

Minimise potential side effects of
prostate radiation therapy and
improve your quality of life¹

with **BARRIGEL** hyaluronic acid spacer



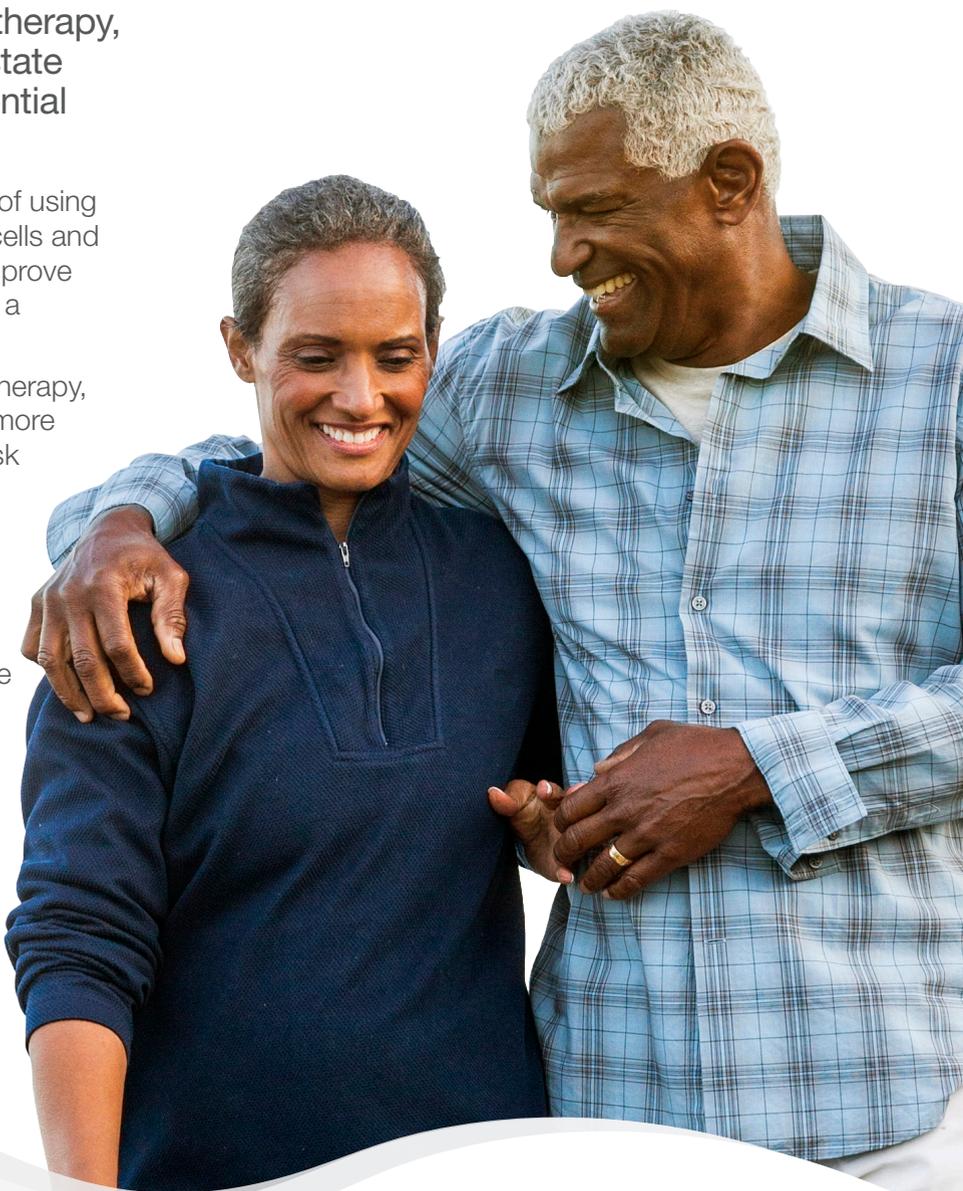
BARRIGEL[®]

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 prostate spacer to help minimise the potential side effects.

Radiation therapy - the standard practice of using energy beams to ablate (destroy) cancer cells and stop them from spreading - can greatly improve your prognosis and quality of life following a prostate cancer diagnosis.

With technological advances in radiation therapy, treatment planning is more accurate and more precise than ever before. But, there is a risk that radiation beams can potentially affect healthy organs near the prostate.

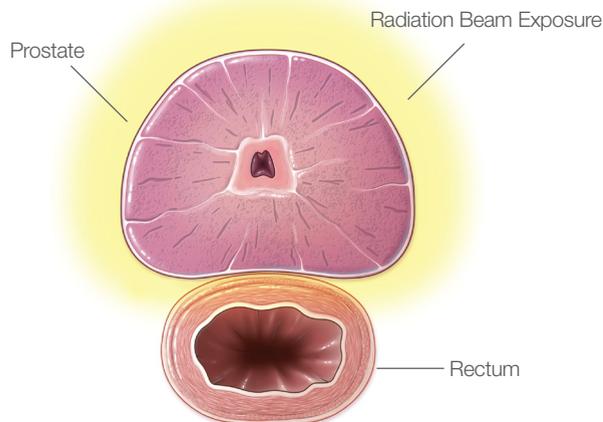
As a result of treatment, patients can experience bowel, urinary, and sexual complications. A prostate spacer helps protect healthy organs around the prostate by minimising their radiation exposure.



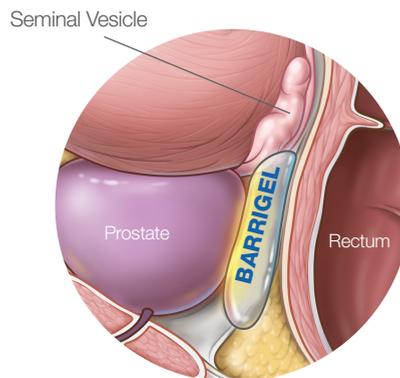
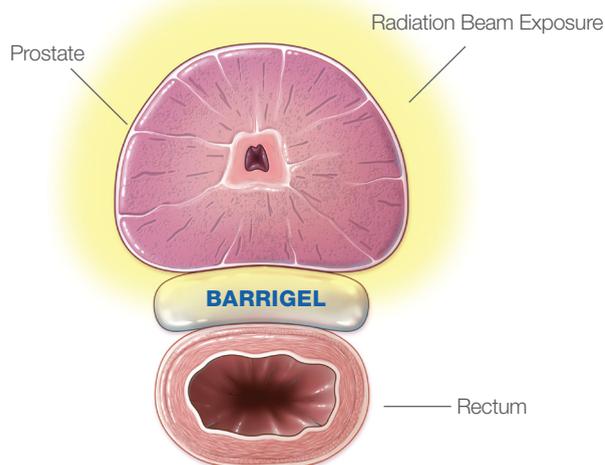
BARRIGEL

Proven to be **safe and effective**
at minimising the complications associated
with radiation therapy¹

Potential risks and side effects of advanced radiation therapy treatment for prostate cancer include bowel problems such as rectal pain, burning and/or diarrhea. Due to its close proximity to the prostate, the rectum is the primary organ at risk for radiation exposure.



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



The seminal vesicles are also at risk for radiation exposure which can negatively impact sexual function.

Unlike other spacing products, BARRIGEL is a sculptable gel which allows your physician to carefully and effectively **sculpt the spacer** to your anatomy. This allows optimal placement and coverage of the area surrounding the prostate, including the area around the seminal vesicles.

The procedure

- BARRIGEL is typically placed at the same time as fiducial markers under anaesthesia.
- Spacing procedures are performed in hospitals, outpatient clinics or doctors' offices prior to the start of radiation treatment.
- BARRIGEL is custom-sculpted to your anatomy by your physician using a medical imaging device called transrectal ultrasound (TRUS).

About **BARRIGEL**



Generation Next

BARRIGEL is an advanced prostate spacer made from **hyaluronic acid** - a substance naturally present in the human body. Highly compatible and fully absorbable by the body, it is a natural alternative to synthetic spacers.

Personalised Fit

The unique sculptable nature of BARRIGEL remains soft during insertion allowing your physician to **sculpt the spacer** in place creating an optimal fit for your body.

Staying Power

BARRIGEL **remains stable** throughout the course of your treatment until it is safely and fully absorbed by your body.²

Visually-Guided Spacing

BARRIGEL is the only gel spacer that can be viewed clearly on transrectal ultrasound (TRUS) **during the procedure**.³ This added visibility during insertion provides your physician greater control and precision over the placement of the spacer.

Procedural TRUS Imaging

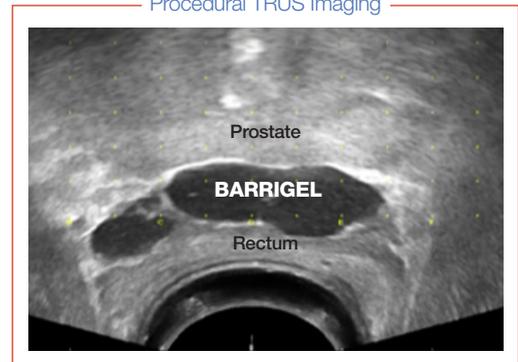


Image provided by Dr. Michael Chao
Radiation Oncologist, Victoria, Australia

About **NASHA**

Safe, effective and proven

Made from Non-Animal Stabilised Hyaluronic Acid (known as NASHA®), BARRIGEL is the first commercially available hyaluronic acid prostate spacer.

Hyaluronic acid is a substance naturally present in the human body. **Highly compatible** and **fully absorbable by the body**, it is a natural alternative to synthetic spacers.

NASHA has been used for over **two decades** in more than **40 million procedures** in men, women and children worldwide.⁴

It is an especially well-known technology in the aesthetic market as a dermal filler that is proven to be safe and effective.^{5,6}

2 decades

40

million procedures



Frequently Asked Questions

What is BARRIGEL made of and is it safe?

BARRIGEL is the first and only hyaluronic acid prostate spacer on the market. BARRIGEL is made from Non-Animal Stabilised Hyaluronic Acid, known as NASHA. NASHA has a long history of safety, efficacy and biocompatibility in a wide variety of medical applications, including paediatric medicine.^{5,6} It is a well-known technology in aesthetic markets as a dermal filler, and has been used in over 40-million treatments globally across all approved indications.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 mild to moderate sensation of rectal filling. Talk to your doctor about the risks associated with BARRIGEL.

How is BARRIGEL placed?

BARRIGEL is placed in between the rectum and the prostate through a needle in an outpatient setting. Your physician will use imaging technology during the procedure to sculpt the BARRIGEL spacer to your anatomy.

Where is the procedure done?

BARRIGEL can be placed during an outpatient procedure in a hospital or outpatient clinic prior to the start of radiation treatment. BARRIGEL is typically inserted at the same time as fiducial marker placement.

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

Your physician is the best person to consult for timing on returning to your regular activities.

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 begins to safely reabsorb into your body after 9 months. It is important to note that BARRIGEL may be detected during anorectal examinations and medical imaging of the pelvis. It is important to inform your future physicians that you have had treatment with BARRIGEL.

Which types of radiation therapy can BARRIGEL be used with?

There are two main types of radiation therapy available for prostate cancer treatment, external beam and internal (brachytherapy). The specific radiation therapy your physician recommends depends on many factors, some of which include: the type of cancer, size of the tumor, tumor location, general health, age, and medical conditions. BARRIGEL can be used with all forms of radiation therapy available for treating prostate cancer patients with clinical stage T1-T3.⁷ Talk with your doctor to find out if BARRIGEL is right for you.

REFERENCES: **1.** Prada PJ, Fernández J, Martínez AA, et al. Transperineal injection of hyaluronic acid in anterior perirectal fat to decrease rectal toxicity from radiation delivered with intensity modulated brachytherapy or EBRT for prostate cancer patients. *Int J Radiat Oncol Biol Phys.* 2007;69(1):95-102. **2.** Mok G, Benz E, Vallee JP, et al. Optimization of radiation therapy techniques for prostate cancer with prostate-rectum spacers: A systematic review. *Int J Radiat Oncol Biol Phys.* 2014;90(2):278-288. **3.** Struik GM, Pignol JP, Kolkman-Deurloo IK, et al. Subcutaneous spacer injection to reduce skin toxicity in breast brachytherapy: a pilot study on mastectomy specimens. *Brachytherapy.* 2019;18(2):204-210. **4.** Galderma. Restylane. Available at: <https://www.galderma.com/uk/restylane>. Accessed September 1, 2020. **5.** Q-Med. Nasha- the Monograph. Uppsala, Sweden. **6.** Cerwinka WH, Scherz HC, Kirsch AJ. Endoscopic treatment of vesicoureteral reflux with dextranomer/hyaluronic acid in children. *Advances in Urology.* 2008; 1-7. **7.** BARRIGEL [product inset – Europe]. Uppsala, Sweden. Galderma; 2018.



For product information, adverse event reports,
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BARRIGEL is used to increase the distance between the prostate and the anterior rectal wall, with the intent to decrease radiation dose delivered to the rectum when treating prostate cancer with radiation. The product should be injected into the anterior perirectal fat. The correct injection technique is important for the final result of the treatment. Before the first treatment session, contact the local BARRIGEL representative for more information about injection techniques and training opportunities. BARRIGEL shall only be administered by qualified and properly trained physicians with experience in ultrasound guidance techniques and injection techniques in the urogenital/pelvic area. Please see complete Prescribing Information for BARRIGEL.

Q-Med AB is the current legal manufacturer and holds the CE Mark.