

Patient: _____ **DOB:** _____

Consent for Arteriography and Possible Angioplasty, Stent Placement, Atherectomy or Lytic Therapy in the Bilateral Right Left Lower Extremity

1. I hereby request and authorize Primary Vascular Physicians, _____ (my "Operating Physician") or his/her designees, and/or any assistants that may be selected and supervised by him/her (collectively, the "Primary Vascular Care") to perform upon me the Procedure.

2. **Introduction:** Your physician has requested that you undergo an arteriogram to further assess your circulation. Based on the findings of this study, additional interventions, such as an angioplasty, stent placement, or lytic therapy may be performed. We are asking you to read and sign this form so that we can be sure you understand the procedure and potential benefits, along with the associated potential risks, complications, alternatives, the likelihood of achieving the goals, and the recuperative process. Please ask questions about anything on this form that you do not understand.

Procedure: An arteriogram involves the placement of a plastic tube (catheter) into an artery in either your leg or your forearm. Before the catheter is inserted, numbing medicine will be injected in the skin over the artery that will be used. Intravenous medications may also be given to you to make you more comfortable and relaxed. This is known as moderate sedation. Once the catheter has been placed into the artery, it will be advanced through the blood vessels. During this time, x-ray contrast material (x-ray dye) will be injected through the catheter and x-ray pictures taken. You may be asked to hold your breath for several seconds as these pictures are taken. During the injection of x-ray contrast material, you may experience a warm feeling or a strange taste in your mouth. Both of these sensations are temporary and will go away soon. Depending on the results of the arteriogram, an angioplasty, stent placement, and/or lytic therapy may be performed. If the arteriogram shows an area of blockage, an angioplasty may be performed in an attempt to open up the area. This involves the insertion of a special tube, which has a tiny deflated balloon. The balloon is positioned at the site of the blockage and is then inflated. Following an angioplasty, if there still is not enough blood flow through the area of blockage, atherectomy may be performed and/or a metal mesh tube (stent) may be placed at the site. Atherectomy is performed with a specialized catheter and is the word used to describe the process of removing atheromatous plaque that contributes to the narrowing of the blood vessel. The stent will widen the vessel and improve the blood flow. If the arteriogram shows that a blood clot is blocking one of your vessels, a special drug may be given to dissolve the clot. This is known as lytic therapy. Additional arteriogram x-ray pictures may be taken to determine the progress of the dissolving blood clot. At the completion of the arteriogram, the catheter will be removed and pressure will be applied to the insertion site until the bleeding has stopped. To help prevent bleeding, it will be very important for you to lie flat in bed without moving your arm or leg for up to six hours.

Risks: Risks associated with the procedure include, but are not limited to, pain or discomfort at the catheter insertion site, bleeding at the site, injury to a blood vessel, infection which may result in an infection of the blood stream, the development of a blood clot (embolization), and stroke. Risks associated with the x-ray contrast material include an allergic reaction and reduced kidney function. The medications used for the moderate sedation are associated with the risks of aspiration (inhaling food or liquid into your lungs) or respiratory depression. In addition to these potential risks associated with the procedure, the x-ray contrast material, and the moderate sedation medications, there may be other unpredictable risks including death.

Alternatives: There may be other procedures that can be performed to further evaluate your circulation and/or treat an area of blockage. If you are unsure about having an arteriogram, along with a possible angioplasty, stent placement, or lytic therapy performed, please discuss these other alternatives with your physician.

Patient: _____ **DOB:** _____

3. I understand that the Primary Vascular Care's Privacy Notice describes any limitations on the confidentiality of my information, and my Operating Physician has informed me of any special reporting obligations of which he or she is aware.

4. I am aware that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantees or assurances have been made to me concerning the results of the proposed Procedure(s) and anesthesia, and the potential hazard of radiation to women of childbearing age, if applicable.

5. I have had sufficient opportunity to discuss my (the patient's) condition and treatment with the Operating Physician and all of my questions have been answered to my satisfaction. I believe that I have adequate knowledge and understanding upon which to base an informed consent to the proposed Procedure(s).

6. I consent to the performance of additional operations and procedures different from those now contemplated and deemed necessary or advisable during the course of the authorized Procedure(s) or anesthesia.

7. I understand that after the Procedure, I may need to receive additional procedures as indicated on my treatment plan and that such treatment plan may require several sessions.

8. I consent to the retention or disposal of any tissues or parts which may be removed during the procedure(s).

9. I consent to the photographing, videotaping, or televising of the Procedure for the advancement of medical knowledge and /or education, with the understanding that my/the patient's identity will not be disclosed outside of the Primary Vascular Care.

10. I consent to the administration of sedative medications and exposure to the medical use of radiation by or under direction of the physician named above or the physician in charge of my sedation care. I acknowledge that I have been informed of the nature of the planned sedation and that I understand the risks of sedation and radiation to include: allergic reactions to medications, changes in breathing, changes in blood pressure and heart function, nausea and vomiting, aspiration of stomach contents and/or excrement. I understand that recall of the procedure is possible.

All types of anesthesia carry some risk of severe complications. Although rare, these include infection, drug reactions, blood clots, paralysis, stroke, heart attack, brain damage, and death. Anesthesia and radiation could injure a fetus if you are pregnant. Sometimes the type of anesthesia may be changed during surgery to better care for you or aid the surgeon's task. My clinician has fully explained to me the risks (both during administration of anesthesia and during the recuperation period), benefits and possible alternatives to administration of anesthesia, including not undergoing the procedure. I have been given an opportunity to ask questions, and all of my questions have been answered fully and satisfactorily. I acknowledge that no guarantees or assurances have been made to me concerning the results intended from the administration of anesthesia.

11. I consent for the temporary suspension of any advanced directives and understand all resuscitation efforts will be made, should any unforeseen condition arise, during the course of the procedure and the immediate time under monitored care in recovery.

I, _____, had an informative discussion with the consenting party regarding each line item above.

All questions were answered fully and satisfactorily and the treatment plan and intervention was agreed upon. Reading materials were suggested for review and made available digitally at www.primaryvascularcare.com, or by fax, as a supplement to our discussion. The supplement includes a description of the treatment plan, procedure expectations, risks, and potential complications.

Patient: _____ **DOB:** _____

INFORMED CONSENT

I confirm that I have read and fully understand the above and that all the blank spaces have been completed prior to my signing. I agree that all of my questions have been answered fully and satisfactorily.

HCP/Family consent obtained and noted below.

Patient/Agent/Guardian/Surrogate:

Name: _____ Relationship, if signed by other: _____

Signature: **X** _____ Date/Time: _____

	Signature of Interpreter (if used): _____
	Print Name: _____
	or Interpretation Line #: _____



Patient: _____ **DOB:** _____

OPERATING PHYSICIAN'S and ASSISTANT CLINICIAN'S CERTIFICATION

I hereby certify that I have explained the nature, purpose, benefits, risks, and alternatives to the above named procedure(s) / operation(s). (When applicable) I have provided counsel regarding the possible use of blood and / or blood products, its benefits, attendant risks and alternative options including autologous blood, directed donor and intraoperative blood salvage. I believe that the patient or his / her representative understands what I have explained and answered. I have reviewed the information about the Procedure prior to the induction of anesthesia, and hereby confirm that the Procedure(s) is accurately described above.

Assisting Clinician's Signature

Date / Time

Operating Physician's Signature

Date / Time