

# SpaceOAR® Hydrogel

What Urologists Should Know

**David Beyer, MD**

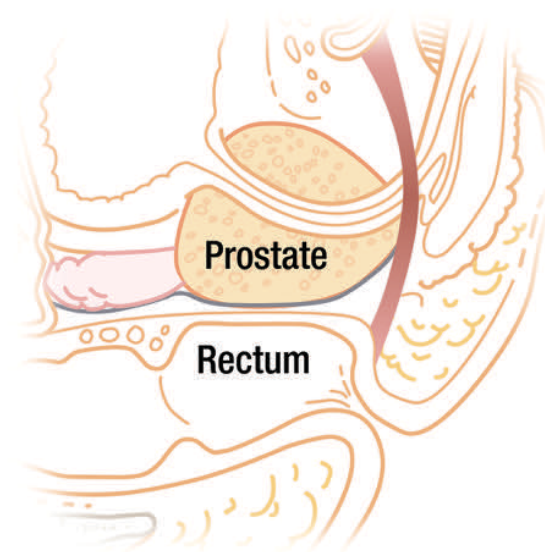
Medical Director of Radiation Oncology  
Cancer Centers of Northern Arizona Healthcare

# Agenda

- Why use a prostate-rectum spacer
- What is SpaceOAR hydrogel
- Clinical Evidence- Trial Results
- Application
- Reimbursement
- Conclusion

# Prostate Cancer

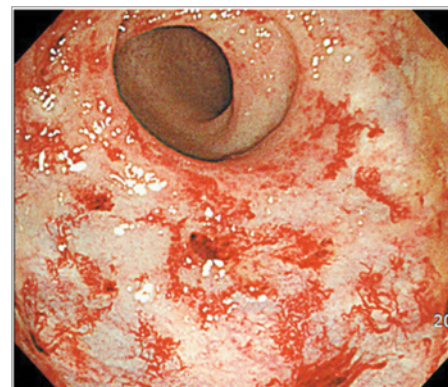
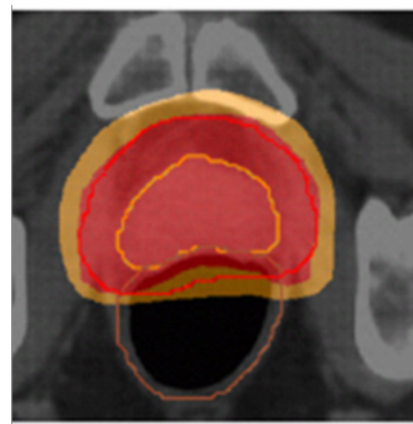
- Incidence 161,360<sup>1</sup>
- Mortality: 26,730<sup>1</sup>
- Radiation is common treatment
  - 3D conformal radiation therapy (3D CRT)
  - Intensity-modulated radiation therapy (IMRT)
  - Stereotactic body radiotherapy (SBRT)
  - Brachytherapy (LDR & HDR)
  - Proton
- Complications
  - Urinary
  - GI
  - Sexual



1. <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>

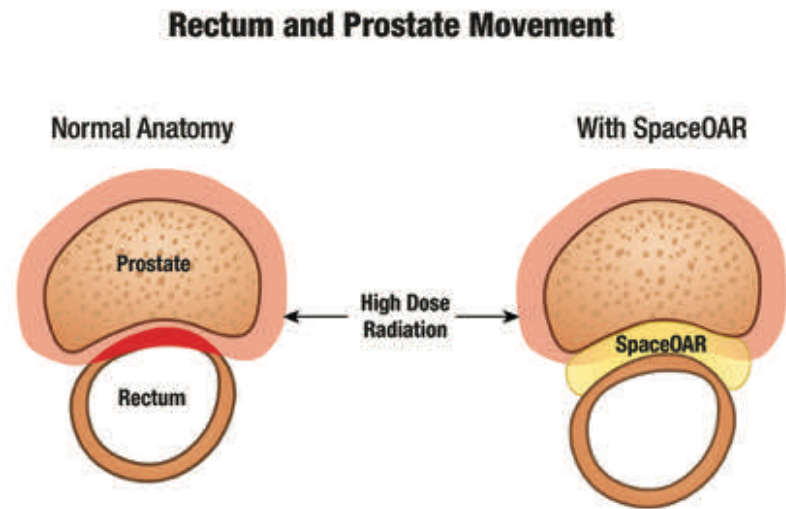
# OAR – Organ at Risk

- Rectum has been the dose-limiting factor
- Rectal Toxicity / Rectal complications
  - Bleeding, frequency, urgency, pain, fistulas
- Loss of QOL - Rectal injury can lead to bowel, urinary and sexual symptoms that can affect patient health and quality of life during RT and for years afterward

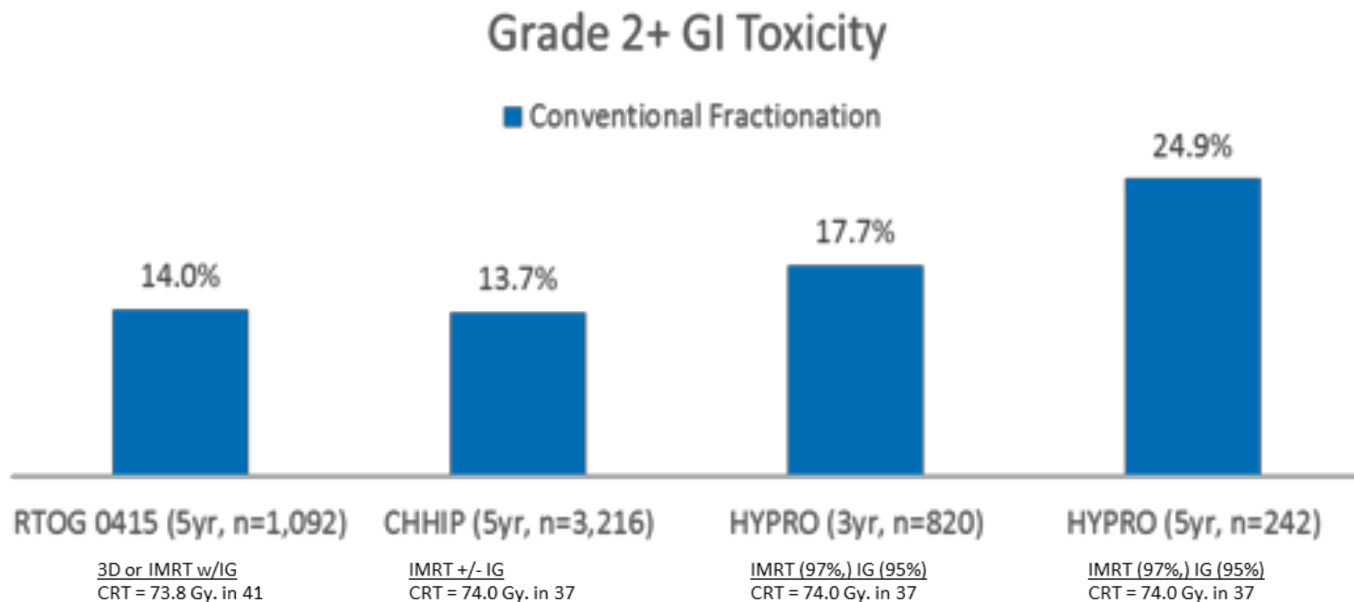


# Radiation Exposure to Rectum is Inevitable without Prevention

- Rectal radiation is currently unavoidable
- Close proximity to prostate
- Prostate movement between treatments
- Prostate movement during treatments



# GI toxicity Rates in Recent, Large, Multicenter, Hypofractionation Trials – 14% to 25%

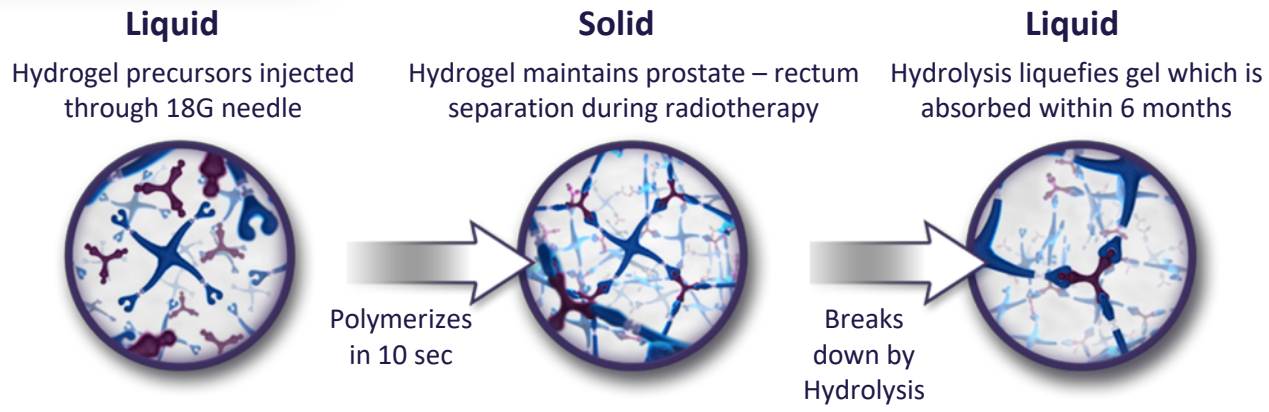
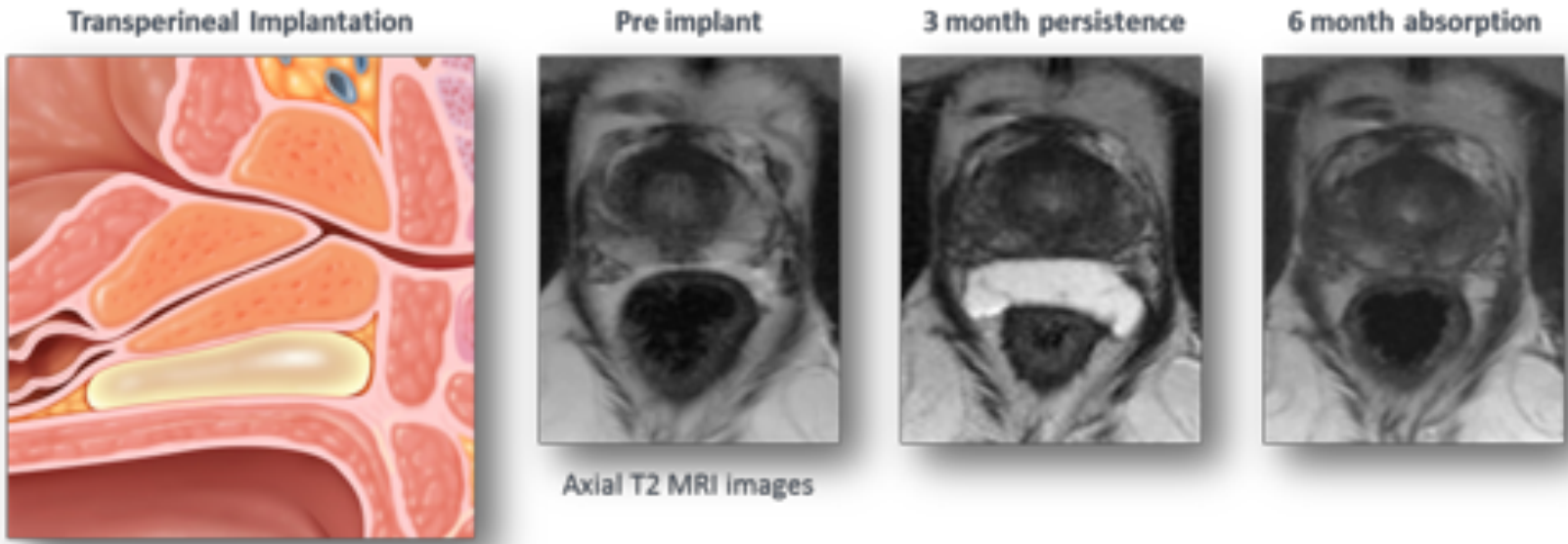


Source: Lee, *Journal of Clinical Oncology*, July 2016; Dearnaley, *The Lancet*, June 2016; Aluwini, *The Lancet*, April 2016; Wortel, *Int J of Rad Onc*, Jan 2016

# SpaceOAR Hydrogel

- Indication: SpaceOAR 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 System to reduce the radiation dose delivered to the anterior rectum.
- FDA cleared April 2015
- SpaceOAR hydrogel temporarily positions the anterior rectal wall away from the prostate creating a space of ~1.3 cm
- The created space reduces radiation dose delivered to the anterior rectum, significantly reducing the risk of rectal adverse events

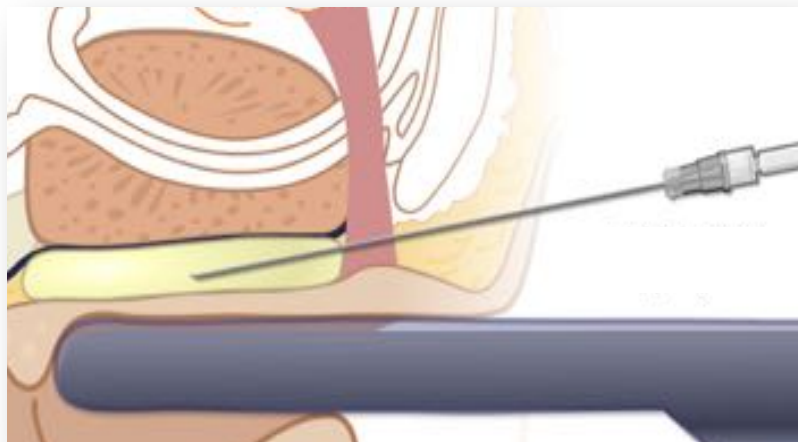
# Prostate-rectum Spacing





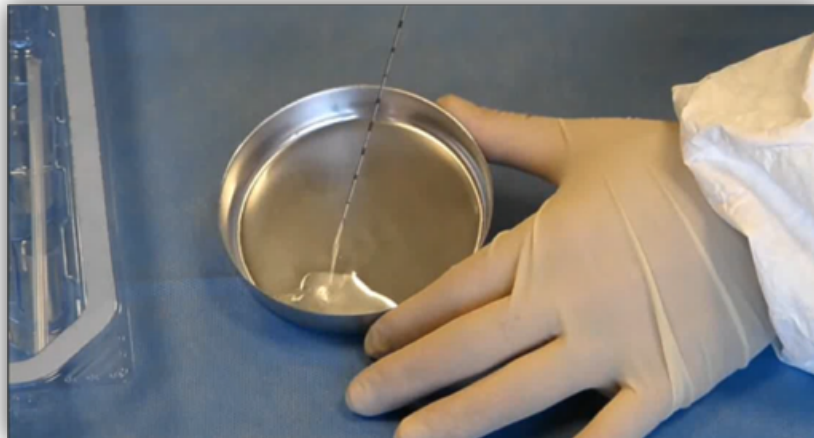
# SpaceOAR System

## Application



- **Injected:** 18G, liquid hydrogel precursors
- **Solidifies:** within 10 seconds
- **Persistence:** lasts about 3 months
- **Absorbs:** in about 6 months

## PEG hydrogel chemistry



## Gel polymerization

- Water based polymer
- Does not heat up during polymerization
- Breaks down via hydrolysis
- Flows through perirectal fat, locking it in place

# SpaceOAR Hydrogel

## Material

- Made of mostly water and polyethylene glycol (PEG)
- PEG is used in many medical products including artificial tears, prescription drugs, medical implants
- Synthetic, Biocompatible, Non-toxic
- Absorbs in approximately 6 months

## Procedure

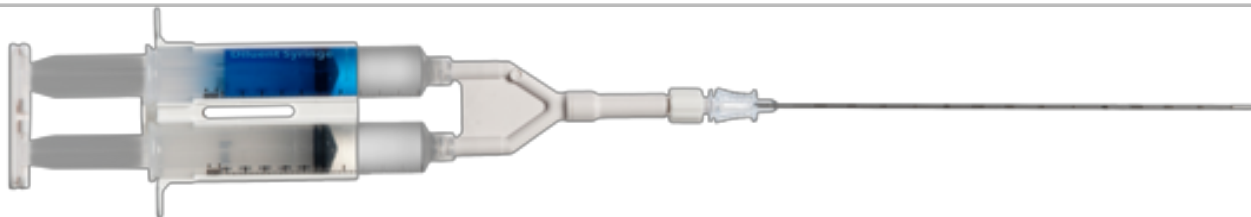
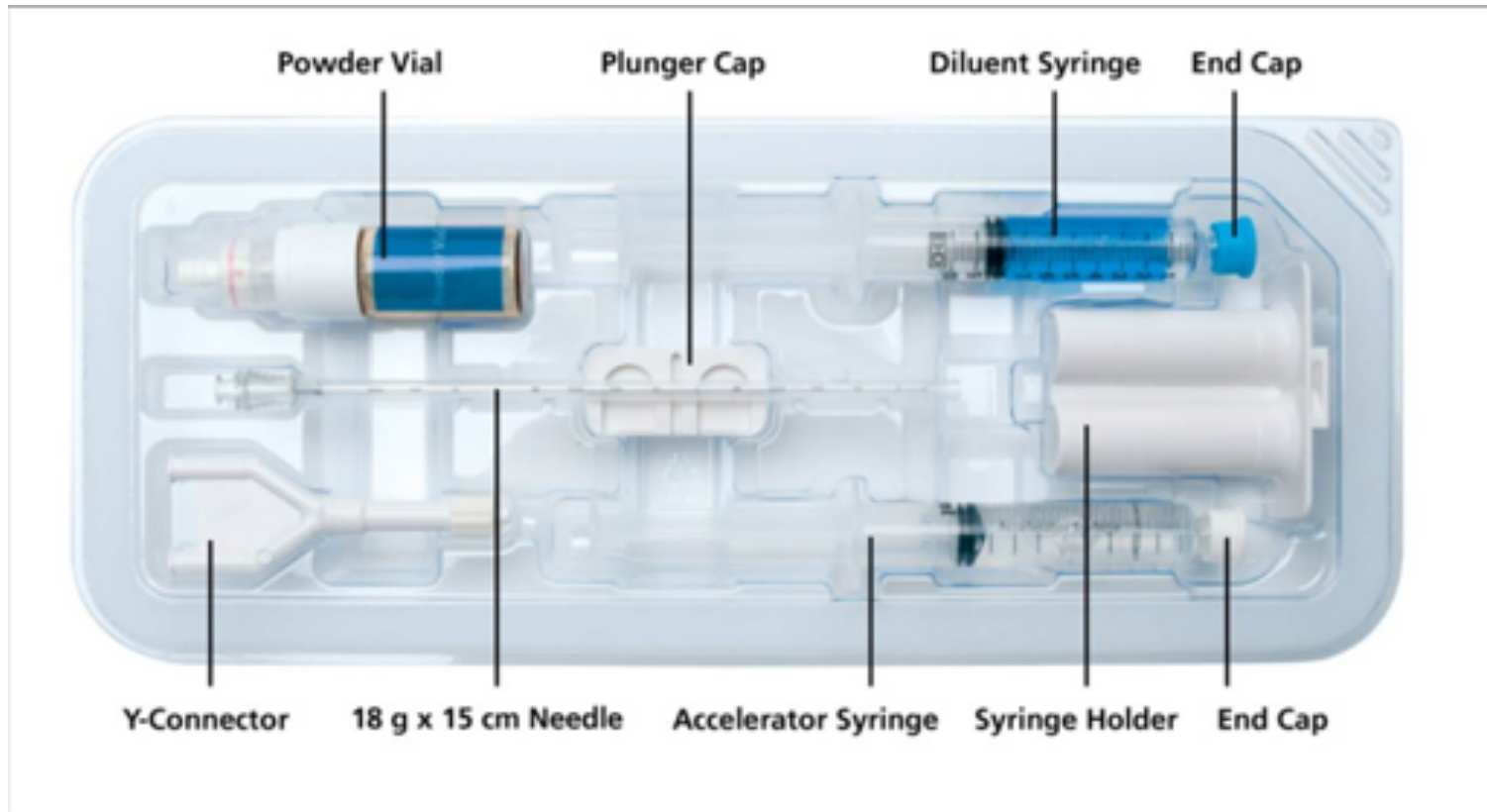
- In-office procedure
- Local, regional or general anesthesia
- One transperineal injection

## Enables Dose Escalation & Hypofractionation

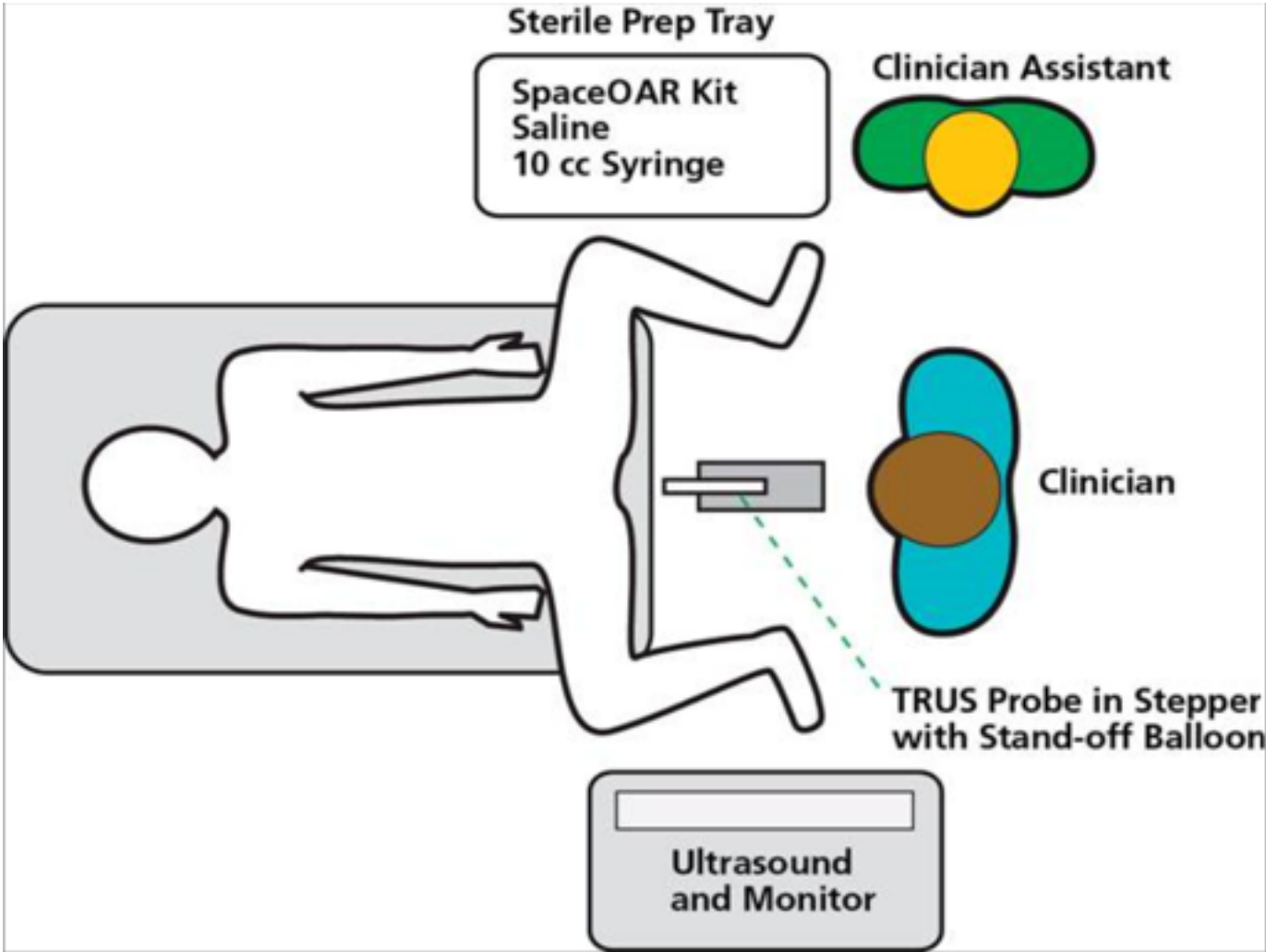
- ~1 cm (1/2") space for 3 months
- 73.5% reduction of rectal V70
- 0% late GI toxicity greater than Grade 1

# SpaceOAR Application

# SpaceOAR Kit



# Procedural Setup



# Skin Prep & Local Anesthesia Supplies

Space OAR Application Video - Dr. Fagundes MD, PhD Rev A



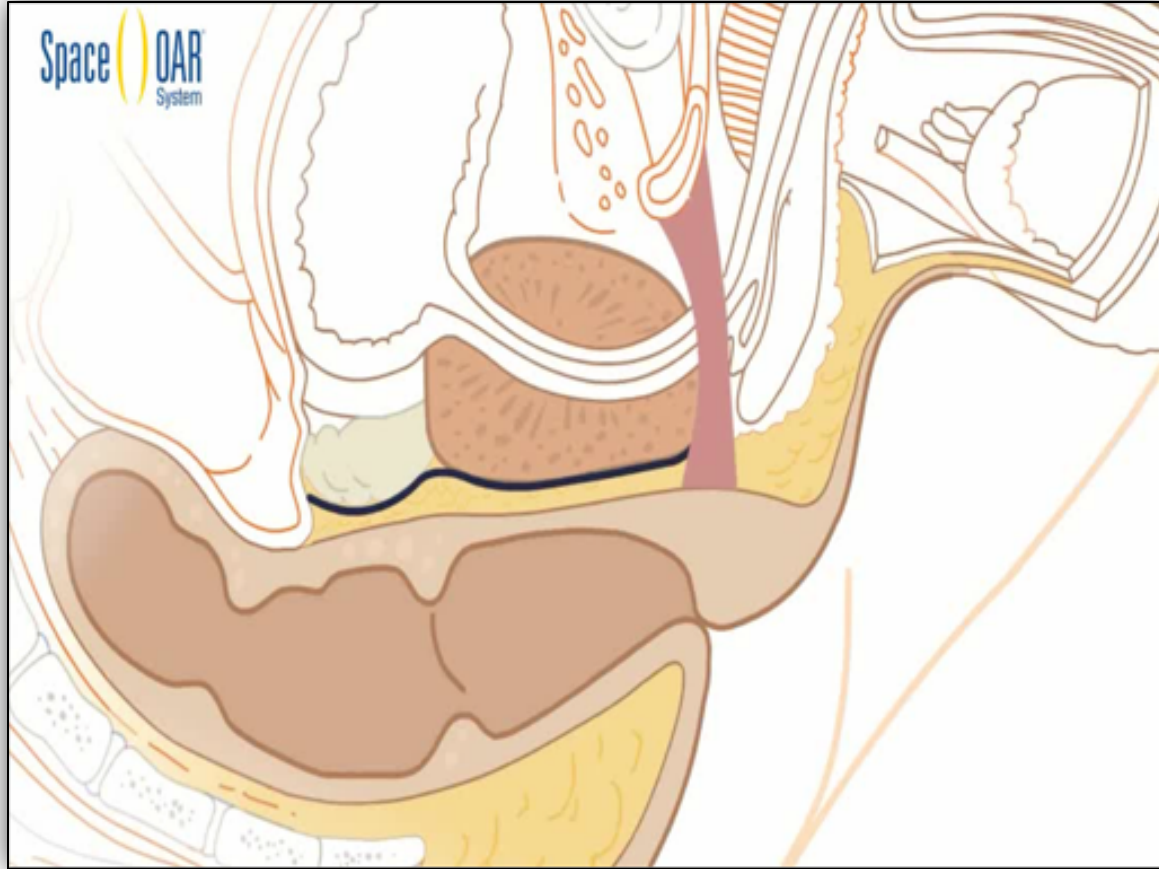
**Skin Prep and Local Anesthesia Supplies**

- Chlorhexidine
- 20mL Syringe
- 2% Lidocaine HCL (without epinephrine) and 8.4% Sodium Bicarbonate (10:1)
- 22G x 6in. Spinal Needle
- Saline Syringe

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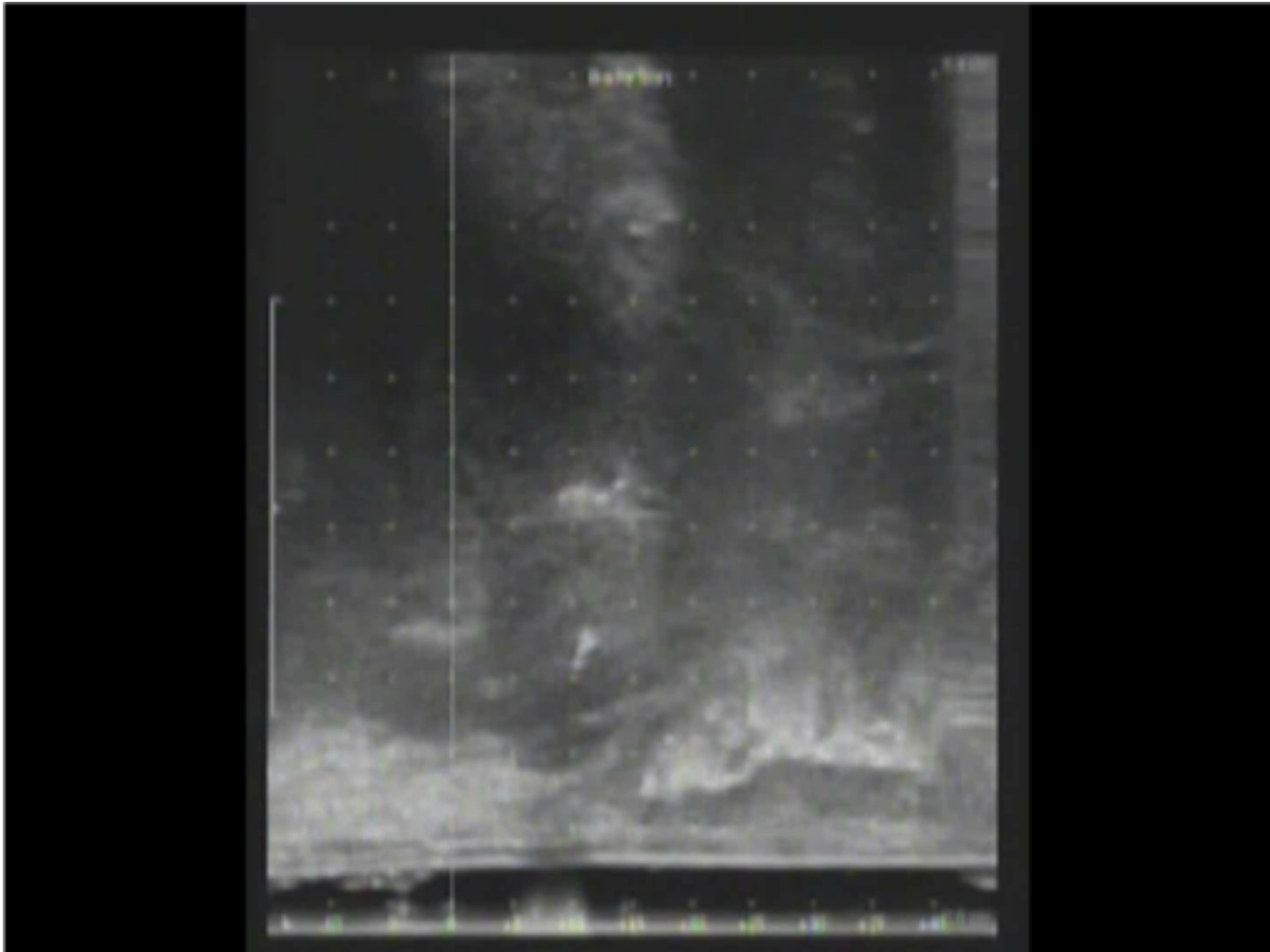
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# SpaceOAR System Application



Animation Application Video

# Procedural Ultrasound





# SpaceOAR Clinical Trial Results

# US Pivotal Study Overview – STUDY DESIGN

## **Patients**

- T1 or T2 , Gleason Score  $\leq 7$ , PSA  $\leq 20$ ng/mL,  $\leq 50\%$  positive cores

## **Design**

- Prospective, randomized parallel arm, single-blind, multicenter, controlled

## **Size**

- 222 patients, randomized 2:1 (Spacer: control)

## **Sites**

- 20 US Sites

## **Procedure Design**

- Anesthesia: General (37%), local (32%), MAC (25%)
- Prophylactic antibiotics: 95% of patients
- Fiducial/Spacer implant: Transperineal

# US Pivotal Study Overview - RESULTS

## Perirectal Space

Post implant	12 weeks	13 weeks
12.6 $\pm$ 3.9 mm	10.9 $\pm$ 5.8 mm	6.8 $\pm$ 5.4 mm

12 months: Absorbed

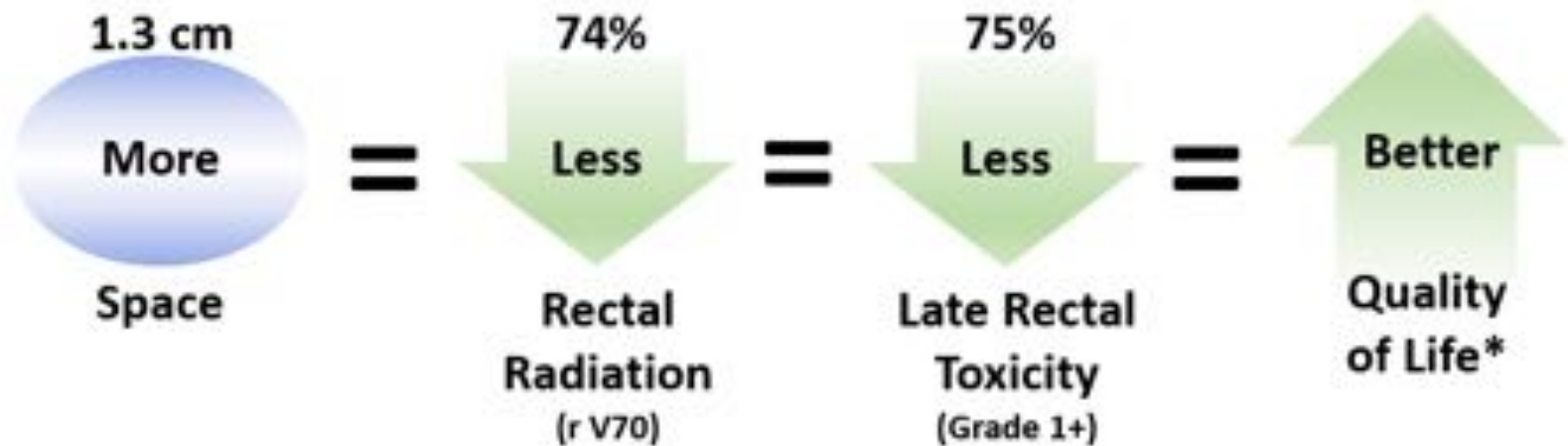
Technical success: 99% (gel present)

Difficulty: 99% of applicators rated the procedure easy or very easy

## Safety Results:

- No device related adverse events
- No delays to onset of IMRT
- No implant infections
- No rectal wall ulcerations
- 10% with mild transient procedure events

# US Pivotal Study Results Summary



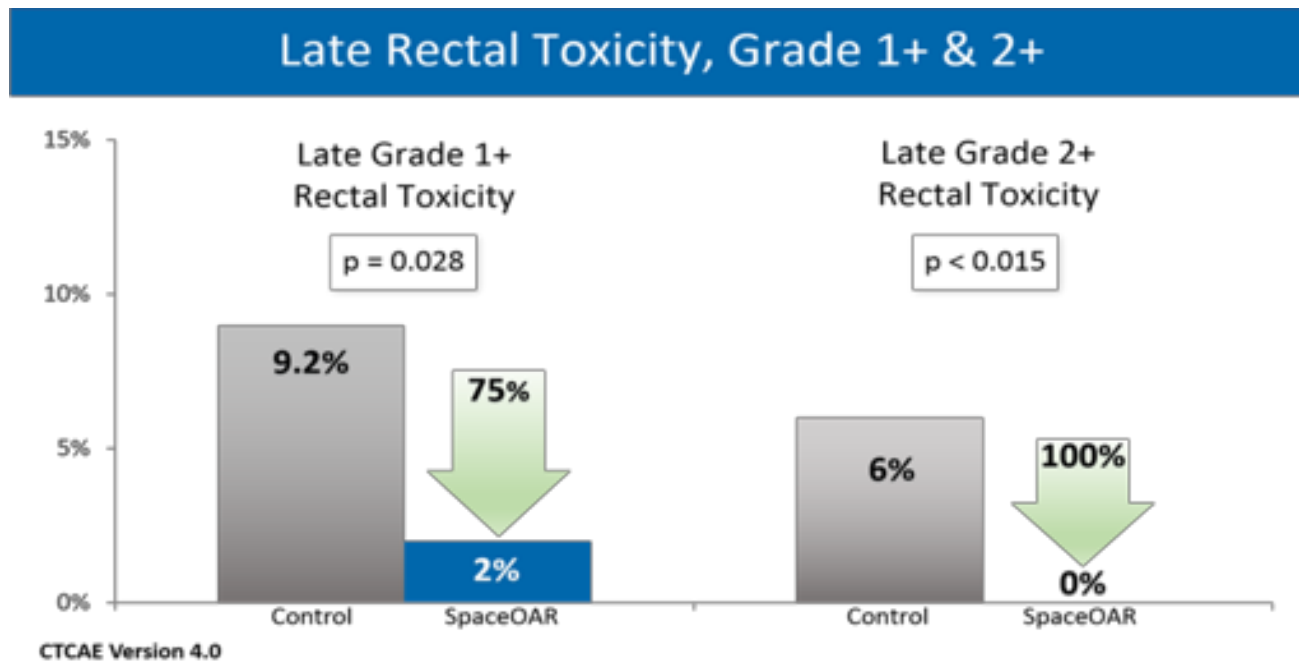
In the pivotal trial, SpaceOAR patients did not experience any Grade 2 or greater rectal toxicity (e.g. proctitis, rectal bleeding, or fecal incontinence).<sup>1,2</sup>

1) Hamstra D, et al. Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial. Int J Radiation Oncol Biol Phys, Vol. 97, No. 5, pp. 976-985, 2017

2) Hamstra D, et al. Evaluation of sexual function on a randomized trial of a prostate rectal spacer. J Clin Oncol 35, 2017 (suppl 6S; abstract 69)

# US Pivotal Study

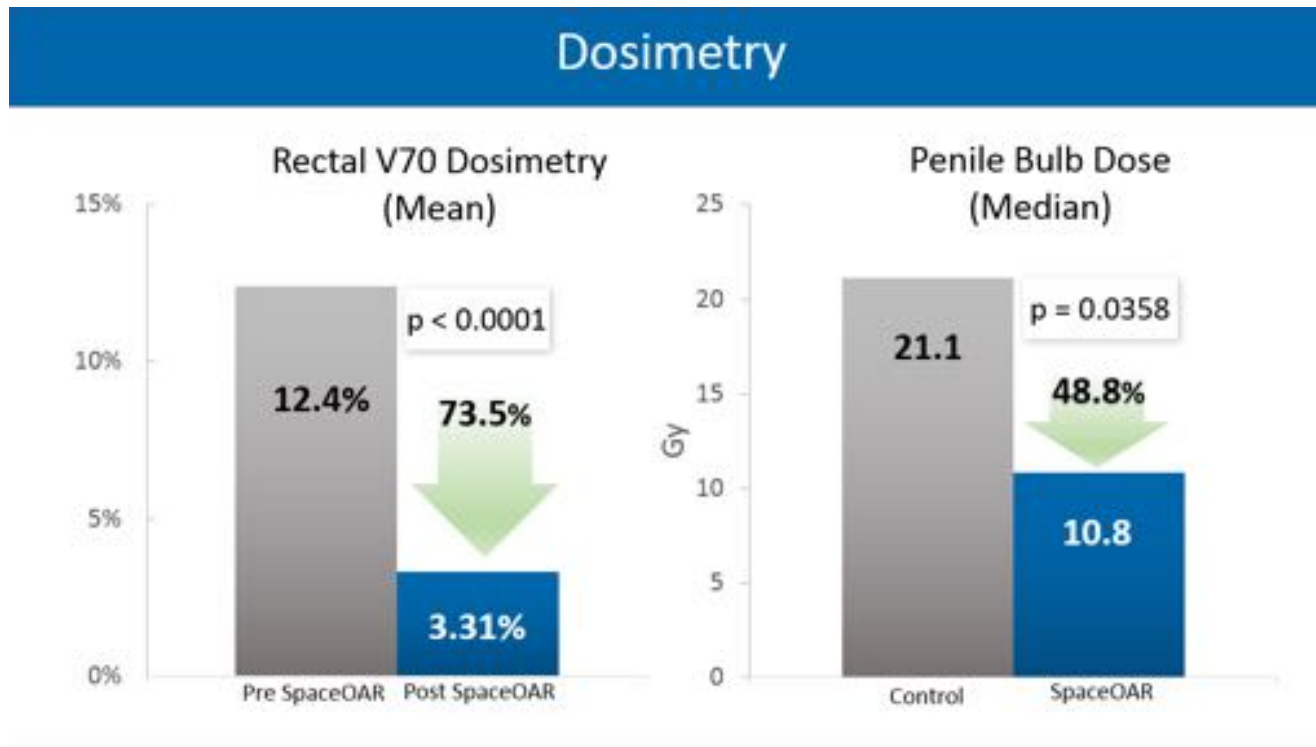
## Late Rectal Toxicity vs Control



- **75%** relative reduction in late grade 1+ rectal toxicity
- **100%** relative reduction in late grade 2+ rectal toxicity
- **Zero** late grade 2+ rectal toxicity
- **73%** relative reduction in cumulative grade 1+ urinary incontinence

# US Pivotal Study

## Reduced Dose to Rectum and Penile Bulb



- **73.5%** relative reduction in rectal V70 dose<sup>1</sup>
- **48.8%** relative reduction in median penile bulb dose<sup>2</sup>
- **97.3%** of subjects had at least a 25% relative reduction in V70<sup>1</sup>

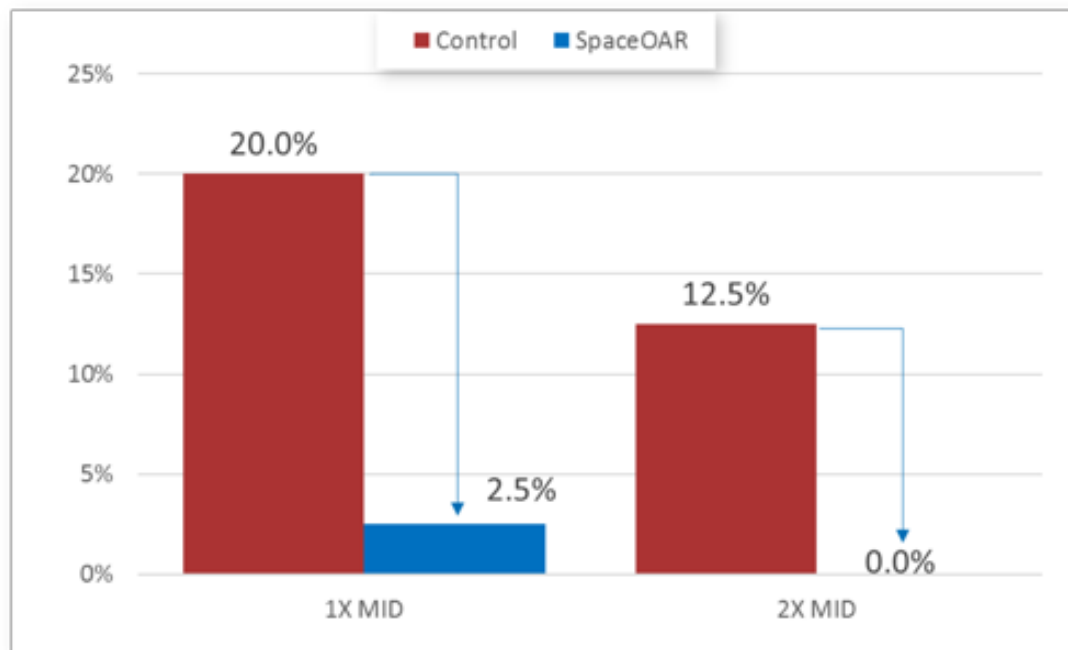
1) Hamstra D, et al. Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial. Int J Radiation Oncol Biol Phys, Vol. 97, No. 5, pp. 976-985, 2017

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# SpaceOAR US Study 37 Month Results

## Overall Benefits / Patient Wellness

Men with 1X and 2X MID\* declines in all 3 Domains (Bowel, Urinary and Sexual), at 3 years



Control patients experienced a clinically significant (1X MID) decline in bowel, urinary and sexual QOL 8 times more often than SpaceOAR patients.

1) Hamstra D, et al. Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial. Int J Radiation Oncol Biol Phys, Vol. 97, No. 5, pp. 976-985, 2017

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# US Pivotal Study Summary

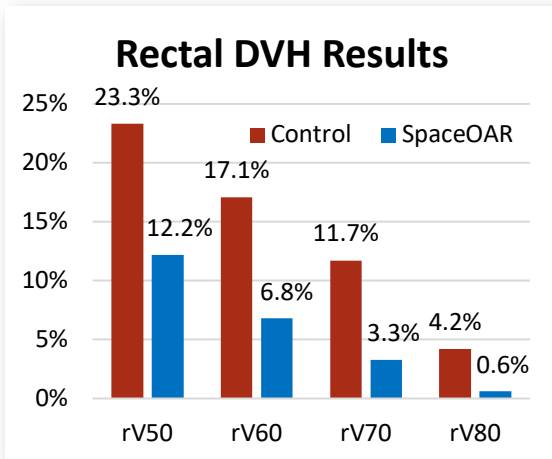
## Reliable

Space Creation  
99% Procedural Success



## Significant

Rectal Dose Reduction  
73.5% reduction in rV70



## Meaningful

Clinical Benefits  
Late toxicity reduction  
Bowel QOL benefits

### Odds for late rectal toxicity

Control Group  
(1 in 14.2 patients)



SpaceOAR Group  
(1 in 49.3 patients)



Grade 1  
 ≤ Grade 3

Significant rectum dose reduction results in  
meaningful long term toxicity and QOL benefits



# SpaceOAR Reimbursement Landscape

# Medicare

- Nationwide Medicare Reimbursement



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SERVICE OPTIONS, INC.



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Healthcare Solutions

Noridian Healthcare Solutions, LLC



**NOVITAS**  
SOLUTIONS



**PALMETTO GBA®**

A CELERIAN GROUP COMPANY

**WPS** | GOVERNMENT  
HEALTH  
ADMINISTRATORS

# Recently Added Commercial Insurers

- Added Independence BC
  - 4,757,521 covered lives



- Added BCBS North Carolina
  - 2,526,856 covered lives



# Commercial Insurers

## U.S. Health Plans Ranked by Total Medical Enrollment

Commercial Rank	Company	Commercial or Government (Managed Medicaid, State Exchange, etc.,)	Enrollment	SpaceOAR Coverage
1	United Healthcare	Commercial	49,136,085	NO
2	Anthem (BCBS CO, CT, IN, KY, ME, MO, NH, NV, OH, VA, WI)	Commercial	35,180,683	NO
3	Aetna	Commercial	21,724,022	YES
4	Cigna	Commercial	14,624,275	NO
5	Health Care Svc Corp (BCBS IL, MT, NM, OK, TX)	Commercial	14,394,135	NO
N/A	Centene Corp	Government	11,678,500	N/A
6	Kaiser Permanente	Commercial	11,175,486	YES
7	Humana	Government	8,763,400	NO
N/A	Molina Healthcare	Commercial	4,766,000	N/A
8	Independence BC	Commercial	4,757,521	YES
9	Highmark BCBS	Commercial	4,568,690	NO
10	BCBS Michigan	Commercial	4,386,563	YES

Source: A.S. Direct, Inc. Health Plans: 2017

# Medicare Reimbursement Rates

## 2018 Medicare Nat'l Avg Reimbursement<sup>1</sup>

CPT Code <sup>®2</sup>	Professional Fee (Non-Facility)	Professional Fee (Facility)	Outpatient Dept	ASC
55874	\$3,797	\$173	\$3,707	\$1,757

- Rates are geographically adjusted +/- 15%



# SpaceOAR Utilization

## Utilization summary

- Currently used in **19 out of the Top 20** US Cancer Centers (2018 *U.S. News & World Report*)
- Over **30,000** cases worldwide
- Over 300 centers in the US
- Positive professional society written policy statements
  - American College of Radiology (ACR)
  - American Society of Radiation Oncology (ASTRO)
  - National Comprehensive Cancer Network (NCCN)

# Summary

- Toxicity reduction - Offering the best patient care
- Easily implemented into a Urologist practice
- In-office procedure/local anesthesia
- Market differentiation
- Favorable reimbursement