

Front cover:

SurVeil™ Drug-Coated Balloon (DCB)

A Guide for Patients and Their Families



This guide is provided to you by the makers of the SurVeil™ Drug-Coated Balloon. Your doctor has given you this guide because he or she thinks you may need treatment for peripheral artery disease (PAD). This guide will explain what PAD is and possible treatment choices.

The SurVeil™ Drug-Coated Balloon is authorized by Federal (U.S.) law for use in the treatment of patients with PAD; specifically, femoral or popliteal artery stenosis, which is a narrowing caused by a build-up of fatty materials inside the artery.

In this guide, you will learn what will happen before, during and after your angioplasty procedure. As you read, you might think of more questions to talk about with your doctor or nurse. You will find a place in the back of this guide to write your questions and notes.

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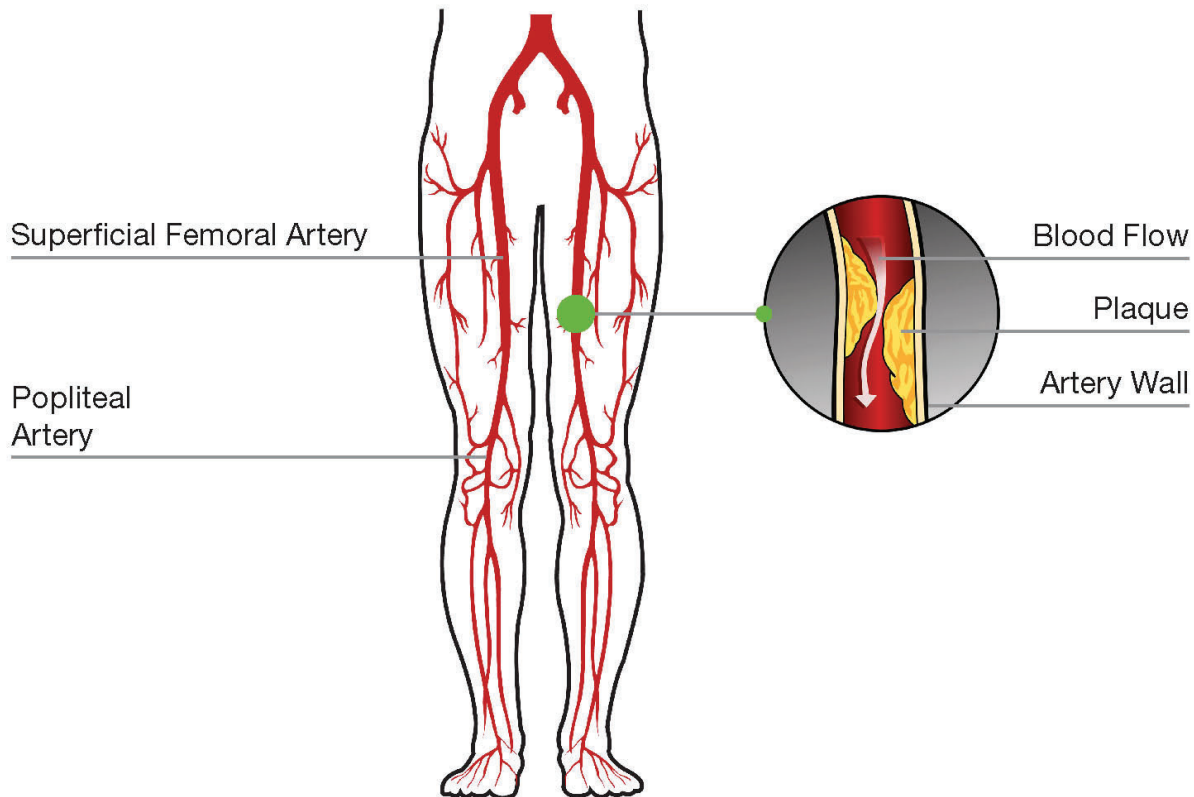
Peripheral Artery Disease

What is Peripheral Artery Disease (PAD)?

Peripheral Artery Disease (PAD) is caused by a build-up of plaque in the arteries of the legs. A plaque forms when fatty deposits, such as cholesterol, build up over time in the lining of the arteries. The plaque build-up narrows the inside of the artery. The narrowing of a blood vessel is also called a stenosis.

Two of the arteries in the legs commonly affected by PAD are the superficial femoral artery (SFA) and the popliteal artery. Figure 1 shows where your superficial femoral and popliteal arteries are in your legs. Each leg has a superficial femoral artery (SFA) that carries blood from the femoral artery through the thigh to the knee. The SFA joins with the popliteal artery just above the knee. The popliteal artery continues below the knee to supply blood to your lower leg.

Figure 1 – Your Superficial Femoral and Popliteal Arteries



The narrowing in these arteries lowers the amount of blood that flows to the leg, and blood flow can be blocked if the arteries narrow too much. This lowered blood flow may cause pain in your legs or buttocks when you walk which gets better when you stop to rest. This pain is called “claudication.” In more severe cases, the decreased blood flow may cause pain in your legs or feet even when you are at rest. The decreased blood flow can also cause open sores on your feet that do not get better.

What are the Risk Factors for PAD?

Some people are more likely to develop PAD if they have certain risk factors. A risk factor is something that might increase your chance of developing PAD. Some risk factors cannot be changed while others can.

Risk factors that you cannot change:

- Your age, gender, or race
- If you or a close relative have had a heart attack or stroke

Risk factors that you can change:

- High blood pressure, high cholesterol, or diabetes
- If you are overweight
- If you smoke cigarettes or use tobacco

How Will My Doctor Know if I Have PAD?

The most common symptom of PAD is leg pain that happens when walking (claudication). Often, the pain goes away after a person stops and rests for a few minutes.

To find out if you have narrowing of the arteries, your doctor will ask you questions about your medical and family history, perform a physical exam, and look at and touch your legs and feet. Your doctor may recommend tests to determine if you have PAD. One common test is an ankle-brachial index (ABI). For this test, your blood pressure is measured in both arms and both ankles. These blood pressure numbers are used to calculate your ABI. Your doctor will use this to help decide if you might have PAD.

One other possible test is an ultrasound. An ultrasound uses sound waves to get images of the inside of your artery. This test is done from outside the body.

Your doctor may also perform a special procedure called angiography to look inside your arteries. Angiography is an X-ray based picture that is performed in a catheterization laboratory (cath lab). A cath lab is a room with special monitors that the doctor will watch during your procedure. Your doctor will insert a long, thin, hollow tube (catheter) into an artery in your groin area. The catheter will be passed through your blood vessels. Your doctor will inject a special dye (contrast solution) through the

catheter. This dye helps the doctor to see how much narrowing there is and where it is located in your artery.

Another possible test is called Magnetic Resonance Angiography (MRA), which uses a strong magnet to create images of your arteries.

Using the information from one or more of these tests, your doctor will be better able to recommend the best treatment for you.

Your Treatment Choices

Your doctor will talk with you about the possible choices for treating your PAD. There are several ways to treat PAD. The goal of treatment is to improve blood flow through your legs. Your doctor will suggest what is best for you, which may include multiple treatment choices.

Exercise: Although this may sound strange to you, exercise is actually good for someone with PAD. Exercise, such as walking, helps keep blood flowing to the legs. Even if you have pain when you walk, you can stop and rest until the pain goes away. Exercise will not make your arteries less narrow, but it may prevent them from becoming even more narrow.

Medicine: Medicine can be used alone or with other treatments. Medicine does not make your arteries less narrow but can be used to improve blood flow to your legs. Your doctor may also tell you to take medicines to control other risk factors such as high cholesterol or high blood pressure.

Surgery: A surgeon can operate on your artery to clean out or bypass the narrowed part of your artery. Surgery is usually done under general anesthesia (you are asleep).

Atherectomy: A doctor inserts into the artery a catheter (tube) that has tiny blades or laser attached at its end. The blades or laser is then used to cut or vaporize away the plaque. Patients are usually awake during the procedure. Your doctor may give you some medicine to help you relax.

Angioplasty: A doctor inserts a small, deflated balloon through a catheter (tube) into the narrowed part of your artery. The balloon may either be uncoated or coated with a drug. The balloon is inflated to open the narrowed part of the artery. The doctor will take the balloon and catheter out of your body when the procedure is done. Patients are usually awake during the procedure. Your doctor may give you some medicine to help you relax.

Stenting: A stent is a small, mesh tube that holds open the narrowed part of your artery. It is packaged inside a catheter, which allows your doctor to move it through your arteries and place it to treat the narrowed portion of your artery. The stent stays in the artery permanently. Patients are usually awake during the stenting procedure. Your doctor may give you some medicine to help you relax.

Drug-Coated Balloon Angioplasty Procedure

Device Description

The SurVeil™ Drug-Coated Balloon is an angioplasty balloon catheter with the drug, paclitaxel, applied to the balloon. Drug-coated balloons are used in angioplasty procedures to treat narrowed or blocked blood vessels in the leg and may alleviate the need for a permanent stent implantation

What is paclitaxel?

The SurVeil™ Drug-Coated Balloon is coated with a small amount of paclitaxel which is applied directly to the vessel wall when the balloon is inflated. Paclitaxel is the active drug component of the SurVeil™ Drug-Coated Balloon which may help prevent re-narrowing of the artery.

Figure 2 – SurVeil™ Drug-Coated Balloon



Discussions with Your Doctor

Before deciding to have a Drug-Coated Balloon (DCB) angioplasty procedure, you should talk to your doctor:

- About all medicines you take, including non-prescription medicines.
- About allergies to contrast dye or iodine, plastics or anything else, including medications.
- If you cannot take aspirin. Aspirin and other medicines are started before the

procedure and may be used for several months after the procedure.

- About how long you will have to be in the hospital for the procedure.
- About the possible risks and benefits of the DCB angioplasty procedure. Your doctor can answer any questions you or your family may have.

Once you and your doctor decide on a DCB angioplasty procedure:

- Be sure you understand the risks and benefits before you agree to treatment.
- Your doctor may tell you not to eat or drink anything for several hours before your procedure. This time will depend on when your procedure is scheduled.
- Follow all instructions given to you by your doctor, nurse or health care professional.

Prior to Your Procedure

- In the procedure room, you will lie on a special table. The staff will make you as comfortable as possible.
- You will be attached to monitors that will keep track of your heart rate and oxygen levels. The doctor and staff will watch these monitors throughout your procedure.
- You may be given medicine to help you relax. This medicine may make you sleepy.

During Your Procedure

- Your narrowed artery will be accessed through an artery in your groin area. This place is called the access site.
- The access site will be washed with an antiseptic solution and covered with a sterile sheet.
 - You will receive medicine to numb the area around the access site. You may feel a sting from the needle and a brief warm feeling when the medicine is injected.
 - Next, your doctor will put a needle into the artery in your groin. When the needle is first put into the artery, you may feel some pressure. A guide wire will be fed through your artery and the needle will be removed. Then a sheath (tube) will be fed over the guide wire through your artery. Contrast dye will be injected so the doctor can view your arteries.

If your doctor has chosen to use the SurVeil™ Drug-Coated Balloon, the procedure will be conducted as follows:

- The narrowed section of the artery may need to be enlarged to make room for the drug-coated balloon. To do this, the doctor may use other devices to push the plaque to the side.
- When the physician is satisfied with the size of the lumen, the drug-coated

balloon will be inserted (Figure 3).

- After the drug-coated balloon is inserted, it is inflated to make contact with the artery wall, allowing the drug to be released (Figure 3). The device is then removed from the access site.
- Pressure is applied to the access site until bleeding stops. A special closure device may be used to close the small incision in the artery.
- The drug from the balloon is absorbed into the artery and is designed to help keep the artery open and prevent future narrowing of the artery.

Figure 3 – Positioning of balloon in Narrowed Artery



After Your Procedure

- You may feel sleepy until the medicine you received wears off.
- You will be taken to a special area where nurses and doctors monitor your heart rate, blood pressure and the access site.
- You may need to stay in bed for several hours to allow the access site to heal.
- Do not try to sit up until your nurse or doctor tells you to do so. It is important to lie flat and keep still to prevent bleeding from the access site. If you see any bleeding, tell your doctor or nurse immediately.
- You should drink plenty of fluids to help your kidneys get rid of the dye that was injected into your arteries.
- Let the nurse or doctor know if you have any pain in your back, at the access site or anywhere else.

Your Recovery

It is important to take all your medicines as your doctor told you. Ask your doctor about any side effects the medicines may cause and when you should call if you are having a side effect. Do not stop taking your medicines unless your doctor tells you to. Your doctor may be able to give you a different medicine.

Avoid lifting and activities that could tire you for as long as your doctor tells you. Your

doctor may talk to you about making changes to your diet or lifestyle.

Make sure to keep all scheduled follow-up appointments. It is important for your doctor to check the condition of your artery after treatment.

Ask your doctor about when you should call if you are not feeling well.

Safety Information

Benefits

Drug-Coated Balloon (DCB) angioplasty can improve blood flow to your legs. The drug from the balloon is absorbed into the artery and is designed to help keep the artery open and prevent future narrowing of the artery. The DCB angioplasty procedure does not require a large cut and stitches. The healing process after a DCB angioplasty procedure is usually faster and may be less painful than surgery. The SurVeil™ Drug-Coated Balloon was studied in a clinical study in the United States. The results show that the use of the SurVeil™ Drug-Coated Balloon to treat PAD is safe and effective. Your doctor can help explain the risks and benefits that are specific to you. If you have any more questions, now is the time to discuss them with your doctor.

When a SurVeil™ Drug-Coated Balloon Might Not Be Appropriate

Your doctor may not choose SurVeil™ Drug-Coated Balloon if:

- You have a sensitivity or risk of allergic reaction to the drug (paclitaxel) used on the SurVeil™ Drug-Coated Balloon. If you are at risk, your doctor will choose another therapy for your PAD treatment.
- You cannot receive recommended anti-platelet and/or anticoagulant therapy.
- You are breastfeeding, pregnant or intending to become pregnant, or are intending to father children.
- You have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.
- You have a lesion in the coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries.

Potential Complications (Risks)

Complications can occur during any procedure performed through the blood vessels. The following lists some of the possible risks of balloon angioplasty procedure in the superficial femoral artery or popliteal artery. Ask your doctor to provide you more information on your risks for the procedure.

As with any angioplasty procedure, there is a chance that complications may occur, including, but not limited to the following:

- Allergy or reaction to medicine, the catheter system material or contrast (dye)
- Loss of limb
- Aneurysm (Balloon-like bulge in the vessel wall)
- Problems with the rhythm of your heart, such as slow heartbeat or uneven heartbeats
- Abnormal connection or passage between an artery and a vein
- Bleeding
- Death
- Infection in the inner lining of the heart chambers and valves
- Nerve damage at the access site
- Bruising, bleeding or blood clot at the access site
- Restricted blood supply/tissue death
- Kidney damage or failure
- Infection (local and systemic)
- Formation of blood clots inside a blood vessel, obstructing the flow of blood through the circulatory system
- Low blood pressure
- Pain or discomfort
- A collection of blood from a ruptured vessel that gives the appearance of an aneurysm; also known as a false aneurysm.
- Fever
- Difficulty breathing
- Stenosis (narrowing), restenosis (re-narrowing) or total closure of the dilated artery
- Presence of bacteria, other infectious organisms, or toxins created by infectious organisms in the bloodstream that spread through the body.
- Temporary change in blood pressure
- Stroke
- A vessel is blocked or obstructed anywhere in the circulatory system in the body.
- Damage or injury to your blood vessels; spasm of the vessel wall

Potential complications which may be unique to the paclitaxel drug coating include:

- Allergic/immunologic reaction
- Loss of hair
- Anemia
- Disturbances of the gastrointestinal (GI) track and stomach

- Changes of the tissue in the vessel wall including inflammation, cell injury and cell death
- Abnormal liver values
- Changes in blood profile (decrease of white and red blood cells and platelets)
- Muscle pain/joint pain
- Bone marrow abnormality
- Nerve disease in arms and legs

Your doctor and nurses will watch you during and after the procedure for any complications. If any of these complications happens to you, your doctor will treat you as needed. Treatments will vary widely depending upon the type of complication and your medical history.

General Warnings and Precautions for Paclitaxel-Coated Devices: A signal for increased risk of late mortality 2-3 years post-treatment has been identified following the use of paclitaxel-coated balloons. The magnitude and mechanism of the increased late mortality risk is uncertain, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss the late mortality signal and the risks and benefits of available treatment options for their specific disease or condition with their patient. A study published in December 2018 in the Journal of the American Heart Association reported an increased risk of death starting at 2 years and up to 5 years after treatment with paclitaxel-coated devices in the upper leg compared to treatment with uncoated devices. The U.S. Food and Drug Administration also observed the increased risk of death associated with paclitaxel-coated devices that are approved in the U.S. Additional studies are being conducted to better understand this risk. Although so far the cause for this increased risk of death is unknown, this is important information for you to have when making a decision about treatment options. Your doctor can explain the risks and benefits of paclitaxel-coated devices that are specific to you.

Summary of Clinical Information

The TRANSCEND Clinical Study evaluated 446 patients to determine if the SurVeil™ Drug-Coated Balloon was safe and effective at 12 months after treatment when compared to another drug-coated balloon (IN.PACT® Admiral®).

The study demonstrated that the SurVeil™ Drug-Coated Balloon achieved similar clinical benefits when compared to the other drug-coated balloon. The SurVeil™ Drug-Coated Balloon can safely and effectively treat superficial femoral or popliteal artery stenoses. Your doctor can further explain the benefits and risks of the treatment recommended for you.

Lifestyle Changes

PAD can be treated, but it has no cure. Keep all follow-up appointments and take all of

the medicine your doctor has given to you. Your doctor may also recommend some of the following lifestyle changes.

Stop smoking: If you smoke, quitting is the single most important thing you can do to lower your risk of further PAD. Chemicals in cigarette smoke may make it easier for plaque to build up on your artery walls. Smoking increases your heart rate and blood pressure, which also raises your risk of heart attack and stroke. If you are ready to quit, ask your doctor for advice – he or she can recommend ways to help you quit.

Increase your activity: Regular exercise can help lower your blood pressure and blood cholesterol. It can help you reach a healthy weight. Exercise can also help you deal more easily with daily stresses. Your doctor can recommend an activity program that meets your needs.

Eat a healthy diet: Choose a healthy diet that is low in saturated fats and cholesterol. This can help you reach a healthy weight, as well as help you control your blood pressure and cholesterol levels.

