



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent

This information is given to you so that you can make an informed decision about having **Trans-arterial chemoembolization (TACE)**.

Reason and Purpose of the Procedure

TACE is an image-guided procedure that is used to treat cancerous tumors. A catheter (small tube) is placed in an artery. The catheter is used to deliver chemotherapy drugs and a material that blocks the blood vessels going to the tumor. This may stop the growth of the tumor and shrink it.

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.

- TACE may shrink and control the size of the tumor.
- May help you avoid or reduce the side effects of standard chemotherapy.

Known Potential Side Effects of the Procedure

Post-embolization syndrome: This may include:

- low grade fever.
- pain.
- flu-like symptoms.
- fatigue.
- nausea and vomiting.
- decreased appetite.
- change in taste.
- hair loss.

The symptoms usually begin 24 - 48 hours after the procedure. They may last 1 – 2 weeks. There are medications that may help to reduce some of these symptoms.

Risks of this Procedure

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

- **Bleeding at the area the catheter is placed, or internally.** You may need another procedure to stop the bleeding.
- **Infection.** You may need antibiotics or other treatment.
- **Worsening liver function.** This may happen due to the effect of the drug on the liver. This could cause liver failure. In rare situations this could cause death.
- **Hepatic (liver) abscess.** You may need treatment with antibiotics or drain placement.
- **Part of tumor may remain or grow back.** You may need more treatments to control the tumor.
- **A normal vessel may become blocked.** This may cause damage to normal tissue.
- **Allergic reactions to drugs and/or the contrast dye.** This is rarely severe. Your breathing and vital signs will be watched. You may need more treatments with medications.
- **Kidney failure.** This can be caused by the contrast. If this happens you may need dialysis.

- **Reaction to the sedation may occur.** The most common reactions are nausea and vomiting. In rare cases, death may occur. Your breathing and vital signs will be monitored

Potential Radiation Risks to you include

- **Any exposure to radiation may cause a slightly higher risk for cancer later in life. This risk is low.**
- **Skin rashes.** Very rarely, skin rashes may lead to tissue breakdown and possibly severe ulcers.
- **Hair loss.** The chance of this happening depends on each individual. This does not happen to everyone. This can be temporary or permanent.
- **You or your family will be advised if we used much higher amounts of radiation during the procedure.**
- **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:

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

If you choose not to have this treatment:

- Your oncologist can discuss the alternative treatments with you.

General Information

- During the procedure the doctor may need to do more tests or treatment.
- During this procedure, the doctor may need to perform additional or alternative procedures than I agreed to.
- Tissues or organs taken from the body may be tested. They may be stored 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.
- Radiology images will be obtained 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: **Trans-arterial chemoembolization (TACE).**
- I understand that my doctor may ask a partner to do the surgery/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 surgery. IF so, please obtain consent for blood/product.

Patient Signature _____ Date: _____ Time: _____

Relationship: Patient Closest relative (relationship) _____ Guardian

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

Interpreter: _____ 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: _____