



Affix Patient Label

Patient Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

This information is given to you so that you can make an informed decision about having an endovascular cerebral vessel embolization.

**Reason and Purpose of the Procedure:** You have cerebral blood vessel disease. This could be an aneurysm, tumor, arteriovenous fistula or malformation (a connection between the arteries and veins in the brain that is not normal). These problems can cause headache, nerve paralysis, or incorrect blood flow in the brain. The malformations can burst and cause internal bleeding that can cause a stroke or death. Embolization or blocking of these malformations can prevent more problems. Your doctor will thread a small tube through a blood vessel in your groin to the area in the brain he wants to treat. The doctor may send metal coils through the tube to block the blood vessel.

**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.

- Embolization may prolong life and relieve symptoms.
- This treatment is less invasive than an open brain surgery. It can reach blood vessel problems in areas where brain surgery cannot reach.
- The incision in your leg is much smaller than an open brain surgery. Your recovery time will be shorter.

**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.

**General risks of the procedure:**

- 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. 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.

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**Risks of this Procedure:**

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- **Coil malposition.** There is a small chance that the coils may lodge in the wrong place. This may block the blood flow to normal brain tissue. This may lead to stroke and may need more treatment.
- **Contrast reaction.** You may have an allergic reaction or kidney damage from the contrast dye used during the procedure. Tell your doctor if you have any kidney problems or are allergic to iodine or IV contrast dye.
- **Failure of the procedure.** Even with careful planning and treatment, the doctor may not be able to block the entire aneurysm or fistula. This is mainly due to the shape or size of the aneurysm. This may need more treatment. You may need open brain surgery.
- **Infection.** Infection can occur at the incision or deep in the area treated, including the brain. You may need antibiotics or more treatment.
- **Radiation exposure.** During the procedure, the doctor will use x-ray to help place the coils. Your doctor will use the least amount of x-rays necessary. This does slightly increase your lifetime risk of developing cancer. You may also have hair loss. This is usually temporary.
- **Recurrence.** In some cases, an aneurysm may regrow. This may need more treatment in about 10% of patients.
- **Rupture.** There is a small chance that the catheter or coils may cause the aneurysm or vessel to rupture or burst.
- **Vasospasm.** Vasospasm is an abnormal narrowing of an artery caused by irritation from blood or from the catheter. This may result in neurological changes. This may need more treatment.
- **Vessel damage.** The catheter may injure the blood vessel. This results in bruising or bleeding at the incision.
- The tube may become stuck in the vessel if certain embolic material is used for example NBCA or ONYX glue.

**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 infection. It can also lead to heart and lung complications and clot formation.

**Risks specific to you:**

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### **Alternative Treatments:**

Other choices:

- **Monitor the blood vessel with periodic angiograms or radiology exams.**
- **Open brain surgery may be an option. Your doctor will discuss this possibility with you.**
- Do nothing. You can decide not to have the procedure.

### **If you chose not to have this treatment:**

- **If you are at high risk, your aneurysm may rupture and cause stroke, serious brain injury, or 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.

### **Implants or explants:**

I agree to release my social security number, my name and address, and my date of birth to the company that makes a 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 statement:** 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: **Endovascular Vessel Embolization of** \_\_\_\_\_
- 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 translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

\_\_\_\_\_ 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's 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 \_\_\_\_\_ (patient signature)

Validated/Witness: \_\_\_\_\_ Date: \_\_\_\_\_

Time: \_\_\_\_\_