



Patient Resource Guide



Sponsor: TriReme Medical, LLC.
**Device: Chocolate Touch Paclitaxel Coated
Balloon Catheter
(Chocolate Touch)**

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**“Caution: Federal law restricts this device
to sale by or on the order of a physician”.**

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What is Peripheral Arterial Disease (PAD)?

PAD is caused by the blockage or narrowing of arteries in the limbs. It can result from the build-up of fat, cholesterol, collagen or calcium deposits called plaque in a process known as atherosclerosis. This plaque buildup results in vessel narrowing and over time can build to a total blockage of the artery. Plaque buildup will prevent proper blood flow and oxygen supply to the limbs which may cause pain to the extremities, especially during movement. Indicators of PAD can include pain or burning sensations in your leg or foot, numbness or weakness, a cold feeling, change of color, or even wounds that tend not to heal in your lower leg or foot. If PAD is suspected, your doctor can recommend tests to help diagnose the condition. If PAD is left untreated it could lead to total loss of blood flow to the legs and feet and can cause gangrene or loss of a limb.

Risk factors for PAD include age, smoking, diabetes, poor diet, genetics, high blood pressure, high LDL (“bad”) cholesterol and low HDL (“good”) cholesterol, and an inactive lifestyle.

Peripheral artery disease signs and symptoms:

The most common symptom of Peripheral Artery Disease (PAD) is a painful cramping in the hips, thighs or calves when walking, climbing stairs or exercising.

Other potential PAD symptoms include:

- Leg pain
- Wounds on the foot or toe that will not heal
- Gangrene
- Noticeable decrease in temperature of your leg or foot

Diagnosing PAD

A physical exam

Your physician will check for weak pulses in the legs. Checking for weak pulses is usually performed by checking the pulse at your hips, knees and feet.

An Ankle-Brachial Index (ABI) test

The Ankle-Brachial Index (ABI) test measures the ratio of blood pressure in the ankle compared to the blood pressure in the arms. Compared to the arm, lower blood pressure in the ankle is a symptom of blocked arteries (peripheral vascular disease). Sometimes PAD can be present even if the ABI is relatively normal.

A non-invasive Doppler Ultrasound test

The test involves a non-invasive method that visualizes the artery with sound waves and measures the blood flow in an artery to indicate the presence of a blockage.

Angiography

Using a dye injected into your blood vessels, this test allows your doctor to view blood flow through your arteries as it happens. Your doctor can trace the flow of the dye using imaging techniques, such as X-rays (fluoroscopy), magnetic resonance angiography (MRA) or computerized tomography angiography (CTA). Catheter angiography is an invasive procedure that involves guiding a small hollow tube (catheter) through an artery near your groin or wrist to the affected area and injecting the dye. This type of angiography allows your doctor to treat a blocked blood vessel at the time of diagnosis. After finding the narrowed area of a blood vessel, your doctor can then

widen it by inserting and expanding a tiny balloon or by administering medication that improves blood flow.

Blood Tests

A sample of your blood can be used to measure your cholesterol and glycerides and to check for diabetes.

Management and Treatment of PAD

Your doctor may offer a number of options to treat PAD, depending on the severity of your case. These may include a change of lifestyle, medications, and/or a medical procedure. Medical procedures may include minimally invasive or surgical procedures. A patient should fully discuss these alternatives with their clinical team to select the method that best meets expectations and lifestyle.

Lifestyle Changes

Doctors may prescribe lifestyle changes to relieve mild symptoms of PAD, such as:

- Quitting smoking
- Controlling your diabetes
- Exercising
- Watching your cholesterol
- Keeping your blood pressure under control

Medications

When lifestyle changes are not enough but symptoms remain mild to medium, your doctor may prescribe medications to help lower cholesterol, manage blood sugar levels, or prevent clots with antiplatelet or anticoagulant therapies.

Minimally Invasive Treatment

Serving to restore blood flow to the lower legs and feet to relieve medium to severe symptoms, doctors may employ minimally invasive procedures such as balloon angioplasty, endovascular stenting or a plaque modification technique known as directional atherectomy.

- Angioplasty is a procedure defined by balloon catheter insertion into an artery which is then directed to the narrowed segment. The balloon catheter is then inflated to expand the artery and reduce the blockage. The balloon can either be uncoated or coated with a drug.
- Stenting, which can be combined with balloon angioplasty, is the implantation of a small mesh tube into the artery to keep it open over time and prevent re-narrowing of the vessel.
- Directional atherectomy is a device used in more severely calcified arteries to debulk the plaque buildup.

Surgery

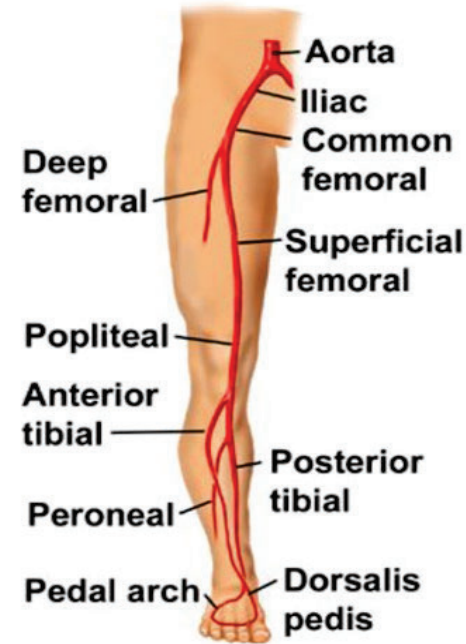
For patients with severe narrowing or full blockage of an artery, surgical bypass of the affected area may be necessary. In a bypass procedure, a healthy vessel from your leg is removed and used to redirect blood flow around the narrowed or blocked region.

Sometimes a combination of the above treatments will be recommended by your doctor, treatment protocol is dependent on your disease state, symptoms and desired outcomes.

Treatment of PAD: Drug Coated Balloons

Utilizing a drug-coated balloon to treat PAD in the superficial femoral or proximal popliteal arteries is a common and minimally invasive procedure. This procedure serves to open the narrowed artery and deliver drug therapy to the diseased vessel wall. This procedure may improve the blood flow in your legs and reduce associated symptoms such as leg and resting pain, improving your quality of life and mobility.

The superficial femoral and proximal popliteal arteries are a set of arteries in each thigh. Starting at the groin and extending to the knee, these arteries serve as the primary source of blood flow and oxygen supply to the lower legs and feet. The superficial femoral arteries, specifically, start at the groin and connect to the popliteal arteries at the knee which then connect to the smaller arteries as shown in the figure, right.

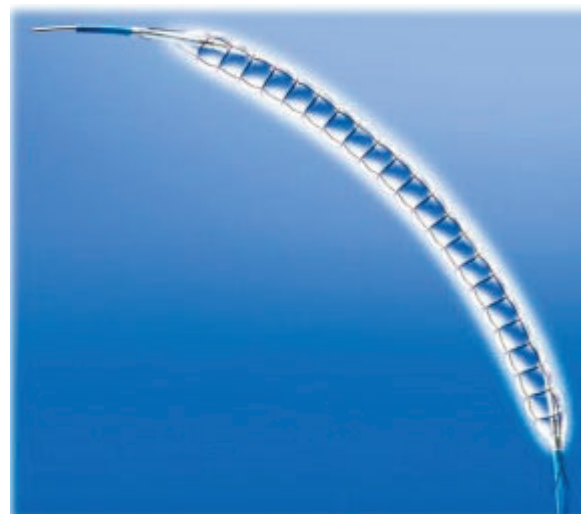


The Chocolate Touch[®] Paclitaxel-Coated PTA Balloon Catheter

TriReme Medical has developed a device for the treatment of Peripheral Arterial Disease, The Chocolate Touch Paclitaxel-Coated PTA Balloon Catheter. The Chocolate Touch is a balloon catheter with the drug paclitaxel applied to the balloon. Drug-coated balloons are inflated inside of blood vessels to treat blockages and prevent re-narrowing. The Chocolate Touch balloon is unique because it has a flexible metal constraining structure around the outside of the balloon. The flexible metal is a material called nitinol. When the balloon inflates, this constraining structure shapes the balloon to form unique pillows and grooves.



The Chocolate Touch Balloon Catheter is inserted via an upper leg access site and directed to the site of interest. It is then that the Chocolate Touch balloon is inflated to expand the narrowed artery. When the balloon is inflated, its full diameter will contact the vessel wall, therefore the paclitaxel coating is applied directly, treating this affected region. Paclitaxel is intended to aid in the healing of the diseased vessel and to prevent re-narrowing, promoting healthy blood flow long after the procedure is complete. After the procedure is complete, the balloon is deflated and the catheter (with attached balloon and containing structure) is removed. No part of the device is left behind in your artery.



Indications for Use

The Chocolate Touch® (Paclitaxel Coated PTA Balloon Catheter) is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation of de novo or restenotic lesions up to 180 mm in length in native femoral or popliteal arteries with reference vessel diameters of 4.0 mm to 6.0 mm.”

Contraindications

The Chocolate Touch® (Paclitaxel Coated PTA Balloon Catheter) is contraindicated for use in the following anatomy and patient types:

- Use in the coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Lesion is unable to be crossed with a guidewire.
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients with known allergies or sensitivities to paclitaxel
- Pregnant or breast-feeding women or women who are intending to become pregnant, or men intending to father children.

Risks and Benefits

Potential Risks or Discomforts

There is a chance that complications can occur, including but not limited to those listed below. Ask your doctor to discuss the risk of these complications, as some are extremely rare. Potential risks associated with use of the Chocolate Touch Balloon include but are not limited to:

- Access-site complications
- Allergic reaction to medication, paclitaxel, contrast medium or nitinol
- Amputation
- Aneurysm
- Arterial dissection or perforation
- Arterial rupture
- Arterial spasm
- Arterio-venous fistula
- Bleeding Complications
- Cardiac arrest
- Cardiac arrhythmia
- Death
- Device malfunction or failure
- Emboli (air, tissue, thrombi, material from device(s) used in the procedure)
- Emergency or non-emergency arterial bypass surgery
- Extravasation of contrast media
- Fracture of the guide wire or any component of the device that may or may not lead to device embolism, serious injury or surgical intervention
- Gastrointestinal bleed
- Hemorrhage or hematoma
- Hypotension
- Infection, local or systemic
- Inflammation
- Myocardial infarction or coronary ischemia
- Neurological deficit
- Pain or tenderness
- Peripheral limb ischemia
- Placement of a bail-out stent
- Pseudo-aneurysm
- Radiation exposure
- Reaction to contrast media / medication
- Renal insufficiency or failure
- Respiratory distress or failure
- Restenosis of treated artery or segment

- Sepsis or systemic infection
- Stroke or TIA
- Surgical repair of vascular access site
- Thrombosis
- Transfusion
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair (conversion to open surgery)
- Worsening of peripheral arterial disease

Potential complications of balloon catheterization include, but are not limited to, the following:

- Balloon rupture
- Detachment of a component of the balloon and/or catheter system
- Failure of the balloon to perform as intended
- Failure to cross the lesion.

Potential complications which may be associated with the use of paclitaxel include, but are not limited to:

- Allergic/immunological reaction to paclitaxel
- Alopecia
- Anemia
- Gastrointestinal symptoms (diarrhea, nausea, pain, vomiting)
- Hematologic changes in vessel wall including inflammation, cellular damage, or necrosis
- Myalgia/Arthralgia
- Myelosuppression
- Peripheral neuropath

The type of material and the drug used for the Chocolate Touch Balloon Catheter are also used in other balloon catheters. The risk of reaction to these materials is thought to be minimal. Your doctor will expand on the risks of angioplasty as well as the benefits with you.

Product Comparison

Currently available balloon catheters, including other paclitaxel coated balloons, are designed with a balloon that inflates as a single structure. The Chocolate Touch Balloon is designed to open in small sections using pillow-like structures that are formed by the metal structure shaping the balloon.

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 this increased risk of death associated with paclitaxel-coated devices that are approved in the U.S. 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.

The Chocolate Touch[®] Procedure

Preoperative Instructions

You will have the same tests that you would have if you were treated with any device used to treat peripheral vascular disease, including a physical exam and routine blood tests. Your doctor may also ask you to take a blood thinning medicine called clopidogrel (or a similar medication), along with aspirin, and/or other medications before your procedure.

During the Procedure

The procedure will be conducted through an incision in your upper leg or forearm area. The doctor will use this incision to move devices through your blood vessels to find the area that is blocked. As a part of the procedure, dye will be injected into the arteries, and a picture taken, so that your doctor can see the narrowing clearly. There will also be images taken of the blood flow in your vessels, this process is called angiography. Once the angiography is complete, the doctor will review this information to decide how to treat the narrowing. This occurs as a part of the normal standard of care for your condition. After the angiography, if your disease is appropriate for a drug-coated balloon, your doctor will insert a wire which will be used to guide the balloon to the appropriate location. First, a small non-drug coated balloon will be inflated at least one time to make a path for the drug-coated balloon, this is called pre-dilatation. Once the pre-dilatation is complete, you will be treated with the Chocolate Touch™ balloon. The Chocolate Touch balloon is placed inside the narrowed part of the vessel. It is then inflated to clear any blockage and pushes against the wall of the artery; this is called angioplasty. More than one balloon can be used if your doctor thinks this is necessary to best treat your blockage. After inflation of the drug-coated balloon it is deflated and removed, no part of the device is left behind, although, some drug will remain in your blood vessel. You may feel some pressure or discomfort in your leg when a balloon is inflated. The discomfort will usually go away when the balloon is deflated. You may be given

some pain relief medication to help if you are uncomfortable. This process, and the associated pressure and pain, should be the same with the any angioplasty balloon used on your leg.

Postoperative Care

Once the procedure is completed you will be monitored in the hospital until you are ready to go home. After the procedure, your doctor will order medications to thin your blood to help reduce the risk of blood clots forming in the arteries. Aspirin may be prescribed by your doctor.

The Chocolate Touch[®] Clinical Data Summary

The Chocolate Touch Study was a prospective, randomized, multi-center, single-blind study comparing Chocolate Touch to the Lutonix 035 Drug Coated PTA Catheter, (BD, Franklin Lakes, BARD Peripheral Vascular, Inc) for treatment of femoropopliteal arteries in a single limb. TriReme Medical performed a clinical study with 34 sites in varying locations in the USA, Germany, Austria, and New Zealand under IDE # G160085. Patients were treated between July 26, 2017, and May 26, 2020.

The study included 333 patients, randomized 1:1 to the Chocolate Touch DCB (n=152) or the control DCB device (n=161). After one year, it was determined that the outcome of the clinical study was successful in treating Peripheral Artery Disease, (PAD). The results of this study showed that the Chocolate Touch Drug Coated Balloon is safe and effective for treating superficial femoral or popliteal artery stenosis. Follow-up to 5 years is ongoing. Your doctor can explain the risks and benefits that are specific to you.

Glossary

Angioplasty: A minimally invasive medical procedure to treat blood vessels that have narrowed.

Angioplasty is used to open up the blood vessels and restore blood flow.

Artery: A blood vessel that delivers oxygenated blood from the heart and lungs to the rest of the body.

Catheter: A thin tube that is inserted through a small opening in the body.

Diabetes: A chronic health condition where the body is unable to produce insulin and properly break down sugar (glucose) in the blood. Symptoms may include hunger, thirst, excessive urination, dehydration and weight loss.

Drug-Coated Balloon (DCB): A drug-coated angioplasty balloon that delivers paclitaxel to the artery.

Paclitaxel: A drug that inhibits cell growth. It prevents cellular division and replication.

Peripheral arterial disease (PAD): The narrowing of blood vessels caused by plaque along the inner lining of the artery wall.

Plaque: Waxy substance made of fats and cholesterol that can build up on the inner lining of your arteries.

Sedentary: Spending a lot of time sitting, inactive.

Stent: A small, metal mesh tube that acts as a scaffold to keep a blood vessel open.

Vein: A blood vessel that returns blood from the rest of the body back to the heart

DOCUMENT HISTORY

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