

Company

Boston Scientific

Drug or Device Name

SpaceOAR VUE™ Hydrogel

Category

Medical Technology

Compound/Technical Name

SPACEOAR VUE

Trade Name

SpaceOAR VUE Hydrogel

Date of Approval

07/19/2019

Therapeutic Categories

The SpaceOAR VUE™ Hydrogel is a radiopaque perirectal spacer for radiation therapy used during the treatment of prostate cancer and has been shown to: •Be effective in reducing the risk of radiation related bowel, urinary and sexual complications •Minimize radiation related side effects and better maintain quality of life measures after radiotherapy when compared with patients who did not receive a perirectal spacer •Allow the use of CT imaging for pre-treatment planning in place of MRI, eliminating the need for additional MRI scanning after diagnosis, and enable the use of perirectal spacers for patients who are incompatible with MRI

Indications

The SpaceOAR VUE System 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 System to reduce the radiation dose delivered to the anterior rectum. The SpaceOAR VUE System 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. Please see attached PDF for entire submission and references.

Background

An estimated 1 in 8 men will be diagnosed with prostate cancer at some point, making it the second most frequently occurring cancer among men. Radiation therapy is a commonly selected treatment option, with roughly 60,000 men in the United States undergoing this treatment annually. Radiation therapy begins with pre-treatment planning, with the utilization of MRI and CT scans to develop a treatment plan which defines the tissue to be targeted, including the surrounding margins, and the therapeutic dose of radiation which will be delivered. This planning process also predicts the radiation dose that will be delivered to adjacent organs due to the treatment plan, such as the rectum.

Irradiation of adjacent organs may cause side effects impacting bowel, urinary, and sexual function. As a result, physicians are faced with the challenge of developing a treatment plan aggressive enough to treat the cancerous tissue and surrounding margins that also minimizes the risk of damage to the adjacent organs. SpaceOAR VUE is an iodinated, Polyethylene Glycol (PEG) based hydrogel that has been shown to increase the space between the prostate and rectum from about 2mm to 13mm after implantation. This additional space is intended to improve targeting of the treatment area, while minimizing the radiation dose delivered to the rectum, reducing the risk of the patient developing radiation-related side effects. The use of iodinated PEG in the perirectal spacer increases the visibility of the hydrogel on CT imaging, streamlining the pre-treatment planning workflow by removing the need for secondary MRI and allowing for more accurate tissue contouring and patient positioning via CT. Additionally, the enhanced CT visibility SpaceOAR VUE provides offers patients who are unable to undergo MRI scanning due to factors such as existing metal implants, obesity, or claustrophobia an option for perirectal spacer protection. Please see attached PDF for additional details. References are included in the overall submission document (product section).

Development

SpaceOAR VUE builds off the technology of the SpaceOARTM Hydrogel, a perirectal spacer which received 510k clearance from the FDA in 2015. The two hydrogels are similar as they both utilize a PEG-based chemistry and share the same delivery system and mechanism of action (formation of a hydrogel to temporarily create space between the prostate and rectum). Also, like SpaceOAR, SpaceOAR VUE appeals to patients and physicians because it is fully absorbable and implanted in a minimally invasive fashion during a roughly 30-minute percutaneous procedure using ultrasound guidance (including preparation time). Both products create and temporarily maintain space between the prostate and rectum for about 3 months and are fully absorbed and safely removed via renal filtration about 6-7 months after implantation. However, SpaceOAR VUE is unique due to its enhanced radiopacity and resultant CT visibility, providing true benefit to both patients and physicians. •From a patient's perspective, SpaceOAR VUE: o Provides an opportunity to reduce the risk of developing radiation-related bowel, urinary and sexual side effects for those who are unable to undergo MRI. •From a physician's perspective, SpaceOAR VUE: o Reduces the need for post-spacer implantation MRI, streamlining pre-treatment workflow o Improves pre-treatment planning and contouring accuracy due to the hydrogel's enhanced contrast compared to adjacent tissues on CT imaging o Improves patient positioning accuracy and consistency during each treatment as patients are commonly positioned using CT guidance Due to their similarities in material composition and mechanism of action, the extensive clinical evidence generated for the original SpaceOAR Hydrogel applies directly to SpaceOAR VUE, and studies show that the use of SpaceOAR reduces grade 1 rectal toxicity by 75%, urinary decline by 60% and that those men who had a SpaceOAR implanted reported significantly favorable outcomes relating to erection ability, orgasm ability, erection quality and erection frequency. Please see attached PDF for further details. References are included in the overall submission document (product section).

Innovation

SpaceOAR VUE is a huge advancement for perirectal spacers because it marries the best properties from the widely used SpaceOAR Hydrogel (minimally invasive placement, durable perirectal space creation, and absorbable materials) with an optimized chemistry which enhances the device's radiopacity and ultimately its visibility on CT imaging. The ability to offer ALL patients an opportunity to reduce the risk of developing post-radiation bowel, urinary, and sexual function related side effects has tremendous value, especially to those patients who are unfortunately incompatible with MRI. For some

patients, the use of a perirectal may be a key factor influencing the decision to choose radiation therapy over surgery: why not consider a non-surgical treatment with radiation therapy if they can avoid unpleasant radiation-related side effects? Patient testimonials often reference that the simple and safe implantation procedure coupled with less invasive radiation therapy (when compared to surgery) is very appealing. Patients frequently make comments like: ·Pierre from Texas said, "...it was an easy to tolerate procedure. After the fact, I couldn't tell anything was there. As for the cancer treatment, I'd rather have brachytherapy than a cold!" ·Ron from Florida described the experience as, "...I tolerated the procedure very well... From that point on, I felt even more confident that my surrounding organs would be protected during radiation. When the procedure was complete, I was able to go back to work and exercise without any adverse reactions." ·Dr. James Gray, a radiation oncologist and prostate cancer patient and SpaceOAR recipient himself said, "seeing my own CT scan and I know that we're going to be able to execute a plan to treat my prostate without including my rectum in part of that planning, it really hit home." Please see attached PDF for further details and associated links. References are included in the overall submission document (product section).

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Attachments

- 1654018418PrixGalien_SpaceOAR_Submission.pdf
- 1654007980PrixGalien_SpaceOAR_Background_Section.pdf

- 1654008046PrixGalien_SpaceOAR_Development_Section.pdf
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