



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent: Image-Guided Ablation (Tumors)

This information is given to you so that you can make an informed decision about having an **image-guided ablation (tumors)**. This procedure is most often done with moderate sedation or anesthesia.

Reason and Purpose of this Procedure:

An image guided ablation is a treatment for benign and malignant tumors. Ablation means removing tissue or abnormal growth. The procedure involves using imaging equipment (typically CT) to guide probes into a tumor. The purpose is to destroy cells. There are three different ablation types:

- Radiofrequency Ablation (RFA) – Needle electrodes are placed into the tumor. They are heated and burn the tumor.
- Microwave Ablation (MWA) – Electromagnetic waves create heat around a needle to a temperature that burns the tumor.
- Cryoablation – Uses hollow needles to circulate cooled fluids at a temperature that freezes the tumor. Cycling between freezing and thawing causes tumor cells to die.

The radiologist has reviewed your history and talked with your oncologist to decide the safest and most effective method.

Benefits of this Procedure:

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.

- Decreased tumor size
- Ablations are minimally invasive. Patients have a quick recovery period.

Risks of this Procedure:

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.

- Infection. You may need medicines or other treatment.
- Allergic reaction to the contrast or dye. Fluids and /or medications may be needed.
- Needle tract seeding. This refers to implantation of tumor cells by contamination when instruments such as probes or needles are used. Implantation along the path of the needle may change the stage of the tumor. This is very rare.
- A risk of kidney ablation is urine leak. Narrowing or blockage of the urinary tract may result. You may need a procedure to fix.
- A risk of liver ablation is bile duct leakage or narrowing or blockage of the bile duct. You may need a procedure to fix.
- Temporary or permanent nerve injury.
- Ablation may not destroy all tumor cells or tumor may come back. Long-term follow up is necessary. May need additional procedures.
- Residual or recurrent tumor.
- Ablation of surrounding tissue with possible injury to organs.
- Kidney failure. This may require temporary or permanent dialysis.
- Bleeding or blood clots. This may require treatment.
- Death may occur.
- 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.

Potential Radiation Risks:

- **Any exposure to radiation may cause a slightly higher risk for cancer later in life.** This risk is low.
- **Skin rashes.** Skin rashes may lead to breakdown of skin and possibly severe sores. This is rare.
- **Hair loss.** This does not happen to everyone. This can be temporary or permanent.
- **It is possible we may have to use higher doses of radiation.** If we do, we will tell you.
- **If you see changes with your skin, you should report them to your doctor.**

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:

- Observation.
- Open surgery.
- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- Your symptoms and disease may get worse.

Information on Moderate Sedation:

You will be given medicine in an IV to relax you. This medicine will also make you more comfortable. This is called “moderate sedation”. You will feel sleepy. You may even sleep through parts of your procedure. We will monitor your heart rate and your blood pressure. We will also monitor your oxygen level.

If your heart rate, blood pressure or oxygen levels fall outside the normal range, we may give medications to reverse the sedation. We may be unable to reverse the sedation. We may need to support your breathing.

Even if you have a NO CODE status:

- You may need intubation to support your breathing.
- You may need medications to support your blood pressure.

We will re-evaluate your medical treatment plan and your NO CODE status when sedation has cleared your body.

Benefits of Moderate Sedation:

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.

- Less pain during the procedure.
- Less anxiety or worry.
- Decreasing your memory of the procedure.

Risks of Moderate Sedation:

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. The list includes:

- Decreased breathing during the procedure and dropping oxygen levels. To help you breathe, a tube may be placed into the

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mouth or nose and into the trachea to help you breathe.

- Allergic reactions: nausea & vomiting, swelling, rash.
- Vomit material getting into the lungs.
- A drop in blood pressure. This needs fluids or medicine to increase blood pressure.
- Heart rhythm changes that may require medicines to treat.
- Not enough sedation or analgesia resulting in pain or discomfort.

Your physical and mental ability may not be back to normal right away. You should not drive or make important decisions for at least 24 hours after the procedure.

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.

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

Pictures and videos may be taken 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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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: **Image-Guided Ablation (Tumors)** _____
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- I understand that my doctor may ask a partner to do the procedure.
 - I understand that other doctors, including medical residents or other staff may help with the procedure. 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 procedure. If so, please obtain consent for blood/products.

Patient Signature: _____ Date: _____ Time: _____

Relationship: Patient Closest relative (relationship) _____ Guardian/POA Healthcare

Reason patient is unable to sign: _____

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: _____ ID #: _____ Date: _____ Time: _____

Telephone Consent ONLY: *(One witness signature MUST be from a registered nurse (RN) or provider)*

1st Witness Signature: _____ 2nd Witness Signature: _____ Date: _____ Time: _____

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:

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: _____