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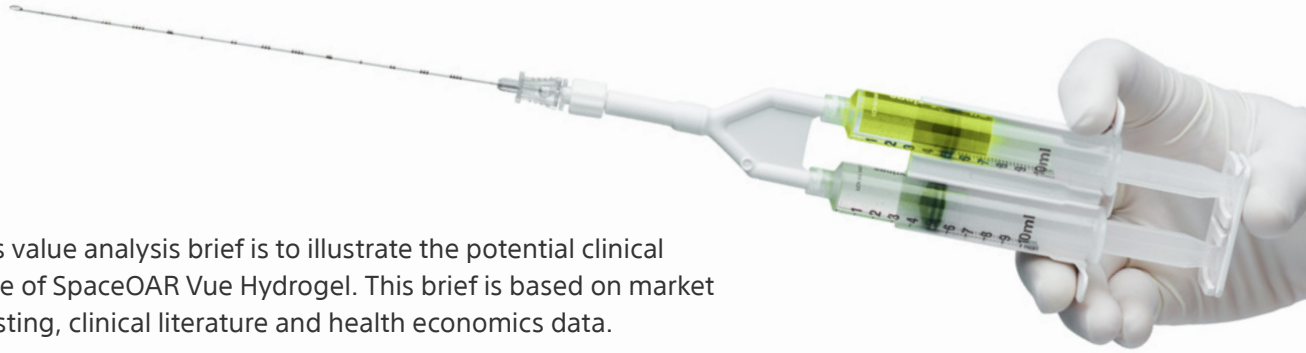
SpaceOAR Vue™ Hydrogel

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.[1] 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.[1] 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.[1]
- 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.[1]
- 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.[2-4]
- 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.[1]
- Integrates into existing practice patterns, fiducial markers can be implanted via the transperineal approach prior to SpaceOAR™ Hydrogel injection.[1]
- 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.[4,5]
- Reimbursement[1,5,6]
  - 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.[7] The average annual cost of treating prostate cancer with radiation therapy, including recurrence or side effects, is $10,810.[8] 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.
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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.

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. 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.

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