## SpaceOAR<sup>™</sup> Hydrogel

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Hydrogel spacer distribution within the perirectal space in patients undergoing radiotherapy for prostate cancer: Impact of spacer symmetry on rectal dose reduction and the clinical consequences of hydrogel infiltration into the rectal wall

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## Limitations of this report include:

Spacer placement was supervised by trained professionals and might be more accurate than real-world placement by unsupervised physicians. As with any technical procedure, however, the placement of hydrogels is likely to improve with experience. This study depicts results from physicians in the initial training phase of placing the hydrogels. Additional studies will be needed to better understand the effects of technique for optimal hydrogel symmetry and avoidance of rectal wall infiltration.

## "Significant reduction of rectal dose can still be achieved even in the setting of asymmetric hydrogel spacer placement."

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All trademarks are the property of their respective owners. © 2022 Boston Scientific Corporation or its affiliates. All rights reserved. URO-1061302-AA APR 2022 The purpose of this secondary analysis of the SpaceOAR Hydrogel US Pivotal trial was to assess hydrogel distribution and its impact on rectal dose reduction during radiotherapy. The study included 149 patients with stage T1 or T2 prostate cancer, Gleason score <7, and a PSA <20 ng/mL who were planning to receive IG-IMRT.

A team of 3 radiation oncologists evaluated the postimplant T2-weighted MRI for all 149 patients and determined hydrogel symmetry using a semiqualitative scoring system. A score of Sym 1 recognizes hydrogel symmetry in all 3 slices (midgland, 1 cm superior and 1 cm inferior to midland). Scores 2-5 represent increasing asymmetry (see Figure 1 below). The symmetry was then correlated to rectal dose reduction using a Student *t* test.

Overall, a symmetrical spacer application was found in 92 (62%) of the midgland and superior axial slices, and 108 (72%) of the inferior slices. Seventy-three (49.0%) patients had spacer symmetry in all 3 axial slices, with 26 (17.4%), 20 (13.4%), 28 (18.8%), and 2 (1.3%) patients with scores of Sym 2 through Sym 5, respectively.

**Conclusion:** As previously demonstrated in the Pivotal trial, SpaceOAR Hydrogel demonstrates significant reduction of rectal dose during IG-IMRT. In this study, asymmetry of hydrogel was found to be common; however, all but the most extreme asymmetry still resulted in significant rectal dose reductions.



Figure 1: Coronal view of the prostate with location of the midgland, superior (Sup), and inferior (Inf) axial slices evaluated. Also shown are symmetry locations, with 1 representing midline, 2L/2R representing 1 cm left and right, and 3L/3R 2 cm left and right, respectively.



Figure 3B: Absolute rectal dose-volume histogram (DVH) for each Sym score group following spacer application.