CLINICAL SUMMARY

# SpaceOAR™ Hydrogel

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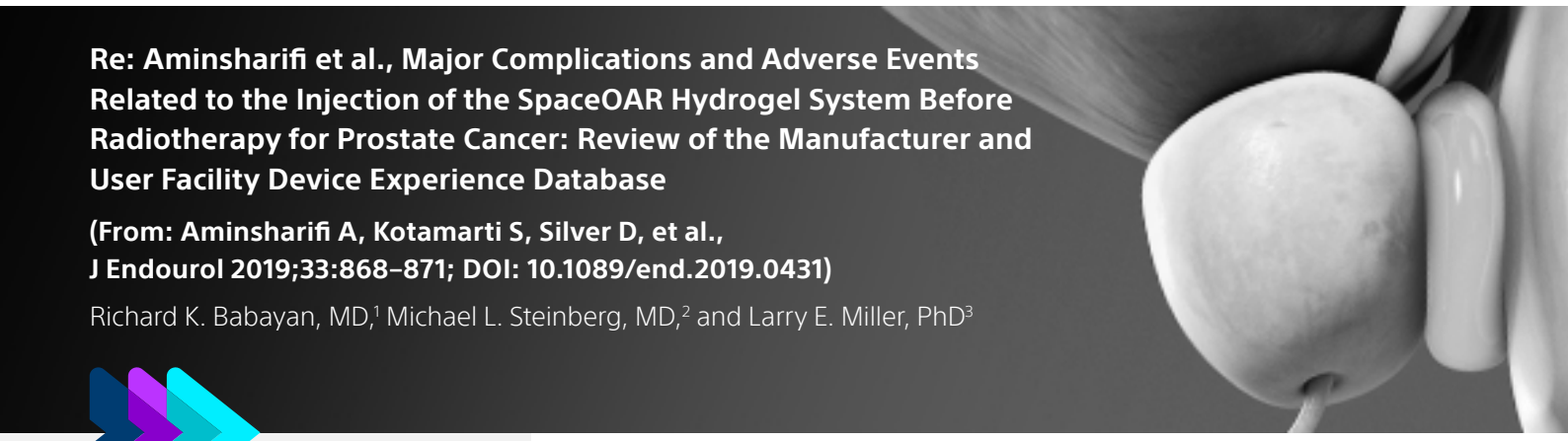
## Re: Aminsharifi et al., Major Complications and Adverse Events Related to the Injection of the SpaceOAR Hydrogel System Before Radiotherapy for Prostate Cancer: Review of the Manufacturer and User Facility Device Experience Database

**(From: Aminsharifi A, Kotamarti S, Silver D, et al., J Endourol 2019;33:868–871; DOI: 10.1089/end.2019.0431)**

Richard K. Babayan, MD,[1] Michael L. Steinberg, MD,[2] and Larry E. Miller, PhD[3]



**In response to the article, "Major Complications and Adverse Events Related to the Injection of the SpaceOAR Hydrogel System Before Radiotherapy for Prostate Cancer: Review of the Manufacturer and User Facility Device Experience Database," by Aminsharifi et al., the authors queried the MAUDE database and summarised information in medical device reports (MDRs) related to SpaceOAR Hydrogel.**

Regarding the increasing number of MDRs since the SpaceOAR Hydrogel FDA approval in 2015, it is intuitive that the number of MDRs would increase over time with increased device utilisation. However, it is misleading to suggest the complication rate is increasing without accounting for the number of cases performed.

Authors of the aforementioned article also state that several unique adverse events reported were not acknowledged as potential risks on the manufacturer's website. However, the device's instructions for use and labelling appear complete.

After contacting the device manufacturer, it was concluded that the number of MDRs has been increasing proportionately with device usage and, consequently, the rate of MDRs has remained relatively constant over time, ranging from 0.3 to 0.6 MDRs per 1000 SpaceOAR cases performed.

We feel that the authors' implications of increasing adverse event rates and inadequate risk labelling with the SpaceOAR device are unjustified.

### Table 1. Medical Device Reports with SpaceOAR Perirectal Hydrogel Spacer Since Commercialisation in the United States

| Year | No. of MDRs | No. of SpaceOAR cases | MDRs per 1000 SpaceOAR cases |
|---|---|---|---|
| 2015 | 1 | 1802 | 0.6 |
| 2016 | 2 | 5544 | 0.4 |
| 2017 | 3 | 9890 | 0.3 |
| 2018 | 14[a] | 22,225 | 0.6 |
| 2019[b] | 5 | 8361 | 0.6 |

a Indicates 11 MDRs involving 14 cases
b Reported through March 31, 2019
MDR = medical device report

**Link to full article: https://pubmed.ncbi.nlm.nih.gov/31914809/**

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R.K.B. served on the Clinical Events Committee (CEC) for the SpaceOAR randomized pivotal trial (ClinicalTrials.gov Identifier: NCT01538628). Michael Steinberg discloses consultancy with Boston Scientific and Vision RT and received honorarium from ViewRay. L.E.M. discloses consultancy with Boston Scientific.