# SpaceOAR™ Hydrogel

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# A Multi-Institutional Phase II Trial of High-Dose SAbR for Prostate Cancer Using Rectal Spacer

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## Limitations of this report include

- The SpaceOAR Hydrogel pivotal study did not use SBRT so the results may not be comparable.
- This study was not randomized and definitive claims about the benefits of a spacer cannot be made.
- These results may not be achieved with other SBRT protocols.
- Weaknesses of the study are primarily in terms of secondary endpoints, as the patient cohort was small with a median follow-up of 48 months to date.
- While it is early to interpret biochemical control results, and this Phase 2 trial is not powered or structured for rigorous comparison across other prospective trials, they are promising with a 4-year FFBF of 93.8% despite over half the treated patients considered unfavorable IR, and no patients receiving concurrent or adjuvant ADT.

High-dose stereotactic ablative radiotherapy (SAbR) for prostate cancer (PCa) offers the radiobiologic potency of the most intensified radiation therapy regimens, but was associated with >90% rates of ulceration of the anterior rectal wall on endoscopic assessment that infrequently progressed to severe rectal toxicity in prior prospective series. A multi-institutional Phase II prospective trial was conducted to assess whether placement of a peri-rectal hydrogel spacer would reduce acute periprostatic rectal ulcer events following high dose (> 40 Gy) SAbR.

**45Gy/5 Fractions**

| | Acute | | | Late | | |
|---|---|---|---|---|---|---|
| | Grade 1 | Grade 2 | Grade 3 | Grade 1 | Grade 2 | Grade 3 |
| Genitourinary (Any) | 28 (65.1%) | 20 (46.5%) | 1 (2.3%) | 27 (64.3%) | 14 (33.3%) | 1 (2.4%) |
| *Irritative* | *19 (44.2%)* | *16 (37.2%)* | *1 (2.3%)* | *18 (42.9%)* | *12 (28.6%)* | *0 (0.0%)* |
| *Obstructive* | *18 (41.9%)* | *5 (11.6%)* | *0 (0.0%)* | *14 (33.3%)* | *6 (14.3%)* | *1 (2.4%)* |
| Gastrointestinal | 25 (58.1%) | 10 (23.3%) | 0 (0.0%) | 14 (33.3%) | 6 (14.3%) | 0 (0.0%) |
| Reproductive | 14 (32.6%) | 6 (14.0%) | 0 (0.0%) | 6 (14.3%) | 6 (14.3%) | 0 (0.0%) |

***"This is the first prospective study to evaluate the efficacy of a temporary hydrogel spacer for patients undergoing high-dose SAbR (45 Gy in 5 fractions) for LR and IR PCa. Hydrogel spacer placement prior to high-dose SAbR treatment for LR and IR PCa increases the distance between anterior rectal wall and prostate. This increased space for dose falloff and reduction in incidental dose to the rectal wall is associated with a significant reduction in the incidence of rectal ulcer events to only 14.3% compared to prior studies, facilitating the safe delivery of high-dose SAbR. This is expected to reduce long-term rectal toxicity; there have been no (0%) high-grade (Grade ≥ 3) GI events noted on study to date."***

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SBRT was not the method used in the SpaceOAR™ Hydrogel single-blind Phase III trial performed to evaluate dosimetric and clinical effects of SpaceOAR Hydrogel. IG-IMRT delivered at 79.2 Gy in 1.8-Gy fractions was the method used.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

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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

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