BRONSON

Affix Patient Label	
Patient Name:	Date of Birth:

Informed Consent: Carotid Endarterectomy / TransCarotid Artery Revascularization / Carotid Artery Surgery

This information is given to you so that you can make an informed decision about having **carotid artery surgery.**

Reason and Purpose of this Procedure:

Narrowing or blockage of carotid arteries (blood vessels) happens when the inside wall of the blood vessels thicken. This is caused by buildup of cholesterol or other substances in the blood. The buildup is called plaque. The plaque narrows the blood vessel. This makes it hard for blood to flow through it. When the narrowing is severe the plaque can break and form clots. The clots can move to the brain causing stroke. A large or complete blockage can also cause a stroke.

Opening the carotid artery and removing the plaque will improve blood flow to the brain. This decreases the risk of stroke. If a stent is chosen, this will open the carotid artery and reduce risk of plaque from traveling to the brain.

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.

- Improve blood flow through the blood vessel.
- Reduce risk of stroke.

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. If bleeding is extreme, 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 the risks associated with general anesthesia.

Risks of this Procedure:

- Bruising and/or swelling along the incision site. This may cause discomfort.
- A mass of clotted blood or hematoma may form. This may require more surgery.
- Pain that may require medications.
- Infection which may require antibiotics. Other treatment may be needed.
- A blood clot in the artery. This can cause stroke and can require more surgery. The effects of the stroke may be permanent.
- Blood clots, air bubbles or broken pieces of plaque that travel through the blood vessels. This can cause a stroke.
- Abnormal heart rate and difficulties managing blood pressure during and after surgery. Fluids or medications maybe needed.
- Heart attack. Life saving measures may be required.
- Death may occur.
- Cranial nerve injury. Most of the time this is temporary, but it can be permanent. This can cause hoarseness of voice, difficulty swallowing, and affect movement of the tongue.
- Swelling of the brain and bleeding. This may require more surgery.

Risks of Iodinated Contrast Dye:

- If intravenous contrast dye is necessary for your procedure, you could have a reaction to the dye during the procedure. Sometimes this reaction is life threatening and can require insertion of a breathing tube for an extended period.

- Sometimes the contrast dye can decrease the function of your kidneys requiring the need for temporary or permanent dialysis.

Risks of Percutaneous Access:

- If percutaneous access is required, it is possible to have bleeding or swelling at access site. Occasionally this can require surgery to repair a bleeding vessel.

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.
- Using medications that help prevent blood clots and high cholesterol.
- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- The plaque in your blood vessel may keep building up. This will make the blood vessel narrower and may lead to complete blockage. This can increase your risk of stroke. Stroke can result in permanent neurological problems.

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 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.

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: ☐ **Right** ☐ **Left** | ☐ **Carotid Endarterectomy**
  ☐ **TransCarotid Artery Revascularization**
  ☐ **Carotid Artery Surgery (Right/Left)**

  _____
- 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: _____