

Patient Information Guide

Prostatic cryotherapy

By the time you read this guide, you've been through a lot. You've received a shocking prostate cancer diagnosis, and you've pondered your treatment options. You may have had numerous consultations with doctors, loved ones, and trusted friends. Perhaps you attended support groups or "surfed the net" to learn what other patients chose and how well they did.

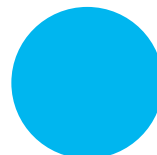
Q&A

What are my treatment options?

Some treatment options for prostate cancer include surgical therapies, radiation therapies, and cryotherapy. This guide provides more detailed information about cryotherapy.

What is cryotherapy?

Cryotherapy, or more simply "cryo," doesn't use major surgery to destroy cancer. Instead, advanced technology allows the doctor to use a minimally invasive approach. He or she uses ultrasound to "see" what's happening inside the body as slender probes are inserted into position and an ice ball forms to kill the cancer. The cancer cells and their blood supply are destroyed by a lethal freeze that ruptures the cell walls.



What are the benefits of cryotherapy?

- Non-surgical, minimally invasive, and often performed as an outpatient procedure
- Cryotherapy treatment typically results in the return of baseline urinary function within 12 months.¹
- Tumors are typically destroyed in one treatment with biopsies showing no cancer in 87% to 98% of patients.¹
- Cryotherapy can be repeated if any cancer cells are detected after the original treatment, or if your cancer returns. It can also be used as a salvage treatment for patients whose cancer comes back after radiation therapy.¹
- A urethral warming system is used during the procedure to preserve the urethra, providing the potential to preserve urinary control.¹

What happens during cryotherapy?

Preparation for cryo is typically the same as for any procedure requiring anesthesia. This means you will be instructed to have no food or drink after a certain time.

Right before the procedure, you will have an IV inserted into a vein to supply your body with fluid and any necessary medications such as a relaxant and/or an antibiotic. You will be under anesthesia, either general (you are asleep) or spinal/epidural (you are mildly sedated, and numb from the waist

down). You should not feel anything during your cryo procedure. It is performed in a sterile environment to reduce the risk of infection.

Afterwards, you will wake up in a room where your vital signs are watched. If your cryo is done on an outpatient basis, you will be allowed to leave when you are stable and comfortable, with someone to drive you home. If it is done as an inpatient procedure, you will spend the night being monitored in the hospital, and most likely be allowed to leave the next day. Your doctor will make the decision about whether you are admitted to the hospital and your doctor will determine when you are ready to go home. Most patients go home with a catheter, which is a tube to help urine drain from the bladder. There are two types of catheters, described in the Glossary section. Which one you will have is up to your doctor.

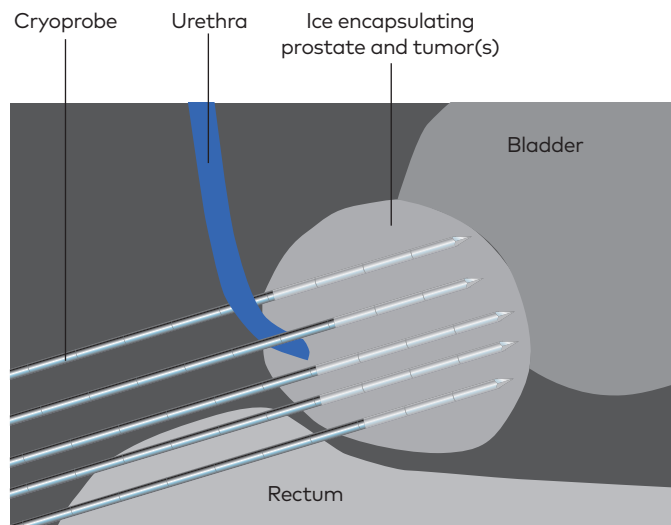
Whether you are an outpatient or inpatient, be sure you leave with written instructions for your recovery at home, catheter care, and any necessary medications or prescriptions, as determined by your doctor. Also, know when your follow-up appointment is, and know how to reach your doctor in case of questions or an emergency. For life-threatening emergencies, always call 911 first.

What can I expect after cryo?

Every person's body differs somewhat from everyone else's body. Some men recover very quickly from the procedure, while others may take a little longer to heal. Short-term side effects, experienced by some patients, can include:

1. Swelling and bruising of the scrotum that should decrease within 1-2 weeks.²
2. Discomfort or minor pain requiring oral medication which should decrease within a week. You may want to ask for a prescription for a pain reliever in case over-the-counter medications are not enough.² Individual results may vary.
3. Possible numbness of the penis for up to one month.²
4. Frequent urination, some burning during urination, and a low level of blood in the urine for 1-2 weeks.²
5. A few drops of blood in the feces for a short time.²

Potential long-term side effects may include loss of urinary control, injury to the rectum, and loss of sexual function.



This illustration demonstrates the use of cryoprobes positioned in the prostate. In this diagram, the ice balls from the cryoprobes are still forming and will eventually reach their maximum size (typically at 10 minutes). The final size can include a safety margin that extends beyond the prostate capsule.



What should I know before the procedure?

When your cryo is scheduled, but no later than a week before, here are some suggested questions to ask yourself. If you don't yet know the answers to some or any of these questions, contact your doctor or their staff and be sure you have all your questions answered.

1. Was my procedure explained so I could understand it?
2. Are there any standard tests I still need to complete before my cryo?
3. What preparation will I need the night before my procedure and when I arrive at the hospital?
4. Will I have an overnight stay in the hospital?
5. What kind of anesthesia will be used (general or spinal block)?
6. What kind of catheter will I have after the procedure?
7. How long can I expect the catheter to be in place? Will someone show me how to care for it before I go home?
8. How soon after the procedure can I get up and walk around? Drive? Exercise? Climb stairs? Lift heavy objects? Engage in sex?
9. What antibiotics will be prescribed after the procedure, and for how long?
10. Should I expect changes to, or quality of, erections? If not spontaneous, how can my doctor help me maintain physical intimacy with my loved one?
11. Can I still experience orgasm after cryo? Will it be any different?

How can I prepare for recovery?

Here are some things you may want to be equipped with for after the procedure. Ask your doctor in advance about:

1. Chemical ice packs to prevent or reduce swelling, and/or instructions for icing.
2. A "donut" pillow in case sitting is uncomfortable.
3. Any necessary prescriptions, such as oral pain medication and routine antibiotics.
4. Written instructions for catheter management.
5. Written instructions for bathing and resuming normal activity.
6. Written list of warning signs, such as difficulty in urination, bladder spasms, fever, unusual bleeding, signs of infection, etc., and what to do if they occur.
7. Plenty of fluids such as water, sparkling water, juices, etc. to keep your catheter flushed and functioning properly.
8. Your favorite relaxation activities: books, magazines, videos/DVDs.
9. Your favorite foods.
10. Absorbent pads in case of slight urine leakage during recovery.

What are the side effects of cryotherapy?

As with any treatment for prostate cancer, side effects may occur after cryotherapy. These side effects may include loss of urinary control, injury to the rectum, and loss of sexual function. Here are some more details:

- Incontinence occurred in no more than 5.6% of patients.³
- Injury to the rectum occurred in less than 0.5% of patients.¹

Other side effects worth discussing with your doctor include temporary swelling, soreness, or discomfort in or around the scrotum or penis for a few days following the procedure.² Talk to your doctor about what you can do to help relieve any swelling or soreness. You should also talk to your doctor about the possibility of seeing blood in your urine and what you should do if you see it. Be sure to speak with your qualified physician to learn more about the benefits and risks that cryotherapy may hold for you.



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How do I decide which treatment option is best for me?

It is important that you understand all of the treatments that are available to you. You should have a detailed discussion with your physician about your options, including benefits and potential risks. The procedures and information described in this document are not intended to be a substitute for a physician's judgment. Only you and your physician can decide which choice is best for you. For more safety information, visit www.varian.com/safety

References

1. Babaian RJ, Donnelly B, Bahn D, et al. Best Practice Statement on Cryosurgery for the Treatment of Localized Prostate Cancer. *J Urol*. 2008; 180(5):1993-2004.
2. Katz AE and Cheetum PJ. Living a Better Life After Prostate Cancer: A Survivor's Guide to Cryotherapy. University Readers 2010. San Diego, CA.
3. Rodríguez SA, et al. Cryotherapy for primary treatment of prostate cancer: intermediate term results of a prospective study from a single institution. *Prostate Cancer*. 2014;2014:571576.

Glossary

Catheter

A catheter is a temporary tube inserted into the bladder to drain urine into a plastic bag. It prevents possible blockage due to sloughing and allows the urethra to heal after cryo. The catheter is usually kept in place 1-2 weeks,² depending on your doctor's advice. It is usually removed during a follow-up office visit. Two types of catheters exist:

- Foley (inserted into the penis).
- Suprapubic (inserted through a small hole in the abdomen).

Cryotherapy (also known as cryoablation and cryosurgery)

Cryotherapy destroys cancer cells and their blood supply by administering a lethal freeze that ruptures cell walls. A double freeze/thaw cycle helps ensure that frozen cells cannot survive or recur.²

Incontinence

Incontinence is the inability to control urine flow, leaking or dripping. Ask your doctor about "Kegel" exercises.

Perineum

The perineum is the area of skin between the scrotum and the anus through which the doctor inserts the cryoprobes into the prostate gland. After the procedure, a pressure dressing is applied to the area. The small puncture holes heal quickly.²

Sloughing (pronounced "sluffing")

Sloughing is the normal and temporary shedding of dead cells from the lining of the urethra following cryo. A temporary catheter is left in place after cryo to help prevent blockage in the urinary tract below the bladder. Sloughing may cause the urine to appear discolored or bloody.²