



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent: Craniotomy for Arteriovenous Malformation (AVM) or Aneurysm

This information is given to you so that you can make an informed decision about having a **craniotomy for an AVM or aneurysm**.

Reason and Purpose of this Procedure:

A craniotomy is an operation where an opening is made in the skull, or cranium. The goal of a craniotomy for a patient with a vascular lesion (wound or injury to tissue involving blood vessels) is to:

- Remove the vascular lesion
- Prevent the vascular lesion from entering the brain blood flow.

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.

- The vascular lesion may be removed.
- Seizures may stop.
- Prevent future bleeding from the vascular abnormality which can cause brain damage, loss of function, and death
- Your doctor can discuss further benefits with you. These will depend on your specific diagnosis.

General Risks of Procedures:

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.

- 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.
- Bleeding may occur. This may require a blood 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 Procedure:

This surgery is safe and effective in most cases. The most common risks that require hospital admission are:

- (1) Infection.
- (2) Deep venous thrombosis.
- (3) Seizures.
- (4) Stroke
- (5) Neurological damage after surgery is possible. This is usually temporary. Risks are higher with emergency surgery.
 - **Balance problems or vertigo (dizziness)**. This may be from the vascular lesion or from the surgery.
 - **Brain injury**. The procedure could cause injury to the surrounding brain.
 - **Death**. Death may occur during or soon after surgery.
 - **Failure of the procedure**. Your condition may not improve. It may not be possible to diagnose or remove the entire lesion.
 - **Functional loss**. You could have difficulty chewing after surgery. You may have problems with strength,

- sensation, speech and language, memory, hearing or vision after surgery. This could be permanent or temporary
- **Hemorrhage.** Some bleeding in the brain following surgery is common and expected. If this is excessive, it may require additional surgery.
 - **Hydrocephalus.** The normal flow of spinal fluid around the brain may change. This may need more treatment, including surgery or placement of a drain.
 - **Increased pain.** Pain or other symptoms may get worse after this procedure.
 - **Infection.** Infection may occur in the incision, either near the surface or deep within the tissues. You could have meningitis (inflammation of tissue that covers the brain and spinal cord) or a brain abscess (pus that collects in an area in the brain). You may need antibiotics or further treatment.
 - **Neurologic decline.** You may have weakness, numbness and speech and memory problems after surgery.
 - This could be from hemorrhage (bleeding) or cerebral edema (buildup of fluid causing swelling and pressure on the brain.)
 - **Recurrence.** There is a chance that the vascular abnormality is not fully removed and continues to have blood flow in the area. This may need more surgery.
 - **Seizure activity.** You may develop seizures.
 - **Spinal fluid leakage.** A spinal fluid leakage may cause a spinal headache or need more surgery.

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 Associated with Diabetes or Immune System Compromise:

The risk of infection, slow wound healing and slow bone healing are increased in:

- Diabetes
- Chemotherapy or radiation therapy
- AIDS
- Steroid use

Risks Specific to You:

Alternative Treatments:

Other choices:

- Endovascular treatment of the vascular lesion. Your doctor can discuss this procedure with you.
- Observation with neurological exams and imaging (CAT Scan or MRI).
- Do nothing. You can decide not to have the procedure.

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If you Choose not to have this Treatment:

- The vascular lesion may continue to grow. Your neurological function will decrease.
- The vascular lesion may cause you to have seizures.
- The vascular lesion may bleed and eventually cause death.

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.

Medical Implants/Explants:

I agree to release my social security number, my name and address, and my date of birth to the company that makes the medical device that is put in or removed during this procedure. Federal laws and rules require this. The company will use this information to locate me.

Humanitarian Device:

My insurance company may not pay for this device or procedure. I know I am responsible for charges not covered by my insurance.



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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: **Craniotomy for Arteriovenous Malformation (AVM) or Aneurysm** _____
Location: _____
- 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 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

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: _____

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: _____