpaceOAR Hydrogel

In a prospective, randomized, multi-center trial, and at a median follow-up of 3 years, SpaceOAR Hydrogel has been shown to minimize the risk of sexual, urinary and bowel side effects.⁷⁻⁹



73% relative reduction in rectal V70*



0% late grade 2+ rectal toxicity**



67% maintained potency***

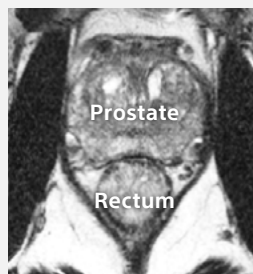


Significantly less decline in urinary and bowel QOL****

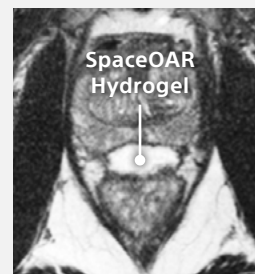
Create space between the rectum and prostate with SpaceOAR Hydrogel

- Approximately 1/2" (1.3 cm) of space⁸
- Space is maintained for approximately 3 months¹¹
- Naturally absorbed in about 6 months¹¹

T2-weighted magnetic resonance images of a SpaceOAR Hydrogel patient⁹



Pre-implant space



3-month persistence



Post-absorption

SpaceOAR Vue Hydrogel is the next-generation hydrogel designed to offer similar clinical benefits that SpaceOAR Hydrogel provides.

* Average dose reduction when comparing pre- and post-treatment plans
 ** In SpaceOAR Hydrogel patients
 *** Compared to 38% in control group; of men who had erections sufficient for intercourse at baseline
 **** Compared to control patients

Reimbursement & billing



SpaceOAR™ and SpaceOAR Vue™ Hydrogel Systems 2020 Coding & Payment Quick Reference

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.

The following codes are thought to be relevant to SpaceOAR™ and SpaceOAR Vue™ procedures and are referenced throughout this guide.

CPT® Code	Code Description
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

Physician Payment – Medicare

All rates shown are **2020 Medicare national averages**; actual rates will vary geographically and/or by individual facility. "Allowed Amount" is the amount Medicare determines to be the maximum allowance for any Medicare covered procedure. Actual payment will vary based on the maximum allowance less any applicable deductibles, co-insurances, etc.

CPT® Code	Work RVU	Non-Facility Practice Expense RVU	Facility Practice Expense RVU	Malpractice RVU	Total Office-Based RVU	Total Facility-Based RVU	MD In-Office Medicare Allowed Amount	MD In-Facility Medicare Allowed Amount
55874	3.03	83.79	1.47	0.27	87.09	4.77	\$3,143	\$172

Hospital Outpatient Payment – Medicare

CPT® Code	Short Descriptor	Payment Status Indicator	APC	Hospital Outpatient Medicare Allowed Amount
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed	T	5375	\$4,231

ASC Payment – Medicare

CPT® Code	Short Descriptor	Subject to Multiple Procedure Reduction Indicator	Final Payment Indicator	ASC Medicare Allowed Amount
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed	Y	G2	\$1,976

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See important notes on the uses and limitations of this information on page 2.

ICD-10 CM Diagnosis Code

ICD-10 CM Diagnosis Code	Description
C61	Malignant neoplasm of prostate

Physician payment rates are 2020 Medicare national averages. Source: Centers for Medicare and Medicaid Services. CMS Physician Fee Schedule – November 2019 release, CMS-1715-F file. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F>

The 2020 National Average Medicare physician payment rates have been calculated using a 2020 conversion factor of \$36.0896. Rates subject to change.

Hospital outpatient payment rates are 2020 Medicare OPPS Addendum B national averages. Source: Centers for Medicare and Medicaid Services. CMS OPPS – November 2019 release, CMS-1717-FC file. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-FC>

ASC payment rates are 2020 Medicare ASC Addendum AA national averages. ASC rates are from the 2020 Ambulatory Surgical Center Covered Procedures List. Source: Centers for Medicare and Medicaid Services. CMS ASC – November 2019 release, CMS-1717-FC file. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1717-FC>

National average (wage index greater than one and hospital submitted quality data and is a meaningful HER user) MS-DRG rates calculated using the national adjusted full update standardized labor, non-labor, and capital amounts (\$6,263.74). Source: August 2019 Federal Register, CMS-1716-FR, FY 2020 rates.

ICD-10 MS-DRG definitions from the CMS ICD-10-CM/PCS MS-DRG v37.0 Definitions Manual. Source: https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0001.html

Comprehensive APCs (C-APCs): In 2014, CMS implemented their C-APC policy with the goal of identifying certain high-cost, device-related outpatient procedures (formerly “device intensive” APCs). CMS has fully implemented this policy and has identified these high-cost, device-related services as the primary service on a claim. All other services reported on the same date will be considered “adjunctive, supportive, related, or dependent services” provided to support the delivery of the primary service and will be unconditionally packaged into the OPPS C-APC payment of the primary services with minor exceptions.

Please note: this coding information may include codes for procedures for which Boston Scientific currently offers no cleared or approved products. In those instances, such codes have been included solely in the interest of providing users with comprehensive coding information and are not intended to promote the use of any Boston Scientific products for which they are not cleared or approved. The Health Care Provider (HCP) is solely responsible for selecting the site of service and treatment modalities appropriate for the patient based on medically appropriate needs of that patient and the independent medical judgement of the HCP.

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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.

Sequestration Disclaimer

Rates referenced in these guides do not reflect Sequestration, automatic reductions in federal spending that will result in a 2% across-the-board reduction to ALL Medicare rates as of January 1, 2020.

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Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com/reimbursement

Ordering Information
1.888.272.1001

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URO-839807-AA JUL 2020

Ordering information

UPN	GTIN Number	Catalog Number	Name	Description
SV-2101	00864661000140	SV-2101	SpaceOAR Vue Hydrogel System	Absorbable Perirectal Hydrogel Spacer

- Moghanaki D, Turkbey B, Vapiwala N, et al. Advances in prostate cancer magnetic resonance imaging and positron emission tomography-computed tomography for staging and radiotherapy treatment planning. *Semin Radiat Oncol.* 2017 Jan;27(1):21-33.
- 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.
- 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):518-27.
- Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2020 © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed July 8, 2020. To view the most recent and complete version of the guideline, go to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
- Potosky AL, Davis WW, Hoffman RM, et al. Five-year outcomes after prostatectomy or radiotherapy for prostate cancer: the prostate cancer outcomes study. *J Natl Cancer Inst.* 2004 Sep 15;96(18):1358-67.
- Sanda MG, Dunn RL, Michalski J, et al. Quality of life and satisfaction with outcome among prostate-cancer survivors. *N Engl J Med.* 2008 Mar;358(12):1250-61.
- 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.
- 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.
- 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.
- Karsh LI, Gross ET, Pieczonka CM, et al. Absorbable hydrogel spacer use in prostate radiotherapy: A comprehensive review of phase 3 clinical trial published data. *Urology.* 2018 May;115:39-44.
- Data on file with Boston Scientific.

* Number of patients is based on units shipped and a BSC proprietary algorithm

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.

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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.

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