Abbott

Esprit™ BTK

Everolimus Eluting Resorbable Scaffold System

Patient Information Guide

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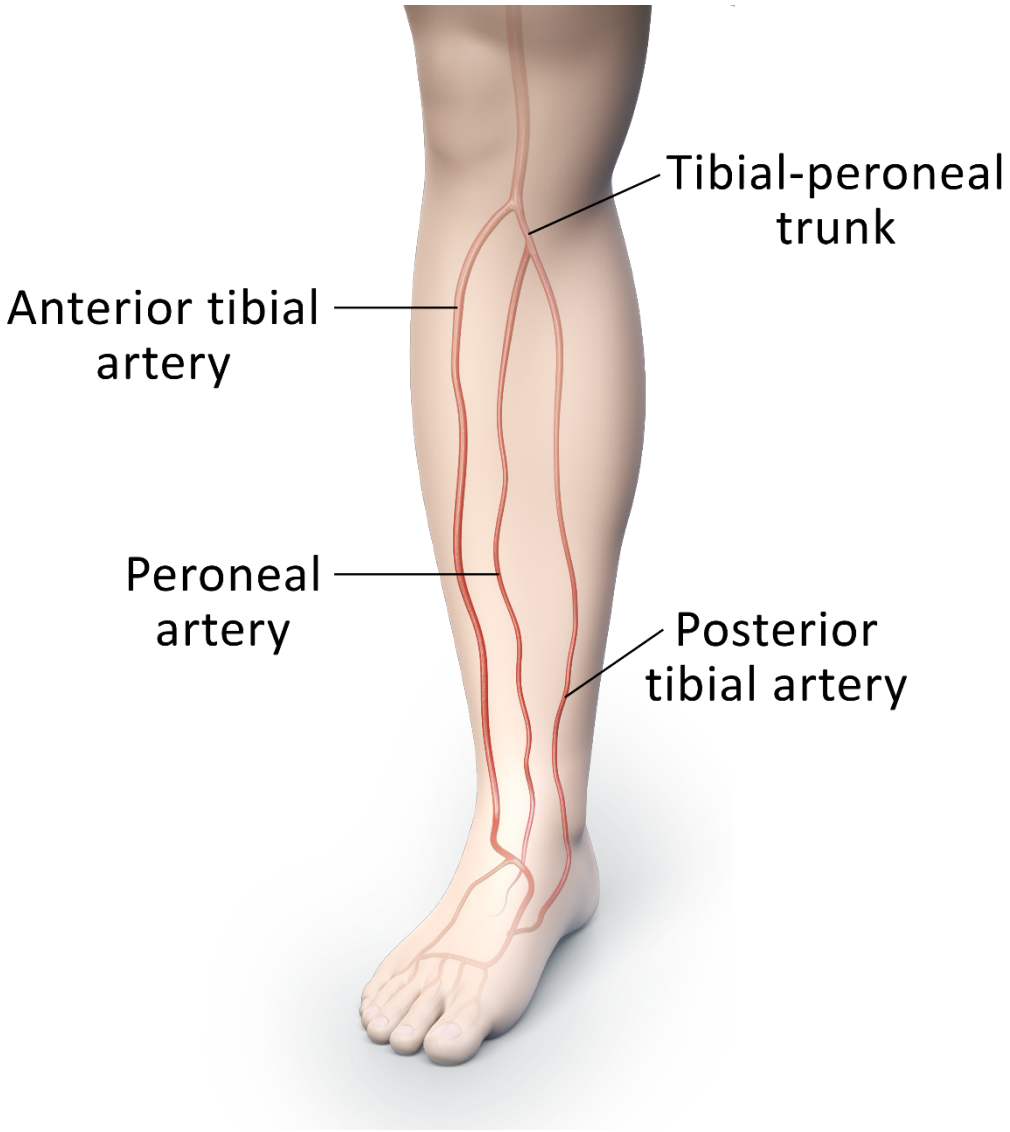
This guide is provided to you by the makers of the Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit BTK System). Your doctor has given you this guide because they think you may need treatment for peripheral artery disease (narrowing of one or more of the blood vessels in your leg that carry blood). This guide will explain peripheral artery disease and its treatment choices. One treatment choice is to place a scaffold in your blood vessel to keep it open. In this guide, arteries are also referred to as "blood vessels."

The Esprit BTK System is authorized by Federal (US) law for use in the treatment of patients with peripheral artery disease below the knee, a narrowing in your blood vessels below the knee 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 scaffold procedure. As you read, you may think of more questions to talk about with your doctor or nurse. Your doctor can explain the risks and benefits of your treatment and answer any questions you or your family may have. You will find a place in the back of this guide to write your questions and notes.

Below-The-Knee (BTK) Arteries (Blood Vessels)



Peripheral Arterial Disease (PAD)

What Are Peripheral Arterial Disease in the Lower Limbs and Below-the-Knee (BTK) Disease?

The Cause

Peripheral arterial disease (PAD) occurs when the blood vessels that supply blood to your leg(s) become narrowed or blocked by a buildup of fatty material called plaque. As a result, there is less blood to the tissues and muscles of the leg(s). Arterial disease occurring in the blood vessels below the level of the knees is referred to as below-the-knee (BTK) disease.

The Effect

PAD symptoms can arise as a result.

These may include:

- Your leg(s) becomes tired, sore, or numb, with cramping when walking or climbing stairs; this is referred to as claudication
- You may only be able to walk short distances, or not at all
- Coldness in your lower leg or foot
- Sore(s) or ulcer(s) on the lower leg, foot and / or toes
- Rest pain, ulcers that won't heal, and gangrene are signs of a severe form of lower limb arterial disease referred to as chronic limb threatening ischemia (CLTI)

Who Is at Risk?

There are some risk factors for PAD that are **beyond your control**, including:

- Increasing age
- Being male or menopausal female
- Family history of heart disease or PAD

But the majority of risk factors **can be controlled** and should be taken into consideration once you've been diagnosed with PAD. When addressed successfully, reducing these risk factors can reduce the risk of worsening PAD:

Smoking

Each cigarette contains 2,000 to 4,000 toxic chemicals that cause direct damage to blood vessels, decrease the amount of oxygen delivered to the body, and increase the risk of developing deadly blood clots.

Obesity

Excess weight increases blood pressure, raises blood fats such as cholesterol and triglycerides in the blood, and lowers high-density lipoprotein (HDL) levels (good cholesterol), which increases the risk of developing PAD.

Lack of Physical Activity

An inactive lifestyle or lack of physical exercise may contribute to PAD.

High Blood Pressure

High blood pressure, also known as hypertension, causes damage to the walls of the blood vessel, making it easier for plaque to form.

Diabetes

In patients with diabetes, the sugar level in the blood is high because the substance needed to control it, called insulin, is either low or the patient is not responding to it. Excess blood sugar can build up within, and lead to damage of the blood vessels of many organs.

High Cholesterol

Too much cholesterol in the blood can lead to atherosclerosis, or the buildup of thick, fatty plaques that clog arteries.

How Is PAD Diagnosed?

If your doctor suspects you have PAD or you have shown symptoms of the disease, you'll likely be asked to take a physical exam and other tests to identify possible blockages in your leg(s).

Some of the tests used to make the diagnosis include:

- **Checking Pulses**
  The doctor will check your pulses (feeling of your heartbeat) at several locations in your legs and feet. A diminished pulse may indicate a restriction in blood flow.

- **Ankle-Brachial Index (ABI)**
  The doctor may measure the blood pressure in your ankle and in your arm and compare the two.

- **Exercise Testing**
  Exercise testing is aimed at determining how far you can walk without pain.

- **Ultrasound**
  This test uses sound waves to get an image of the blood vessels in your leg(s) so that your doctor can look for evidence of narrowing(s).

- **Peripheral Angiogram**
  This procedure is performed by a doctor in a catheterization laboratory (cath lab). A long, thin, flexible hollow tube (also known as an introducer sheath) is inserted into an artery (blood vessel) in the groin or foot. A special dye fluid is injected through the tube to better display the blood vessels on X-rays. Pictures of the X-rays (angiograms) allow the doctor to see any blockage in the arteries and / or narrowing of the leg arteries.

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

What Are Your Treatment Options?

You should discuss with your doctor the kinds of treatment that will help you get better. This may involve a combination of any of the methods listed below:

Medications

PAD may be treated by medications to help relieve the symptoms, improve blood flow to the leg(s), and treat other conditions such as diabetes, hypertension, or high cholesterol levels.

Lifestyle Changes

- Increase physical activity
- Stop smoking
- Diet modification
- Weight loss programs

Interventional Procedures and Surgery

Another way of treating PAD is to try to open the blocked artery that is causing the problem. Opening the blocked artery can be done by either surgery (also known as bypass graft) or by inserting devices into your body without performing surgery. More information about these procedures is provided in the following pages.

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 completely asleep).

Peripheral Angioplasty or Percutaneous Transluminal Angioplasty (PTA)

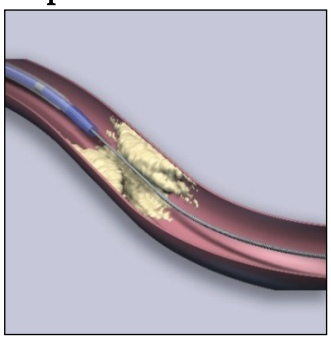
This is a minimally invasive procedure to open blocked arteries using a balloon dilatation catheter. This procedure is performed by a team of specialists, nurses, and technologists in the hospital cath lab.

Step 1: A small, deflated balloon is threaded through a hollow tube (introducer sheath) into the narrowed part of the arteries below the knee.

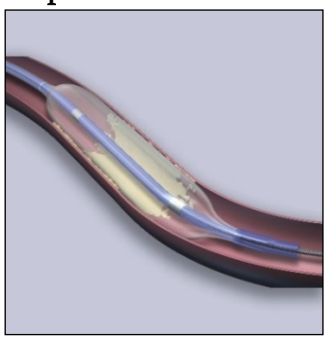
Step 2: The balloon is inflated within the narrowed area of the artery, compressing the plaque in the artery against the vessel wall, thereby creating a larger opening in the artery for the blood to flow through.

Step 3: The balloon is then deflated and the catheter is removed.

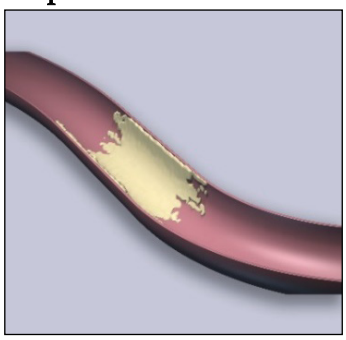
Step 1



Step 2



Step 3



Peripheral Artery Scaffolding

A scaffold is a small mesh tube made out of a material called a polymer, similar to other medical products like dissolving stitches. This scaffold will hold open the narrowed part of the blood vessel in your lower leg. It is packaged on a long narrow tube with a balloon on the end (called “catheter”), which allows your doctor to move it through your arteries and place it to treat the narrowed portion of your artery. The scaffold stays in the artery after the catheter is removed. Patients are usually awake during the scaffolding procedure. Your doctor may give you some medicine to help you relax.

The Esprit BTK™ Everolimus Eluting Resorbable Scaffold System

The Esprit BTK Everolimus Eluting Resorbable Scaffold System (Esprit™ BTK System) is a medical device manufactured by Abbott. The Esprit™ BTK Scaffold is designed to be placed in the blood vessel immediately after a balloon angioplasty, supporting the blood vessel and preventing it from reclosing. The scaffold is coated with a mixture of a drug (everolimus) and a coating that will go away after the drug is released. The scaffold also contains four tiny markers to help the doctor position it properly within your blood vessels. Once implanted, the scaffold releases the drug over a few months, which prevents too much tissue from growing over the scaffold and therefore helps keep the blood vessel open. The scaffold naturally disappears into the body over time, like dissolving stitches, and will be gone from your body in about 3 years.

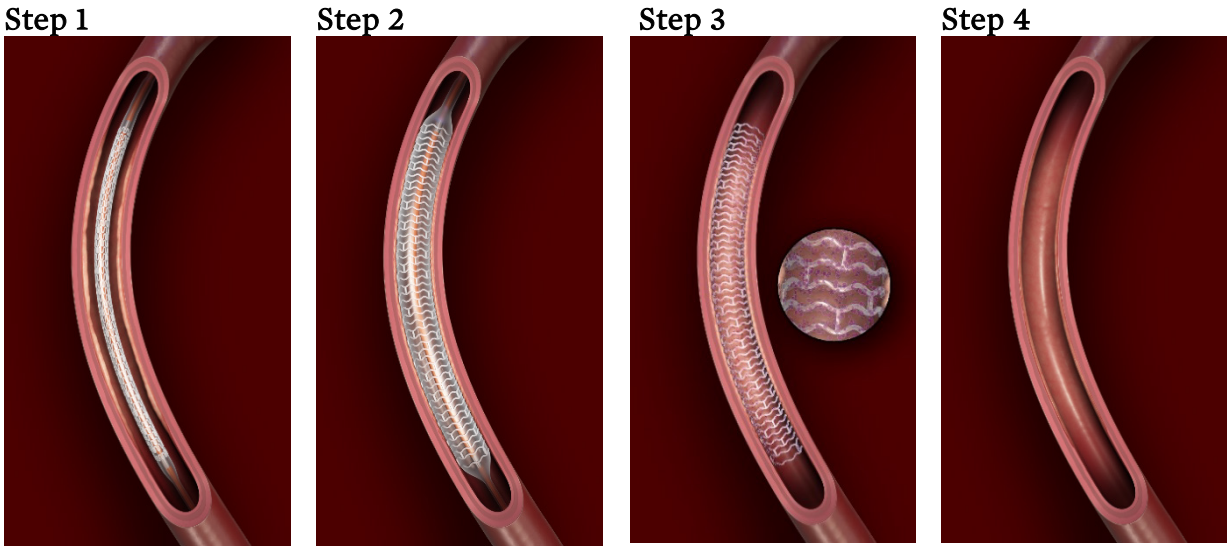
The procedure is similar to the technique required to unblock arteries in the heart, but instead it is used below the knee to restore blood flow to the foot, with the goal of preventing amputation.

Step 1: Similar to angioplasty, a long narrow tube with a balloon at the end (catheter) is guided through the blood vessel to the narrowed part of the artery. The scaffold is on the balloon at the end of the catheter.

Step 2: The balloon is inflated, expanding the scaffold, and pushing the plaque against the blood vessel wall.

Step 3: The narrowed artery is now open and there is improved blood flow to the lower limb. The balloon is then deflated, and the catheter is removed, leaving the expanded scaffold in place. The scaffold is left in place and remains in the body.

Step 4: The scaffold material dissolves over time.



What Happens to the Scaffold?

The scaffold is made from the same type of material that has been used in other medical procedures for many years. When the scaffold begins to dissolve, it turns into natural elements in your body – water and carbon dioxide.

What Are the Contraindications or Situations in Which You Should Not Be Implanted with an Esprit™ BTK Scaffold

- If you cannot take aspirin or blood-thinning medications (also called antiplatelet or anticoagulant therapy).
- If you have an allergic sensitivity to drug (everolimus), scaffold material (polylactide) and / or platinum.

What Are Warnings about the Use of the Esprit™ BTK Scaffold in You?

After the scaffold is placed inside you, you will have to take medicine that prevents your blood from clotting. An example of medicine that prevents blood clotting is aspirin. Take this medicine as instructed by your doctor. If instructed by your doctor, you may also have to take medicine that thins your blood. Make sure to take all medicine(s) as instructed by your doctor.

Potential Adverse Events (Side Effects) Associated with the Esprit™ BTK System

Treatments for PAD have become increasingly common, but as with any invasive procedure, there are potential risk factors and complications. Serious complications do not occur often, and research is ongoing to make these procedures even safer and more effective.

Potential Risks

The risks of using the Esprit™ BTK System are similar to those associated with standard stenting or scaffolding procedures. If blood clot is forming within the scaffold, you may need another angioplasty procedure. It may lead to amputation, or the need for other urgent surgery. Even with successful scaffold implants, there is a chance of re-narrowing in your artery.

Listed below are known potential risks that may originate from either the scaffold or the drug (everolimus):

- Allergic reactions or hypersensitivity to contrast agent, anesthesia, device materials, and drug reaction to anticoagulation, antiplatelet or immunosuppressive drugs
- Vascular complications which may require blood transfusion or additional intervention, including:
    - Complications at the groin or access site
    - Abnormal bleeding during or after an operation
    - Injury to blood vessels
    - Movement of air, tissue, plaque, thrombotic or device material downstream in the vessels resulting in blockage in blood flow
    - Total or sudden blockage of the artery
    - Blood clots

    - Decreased blood and / or oxygen supply to the leg that may result in gangrene or sores
    - Narrowing or re-narrowing of the treated artery
    - Sudden, brief tightening of the muscle cells inside the walls of a blood vessel (vessel spasm)
- Bleeding elsewhere in the body due to blood thinners, everolimus or other drugs
- Additional surgery such as bypass graft surgery or removal of a limb
- Nerve damage caused by injury to the nerve or interruption of blood supply to the nerves
- Pressure on nerves, arteries or veins due to bleeding or injury which may cause nerve or vessel damage
- Tissue damage caused when blood supply returns to a tissue after a period of lack of oxygen
- Excessive blood flow after vessel narrowing is corrected
- New or worsening pain
- Altered organ function in acutely ill patients, usually involving two or more organ systems, including heart, lungs, or kidneys:
    - Heart becomes too weak or stiff to pump blood effectively
    - Heart stops beating (includes fluid in the lining around the lungs)
    - Failure to breathe
    - Kidney failure or insufficiency
    - Shock: a life-threatening condition in which blood pressure is too low to maintain adequate blood flow to your organs
- Other general surgical risks, including:
    - Irregular heartbeats
    - Stroke or mini-stroke
    - Blood clot or clots traveling in the blood stream to and lodging in the lung (with the possibility of resultant difficulty in breathing)
    - Vomiting and/or the urge to vomit
    - Low or high blood pressure
    - Infection which may result in fever
    - Blood disorders or blood count abnormalities
    - Death

Zortress‡ is the brand name of everolimus taken by mouth and developed by Novartis Pharmaceuticals Corporation. It has been tested in clinical trials and approved in the United States to prevent rejection of kidneys transplanted in adults. It is given at the dose of 1.5 milligrams a day. Outside of the United States, Zortress‡ is sold under the brand name Certican‡ in more than 70 other countries. Everolimus is also approved in the United States and in Europe under the brand name Afinitor‡ for patients with advanced kidney cancer at doses of 5 to 10 milligrams a day when taken by mouth.

Other possible side effects not mentioned above that were observed among those taking everolimus by mouth[1] are listed below. The amount of everolimus drug released in your blood from the Esprit™ BTK Scaffold is several times lower than with taking oral doses of 1.5 milligrams to 10 milligrams daily by mouth.

- Abdominal pain
- Blood clot formation that may cause obstruction of the blood vessels in the liver or kidneys
- Swelling that happens just below the surface of the skin, most often around the lips and eyes
- Difficulty passing stool
- Coughing
- Diabetes (high blood sugar)
- Diarrhea (frequent, loose watery stools), which can cause dehydration and may require hospitalization and treatment with intravenous fluids
- Shortness of breath
- Fetal injury or death
- Inflammatory skin disease with redness of the skin
- Headache
- Liver disorders (including inflammation of the liver, yellowing of the skin and eyes, and darkened urine)
- Abnormal blood and urine laboratory test results (increases in waste molecules generated from muscle metabolism; abnormal amount of protein in urine; low or high blood potassium concentrations; changes in blood cholesterol and fat parameters; liver function test abnormalities; decreases in red and / or white blood cells and platelets)
- Cancer of the lymph nodes and skin cancer
- Inability to father children (for men)
- Irregular menses (for women)
- Drug interactions resulting in decreased kidney function (and possible kidney failure)
- Inflammation of the lungs caused by drug reactions, which can cause shortness of breath
- Mouth blisters or sores
- Inflammation of the pancreas causing pain in the upper abdomen. This could become severe and cause nausea, vomiting, fever, and rapid heart rate
- An abnormal accumulation of blood around the heart
- Swelling of arms or legs
- Collection of fluid around the lungs in the chest cavity, which can cause shortness of breath and may require treatment

[1] Certican‡ UK SmPC, Afinitor‡ UK SmPC, Votubia‡ UK SmPC, Afinitor‡ US label, and Zortress‡ US label. Refer to www.MHRA.gov.uk, www.ema.europa.eu, and www.fda.gov for the most recent versions of these SmPC / labels.

- Skin rash
- Wound healing complications (including wound infection and an abnormal collection of lymph fluid)

Please tell your doctor about any medicines you are taking. Everolimus may react with these medicines.

If You Experience Adverse Events or Unwanted Effects from Your Esprit™ BTK Scaffold

If you experience any of these adverse events (side effects) or any other unexpected effects because of the Esprit BTK Scaffold, please report this to your doctor as soon as possible.

Patient Exposure to Materials and Substances

The polymer used to make the scaffold is called polylactide, a biodegradable material that is made from natural sources. This material breaks down in the body to lactic acid, which is produced naturally in the body when your cells need more energy, and then eventually to carbon dioxide and water. The safety of polylactide has been demonstrated by its long history of use in resorbable medical devices, starting with resorbable sutures in the 1960s. There are hundreds of approved medical products, both vascular and nonvascular (e.g., orthopedic devices, such as plates, pins, and screws), that are manufactured from polylactide, or copolymers containing polylactide.

Four platinum markers are located on the Esprit BTK Scaffold and will stay in your artery after the scaffold itself has been fully absorbed. These markers help the doctor place the scaffold in the correct location in your blood vessel using X-rays. The long-term effect of these markers is unknown.

There is a small risk of an allergic reaction to the drug, scaffold material (polylactide) and / or platinum markers.

Esprit™ BTK System Clinical Summary

There is currently one clinical study, called LIFE-BTK, where patients with PAD were treated with the Esprit BTK System. This study showed that the Esprit BTK System is safe and effective, meaning it worked to treat the plaque buildup in the blood vessel, and can be used to treat PAD. A short description of this study is detailed below.

The LIFE-BTK trial is a randomized study, meaning the treatment a patient could receive is by chance, conducted in the United States (US) and outside the US that compared the Esprit BTK System (the scaffold) with a balloon (PTA), which is another treatment option currently available. The trial enrolled a total of 261 patients, with 173 patients in the Esprit BTK System group and 88 patients in the PTA group. All patients will be followed for 5 years.

There were two main ways in the study to test whether the scaffold worked in comparison to the balloon:

(1) to determine if the scaffold was at least as safe as the balloon, and
(2) to determine if the scaffold worked better than the balloon for keeping your vessel open to allow blood to flow down to your foot.

The results were reported after patients had reached 1 year post-procedure, per the trial design requirements. The trial found that the Esprit BTK System is as safe as the balloon. Compared to using a balloon, the scaffold also showed that it worked better in treating the plaque build-up and keeping your blood vessel open. Therefore, both the test for safety and how well the scaffold works demonstrated successful outcomes. Your doctor can explain the risks and benefits that are specific to you.

Your Esprit™ BTK System Procedure

How Do You Prepare for Your Procedure?

In the days prior to your treatment, make sure you:

- Take all of your prescribed medicines.
- Tell your doctor if you are taking any other medication.
- Tell your doctor if, for any reason, you cannot take aspirin and / or antiplatelet inhibitor medications such as Clopidogrel (Plavix‡), Prasugrel (Effient‡), or Ticagrelor.
- Make sure your doctor knows about any allergies you have.
- Refrain from eating and drinking after midnight on the night before your treatment.
- Follow all instructions given to you by your doctor or nurse.

You may be given a mild sedative to help you relax, but you will be awake during the procedure.

There are two reasons for this:

1. Most people find they experience little to no discomfort from the procedure.
2. Your doctor may need to ask you questions and / or ask you to hold very still while X-rays are being taken, to improve the quality of the pictures.

The procedure usually lasts about 90 minutes.

During the Procedure

Your procedure will be performed in a catheterization laboratory (cath lab). You will lie down on the X-ray table, and an X-ray camera will move over the lower part of your body during the procedure. The staff will monitor your heart by attaching several small sticky patches to your chest and using a specialized ECG recorder and monitor.

The groin is the most common site for inserting the devices and requires a very small skin cut to be made on the inside of your upper thigh. The area will be shaved and cleaned with an antiseptic, and you will be given a local anesthetic to numb the area. This small cut will allow a small hollow tube (introducer sheath) to be inserted into your femoral artery (the main artery of the thigh, supplying blood to the leg). A guide wire is then advanced through the hollow tube to the narrowing in the blood vessels below the knee. The guide wire helps carry all the necessary devices required during the procedure.

An additional site for inserting the devices is the foot (pedal approach), where the hollow tube is inserted into one of the arteries on the top or side of your foot. After the tubes are inserted, your doctor will inject a dye through them and into your artery to view the narrowing.

Your doctor will watch the injection on an X-ray monitor, much like a TV screen. While these X-rays are being taken, your doctor may ask you to remain still and not move your leg. The medications commonly used during the procedure are anticoagulants, such as heparin to prevent clotting of the blood, and drugs like nitrates to keep the artery open and relieve any contraction in your blood vessel.

A long narrow tube with a balloon at the end (catheter) will be inserted into the hollow tube (introducer sheath) that is already positioned in the vessel and advanced over a wire through your vessels until it is positioned at the narrowing in the blood vessels below the knee. The balloon will then be inflated. This will compress the plaque against the wall of the vessel and widen the vessel. This procedure is called pre-dilatation. The balloon will then be deflated, and the balloon catheter will be removed.

The Esprit BTK System will be inserted until it reaches the affected blood vessel. The balloon of the Esprit BTK System will be inflated to expand the scaffold, pressing it against the vessel wall. The balloon will be deflated and then removed. Your doctor may choose to expand the scaffold further by using another balloon so the scaffold will make better contact with the vessel wall. This is known as post-dilatation.

After your doctor has checked that the blood flow in the affected artery has improved, all the devices will be removed except for the Esprit™ BTK Scaffold. The Esprit BTK Scaffold will remain in your vessel and dissolve over time.

Immediately after the Procedure

A closure device may be used to seal the incision site in your groin. Pressure will also be placed on the area to prevent bleeding. You will be asked to lie flat without bending your leg for a lengthy period of time, usually between four and six hours, immediately following the procedure. Your hospital stay may be less than one day or up to three days.

Post-Treatment Medications

Antiplatelet medications such as aspirin, Clopidogrel, Prasugrel, or Ticagrelor are the most commonly prescribed medications. They help prevent a blood clot (thrombus) from forming and blocking the vessel that had been opened by the balloon or scaffold. Your doctor or nurse will give you instructions about your medications before you leave the hospital. Upon leaving the hospital, your doctor may prescribe medications as a key part of your treatment to help prevent complications. These medications may include:

- **Aspirin** and other **antiplatelet medications** (as described above) to thin the blood and help prevent blood clots.
- **Beta-blockers** to slow your heart rate and lower your blood pressure.
- **Statins** to lower your cholesterol, which may reduce your risk of heart attack.
- **Calcium channel blockers** to slow your heart rate and lower your blood pressure. They also help widen your coronary arteries and reduce angina.
- **Angiotensin-converting enzyme (ACE) inhibitors** to lower your blood pressure and reduce the strain on your heart.
- **Angiotensin II receptor blockers (ARBs)** work much the same way that ACE inhibitors do, and may be prescribed if you cannot tolerate certain side effects of an ACE inhibitor.

Take All Medications as Instructed

After you leave the hospital, your doctor will instruct you to take a daily dose of aspirin and another antiplatelet drug such as Clopidogrel, Prasugrel, or Ticagrelor. Your doctor will tell you how long you should continue taking the antiplatelet drugs. It is very important that you take these medications exactly as your doctor instructed you:

- Follow your medication schedule exactly to avoid possible complications after you receive your scaffold. Do not miss any doses.
- Call your doctor if you cannot keep taking your medications because of side effects such as rash, bleeding, or upset stomach.
- **CAUTION: Do not stop taking your prescribed medications unless you are instructed to do so by the doctor who performed your scaffold procedure.**
- **CAUTION: Notify your doctor who performed the scaffold procedure or family doctor if you are scheduled to see the dentist while on blood thinner and / or antiplatelet medication. Your doctor may prescribe antibiotics to avoid the potential of an infection. You should review with your doctor any recommendations from your dentist to stop your prescribed medications.**
- **CAUTION: Before undergoing implantation of a drug-eluting scaffold, if you plan to have any type of surgery that may require you to stop taking blood thinner and / or antiplatelet medications, you and your doctor should discuss whether or not placement of a scaffold is the right treatment choice for you.**

If surgery or dental work that would require you to stop taking antiplatelet medications is recommended after you have received the scaffold, you and your doctors should carefully consider the risks and benefits of this surgery or dental work versus the possible risks from early discontinuation of these medications.

If you do require discontinuation of antiplatelet medications because of significant bleeding, your doctor will carefully monitor you for possible complications. Once your condition has stabilized, your doctor may put you back on these medications.

Follow-up Care

You will be discharged to the care of your doctor. You should be able to return to your normal activities soon.

CAUTION: Notify your doctor immediately if you experience more severe or frequent pain in and / or below the area of your body where the scaffold was inserted, especially in the first month after a procedure. These symptoms may indicate a re-narrowing in your scaffolded artery.

Your doctor will ask you to return for follow-up visits. The first visit is usually two to four weeks after your scaffold is implanted, with follow-up visits every six months for the first year. If you had a wound on your foot or leg at the time of your procedure, you may also have additional follow-up visits for wound care. Be sure to keep all appointments for follow-up care, including blood tests.

Keep Your Implant Card Handy

CAUTION: Show your implant card if you report to an emergency room. This card identifies you as a patient who has had a scaffold implanted.

Magnetic Resonance Imaging (MRI) Scanning

An Esprit™ BTK Scaffold can be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury, death, or device malfunction. Full MRI safety information is available for Health Care Professionals in the MRI Safety Information section of the instructions for use which can be obtained at vascular.eIFU.abbott.

Taking Control of Your PAD

Once a PAD care plan has been established by your doctor, its success mostly depends on your commitment to seeing it through. In addition to getting regular checkups with your doctor, there are a number of steps you can take when you commit to making your heart and peripheral arteries healthier:

- If you smoke, create a plan to stop. There are supportive resources you can contact to help encourage you, as well as medications to make stopping easier.
- If losing weight sounds like a difficult challenge, remember that even a 5 lb to 10 lb weight loss could significantly reduce your risk of heart disease.
- Regular physical exercise is a great way to help lose weight and improve your heart health. Make sure you talk with your doctor before starting an exercise program.
- Steps you can take to reduce high blood pressure include limiting sodium (salt) intake, monitoring your blood pressure regularly, and engaging in physical activity. You should always contact your doctor for advice.
- Successful control of blood sugar through diet, exercise, and for some, medications, is key to managing diabetes.
- To reduce elevated cholesterol levels, eat foods that are low in saturated fats and cholesterol, exercise regularly, and maintain a healthy weight.

Set a Goal and Celebrate Your Success

By setting achievable goals for yourself, you may be surprised at the level of success you're able to reach. Do not try to become a new person overnight. Instead, select an area or two to work on and go from there.

Consider the following:

- Focus on incremental change. If you want to lose weight, establish a realistic goal and work toward it. Every pound you lose is a step in the right direction.
- Cutting out sugar completely may work for a few days or a week, but it may prove difficult to stop altogether. Consider restricting desserts to weekends only. Small changes over time increase the chance of making a permanent change.
- Get support from friends or family members. If your goal is to take more walks or join a fitness club, ask a supporter to accompany you.
- Be sure to celebrate your success. When you have achieved a goal, reward yourself.

Toward A Healthier Lifestyle

The more you know about PAD the more you will be able to take control of your therapy and your lifestyle. Do not hesitate to ask your doctor any questions you may have. Every positive step you take can bring you closer to successful management of your PAD.

Definition of Medical Terms

Angioplasty (also referred to as PTA) – A minimally invasive procedure involving a balloon dilatation catheter being passed through to the blocked area of an artery. Once inflated, the balloon compresses the plaque against the blood vessel wall.

Anticoagulant – A medication to prevent or slow the clotting of blood.

Atherosclerosis – A disease that causes narrowing or blockage of arteries caused by a buildup of fat (cholesterol) within the artery wall. This buildup is sometimes referred to as "plaque."

Beta-blockers – A medication that slows the heart rate and lowers blood pressure.

Calcium channel blockers – A medication that slows heart rate, lowers blood pressure, helps widen coronary arteries, and reduces angina.

Catheterization laboratory (cath lab) – A sterile X-ray theater in which catheterization is performed.

Catheter – A thin, hollow, flexible tube used to access the arteries in the leg during an angiogram or during an angioplasty procedure. The catheter can be used to inject medication, fluids, or X-ray dye during your procedure. The word catheter is also used to describe the device used to deliver the balloon or scaffold during an angioplasty procedure.

Drug-eluting Resorbable Scaffold (DRS) – A new treatment option for PAD that has the ability to deliver drug with a scaffold that ultimately leaves nothing behind[2] in the artery.

Peripheral arterial disease (PAD) happens when there is a narrowing of the blood vessels outside of your heart restricting blood flow to the muscles. This can occur in many areas of the body but commonly occurs in the blood vessels of the arms and legs.

Local anesthetic – A substance used to numb the area to which it is applied.

Plaque – Made up of fatty deposits (cholesterol), white blood cells, calcium, and other substances.

Statin – A medication that lowers cholesterol, which may reduce the risk of heart attack.

Thrombus – A blood clot within the vascular system.

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[2] Four platinum radiopaque markers are located in the Esprit™ BTK Scaffold and will stay in your artery after the scaffold itself has been fully absorbed.

Definition of Symbols used in Patient Labeling

Symbol	Definition
	Manufacturer
	MR Conditional
	Rapid exchange
	Unique device identifier
	Catalogue number
	Batch code

Notes

Abbott Medical
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CUSTOMER SERVICE
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This product is intended for use by or under the direction of a physician. It is important to read thoroughly the instructions for use, warnings, and potential complications associated with the use of this device.

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