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SpaceOAR™ Hydrogel

Product Review for the Value Analysis Committee

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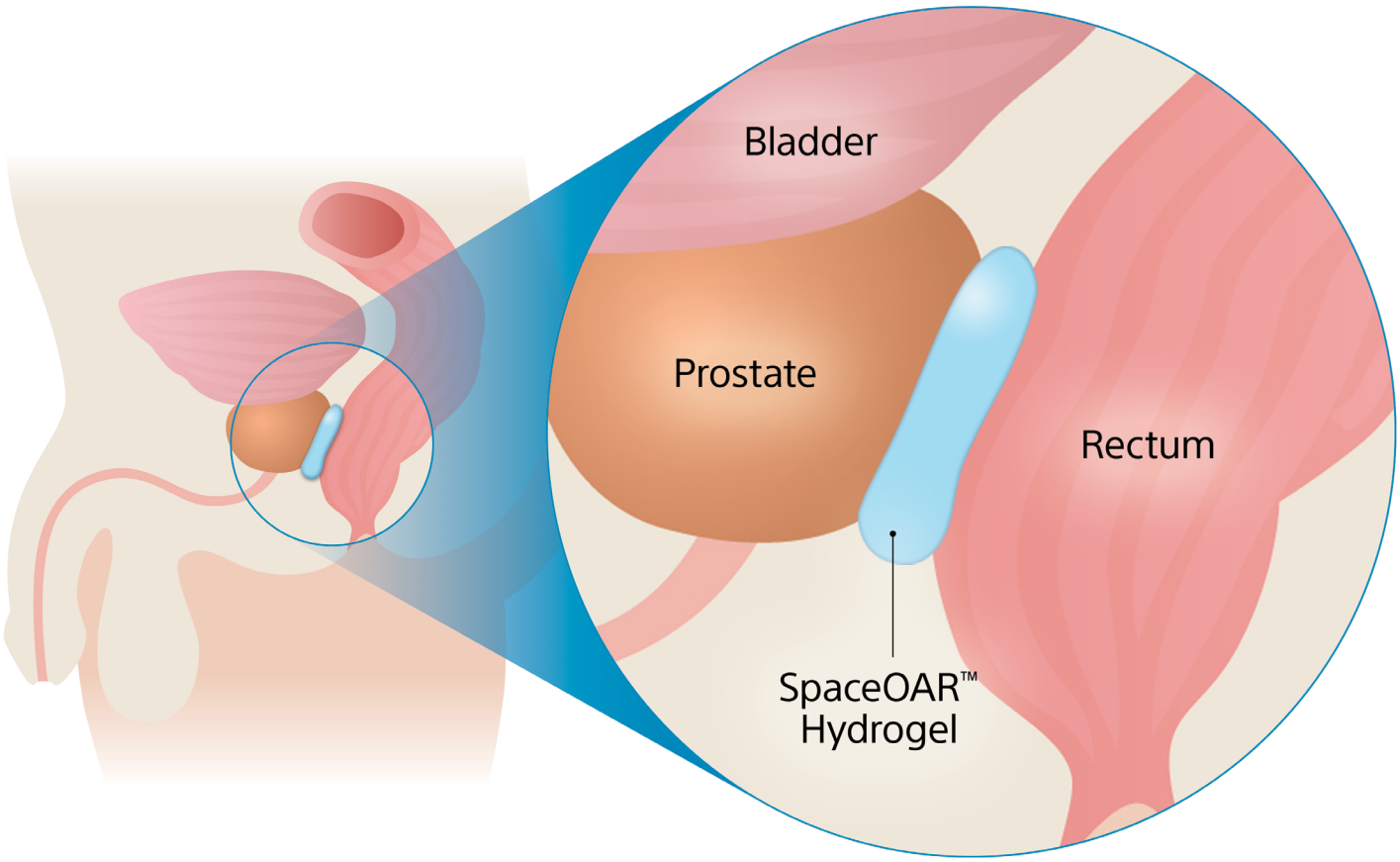
Product overview

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 over 400,00 units of SpaceOAR and SpaceOAR Vue™ Hydrogel have been shipped to date.



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.[1,7] 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."[8]

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.

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.

U.S. FOOD & DRUG ADMINISTRATION

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,

Michael D. O'Hara 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[9]

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

Additional information

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

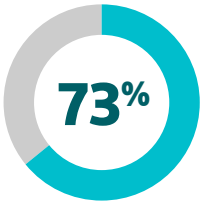
Does this product contain polyvinyl chloride (PVC)? No

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

Clinical data

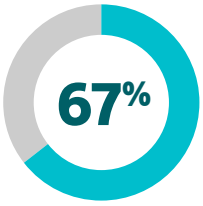
Designed to help minimize prostate cancer radiation therapy side effects

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.[2,8]



relative reduction in rectal V70*[1]

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



maintained potency[***8]**

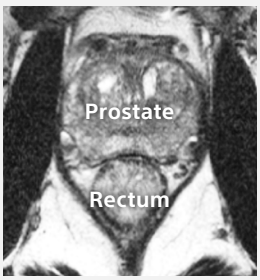
* Average dose reduction when comparing pre- and post-treatment plans
** In SpaceOAR Hydrogel patients
*** Compared to 38% in control group; of men who had erections sufficient for intercourse at baseline
**** Compared to control patients

Significantly less decline in urinary and bowel QOL (p=0.02)[****2]**

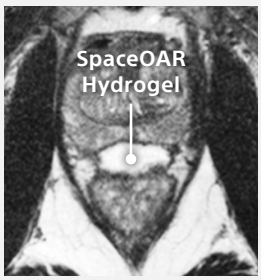
Create space between the rectum and prostate with SpaceOAR Hydrogel

- Approximately 1/2" (1.3 cm) of space created post-spacer application (according to one study)[1]
- Space is maintained for approximately 3 months
- Naturally absorbed in about 6 months but it may take longer to fully absorb

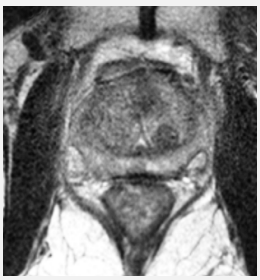
T2-weighted magnetic resonance images of a SpaceOAR Hydrogel patient[1]



Pre-implant space



3-month persistence



Post-absorption

Images used with permission from 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.

Experience rectal protection for patients

SpaceOAR Hydrogel helps to reduce rectal toxicity and maintain quality of life for 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.[10]

Application procedure

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 potentially simplifying scheduling:

- Outpatient procedure in a hospital
- Freestanding ambulatory surgery center
- Doctor's office

Reimbursement & billing

To view the current Coding and Payment Guide, visit https://www.bostonscientific.com/content/dam/bostonscientific/Reimbursement/Urology/pdf/SpaceOAR_Procedure_Coding_and_Payment_Guide.pdf

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. Visit our Benefit Verification and Pre-Authorization Portal for help with benefit verification, pre-authorization, and appeals support: https://www.bostonscientific.com/en-US/reimbursement/benefit-verification-and-pre-authorization.html

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 2026 facility reimbursement is $5,478. Ambulatory Surgery Center (ASC) Medicare national average reimbursement is $4,230. Physician Medicare national average 2026 reimbursement in the office setting is $3,722. Physician facility reimbursement is $143, reflecting 2.95 work RVUs (4.28 total 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

SpaceOAR Systems Brief Summary

Scan the QR code, visit bostonscientific.com/spaceoar-brief-summary, or click to view the SpaceOAR Systems Indications, Safety, and Warnings

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. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. CMS 2023 Physician Worktime File: https://www.cms.gov/files/zip/cy-2023-pfs-final-rule-physician-work-time.zip. Accessed February 13, 2026.
10. 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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