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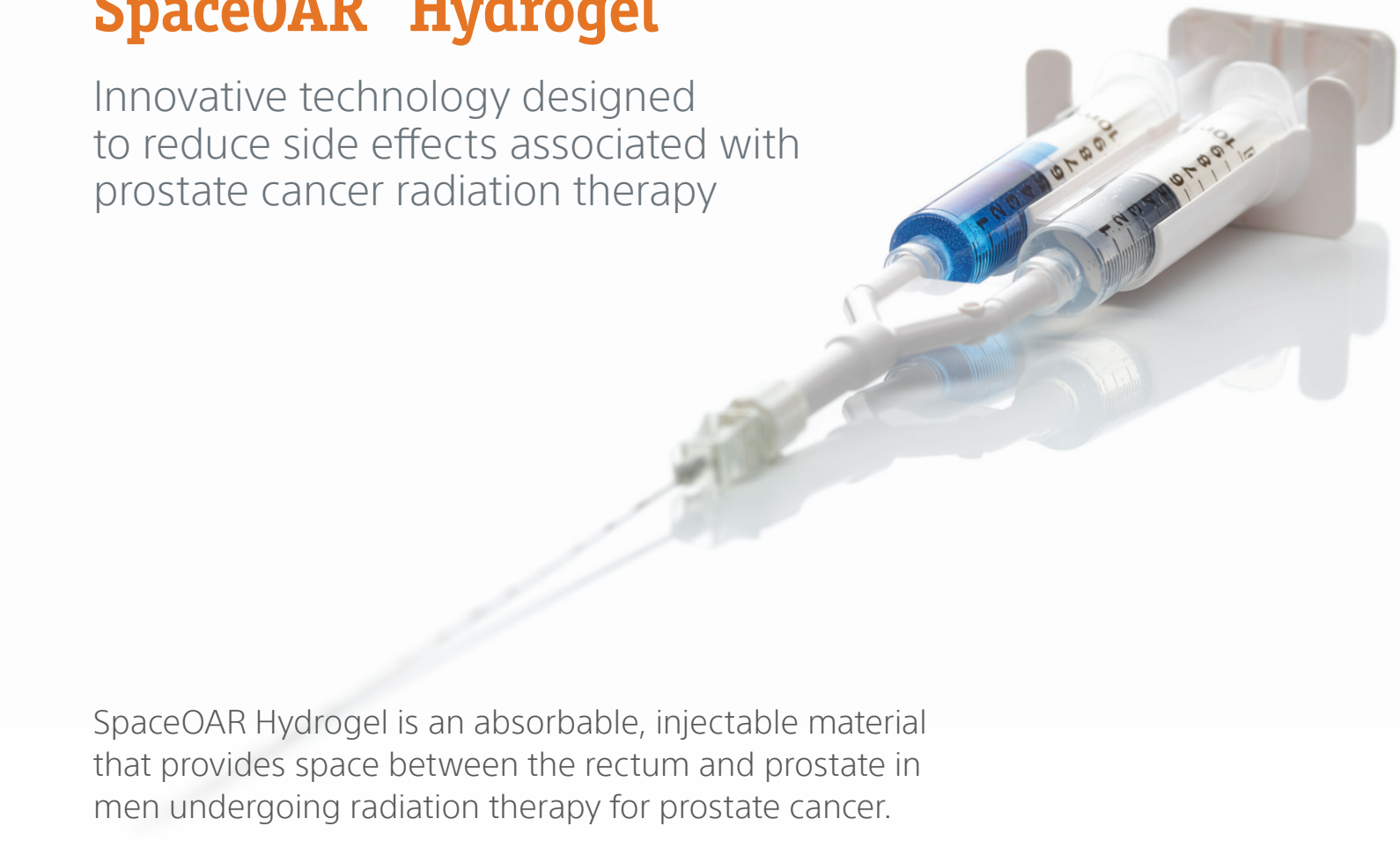
SpaceOAR™ Hydrogel

Innovative technology designed to reduce side effects associated with prostate cancer radiation therapy



SpaceOAR Hydrogel is an absorbable, injectable material that provides space between the rectum and prostate in men undergoing radiation therapy for prostate cancer.

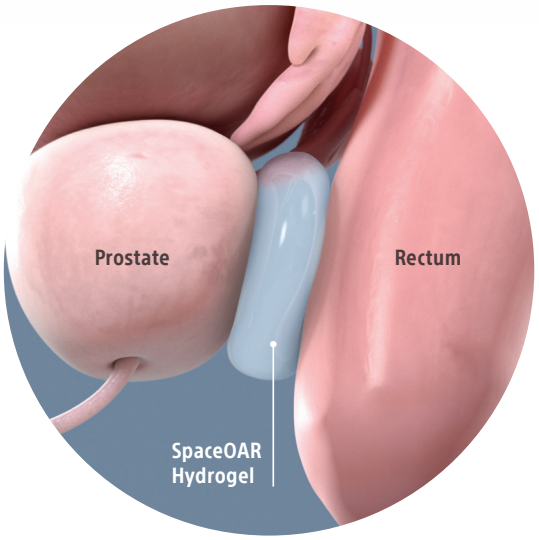
Clinical Effectiveness

At a median 3-year follow-up, SpaceOAR Hydrogel study patients:

- Experienced significantly less decline in **urinary** Quality of Life compared to control patients[1*]
- Experienced significantly less decline in **bowel** Quality of Life compared to control patients[1]
- 67% maintained potency compared to 38% in control group[2**]

Operational Efficiency

- Straightforward, minimally invasive procedure
- Can be implanted using general or local anesthesia
- Can be implanted with fiducial marker placement



* Defined as 2x the minimally important difference; compared to control patients

** Of men who had erections sufficient for intercourse at baseline

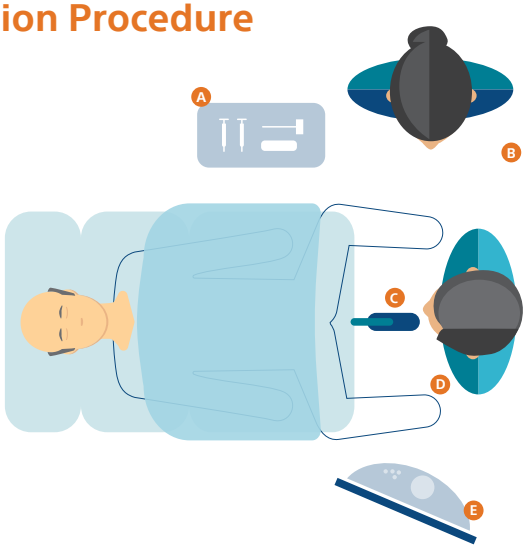
SpaceOAR™ Hydrogel Application Procedure

Required equipment

- Side-fire (biplane) transrectal ultrasound (TRUS) probe
- Stepper stabilizer

Patient preparation

- Bowel prep
- Prophylactic antibiotics (recommended)
- Lithotomy position
- Anesthesia (as needed)
- Perineal skin prep



A Sterile prep tray
SpaceOAR Hydrogel, Saline, 10cc syringe

B Clinician Assistant

C TRUS Probe in stepper with stand-off balloon

D Clinician

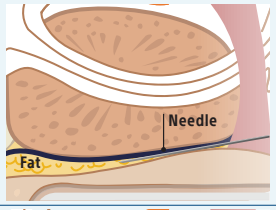
E Ultrasound and monitor

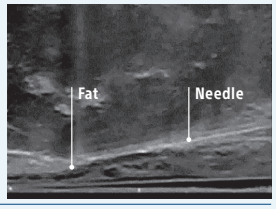
Application Steps

Ultrasound Image - Sagittal

Needle placement

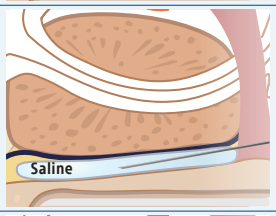
- Attach provided 18G needle to an injectable saline-filled 10cc syringe
- Advance needle tip to midgland perirectal fat; check in axial view to ensure needle tip is midline for optimal placement

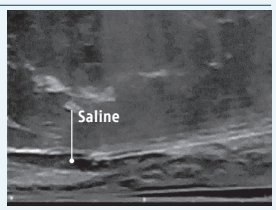




Hydrodissection

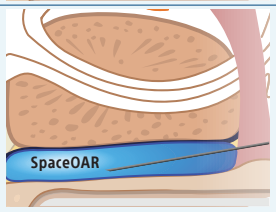
- Slowly inject saline to expand (hydrodissect) perirectal space
- Aspirate to ensure needle is not intravascular

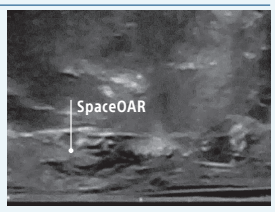




SpaceOAR Hydrogel injection

- Keeping the 18G needle in place, remove saline syringe and attach SpaceOAR Hydrogel applicator
- Inject hydrogel without stopping or pausing
- Remove and dispose of needle





Ordering Information

Product Code	Description
SO-2101	SpaceOAR System
SO-2104SB	SpaceOAR multi-pack, 4 units

Boston Scientific is committed to providing application training. Speak to your local representative for more information or visit www.spaceoar.com

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1. Hamstra DA, Mariados N, Sylvester J, et al. Continued benefit to rectal separation for prostate radiation therapy: Final results of a phase III trial. *Int J Radiat Oncol Biol Phys.* 2017 Apr 1;97(5):976-85.
2. Hamstra DA, Mariados N, Sylvester J, et al. Sexual quality of life following prostate intensity modulated radiation therapy (IMRT) with a rectal/prostate spacer: Secondary analysis of a phase 3 trial. *Pract Radiat Oncol.* 2018 Jan - Feb;8(1):e7-e15.

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; needle penetration of the bladder, prostate, rectal wall, rectum, or urethra; injection of SpaceOAR Hydrogel into the bladder, prostate, rectal wall, rectum, or urethra; local inflammatory reactions; infection; injection of air, fluid or SpaceOAR Hydrogel intravascularly; urinary retention; rectal mucosal damage, ulcers, necrosis; bleeding; constipation; and rectal urgency.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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Ordering Information
1.888.272.1001

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