BRONSON

| Affix Patient Label | |
|---|---|
| Patient Name: | Date of Birth: |

**Informed Consent: Endovascular Cerebral Vessel Embolization**

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 this Procedure:**

You have cerebral blood vessel abnormality. 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 blood flow to these malformations can prevent more problems. Your doctor will thread a small tube through a blood vessel in your groin or wrist to the area in the brain to be treated. The surgeon may use various devices (metal coils, glue, stents, microspheres, etc.) to block the blood vessel and treat the abnormality.

**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 by preventing future bleeding.
- 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.

**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 thromboses. 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.

**Risks of this Procedure:**

- **Device malposition**. There is a small chance that the device 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 abnormality. 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 device(s). 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 embolic device may cause the abnormality 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 or in the brain.
- The tube may become stuck in the vessel if certain embolic material (e.g., glue) is used.

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**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 and slow wound healing are increased in:

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

**Risks Specific to You:**

_____

_____

**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 Choose not to have this Treatment:**

You may choose the alternative treatments listed above.

- 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 Cerebral Vessel Embolization** _____

  **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 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: _____