

**SOUTH DENVER CARDIOLOGY ASSOCIATES P.C.
INFORMED CONSENT FOR CARDIAC CATHETERIZATION
AND
TRANSCATHETER REVASCULARIZATION
(PTCA/DCA/PTCRA/STENTS/BRACHYTHERAPY)**

Patient Name: _____

My Dr. _____ has recommended _____

because I have _____

CARDIAC CATHETERIZATION

DESCRIPTION:

A catheterization of the heart is a test performed through specially designed hollow tubes (catheters) which are laced into an artery and/or vein and advanced to the heart. Through these catheters, dye is injected and heart function is measured. The information obtained from this procedure is vital in making an accurate diagnosis and determining the best course of treatment. The procedure is done under local anesthesia and with light sedation via a blood vessel in the leg or arm. During the procedure the patient is carefully monitored with x-ray, EKG and blood pressure recording equipment. Ordinarily, the patient feels a sensation of pressure in the area where the catheters are exchanged but little else in the way of discomfort.

POTENTIAL COMPLICATIONS:

Procedures of this type carry some element of risk. Serious non-fatal complications, such as stroke or heart attack, are uncommon; approximately 2 out of every 1,000 cases. The risk of death is 1 out of every 1,000 elective cases. In addition, the following problems may occur:

1. The catheter movement may result in a sensation of pain in the groin.
2. The appropriate blood vessel cannot be located or its location may not allow for appropriate catheter positioning. In this case, the procedure may be terminated or another attempt made via the other leg or arm.
3. The introduction of the catheter into the heart may produce a fall in blood pressure or abnormal heart rhythm which results in light-headedness, and/or fainting for which medications or an electrical shock may be administered.
4. Despite administration of an IV blood thinner (heparin) to prevent the formation of blood clots on the catheter and/or blood vessels, a clot may form which may require a surgical procedure to remove. Clot on a catheter could conceivably dislodge and lead to blockage of a blood vessel elsewhere in the body. This is called an "embolus" and can result in stroke, kidney damage, or reduced blood flow to the extremities.
5. Sometimes the "thinned" blood leaks around the catheter, accumulates in the tissue and causes a bruise in the area known as a "hematoma." This rarely requires any intervention, although surgical drainage may be necessary. Quite rarely, substantial blood loss may necessitate blood transfusion or administration of other blood products.
6. The walls of the blood vessel where the catheter is placed can separate, causing a "pseudoaneurysm". This is usually treated with ultrasound-guided compression, but may require surgical repair.

7. The liquid used to visualize the arteries under x-ray is called “contrast media” or “dye” and can cause an allergic reaction. It is important that you inform your doctor of any known allergies particularly to iodine or contrast media, before the heart study.
8. An infection may form at the site of catheter introduction, for which antibiotic therapy may be given as part of the treatment.

Arterial Closure Devices

An arterial closure device may be used following the procedure. These devices are designed to minimize the amount of time you are immobilized in bed. Possible complications with the use of these devices include: failure to seal the artery with subsequent bleeding, thrombosis (clotting) of the artery, infection, and device malfunction requiring surgical vascular repair.

ALTERNATIVE:

Other methods of cardiac evaluation that do not require this procedure have been discussed with me, including the option of doing nothing. I understand the risks and benefits of the alternatives.

TRANSCATHETER REVASCULARIZATION

DESCRIPTION:

Percutaneous Transluminal Coronary Angioplasty (PTCA). Directional or Rotational Coronary Atherectomy (DCA or PTCRA) or Coronary Stent Placement procedures are similar in concept. The goal of these procedures is to reduce the blockage in the coronary artery (arteries) in order to improve the blood flow to that portion of the heart muscle, and thereby provide relief of angina (heart pains) and/or to prevent the development of a heart attack. The recommendation regarding a transcatheter revascularization procedure is made after the coronary angiogram is reviewed. The procedure generally lasts about 1 to 2 hours, but may take longer. Local anesthetic at the site of catheter introduction and light to moderate sedation is usually administered: no general anesthesia is utilized. While similar in nature, these procedures differ as outlined:

- For **PTCA (Angioplasty)** a small flexible balloon-tipped catheter is advanced to the narrow portion of the coronary artery and is inflated several times with increasing pressure and duration, in order to open the narrowing and decrease obstruction. The balloon is then removed.
- For **DCA (Directional Atherectomy)** a “cutting device” is advanced into the coronary artery in a fashion similar to PTCA. A mechanically driven rotating blade then shaves the plaque and stores in a collection chamber until it is removed from the coronary artery.
- For **PTCRA (Rotational Atherectomy)** small diamond-tipped catheters rotate at high speed over a fine wire, pulverizing plaque into pieces smaller than red blood cells which then pass downstream and out of the heart circulation.
- For **Coronary Stent Placement** a metal wire device is preloaded onto a balloon catheter, which is advanced to the coronary artery blockage, and then inflated, expanding the stent to the desired opening. The balloon is then deflated and removed from the artery, leaving the expanded stent in the artery, if necessary, several stents can be placed within the coronary artery with one stent placed adjacent to another.
- **Brachytherapy** is radiation delivered by a special catheter to the coronary artery. It is used when a stent has re-narrowed and is used in conjunction with a radiation oncologist.

POTENTIAL COMPLICATIONS:

The risk of stroke and death is less than 1%. Other possible complications are similar to those of the coronary angiography, such as infection, bleeding, allergy to the contrast media, blood clots, disturbances of the heart rhythm and damage to/or closure of a blood vessel. However, transcatheter revascularization procedures are associated with risk significantly higher than angiography. There is a potential for abrupt coronary artery closure which may result in heart attack (less than 5%) or require emergency by-pass surgery (less than 2%). The risk of complications and death from emergency surgery is approximately 2-3 times higher than with elective surgery. Approximately 20-40% of successful transcatheter interventions will demonstrate restenosis (renarrowing) during the subsequent 3-6 months. Many of these cases can be successfully addressed with a second procedure.

ALTERNATIVES:

Treatment options other than the transcatheter revascularization procedures noted above including the option of doing nothing, have been thoroughly reviewed with me. I understand these other treatment choices, including their risks and benefits.

VISITORS/PHOTOGRAPHY:

Students and/or Medical Sales representatives may be present during your procedure for observation only. Videotaping and photography may be done as part of your procedure. Please let your doctor or cath lab personnel know if you have concerns.

ADDITIONAL PROCEDURES:

I recognize that during the course of the procedure additional or different procedures other than those described above may be necessary. I authorize such procedures which, in my doctor's professional judgment are considered to be in my best interest.

TRANSFUSION OF BLOOD PRODUCTS:

I understand that in the course of my care or the care of the person I am authorized to represent, it may be necessary to receive blood or blood products.

ANESTHESIA / SEDATION:

Risk and complications of anesthesia and sedation have been discussed. I consent to the use of such anesthetics as may be considered necessary.

GUARANTEE:

I understand that there is no guarantee of success and that the procedure may not relieve my condition.

I have been allowed to ask questions about the procedure(s) listed. In addition, I have read this form and/or it has been explained to me. I understand the risks and consent to the proposed procedure. If necessary, I also agree to proceed with emergency coronary artery by-pass surgery.

I acknowledge that Dr. _____
or his/her designee, has explained to me in language I understand the nature of my condition as well as the diagnostic and treatment options, including the proposed procedure(s).

**IF YOU HAVE ANY QUESTIONS ABOUT THIS PROCEDURE
ASK THEM BEFORE SIGNING THIS FORM**

Patient Signature: _____
(or person with authority to sign for patient)

Date:_____ Time:_____

Witness Signature:_____

Relationship:_____
(to signature only)

PHYSICIAN STATEMENT:

The patient (guardian) and I have discussed the procedure, the risks, complications and alternatives.
To the best of my knowledge the patient (guardian) understands the procedure and consents to it.

Physician Signature:_____

Date:_____

NOTE: Any changes or strike-outs **MUST** be initialed by both patient (guardian) and physician.