Boston Scientific
Advancing science for life™

# SpaceOAR™ Hydrogel

## Product Review for the Value Analysis Committee

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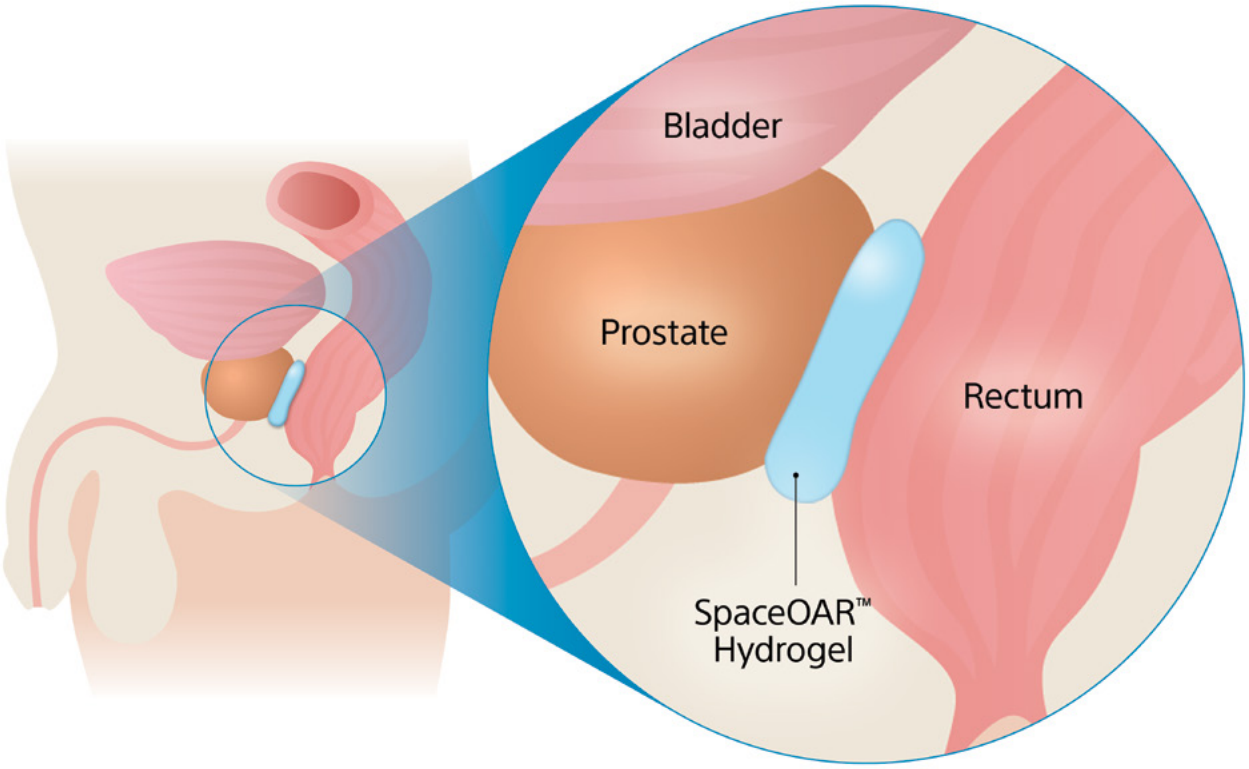
# Product overview

## SpaceOAR™ Hydrogel

The first-generation SpaceOAR Hydrogel is an absorbable, polyethylene glycol (PEG) based 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 demonstrated to help minimize the impact on urinary, sexual, and bowel quality of life for prostate cancer patients undergoing radiation therapy.[1-3] Currently, there are over 280,000 SpaceOAR Hydrogel patients to date and growing.[4,*]




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

# 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.[5]

"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.[6,7] 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.[1,8] 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.[2] 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."[9]

**Please refer to the full NCCN Guidelines for complete details: http://NCCN.org**

# Regulatory information

## What is the intended use?

SpaceOAR™ 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 Hydrogel to reduce the radiation dose delivered to the anterior rectum. SpaceOAR Hydrogel is composed of biodegradable material and designed to maintain space for the course of prostate radiotherapy treatment and is absorbed by the patient's body over time.[4]

## What is the FDA classification of the device?

SpaceOAR 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 latest 510(k) clearance is attached.

Boston Scientific Corporation
% Ms. Jeanne O'Toole
Principal Regulatory Affairs Specialist
100 Boston Scientific Way
MARLBOROUGH MA 01752

August 28, 2020

Re: K202224
Trade/Device Name: SpaceOAR System
Regulation Number: 21 CFR 892.5725
Regulation Name: Absorbable Perirectal Spacer
Regulatory Class: Class II
Product Code: OVB
Dated: August 6, 2020
Received: August 7, 2020

Dear Ms. O'Toole:

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 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,

For

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

# Utilization

**Is this item/technology on contract?**
Please reach out to your Boston Scientific National Account Director.

**Ship unit:** Each

**Mode of transportation:** FedEx™ Delivery

**Lead time to order in working days?** None

**What are the dimensions of the package?**
Single-pack: 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 Instructions for Use (IFU), store at or below 25°C (77°F) in order to maintain product performance.

**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

**Is there a training requirement?**
Yes, users will need to go through a product training process in the presence of a company representative before they can perform procedures independently.

**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 transrectal ultrasound (TRUS) probe and a stepper stabilizer are required for the injection of SpaceOAR Hydrogel; a stand-off balloon is recommended.

**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 transrectal ultrasound (TRUS) probe and a stepper stabilizer are required for the injection of SpaceOAR 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[10]

**Will this product interface with any other equipment/supplies currently utilized at this facility?**
Yes, a saline syringe

# Additional information[4]

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

**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

**Does the product require a Material Safety Data Sheet?** No

**Is this product reusable?** No

**What additional waste or recycle costs are anticipated?**
None. 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 polyethylene glycol (PEG)?** Yes

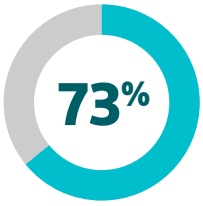
**Does this product contain polyvinyl chloride (PVC)?** No

**Does this product contain PVC halogenated flame retardants/halogenated organic chemicals (HOCs)?** No

# Clinical data

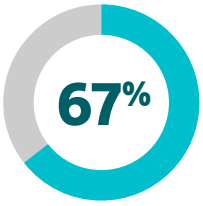
## Designed to minimize prostate cancer radiation therapy side effects

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.[7,9,11]




**relative reduction in rectal V70*[1]**


**late grade 2+ rectal toxicity**[2]**




**maintained potency**[9]***

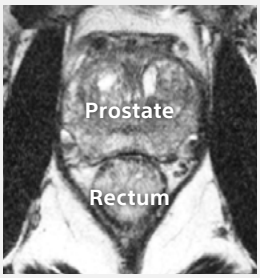
**Significantly less decline in urinary and bowel QOL**[2]****

* 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

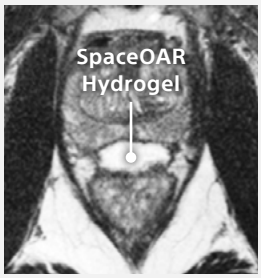
## Create space between the rectum and prostate with SpaceOAR Hydrogel

- At 3 months, approximately 1/2" (1.3 cm) of space is present (according to one study)[1]
- Space is maintained for approximately 3 months[4]
- Naturally absorbed in about 6 months[4]

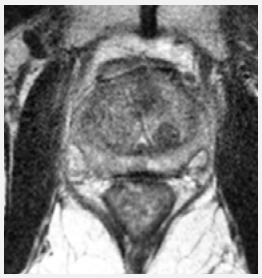
**T2-weighted magnetic resonance images of a SpaceOAR Hydrogel patient[1]**




**Pre-implant space**




**3-month persistence**



**Post-absorption**

## Experience next-generation rectal protection for all patients

3D-CRT, IMRT, and IG-IMRT were milestones in prostate cancer rectal protection. SpaceOAR Hydrogel helps to reduce rectal toxicity and maintain quality of life for all prostate cancer radiation patients post radiation when compared to non-spacer patients.[1,2] In one study, the authors were unable to identify a subgroup within the population studied that did not potentially benefit from spacer placement.[11]

## Delivers potential operational benefits to providers and staff

- Minimally invasive procedure. In the pivotal study:
  - 98.7% SpaceOAR Hydrogel application was rated as easy or very easy[1]
  - 99% SpaceOAR Hydrogel placement success rate[1]
- Can be implanted using general or local anesthesia and at the time of fiducial marker placement
- Can be implanted in multiple sites of service[4] potentially simplifying scheduling:
  - Outpatient procedure in a hospital
  - Freestanding ambulatory surgery center
  - Doctor's office

# Reimbursement & billing

## SpaceOAR™ and SpaceOAR Vue™ Hydrogel Systems

### 2023 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.

To determine whether there are relevant C-codes for any Boston Scientific products, please visit our C-code finder at http://www.bostonscientific.com/en-US/reimbursement/ccode-finder.html.

C-Codes are tracking codes established by the Centers for Medicare & Medicaid Services (CMS) to assist Medicare in establishing future APC payment rates. C-Codes only apply to Medicare hospital outpatient claims. They do not trigger additional payment to the facility today.

It is very important that hospitals report C-Codes as well as the associated device costs. This will help inform and potentially increase future outpatient hospital payment rates.

| CPT® / HCPCS 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 **2023 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 / HCPCS 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 | 83.73 | 1.50 | 0.30 | 87.06 | 4.83 | $2,950 | $164 |

### Hospital Outpatient Payment – Medicare

| CPT / HCPCS Code | Short Description | 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 | $4,702 |

**Considered a device intensive procedure by CMS, SpaceOAR™ material must be reported with device code C1889, on the same claims form as the placement code. See page 2 for more information.*


See important notes on the uses and limitations of this information on page 3.

## ASC Payment – Medicare

| CPT / HCPCS Code | Short Description | 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 | J8 | $3,564 |

**Considered a device intensive procedure by CMS, SpaceOAR™ material must be reported with device code C1889, on the same claims form as the placement code. See page 2 for more information.*

## ICD-10 CM Diagnosis Code

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

## C-Code Information

For all C-Code information, please reference the C-code Finder: http://www.bostonscientific.com/en-US/reimbursement/ccode-finder.html

| Code | Description |
|---|---|
| C1889 | Implantable/insertable device, not otherwise classified |

On claims for Medicare beneficiaries, hospitals should report not only the appropriate CPT® Code, but also C-Code C1889.

- C-Codes are tracking codes established by the Centers for Medicare & Medicaid Services (CMS) to assist Medicare in establishing future APC payment rates. C-Codes only apply to Medicare hospital outpatient claims. They do not trigger additional payment to the facility today.
- It is very important that hospitals report C-Codes as well as the associated device costs. This will help inform and potentially increase future outpatient hospital payment rates.

### Suggested Revenue Codes

| Code | Description |
|---|---|
| 278† | Medical/surgical supplied and devices/other implants |

See important notes on the uses and limitations of this information on page 3.

Physician payment rates are 2023 Medicare national averages. Source: Centers for Medicare and Medicaid Services. CMS Physician Fee Schedule – November 2022 release, CMS-1770-F file. https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1770-f.

The 2023 National Average Medicare physician payment rates have been calculated using the latest updated 2023 conversion factor of $33.06. Rates subject to change.

Hospital outpatient payment rates are 2023 Medicare OPPS Addendum B national averages. Source: Centers for Medicare and Medicaid Services. CMS OPPS – November 2022 release, CMS-1772-FC file. https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientpps/cms-1772-fc.

ASC payment rates are 2023 Medicare ASC Addendum AA national averages. ASC rates are from the 2023 Ambulatory Surgical Center Covered Procedures List. Source: Centers for Medicare and Medicaid Services. CMS ASC – November 2022 release, CMS-1772-FC file. https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1772-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. Source: September 2022 Federal Register, CMS-1771-FR. FY 2023 rates.

ICD-10 MS-DRG definitions from the CMS ICD-10-CM/PCS MS-DRG v38.1 Definitions Manual. Source: https://www.cms.gov/icd10m/version38-1-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.

† According to Medicare, devices do not need to remain in the body to be classified as “implants.”[1,2]

1 Preamble to the Inpatient Prospective Payment update regulation for FY 2009 (73 FR 48462).

2 Revenue Code 278 - Definition in UB-04 manual, National Uniform Billing Committee Summary, August 2009, Page 5: (a) Implantables: That which is implanted, such as a piece of tissue, a tooth, a pellet of medicine, or a tube or needle containing a radioactive substance, a graft, or an insert. Also included are liquid and solid plastic materials used to augment tissues or to fill in areas traumatically or surgically removed. An object or material partially or totally inserted or grafted into the body for prosthetic, therapeutic, diagnostic purposes. Examples of Other Implants (not all-inclusive): Stents, artificial joints, shunts, grafts, pins, plates, screws, anchors, radioactive seeds.

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.

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 2022 but is subject to change without notice. Rates for services are effective January 1, 2023.

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 or other reductions that may be implemented in 2023.

**CPT® Disclaimer**


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

***Ordering Information***
***1.888.272.1001***



Effective: 1JAN2023
Expires: 31DEC2023
MS-DRG Rates Expire: 30SEP2023
URO-737504-AD DEC 2022

# Q&A

## What CPT® Code is used to bill for the SpaceOAR™ Hydrogel system procedure?

CPT Code 55874 (Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed) may be used when billing for the SpaceOAR Hydrogel procedure. An insurance verification/pre-authorization request can be completed by the Urology Procedure Access Program team prior to treatment.  A member of the team will contact the payer, at your request, and report back coverage details.

## Does Medicare reimburse for CPT Code 55874?

All Medicare Administrative Contractors cover the SpaceOAR Hydrogel procedure. Payment varies by geographic locale.

## How is the SpaceOAR Hydrogel procedure reimbursed?

Hospital outpatient department (HOPD) Medicare national average 2023 facility reimbursement is $4,702.

Physician Medicare national average 2023 reimbursement in the office setting is $2,950; physician facility reimbursement is $164 or 3.03 work RVUs.

## Are other procedures included in the payment for CPT Code 55874?

Ancillary services are typically considered bundled and included in the payment for the procedure. However, other specific procedures performed in the same surgical session may result in additional reimbursement. There is a 0-day global period assigned to CPT Code 55874.

# Ordering information

| UPN | GTIN Number | Catalog Number | Name | Description |
|---|---|---|---|---|
| SO-2101 | 00864661000102 | SO-2101 | SpaceOAR™ Hydrogel System | Absorbable Perirectal Hydrogel Spacer |


1. 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;92:971–977.
2. 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;97:976–985.
3. 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;115:39–44.
4. Data on file with Boston Scientific.
5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2023 © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed August 7, 2023. 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.
6. 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;96:1358–1367.
7. Sanda MG, Dunn RL, Michalski J, et al. Quality of life and satisfaction with outcome among prostate-cancer survivors. *N Engl J Med*. 2008;358:1250–1261.
8. Miller LE, Efstathiou JA, Bhattacharyya SK, Payne JA, Woodward E, Pinkawa M. Association of the placement of a perirectal hydrogel spacer with the clinical outcomes of men receiving radiotherapy for prostate cancer: a systematic review and meta-analysis. *JAMA Netw Open*. 2020;3:e208221.
9. 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;8:e7–e15.
10. CMS 2023 Physician Worktime File: https://www.cms.gov/files/zip/cy-2023-pfs-final-rule-physician-work-time.zip. Accessed October 13, 2022.
11. Quinn TJ, Daignault-Newton S, Bosch W, et al. Who benefits from a prostate rectal spacer? Secondary analysis of a Phase III trial. *Pract Radiat Oncol*. 2020;10:186–194.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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, 2023.



SpaceOAR 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 Hydrogel to reduce the radiation dose delivered to the anterior rectum.

SpaceOAR Hydrogel contains polyethylene glycol (PEG).

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 Hydrogel. Potential complications associated with SpaceOAR Hydrogel include, but are not limited to: pain associated with SpaceOAR Hydrogel injection, pain or discomfort associated with SpaceOAR Hydrogel, 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-989608-AB.

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



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Marlborough, MA 01752-1234
www.BostonScientific.com





URO-837104-AB AUG 2023