BRONSON	Affix Patient Label
	Patient Name: Date of Birth:

Informed Consent: Cryoablation of Prostate

This information is given to you so that you can make an informed decision about having **Cryoablation of Prostate**.

Reason and Purpose of the Surgery:

Cryoablation (also called cryosurgery or cryotherapy) is the use of very cold temperatures to freeze and kill cancer cells.

The doctor uses transrectal ultrasound (TRUS) to guide placing several hollow needles through the skin between the anus and scrotum and into the prostate. Very cold gases are passed through the needles to freeze and destroy the prostate. Warm saltwater is circulated through a catheter in the urethra during the procedure to keep it from freezing. The catheter is left in place for about one week to allow the bladder to empty while you recover.

Benefits of this surgery:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Destruction of cancer cells
- Improve symptoms

Risks of Surgery:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

General risks of surgery:

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVTs or deep vein thrombosis. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- A strain on the heart or a stroke may occur.
- Injury to organs, blood vessels and/or nerves can occur. This could be found during the surgery or after the surgery. This could need further surgery or treatments to repair.
- Bleeding may occur. If bleeding is excessive, you may need a transfusion.
- Reaction to the anesthetic may occur. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.

Risks of this surgery:

- **Erectile dysfunction.** This may require medicines, other treatments or surgeries to correct.
- **Pain and swelling of the scrotum and penis.** This usually gets better on its own over several days.
- **Frequent, difficult or painful urination.** This usually gets better on its own over several days.
- **Blood in your urine for several days.** This usually goes away on its own.
- **Loss of bladder control.** This is rare. It can improve in time or you may need other treatments or surgeries to correct.
- **Bleeding or infection in the area treated.** You may need antibiotics or other treatments.

Rarely, side effects can include:

- **Injury to the rectum.** You may need more surgery to correct.
- **Blockage of the tube (urethra) that carries urine out of the body.** You may need more surgery to correct.
- **Infection or inflammation of pubic bone.** You may need antibiotics or other treatments.

Risks associated with smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks associated with obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks specific to you:

_____

_____

_____

_____

Alternative Treatments:

Other choices:

- Radiation treatments
- Do nothing. You can decide not to have the procedure.

If you choose not to have this treatment:

- Your symptoms or condition may worsen and spread which could require more serious surgery.
- Talk with your doctor about other treatment options.

General Information

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure, the doctor may need to do more tests or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

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	Patient Name: Date of Birth:

By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Cryoablation of Prostate** _____
  _____
- I understand that my doctor may ask a partner to do the surgery.
- I understand that other doctors, including medical residents or other staff may help with surgery. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to surgery. If so, please obtain consent for blood/products.

Patient Signature: _____ Date: _____ Time: _____

Relationship: ☐ Patient ☐ Closest relative (relationship) _____ **☐ Guardian**

Interpreter's Statement:

I have interpreted this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

Voice/Video Service: _____ Interpreter ID#: _____ Date: _____ Time: _____

Interpreter's name (print): _____ Agency: _____

Interpreter's Signature: _____ Date: _____ Time: _____
Interpreter (if applicable)

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Patient shows understanding by stating in his or her own words:

____ Reason(s) for the treatment/procedure: _____
____ Area(s) of the body that will be affected: _____
____ Benefit(s) of the procedure: _____
____ Risk(s) of the procedure: _____
____ Alternative(s) to the procedure: _____

OR

____ Patient elects not to proceed: _____ Date: _____ Time: _____
(Patient signature)

Validated/Witness: _____ Date: _____ Time: _____