



MINIMIZE THE SIDE EFFECTS OF PROSTATE RADIATION THERAPY¹



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PROSTATE CANCER

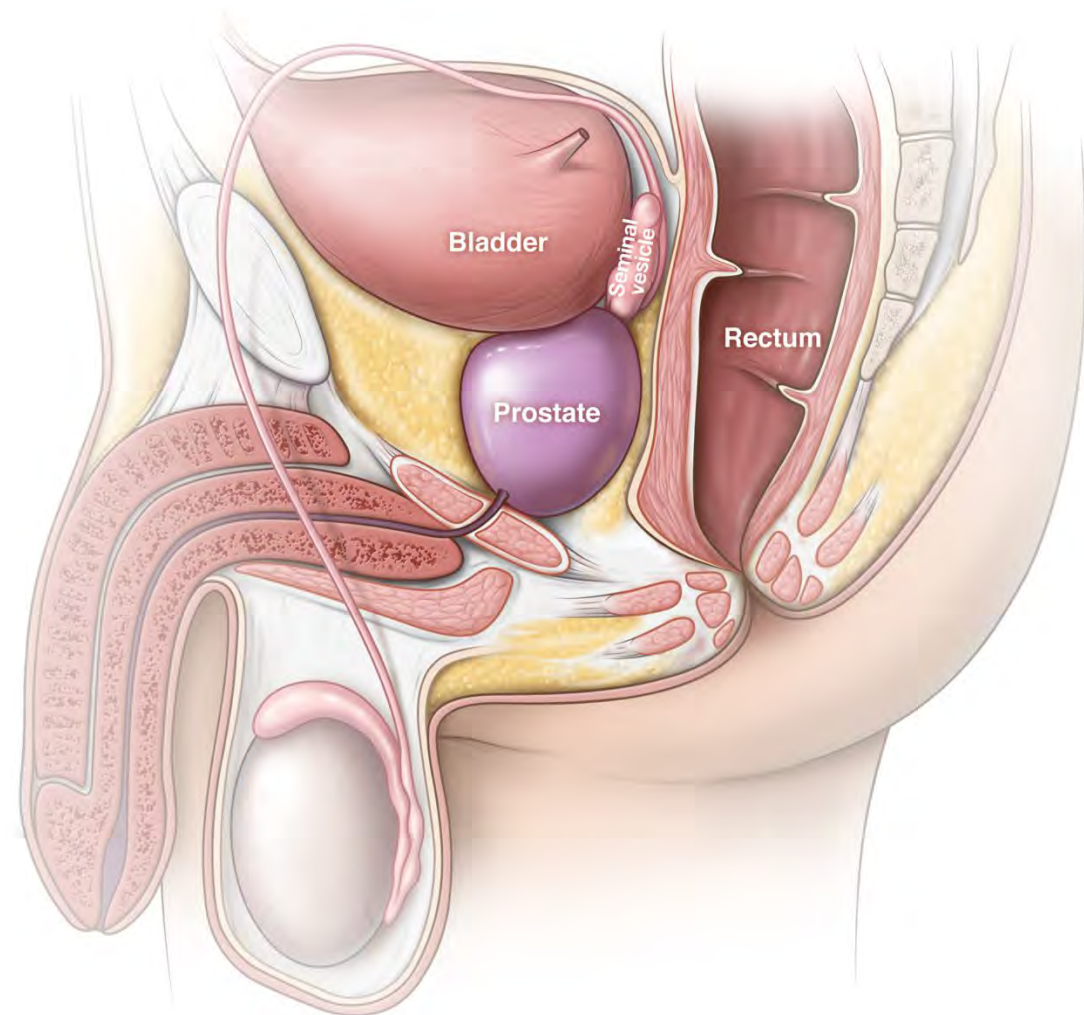
OVERVIEW

WHAT IS THE PROSTATE?

The prostate is a gland about the size of a walnut, found only in men. Its function is to produce part of the fluid contained in semen to nourish and protect the sperm.

WHAT IS PROSTATE CANCER?

Prostate cancer occurs when abnormal cells in the prostate gland begin to grow out of control. Almost all prostate cancers develop from glandular cells. The gland cells make the fluid that is added to the semen.



INCIDENCE AND RISK FACTORS¹



AGE – prostate cancer occurs mainly in older men

- About 6 in 10 cases are diagnosed in men aged 65 or older, and it is rare before age 40
- The average age at the time of diagnosis is 67



ETHNICITY – prostate cancer is more likely to develop in non-Hispanic Black men, and less likely in Asian-American and Hispanic/Latino men



FAMILY HISTORY – having a father or brother with prostate cancer more than doubles a man's risk of developing it. However, most prostate cancers occur in men without a family history of it.

PROSTATE CANCER STATISTICS

for men in the United States[†]

PROSTATE CANCER PREVALENCE[†]

Other than skin cancer,

PROSTATE CANCER IS THE
MOST COMMON CANCER
IN AMERICAN MEN

~300,000

U.S. and American Cancer Society estimates of new cases of prostate cancer in the U.S. (2024)



1 in **8** men in the US will be diagnosed in their lifetime

PROSTATE CANCER SURVIVAL RATE[†]

Prostate cancer is the second leading cause of death from cancer in men; however

97%[†] OF MEN **SURVIVE**
PROSTATE CANCER

[†] Average of all stages of prostate cancer

REFERENCE: 1. American Cancer Society. Key Statistics for Prostate Cancer. www.cancer.org. Accessed: October 12, 2024. www.cancer.org/cancer/prostate-cancer/about/key-statistics.html

WHAT IS RADIATION THERAPY FOR PROSTATE CANCER?

Radiation therapy is a standard form of treatment that uses energy beams to destroy cancer cells and stop them from spreading.

“Radiation for cancer works by making small breaks in the DNA inside cells. These breaks keep cancer cells from growing and dividing and cause them to die.

Nearby normal cells can also be affected by radiation, but most recover and go back to working the way they should.”

- American Cancer Society¹

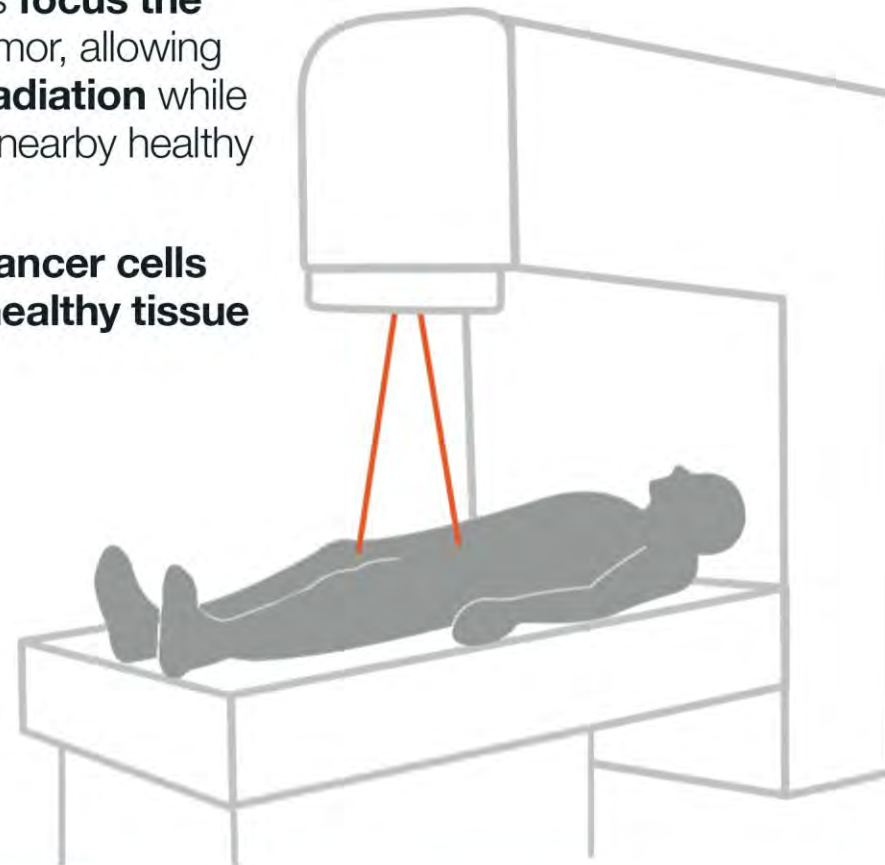
THERE ARE TWO MAIN TYPES OF RADIATION THERAPY

EXTERNAL BEAM RADIATION THERAPY (EBRT)

EBRT directs high-energy beams, such as X-rays or protons, **by a machine from outside the body.**

Advancements in EBRT techniques **focus the radiation** more precisely on the tumor, allowing doctors to give **higher doses of radiation** while reducing the radiation exposure to nearby healthy tissue.

The goal of EBRT is to kill the cancer cells while sparing the surrounding healthy tissue as much as possible.



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INTERNAL RADIATION (BRACHYTHERAPY)

Brachytherapy is a form of radiotherapy where the **radioactive source is placed inside** or next to the area requiring treatment. There are two methods of brachytherapy – low dose rate and high dose rate.

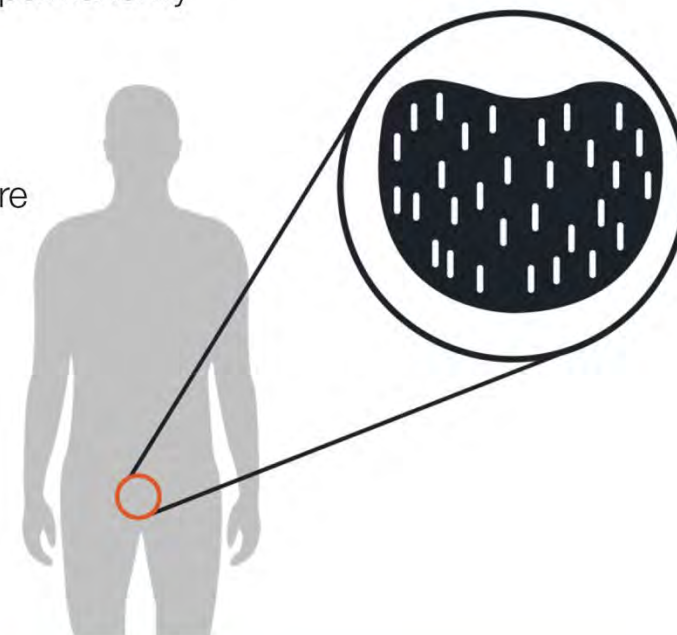
Low dose rate (LDR) brachytherapy

- Radiation deposited over several months
- Radioactive seeds are placed in the prostate gland permanently
- Slow release of radiation over several months

High dose rate (HDR) brachytherapy

- Temporary
- Catheters are placed in the prostate gland just before radiation is delivered, allowing the radiation source to travel temporarily into the prostate gland
- Catheters are removed immediately after the radiation is delivered
- May involve several sessions

Brachytherapy combined with EBRT can be an option for men with a higher risk of the cancer spreading outside of the prostate.



POSSIBLE RADIATION SIDE EFFECTS¹

More than half of all people with cancer receive radiation as part of their treatment therapy.¹ **Radiation beams can potentially affect healthy tissue** near the prostate and result in radiation side effects.



URINARY COMPLICATIONS may include

SHORT-TERM:

- Urinating more frequently
- Quicker need or stronger sensation to urinate (urinary urgency)

LONG-TERM:

- Bladder inflammation (cystitis)
- Blood in the urine
- Weaker urinary stream
- Chronic urinary frequency or urgency



SEXUAL COMPLICATIONS may include

- Taking longer or becoming more difficult to maintain an erection adequate for sexual intercourse



BOWEL COMPLICATIONS may include

SHORT-TERM:

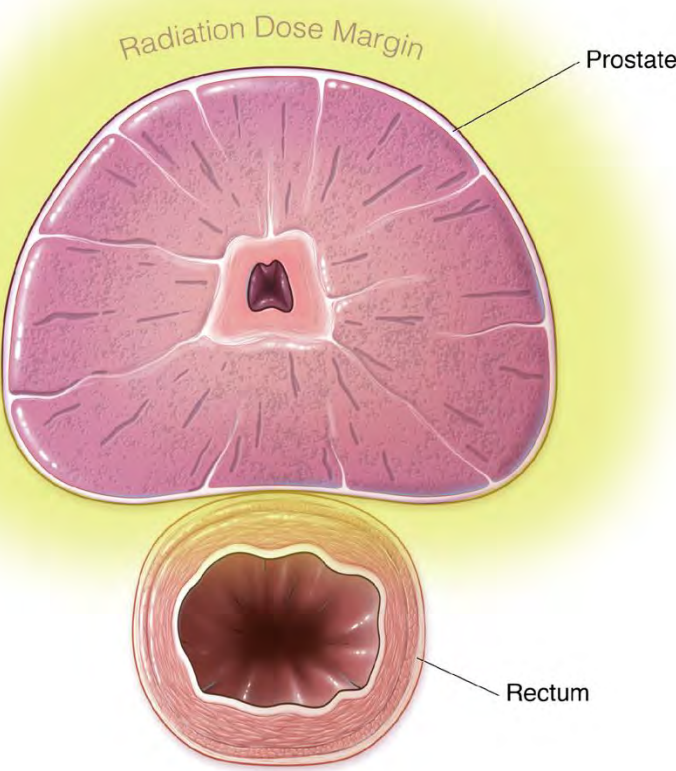
- Needing to have a bowel movement more often than usual
- Diarrhea
- Loose stools
- Hemorrhoids

LONG-TERM:

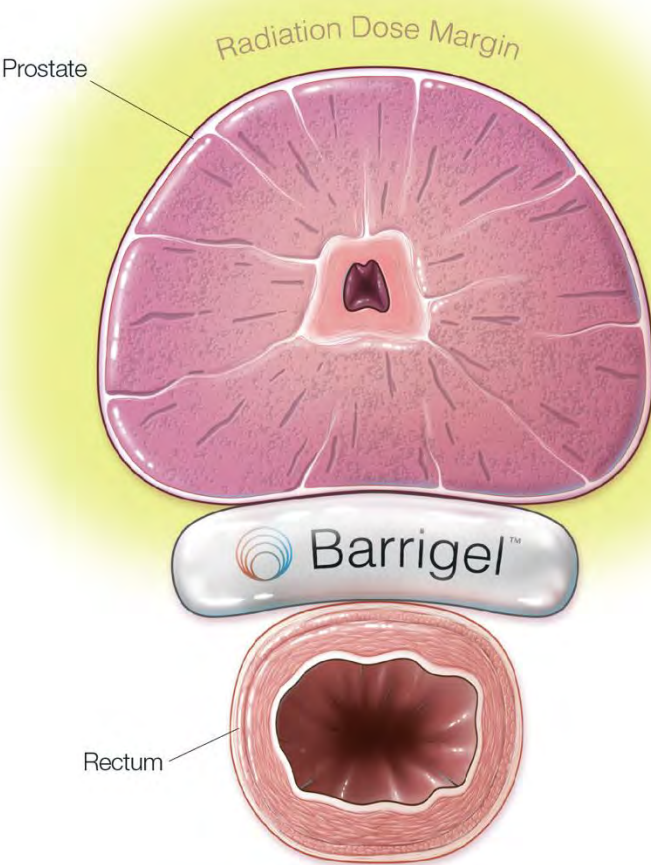
- Inflammation of the rectum (radiation proctitis)
- Rectal bleeding
- Narrowing of the rectum
- Hemorrhoids
- Chronic diarrhea
- Development of an ulcer in the rectum

MINIMIZING THE SIDE EFFECTS OF RADIATION THERAPY¹

Although beneficial in treating cancer, high-energy radiation beams can negatively affect healthy tissue surrounding the prostate.



Barrigel™ rectal spacer creates space between the prostate and the rectum, **moving the healthy organ out of the high-dose radiation area, reducing radiation exposure to the rectum.**¹

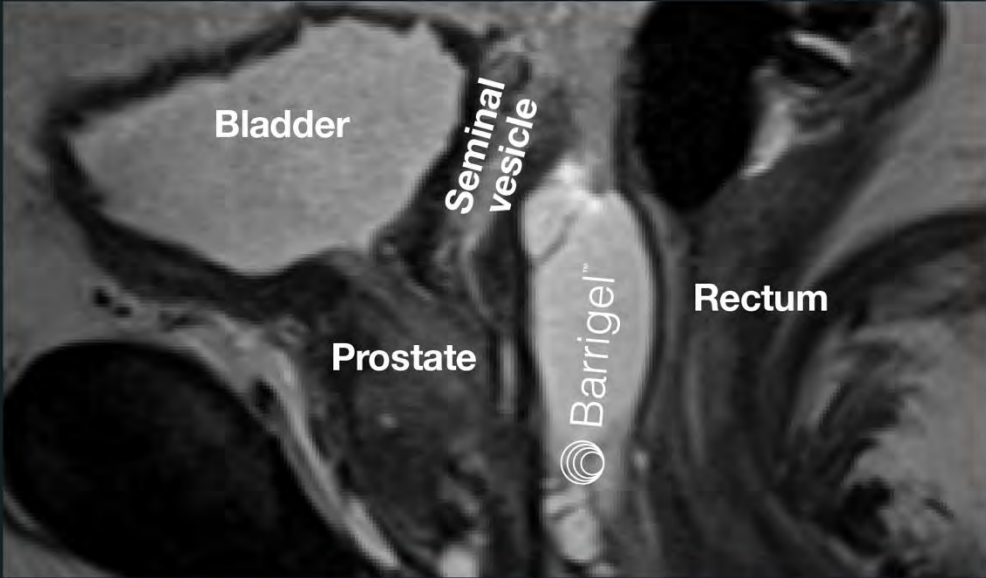
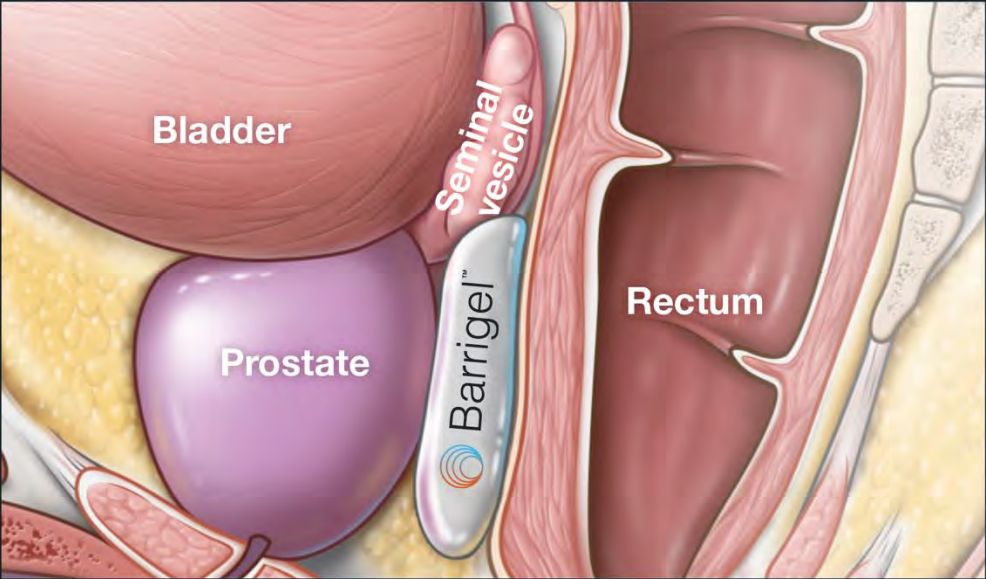


REFERENCE: 1. Mariados NF, Orio PF III, King M et al. *JAMA Oncol* (2023).*

THE **BARRIGEL™** RECTAL SPACER DIFFERENCE

PERSONALIZED COVERAGE FOR OPTIMAL PROTECTION^{1,2}

Barrigel rectal spacer is the first and only rectal spacer that **can be sculpted** in place, to ensure a custom fit for your anatomy.^{1,3-6}



MR image courtesy of Dr. Alex Engelman,
Radiation Oncologist; Florida, United States
Individual results may vary.

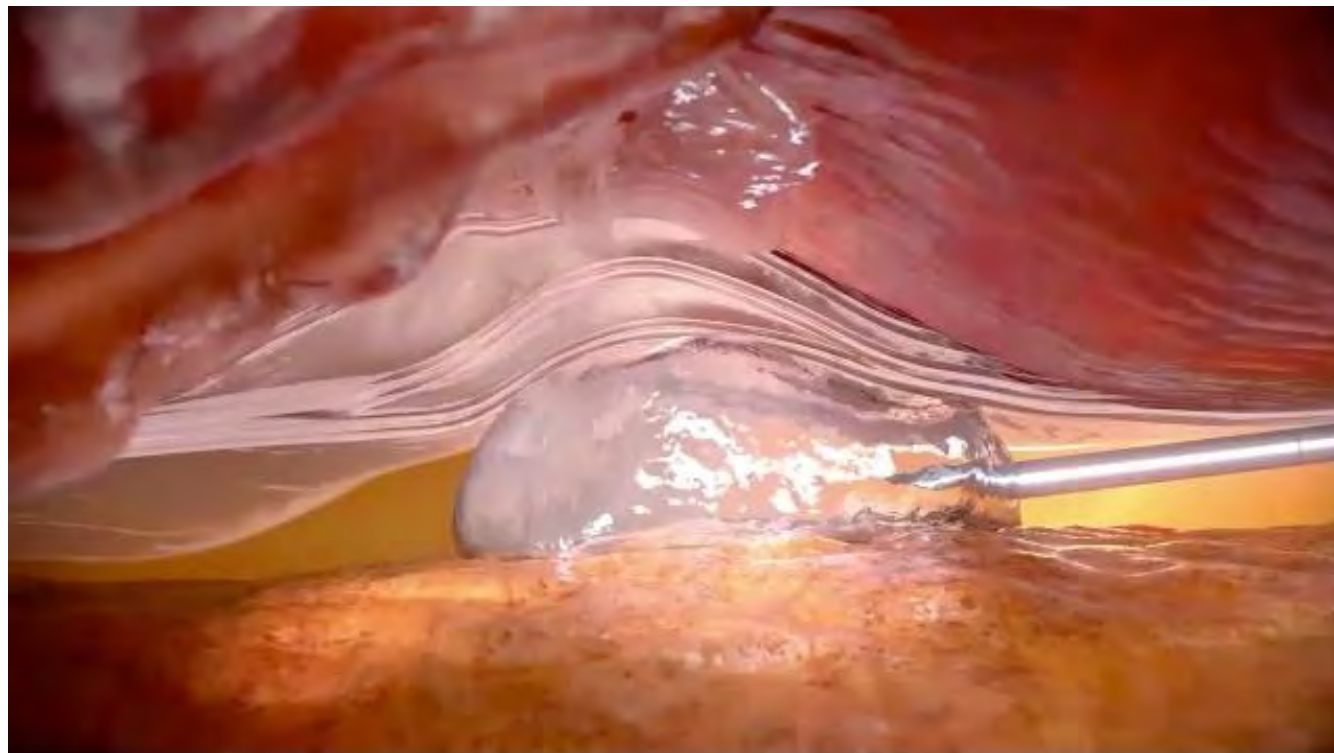
REFERENCES: 1. Mariados NF, Orio PF III, King M et al. *JAMA Oncol* (2023).* 2. King MT, Svatos M, Orio PF III et al. *Pract Radiat Oncol* (2023).* 3. Svatos M, Chell E, Low DA et al. *Med Phys* (2024).* 4. Gejerman G, Goldstein MM, Chao M et al. *Pract Radiat Oncol* (2023).** 5. Williams J, Mc Millan K, Chao M et al. *J Med Imag Radiat Sci* (2022). 6. Data on file. As of 10/01/2024.

THE BARRIGEL™ RECTAL SPACER DIFFERENCE: **HOW IT WORKS**

In rectal spacing, achieving **even, complete coverage** is critical. This provides the most protection against radiation exposure to healthy tissue.

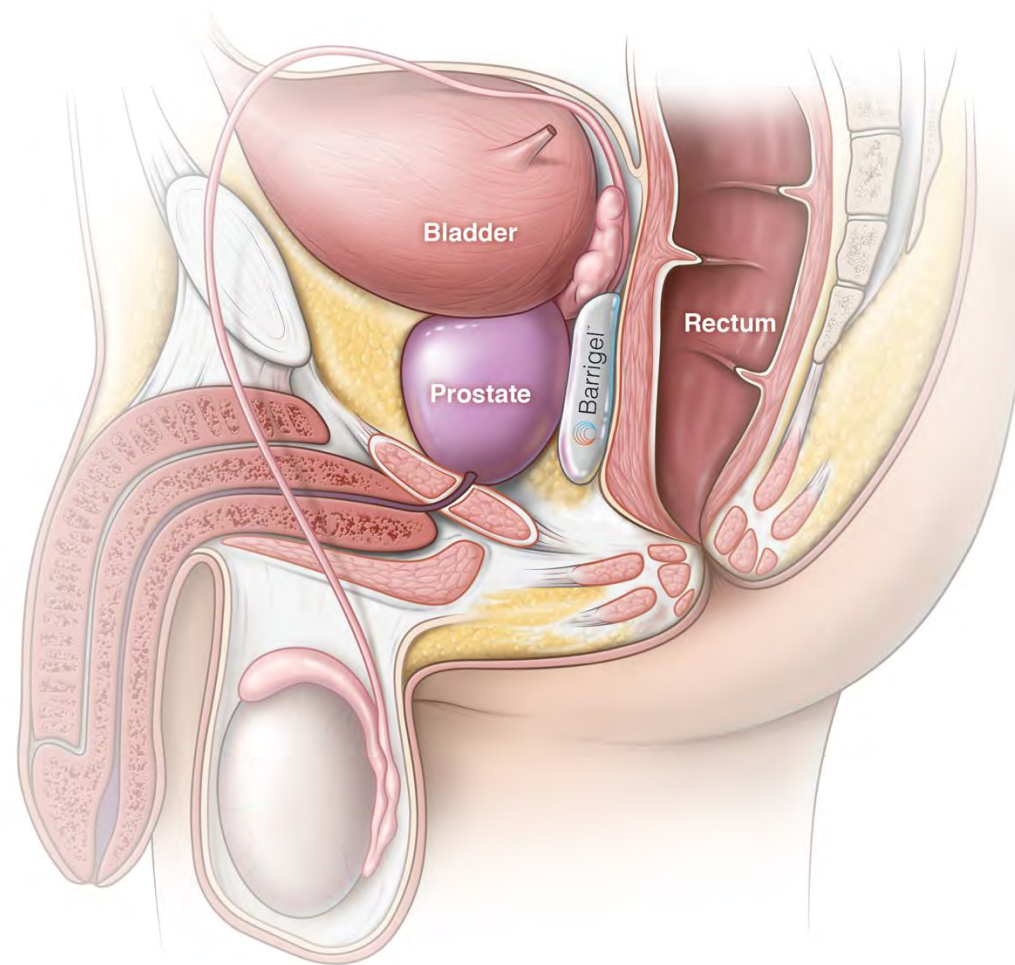
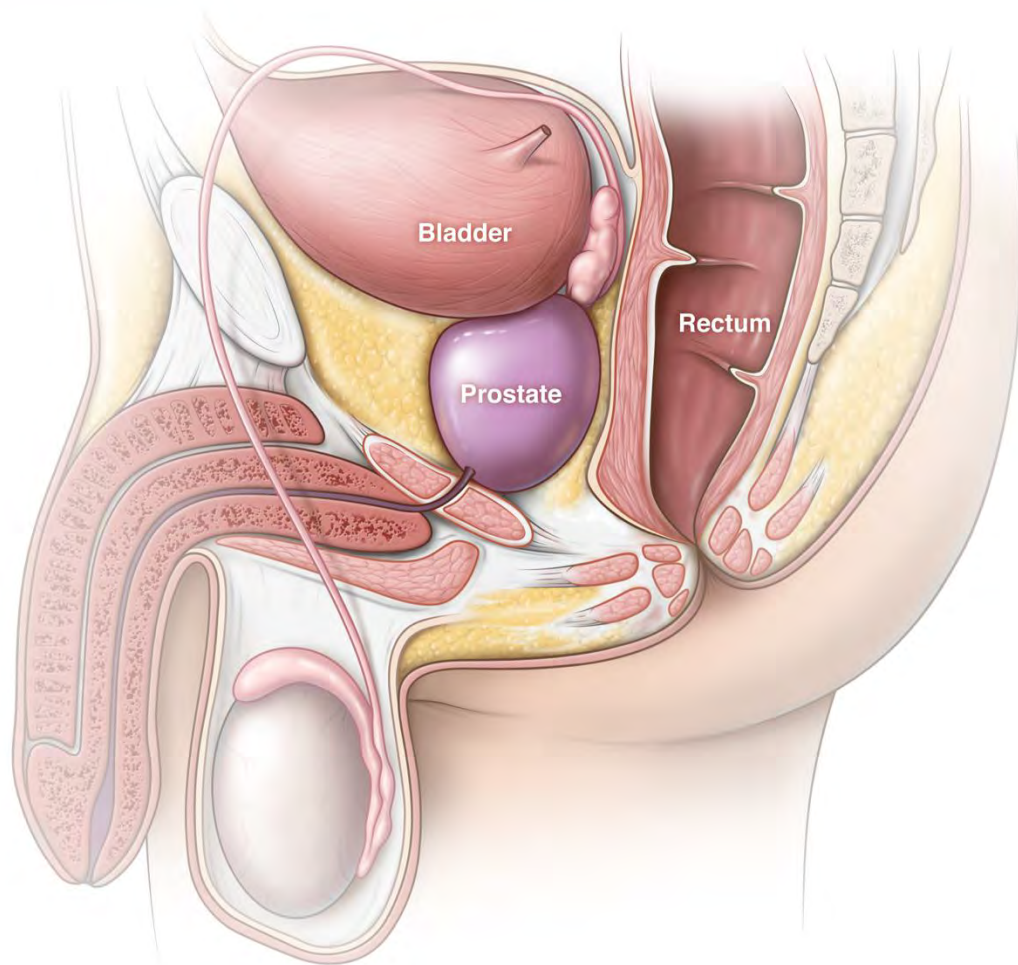
Barrigel rectal spacer remains soft and pliable during insertion, allowing your doctor to **sculpt the spacer in place**.¹⁻³

The result is a **custom implant** tailored to your anatomy.¹⁻⁴



Barrigel rectal spacer is the **ONLY** spacer made from sculptable gel, allowing physician-controlled spacing for a safe implant.¹⁻⁵
In an FDA clinical study, Barrigel spacer had zero patient complaints of device-related pain or discomfort.¹

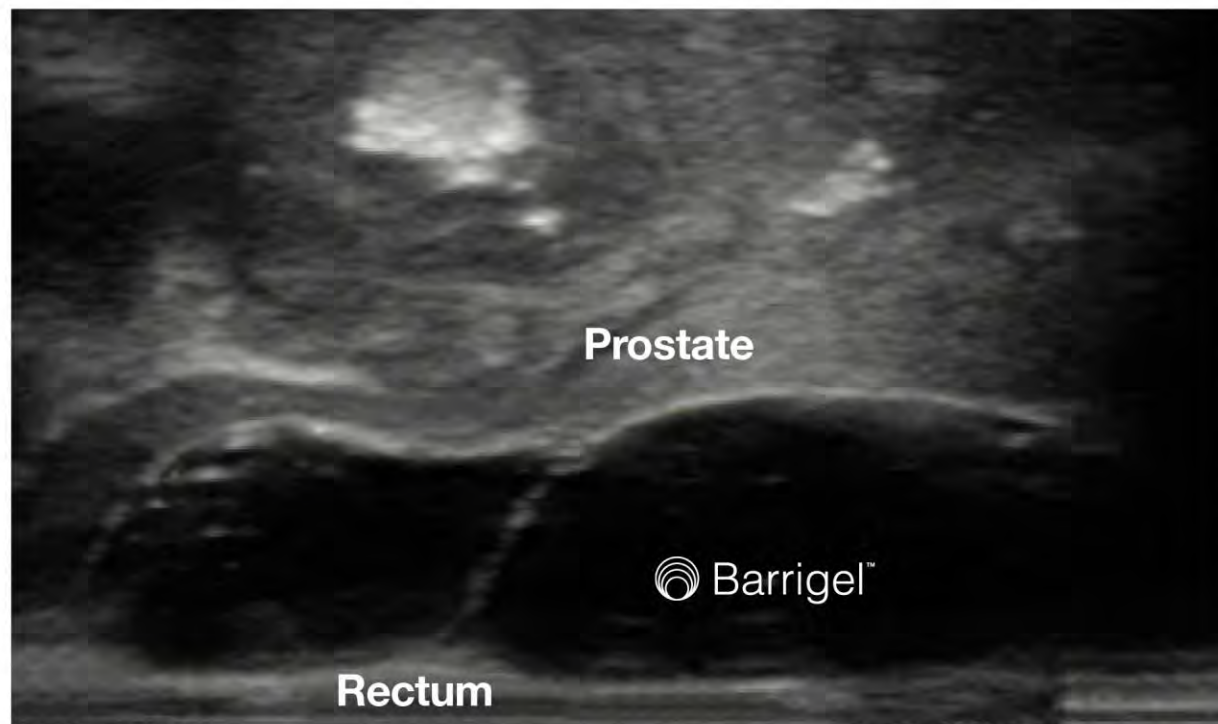
THE BARRIGEL™ RECTAL SPACER DIFFERENCE: **PERSONALIZED PROTECTION**^{1,2}



THE BARRIGEL™ RECTAL SPACER DIFFERENCE: **VISUALLY-GUIDED** SPACING

Barrigel rectal spacer can be **viewed clearly on transrectal ultrasound** (TRUS), the imaging machine used to guide implant placement during the procedure, enabling your doctor to achieve accurate results.¹⁻⁴

This added visibility provides your doctor **advanced control** and **precision** over the placement of Barrigel rectal spacer.¹⁻⁴



TRUS image courtesy of Dr. Rizwan D. Nurani,
Radiation Oncologist; California, United States
Individual results may vary.

NASHA: A LONG HISTORY OF SAFETY^{1,2‡}

over

50

million procedures¹

greater than

25

years of
**PROVEN
SAFETY[‡]**

**Made from Non-Animal Stabilized
Hyaluronic Acid (known as NASHA)³**

Hyaluronic acid is a substance naturally present in the human body that is highly compatible and fully absorbable. It has a proven history of **safety** and **efficacy** and is used in many common medical procedures worldwide.^{1,2}

[‡] Barrigel, made from NASHA, is indicated for rectal spacing in prostate cancer patients and was FDA-cleared in May, 2022.

REFERENCES: 1. Restylane® celebrates 25 years of natural-looking results with its signature line of hyaluronic acid fillers. 2021. 2. Svatos M, Chell E, Low DA et al. *Med Phys* (2024). * 3. Barrigel Injectable Gel Instructions for Use (2022).

CLINICALLY **PROVEN**

TO SIGNIFICANTLY **REDUCE**
UNWANTED RADIATION EXPOSURE¹

In an FDA clinical study,

98.5%
of patients

showed Barrigel™ rectal spacer
to be effective in achieving a
significant reduction in radiation
to the rectum.

What is the benefit of reduced radiation to the rectum?

- ✓ Patients with Barrigel spacer experienced **fewer short and long-term negative side effects** than patients who did not receive Barrigel spacer.¹
- ✓ **Barrigel rectal spacer reduced the rate of complications** including inflammation of the rectum (radiation proctitis), diarrhea, and hemorrhoids.¹



LESS RADIATION TO THE RECTUM



FEWER SIDE EFFECTS



REDUCED COMPLICATIONS

WHAT TO EXPECT - THE PROCEDURE



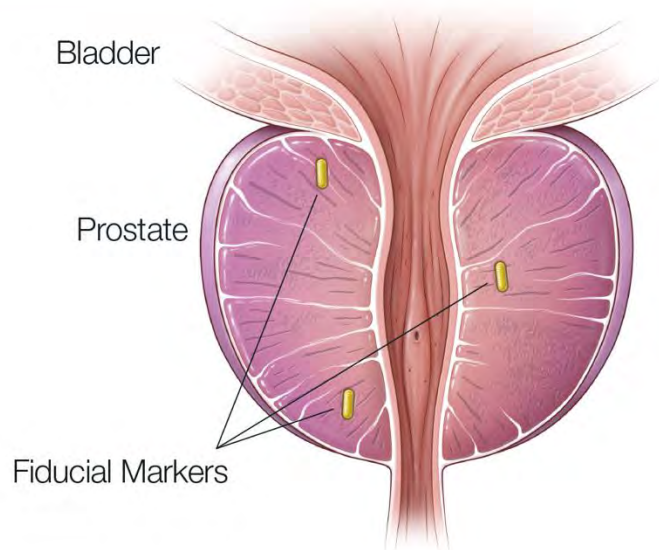
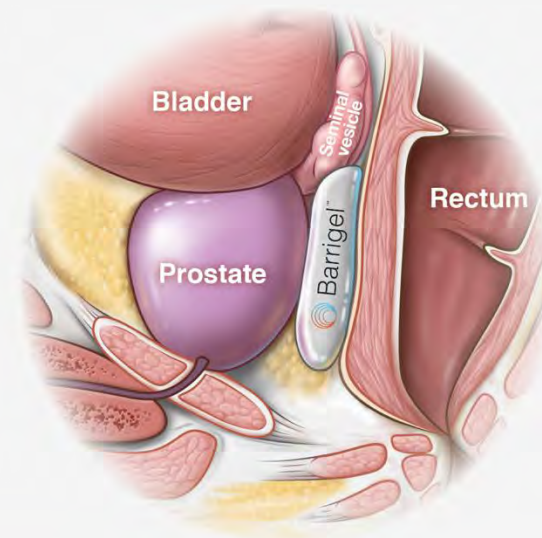
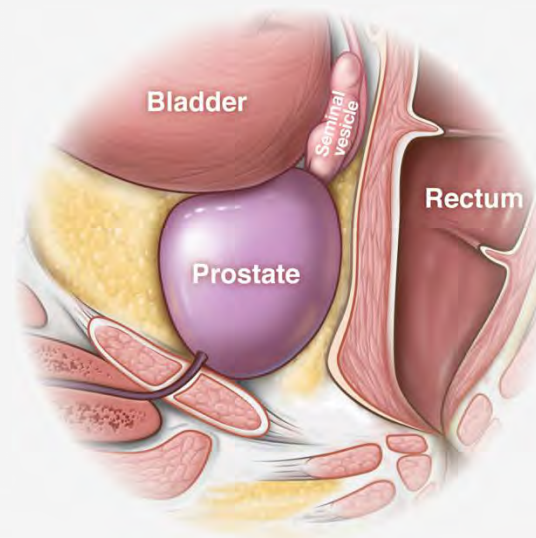
Spacing procedures are performed in hospitals, outpatient clinics or doctors' offices prior to the start of radiation treatment.



The procedure is typically performed in under an hour, and may be performed under **local**, **regional** or **general anesthesia**.



Barrigel™ spacer is placed in between the rectum and the prostate through the perineum.



FIDUCIAL MARKERS

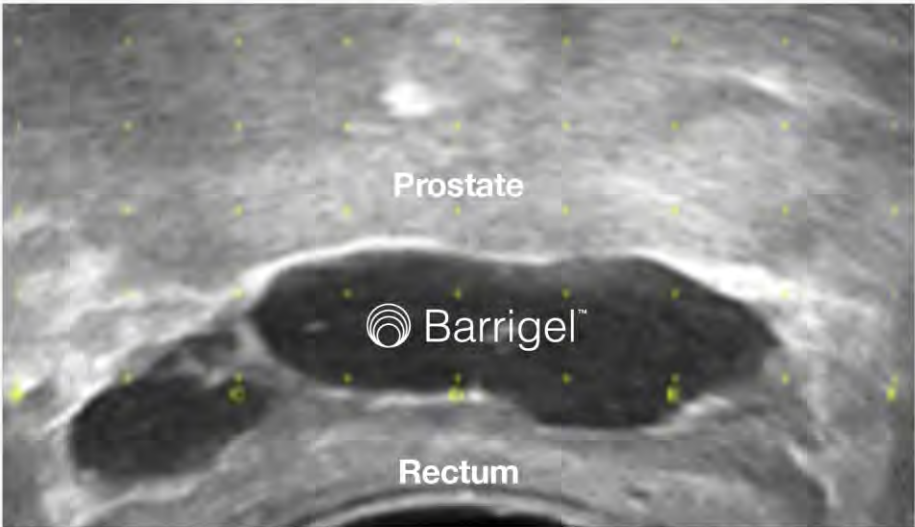
Fiducial markers are **small metal markers that can be placed in your prostate to help your treatment team line up the radiation beams.**

If your doctor determines fiducial markers are appropriate for you, Barrigel rectal spacer may be implanted at the same time.

WHAT TO EXPECT - THE PROCEDURE



Your doctor will use imaging technology called **transrectal ultrasound** (TRUS) during the procedure to sculpt the Barrigel™ spacer to your anatomy.



TRUS image courtesy of Professor Michael Chao, *Radiation Oncologist; Victoria, Australia*
Individual results may vary.



Following the procedure, you can expect to be **monitored in recovery** before being discharged.



Most patients continue with **normal daily activities** shortly after the procedure, although your doctor may ask you to refrain from heavy lifting and strenuous physical activity for a few days.



Barrigel rectal spacer **remains in place** throughout the course of your radiation treatment until it is **safely** and **fully absorbed** by your body.¹

It's important to adhere to all of your doctor's pre-procedure preparation and post-procedure instructions.

READY TO **LEARN** MORE?

Understanding prostate cancer, its treatment options, and the potential side effects of treatment can be a lot to digest. Scan the QR code to view and download resources to help you gain a deeper understanding and feel more informed when making decisions.

Scan the QR code to access
Patient Education Materials



QUESTIONS AND ANSWERS

Thank You.

For product information, adverse event reports
and product complaint reports, contact:

Medical Information Department

Phone: +1 (844) 350-9656

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Email: palettemc@eversana.com

* Study sponsored by Palette Life Sciences, now part of Teleflex.

** Drs Gejerman, Chao, Lederer, and Orio are paid consultants of Teleflex.

Barrigel™ rectal spacer 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 Barrigel™ rectal spacer to reduce the radiation dose delivered to the anterior rectum. Barrigel™ rectal spacer is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment and is intended to be absorbed by the patient's body over time.

Barrigel™ rectal spacer should only be administered by qualified and properly trained physicians with experience in ultrasound guidance and injection techniques in the urogenital/pelvic area.

As with any medical treatment, there are some risks involved with the use of Barrigel™ rectal spacer. Potential complications associated with the use of Barrigel™ rectal spacer include, but are not limited to: pain associated with Barrigel™ rectal spacer injection; needle penetration of the bladder, prostate, rectal wall, rectum, or urethra; injection of Barrigel™ rectal spacer into the bladder, prostate, rectal wall, rectum, urethra, or intravascularly; local inflammatory reactions; infection; urinary retention; rectal mucosal damage, ulcers, necrosis; bleeding; constipation; and rectal urgency. More information on indications, contraindications, warnings and instructions for use can be found in the Instructions For Use at www.barrigel.com. Individual results may vary.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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