

A photograph of a middle-aged couple embracing on a beach. The man, with grey hair and a beard, is smiling warmly at the woman. The woman has curly brown hair and is wearing a pink scarf. They are both wearing sweaters. In the background, there are birds on the beach and the ocean under a clear sky. The image is overlaid with a semi-transparent dark grey circle on the left side.

MINIMIZE THE SIDE EFFECTS
OF PROSTATE RADIATION THERAPY



Barrigel[®]

BY PALETTE LIFE SCIENCES

OVERVIEW

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PROSTATE CANCER

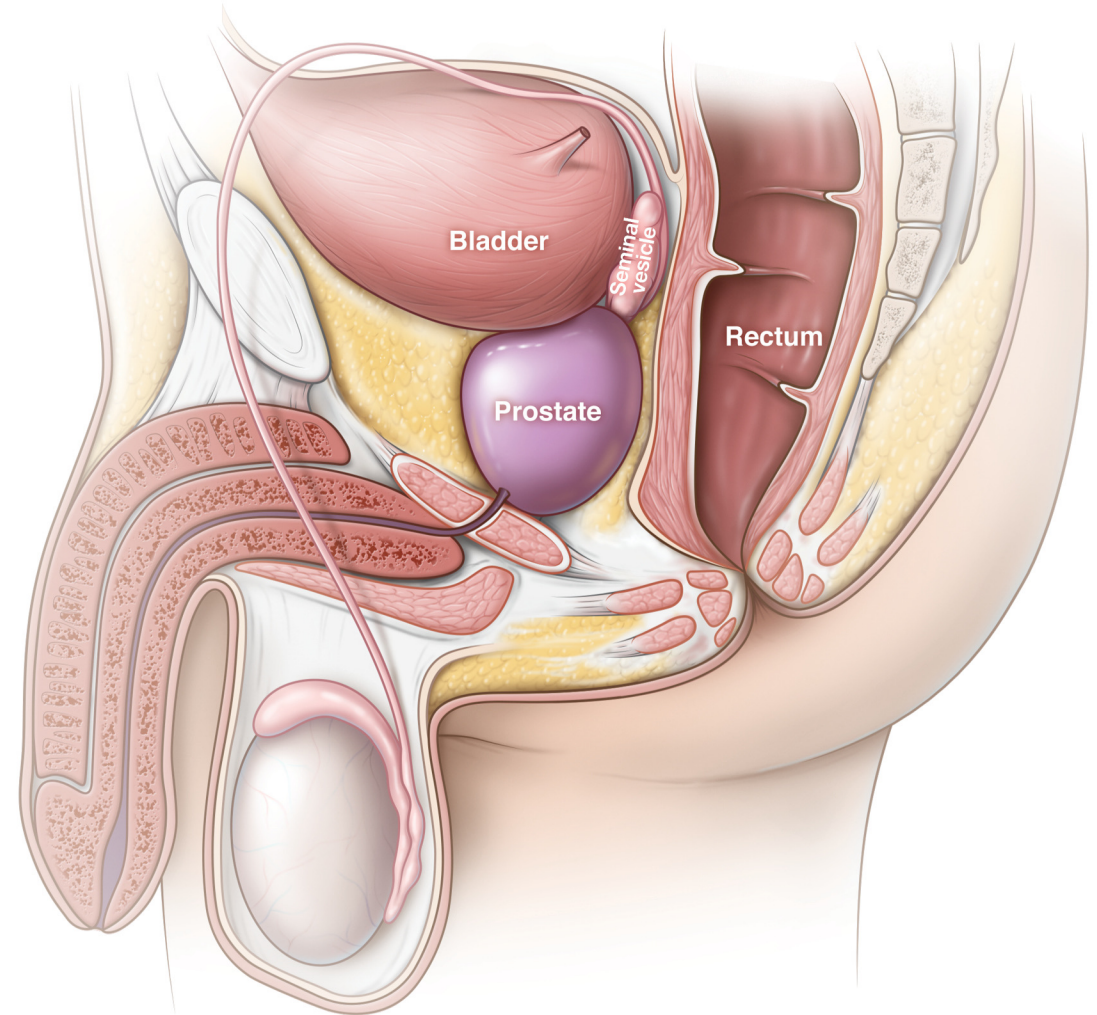
OVERVIEW

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 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

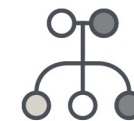


AGE – prostate cancer occurs mainly in older men

- 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 66



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 States¹

PROSTATE CANCER PREVALENCE¹

Other than skin cancer,

PROSTATE CANCER IS THE
MOST COMMON CANCER
IN AMERICAN MEN

~290,000 men in the US are diagnosed
yearly with prostate cancer (2023)



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

PROSTATE CANCER SURVIVAL RATE¹

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

98%* 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: August 20, 2023. 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.

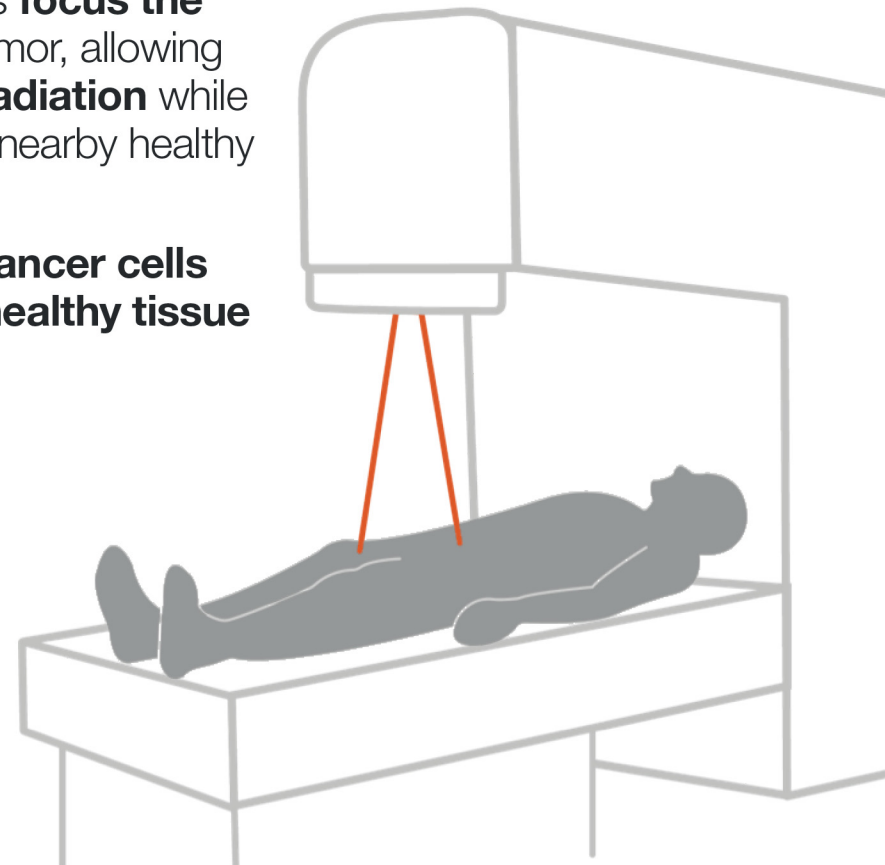
THERE ARE TWO MAIN TYPES OF RADIATION THERAPY

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.



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.

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

THERE ARE TWO MAIN TYPES OF RADIATION THERAPY

INTERNAL RADIATION (BRACHYTHERAPY)

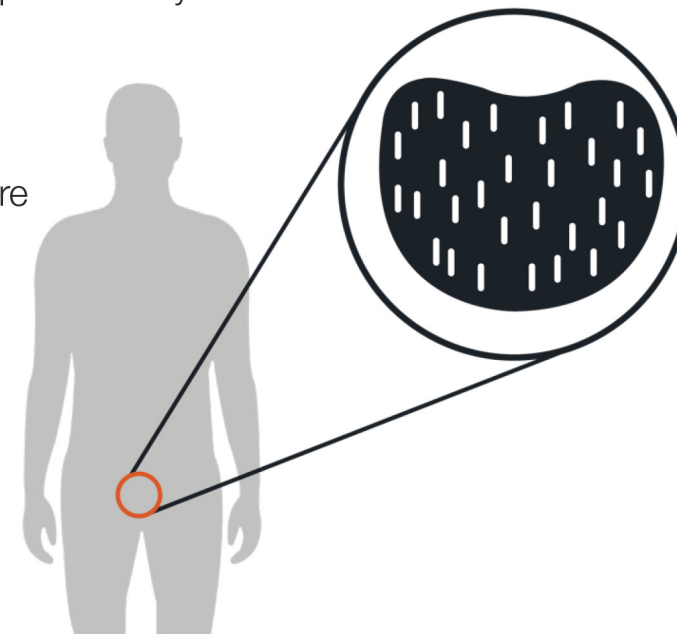
Brachytherapy is a form of radiotherapy where the **radioactive source is placed inside** or next to the area requiring treatment. There are two methods of brachytherapy – low dose rate and high dose rate.

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



POSSIBLE RADIATION SIDE EFFECTS

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:

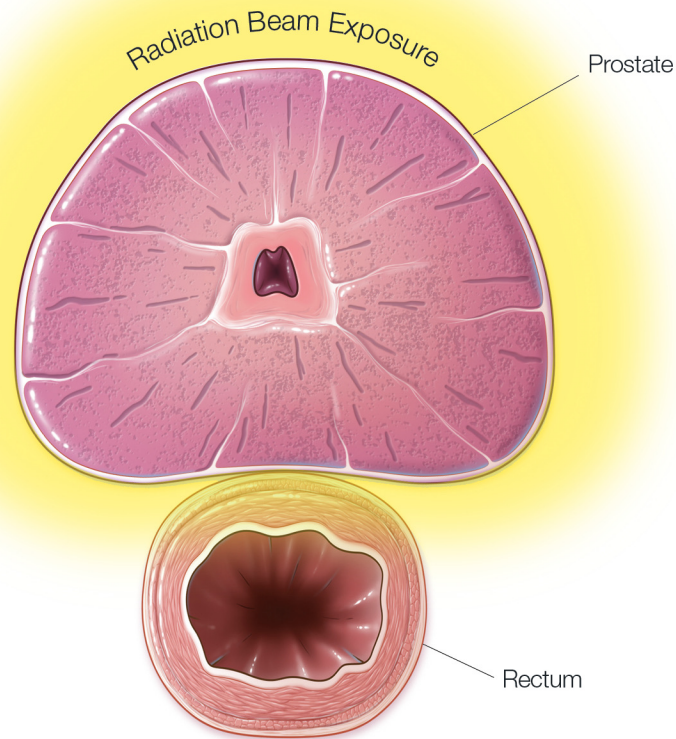
- Needing to have a bowel movement more often than usual (bowel incontinence)
- Diarrhea
- Loose stools
- Hemorrhoids

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.

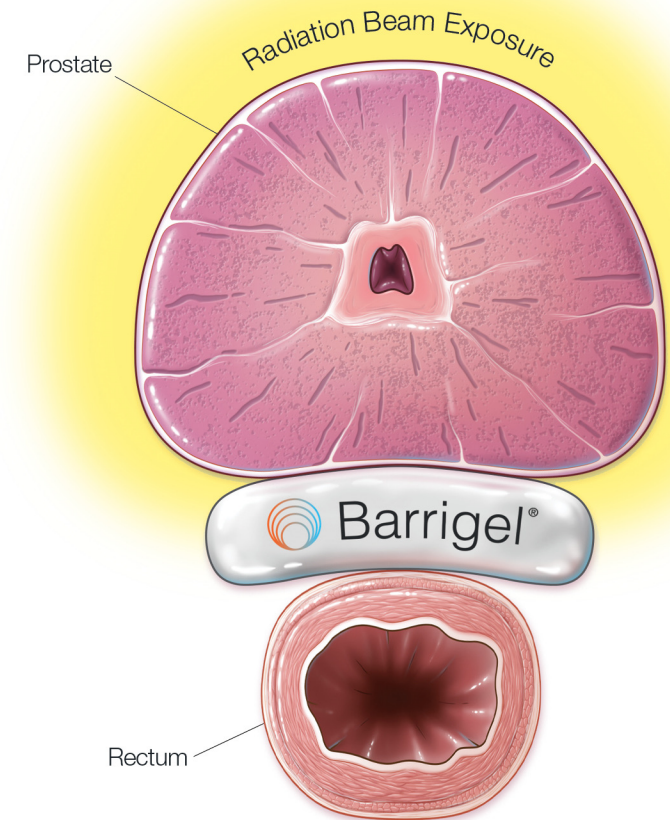


Due to its close proximity to the prostate, **the rectum is most at risk** for radiation beam exposure.

MINIMIZING THE SIDE EFFECTS OF RADIATION THERAPY¹

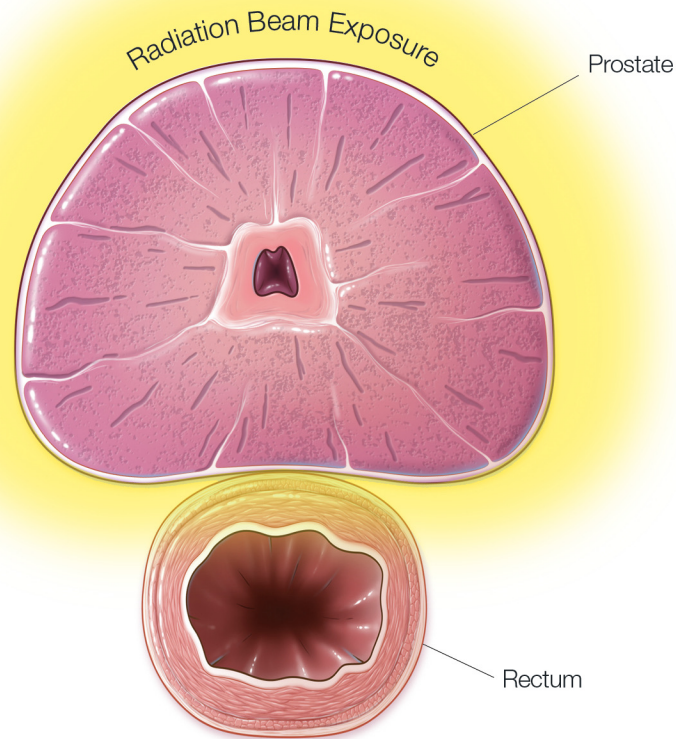
Although beneficial in treating cancer, high-energy radiation beams can negatively affect healthy tissue surrounding the prostate.

Barrigel rectal spacer can help minimize prostate radiation side effects by temporarily positioning the rectum away from the prostate.¹

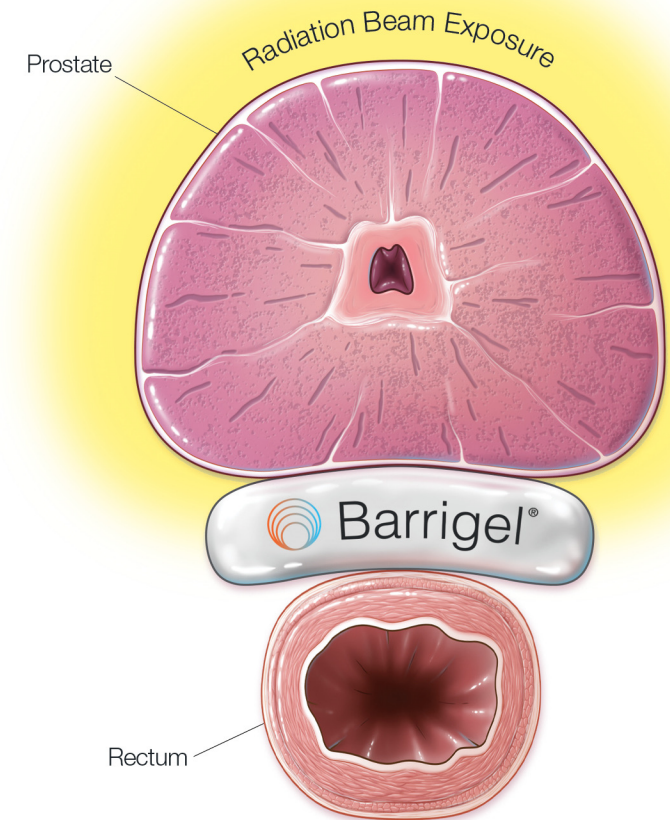


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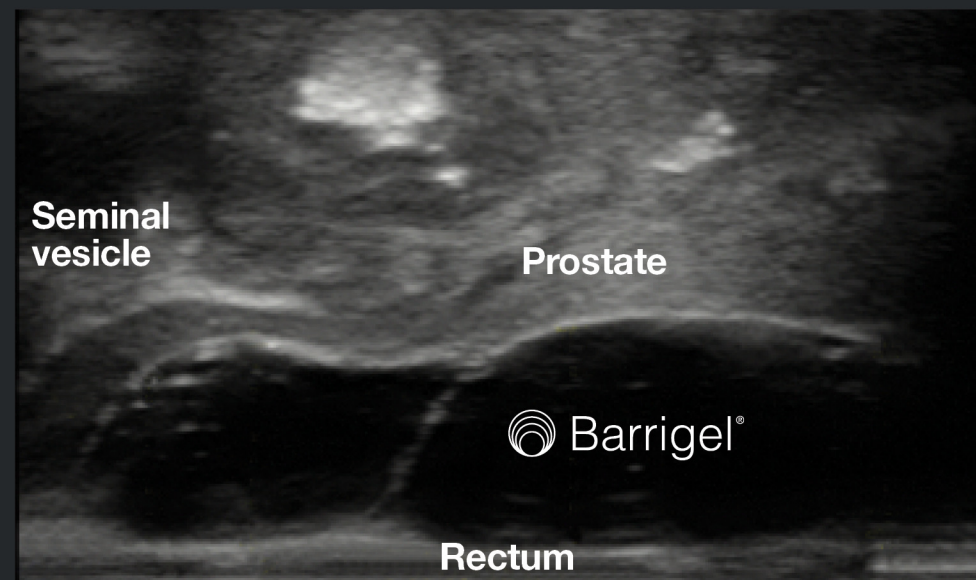
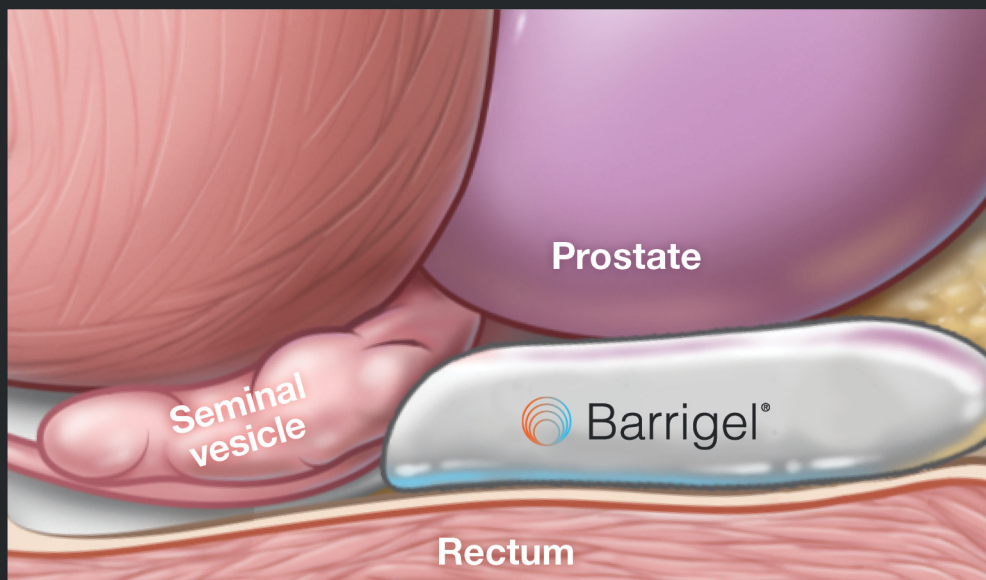
Barrigel creates space between the prostate and the rectum, **moving the healthy organ out of radiation beam exposure.**¹



THE **BARRIGEL** DIFFERENCE

MORE **PERSONALIZED COVERAGE** FOR
MORE **COMPLETE PROTECTION**¹

Barrigel is the first and only rectal spacer that **can be sculpted** in place, to ensure a custom fit for your anatomy.

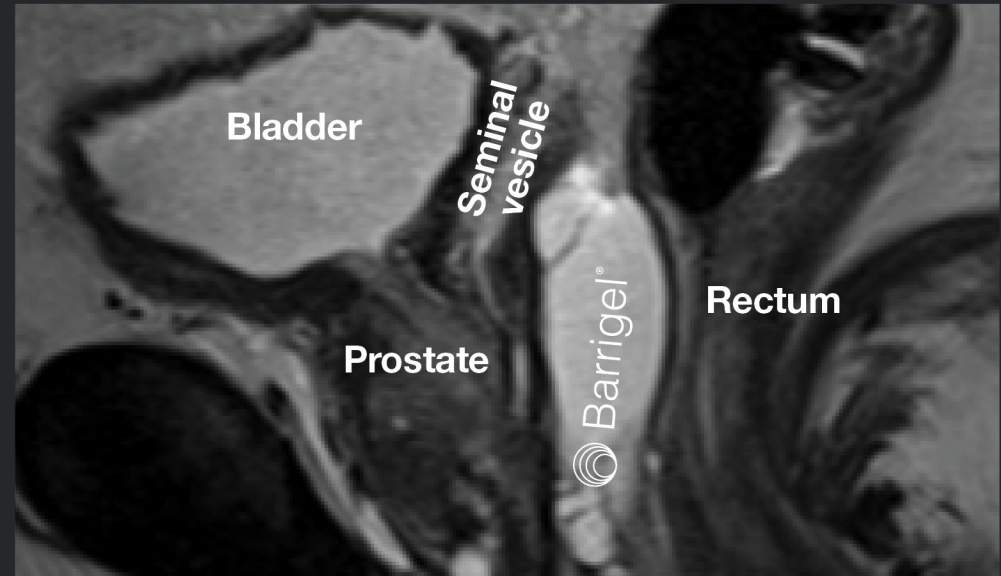
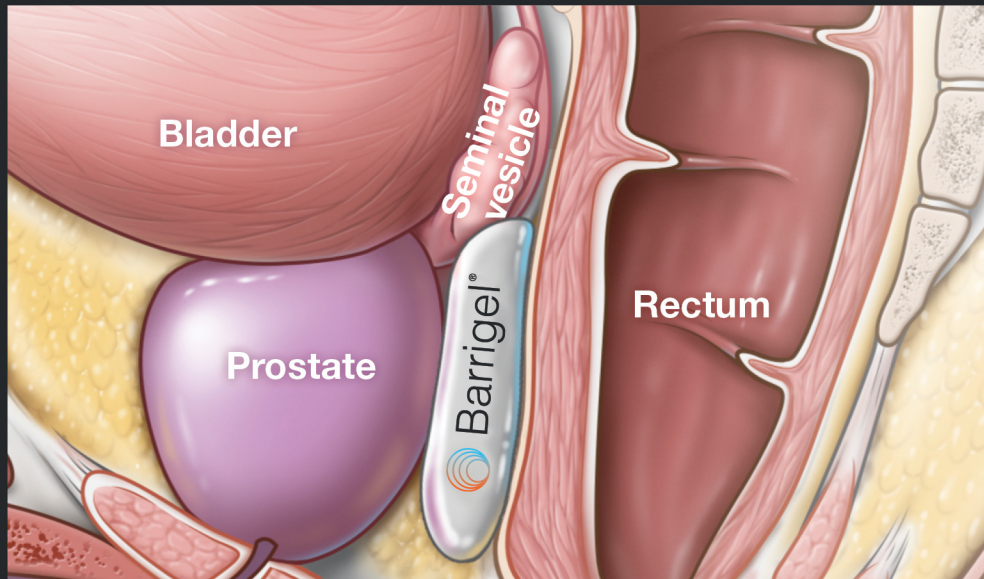


TRUS image courtesy of Dr. Rizwan D. Nurani,
Radiation Oncologist; California, United States

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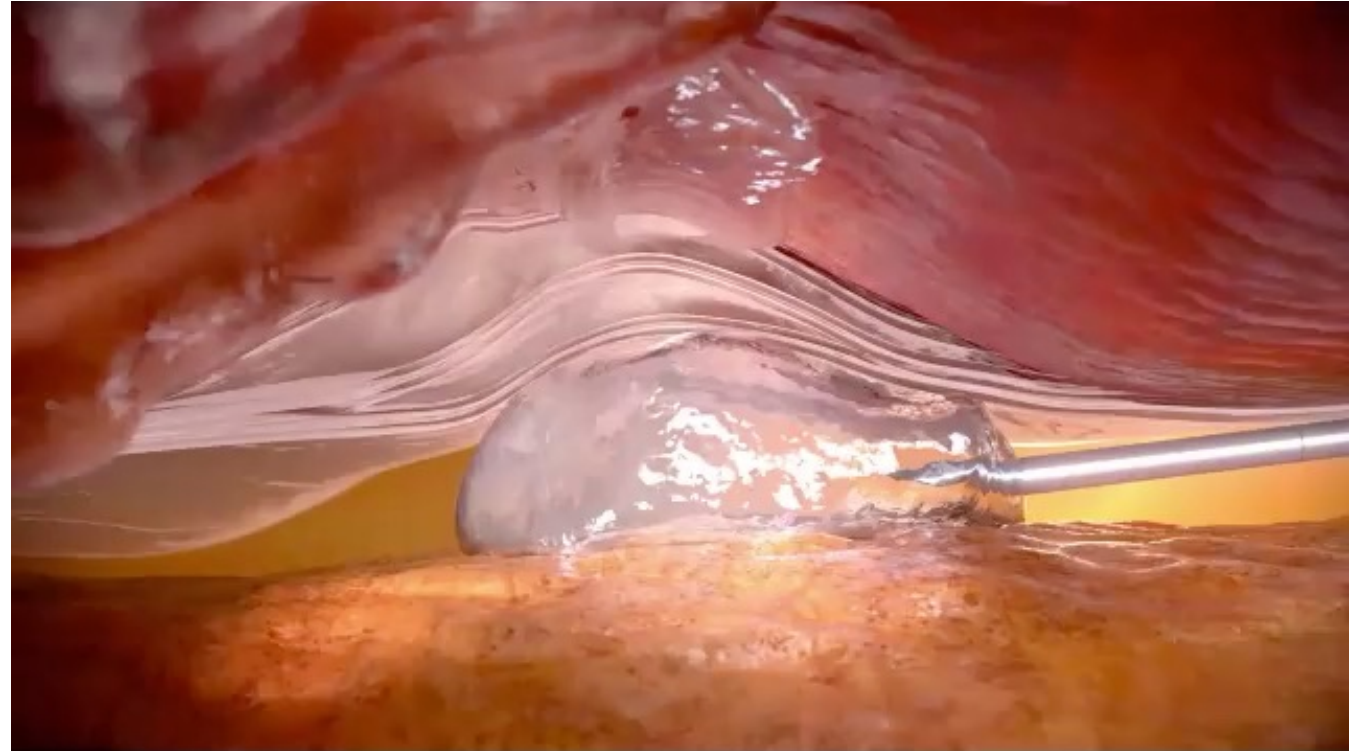
MR image courtesy of Dr. Alex Engelman,
Radiation Oncologist; Florida, United States

THE BARRIGEL DIFFERENCE: **HOW IT WORKS**

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

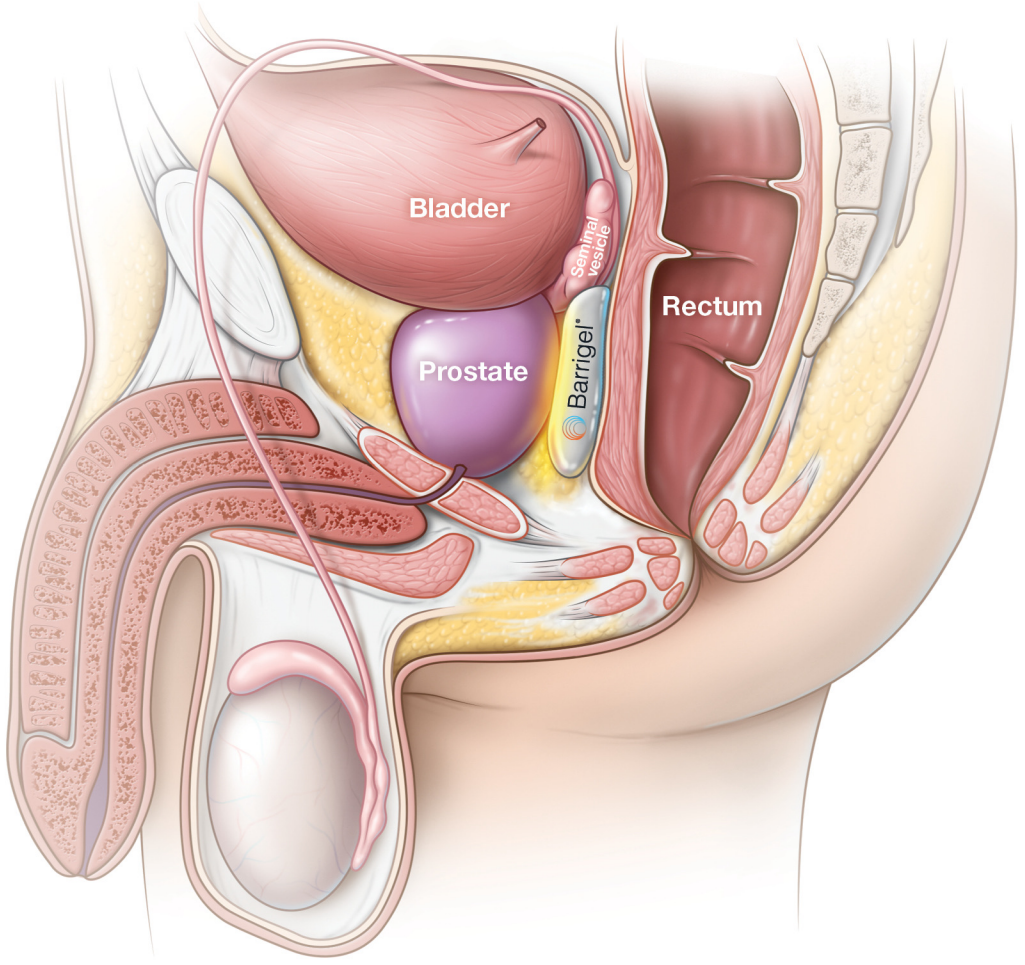
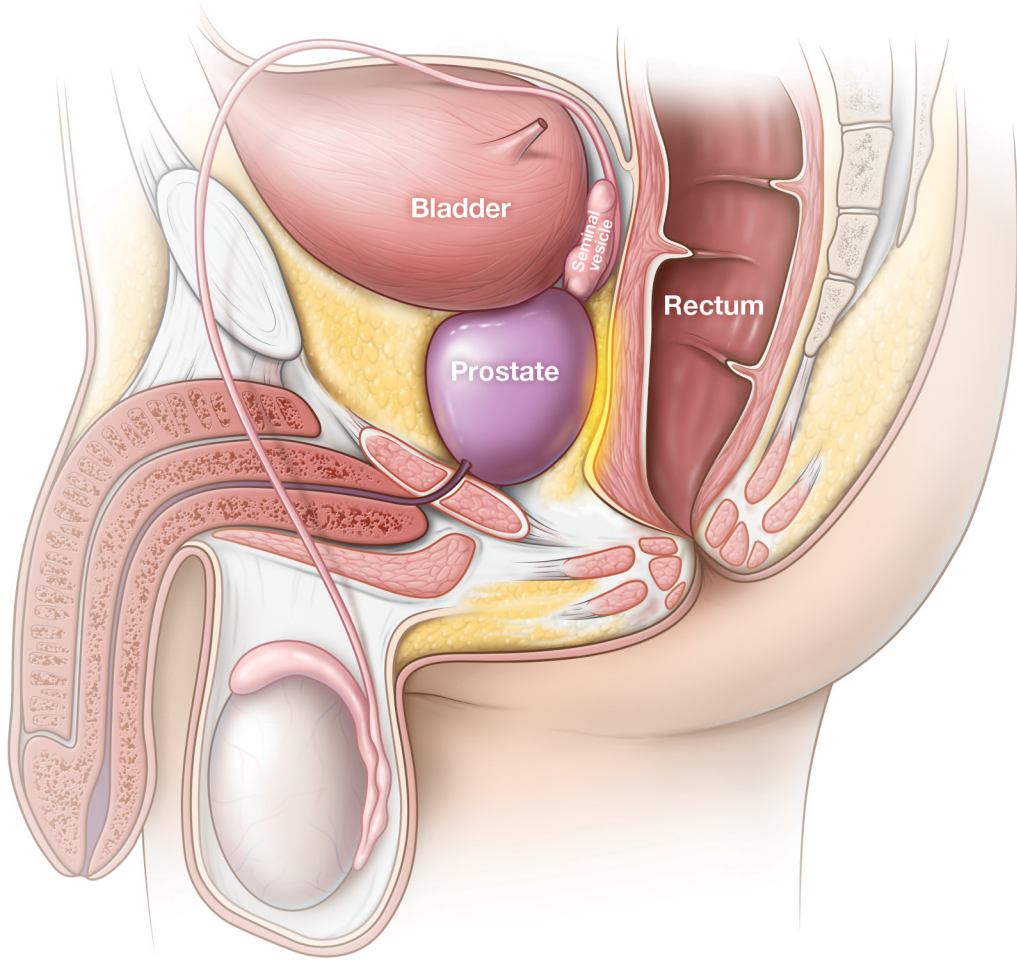
Barrigel remains soft and pliable during insertion, allowing your doctor to **sculpt the spacer in place**.¹

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



Barrigel is the **ONLY** rectal spacer made from soft, sculptable gel which can help minimize discomfort while the implant is in place.¹

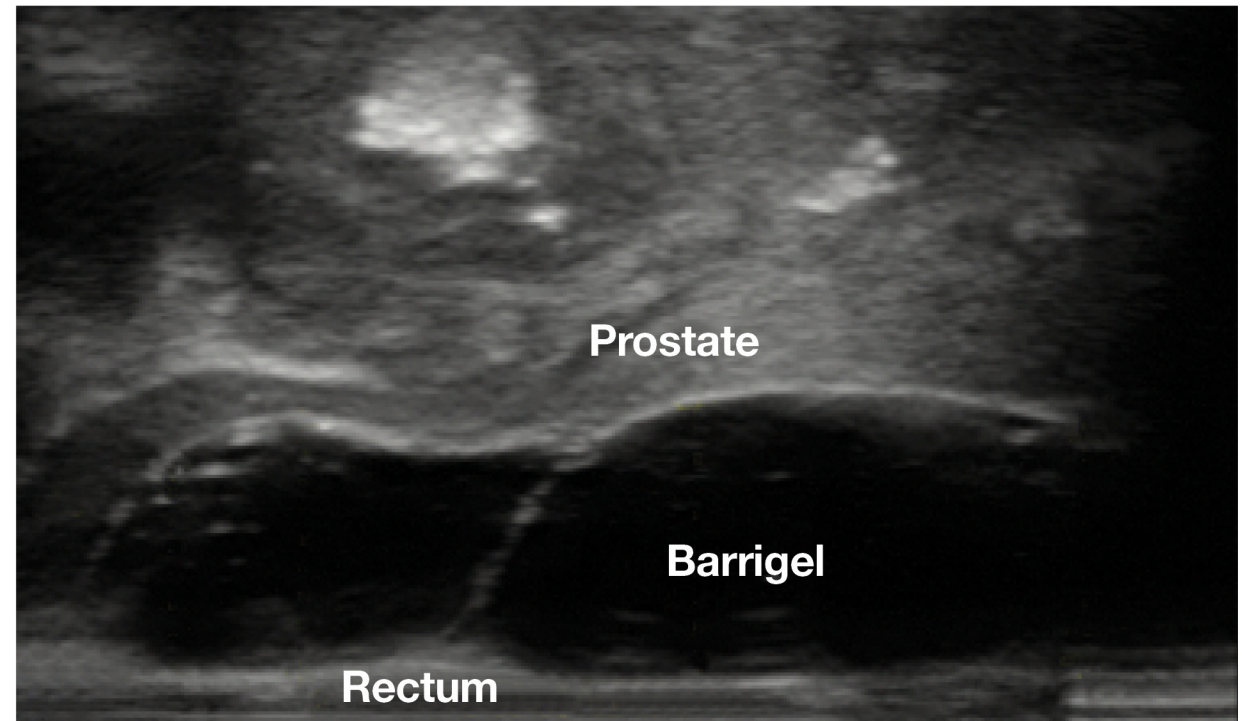
THE BARRIGEL DIFFERENCE: **PERSONALIZED PROTECTION**



THE BARRIGEL DIFFERENCE: **VISUALLY-GUIDED** SPACING

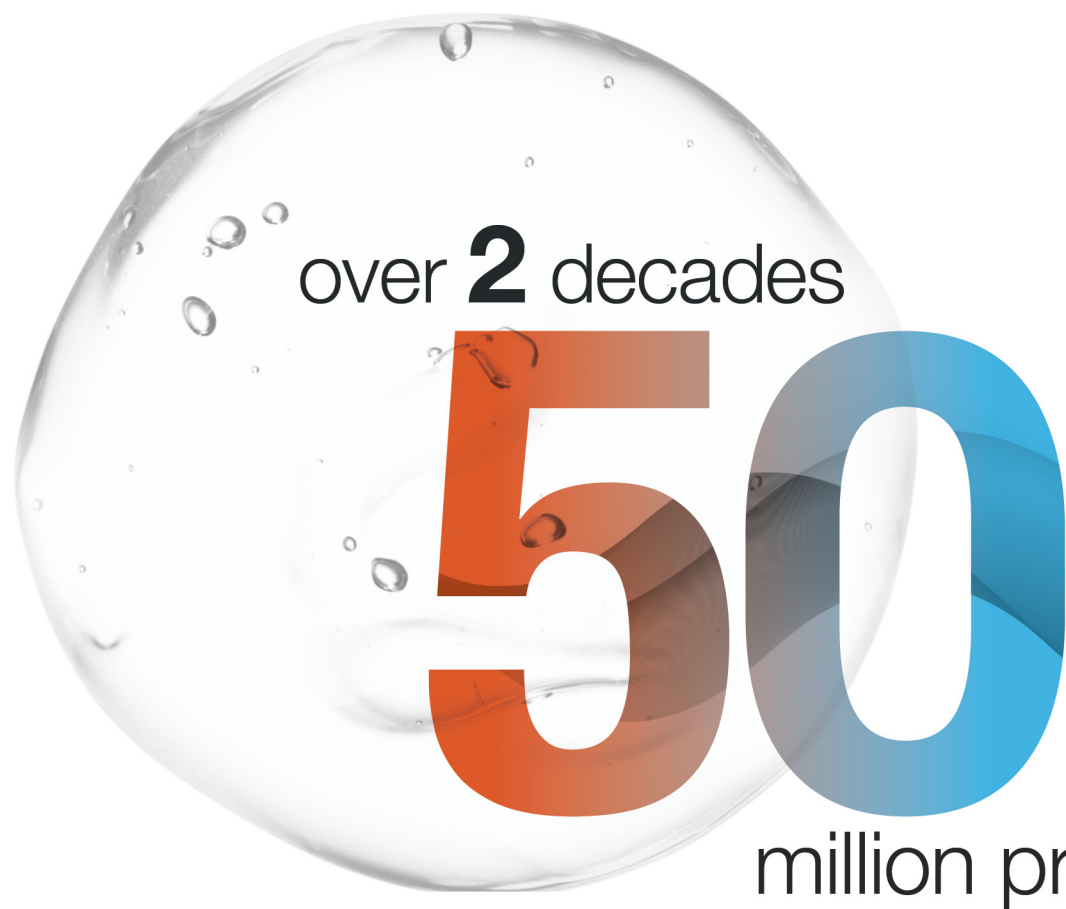
Barrigel can be **viewed clearly on transrectal ultrasound (TRUS)**, the imaging machine used to guide implant placement during the procedure, enabling your doctor to achieve more accurate results.

This added visibility provides your doctor even **greater control and precision** over the placement of Barrigel.¹



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

THE BARRIGEL DIFFERENCE: A LEGACY OF **LONG-TERM SAFETY**



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

NASHA is a mildly stabilized form of hyaluronic acid.¹ Hyaluronic acid is a substance naturally present in the human body that is highly compatible and fully absorbable. It is a **natural substance** used in many common medical procedures worldwide.¹ It is a **natural alternative** to synthetic materials.

CLINICALLY **PROVEN**

TO SIGNIFICANTLY **REDUCE**
UNWANTED RADIATION EXPOSURE¹

In an FDA clinical study,

98.5%
of patients

showed Barrigel 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 experienced **fewer short and long-term negative side effects** than patients who did not receive Barrigel.
- ✓ **Barrigel 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



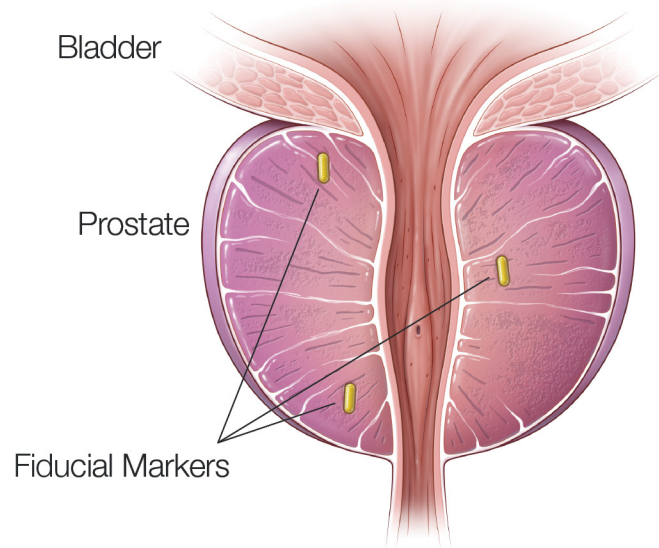
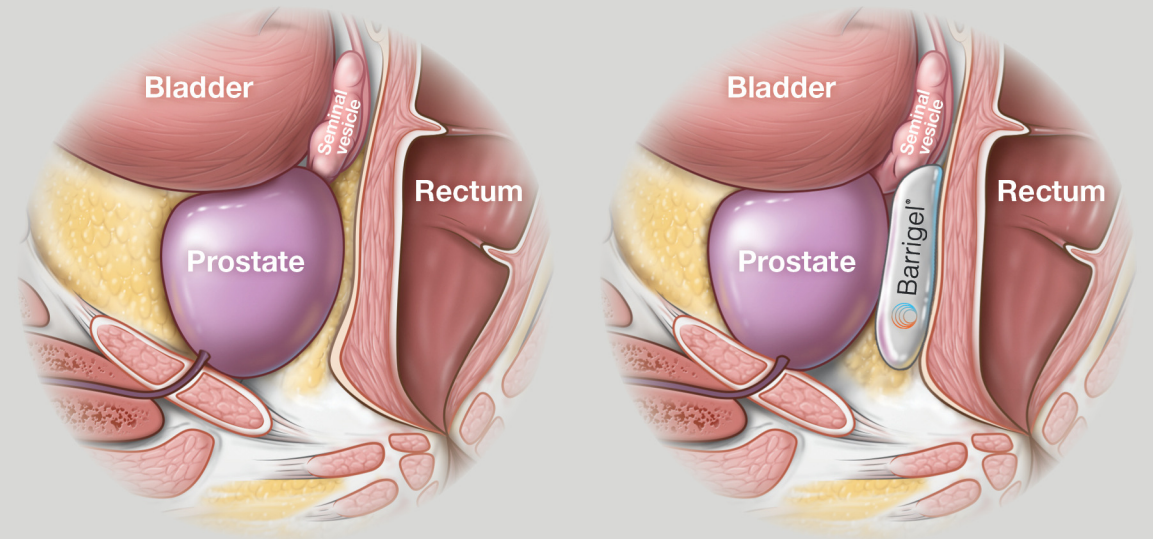
Spacing procedures are performed in hospitals, outpatient clinics or doctors' offices prior to the start of radiation treatment.



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



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



FIDUCIAL MARKERS

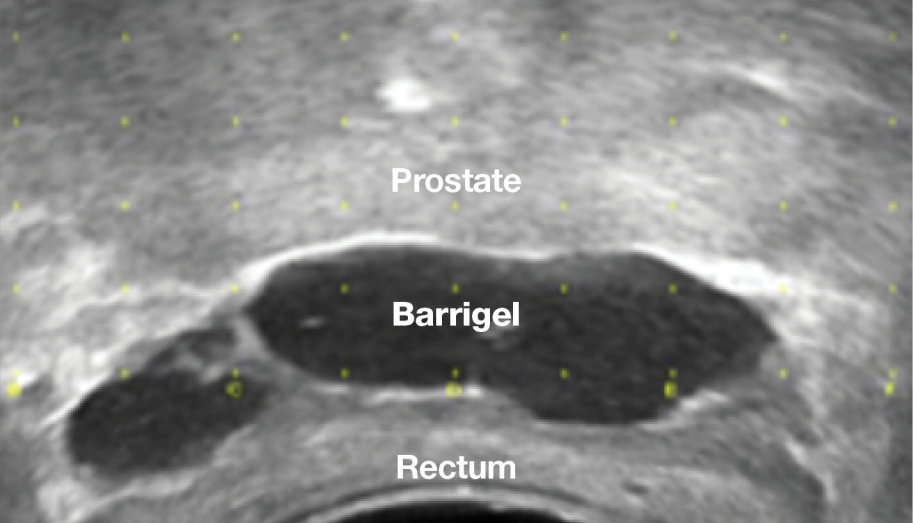
Fiducial markers are **small metal markers that can be placed in your prostate to help your treatment team line up the radiation beams.**

If your doctor determines fiducial markers are appropriate for you, Barrigel 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



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 **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.

REFERENCE: 1. Mariados NF, Orio PF, Schiffman Z et al. Hyaluronic acid spacer for hypofractionated prostate radiation therapy: A randomized clinical trial. *JAMA Oncol.* 2023;e1-e8.

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

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BARRIGEL® is used to increase the distance between the prostate and the anterior rectal wall, with the intent of decreasing radiation dose delivered to the rectum when treating prostate cancer with radiation. BARRIGEL is only administered by qualified and properly trained physicians. BARRIGEL is contraindicated in prostate cancer patients with clinical stage T4 disease.

As with any medical treatment, there are some risks involved with the use of BARRIGEL. Potential complications associated with the use of BARRIGEL include, but are not limited to: pain associated with BARRIGEL injection; needle penetration of the bladder, prostate, rectal wall, rectum, or urethra; injection of BARRIGEL 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. Discuss these adverse effects with your healthcare provider. For more information about BARRIGEL, please visit barrigel.com.

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