



Affix Patient Label

Patient Name:

Date of Birth:

### **Informed Consent: Peripheral Angiography with Possible Percutaneous Transluminal Angioplasty, Atherectomy, and/or Stent Placement**

This information is given to you so that you can make an informed decision about having **Peripheral Angiography with Possible Percutaneous Transluminal Angioplasty, Atherectomy, and/or Stent Placement** with moderate sedation or anesthesia.

#### **Reason and purpose of the procedure:**

You may have a blockage in a blood vessel. This procedure can help your doctor diagnose and possibly treat it. The doctor may use ultrasound, computer tomography (CT), or x-ray to get images of blood vessels. These images will help the doctor guide placement of needles or catheters. A catheter is a small hollow tube. The images will also be used to document results.

The catheter is usually placed into the artery in the groin. X-ray dye is injected and x-rays are taken to see the blood flow in the affected part of your body. If there is significant narrowing, a tiny balloon is inflated in that area to open up the artery (angioplasty). Several attempts may be needed. Blood thinning medicine (heparin) may be given. This helps prevent blood clots from forming.

In some cases, a tiny tube-like device may be placed in the artery to keep it open. This is called a stent. Stents are put on a catheter and placed into the artery. The catheter is then removed and the stent stays in place. A device on the end of a catheter is used to remove deposits of fat and other substances that collect in the lining of the artery wall (plaque). This procedure is called Atherectomy.

#### **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.

- Help your doctor diagnose peripheral artery disease.
- Help your doctor decide the best way to treat the disease.
- If you have peripheral artery blockage, a balloon, stent, or other method may relieve the symptoms caused by the blockage.

#### **Risks of 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.

#### **Information on moderate sedation:**

You will be given medicine in an IV to relax you. This medicine will also make you more comfortable. This is called "moderate sedation". You will feel sleepy. You may even sleep through parts of your procedure. We will monitor your heart rate and your blood pressure. We will also monitor your oxygen level.

If your heart rate, blood pressure or oxygen levels fall outside the normal range, we may give medications to reverse the sedation. We may be unable to reverse the sedation. We may need to support your breathing. Even if you have a NO CODE status:

- You may need intubation to support your breathing.
- You may need medications to support your blood pressure.

#### **Risks of this procedure:**

- **Bruising and/or swelling at the puncture site.** This may need surgery.
- **Blood loss.** You may need fluids or possibly a blood transfusion.
- **Infection.** You may need medicines or other treatment.

- **Stroke.** This may lead to more testing, surgery, and treatment for stroke.
- **Allergic reaction to the contrast or dye.** Fluids and /or medications may be needed.
- **Loss of kidney function.** This may require fluids, medications, or other treatments.
- The procedure may not cure or relieve your condition.
- **Internal bleeding.** You may need surgery. This is rare.
- **Blood clot.** You may need surgery
- **Death may occur.**
- **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.

**Potential radiation risks:**

- Any exposure to radiation may cause a slightly higher risk for cancer later in life. This risk is low.
- **Skin rashes.** Skin rashes may lead to breakdown of skin and possibly severe sores. This is rare.
- **Hair loss.** This does not happen to everyone. This can be temporary or permanent.
- It is possible we may have to use higher doses of radiation. If we do we will tell you.
- 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:**

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**Alternative treatments:**

- Observation.
- Medicine(s) to relieve symptoms.
- Do nothing. You can decide not to have the procedure.

**If you choose not to have this treatment:**

- Your symptoms may get worse.

**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.

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, if needed.



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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: **Peripheral Angiography with Possible Percutaneous Transluminal Angioplasty, Atherectomy, and/or Stent Placement** with moderate sedation or anesthesia \_\_\_\_\_
- 
- 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 surgery. 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: \_\_\_\_\_