

MINIMIZE THE SIDE EFFECTS

of prostate radiation therapy –
with Barrigel^{® 1}



Barrigel[®]

If you or someone you love has been diagnosed with prostate cancer and is planning to undergo radiation therapy, you may want to consider a rectal spacer to help minimize potential side effects.¹

Radiation beams can affect healthy tissue near the prostate and may result in long-term bowel, urinary, and sexual complications.

Due to its close proximity to the prostate, the rectum is most at risk for radiation exposure. Possible long-term side effects include bowel problems such as:

- Rectal swelling
- Pain
- Hemorrhoids
- Diarrhea

Barrigel rectal spacer, implanted prior to radiation therapy, helps protect healthy tissue against unwanted radiation exposure.¹

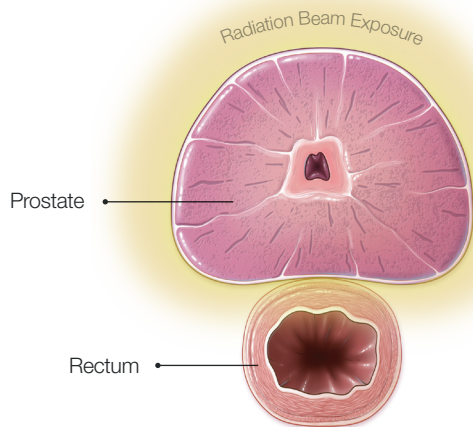


PROVEN SAFE
AND EFFECTIVE at minimizing
the long-term side effects of
prostate radiation therapy.^{1,2}

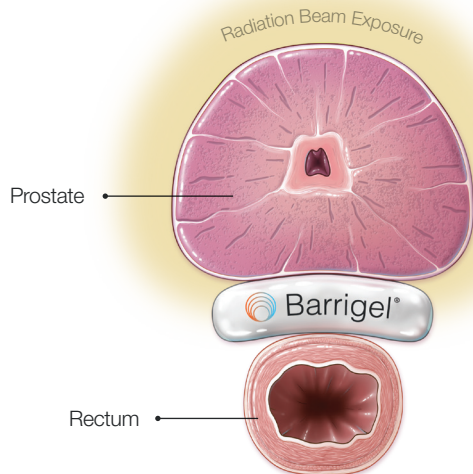
WHAT IS RECTAL SPACING?

Radiation therapy uses energy beams to destroy and stop the spread of cancer cells. These high energy 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



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



THE PROCEDURE

- > Spacing procedures are performed in hospitals, outpatient clinics or doctors' offices prior to the start of radiation treatment.
- > Barrigel may be implanted at the same time as fiducial markers – small markers placed in your prostate to help your treatment team line up the radiation beams.
- > Your doctor will use a medical imaging device called transrectal ultrasound (TRUS) to view your anatomy and place the spacer between your rectum and your prostate.
- > The procedure is typically performed in under an hour.
- > 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.
- > It is important to adhere to all of your doctor's pre-procedure preparation and post-procedure instructions.

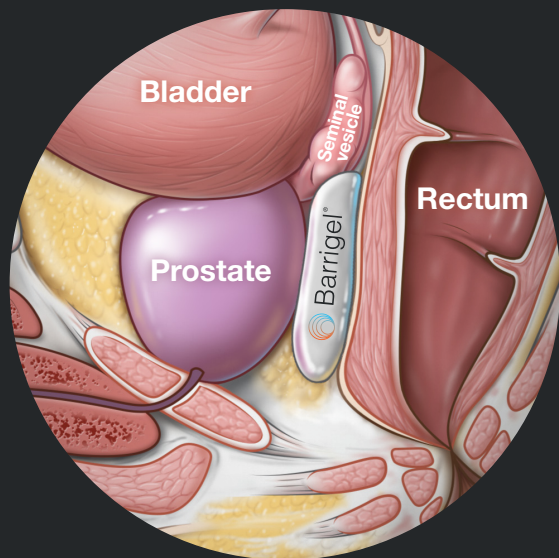
Visit **barrigel.com** for additional resources to help you and your loved ones gain a deeper understanding of how Barrigel can reduce radiation treatment side effects.

THE **BARRIGEL**

DIFFERENCE

More personalized **coverage** for more complete **protection**¹

In rectal spacing, achieving even, complete coverage of healthy tissue is critical. This provides the most protection against radiation exposure. **Barrigel is the first and only rectal spacer that can be sculpted and shaped by your doctor to create a custom fit to your anatomy.**¹

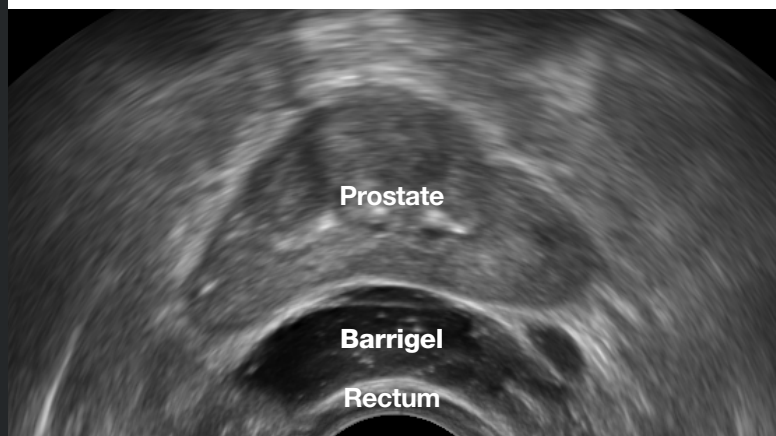


To view a short animation on how Barrigel works, scan the QR code on the back of this brochure.

The seminal vesicles, which produce seminal fluid, are often exposed to radiation when treating prostate cancer. **Protecting the rectum from seminal vesicle radiation exposure can help further reduce potential side effects.**

VISUALLY-GUIDED SPACING

Barrigel is the only spacer that can be **viewed clearly on transrectal ultrasound** (TRUS), the imaging machine used to guide your doctor's placement during the procedure. This added visibility provides your doctor even **greater control** and **precision** over the shape and positioning of the spacer.



TRUS image courtesy of Dr. Neil F. Mariados, Radiation Oncologist; New York, United States

STAYING **POWER**

Barrigel **remains in place** throughout the course of your radiation treatment, maintaining the space between your prostate and rectum until it is **safely and fully absorbed** by your body.¹

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?

- Through 3 and 6 months, patients with Barrigel experienced **fewer short-term and long-term negative side effects** than patients who did not receive Barrigel.^{1,2}
- Barrigel reduced the rate of complications** including inflammation of the rectum (radiation proctitis), diarrhea, and hemorrhoids.^{1,2}



over **2** decades

50
million procedures⁴

A large, clear water droplet is shown in the foreground, partially overlapping the text. The droplet has a soft, glowing effect and contains small bubbles. The number '50' is rendered in a large, bold, 3D-style font with a gradient from orange to blue. Below it, the text 'million procedures' is written in a clean, sans-serif font, followed by a superscripted '4'.

A LEGACY OF LONG-TERM SAFETY

Made from Non-Animal Stabilized Hyaluronic Acid (known as NASHA[®]), Barrigel is the first and only hyaluronic acid rectal spacer. Hyaluronic acid is a substance naturally present in the human body. Highly compatible and fully absorbable by the body, it is a natural substance used in many common medical procedures.³ NASHA has been used for over two decades in more than 50 million procedures in men, women, and children worldwide.⁴

FREQUENTLY ASKED QUESTIONS

What is Barrigel made of and is it safe?

Barrigel is the first and only hyaluronic acid rectal spacer on the market. Barrigel is made from Non-Animal Stabilized Hyaluronic Acid, known as NASHA. NASHA has a long history of safety, efficacy and biocompatibility in a wide variety of medical applications, including pediatric medicine.^{3,4}

What are the risks associated with Barrigel?

As with any injection procedure, there is a risk of infection. Potential procedure-related side effects can include pain at the injection site and a brief period of bleeding from the needle stick. Post-treatment side effects include a mild to moderate sensation of rectal filling. Talk to your doctor about the risks associated with Barrigel.

How is the procedure performed?

Barrigel is placed between the rectum and the prostate through the perineum. Your doctor will use imaging technology called transrectal ultrasound (TRUS) during the procedure to sculpt the Barrigel spacer to your anatomy.

Where is the procedure done?

The Barrigel procedure is usually performed in a hospital or outpatient clinic prior to the start of radiation treatment. Barrigel may be inserted at the same time as fiducial marker placement.

How long before I can get back to regular activities following the procedure?

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.

How long will Barrigel remain in my body?

Barrigel is a hyaluronic acid that is biocompatible with your body. The spacer will stay in place for the duration of your radiation therapy and begin to safely reabsorb into your body after 3 months.¹ It is important to note that Barrigel may be detected during anorectal examinations and medical imaging of the pelvis. You will receive a Barrigel Patient Implant Card following your procedure, which shows how Barrigel may be visible on medical imaging systems. It's recommended that you keep this card for your records and inform your future doctors that you have had treatment with Barrigel.

Which types of radiation therapy can Barrigel be used with?

Barrigel can be used with all forms of radiation therapy when treating T1-T3b prostate cancer.⁵ Talk with your doctor to find out if Barrigel is right for you.



REFERENCES: **1.** Data from Palette Life Sciences 510(k) K220641. **2.** Data on file. Palette Life Sciences. **3.** Q-Med. NASHA- the Monograph. Uppsala, Sweden. **4.** <https://www.prnnews.com/news-releases/restylane-celebrates-25-years-of-natural-looking-results-with-its-signature-line-of-hyaluronic-acid-fillers-301388779.html>. Accessed Sept 30, 2021. **5.** Barrigel [product insert – United States]. Santa Barbara, CA, United States. Palette Life Sciences; 2022.

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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.