



Understanding Peripheral Arterial Disease and the Drug-Coated Balloon Procedure

A Patient's Guide



Innovating for life.

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► THE CIRCULATORY SYSTEM

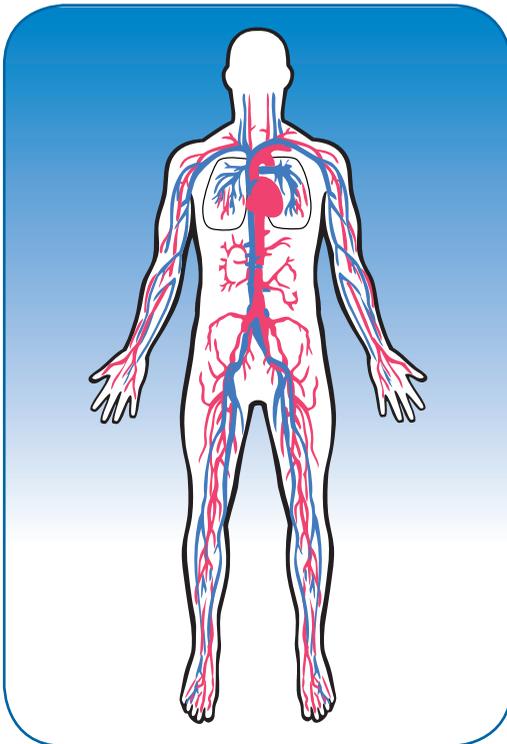
The **circulatory system** (see *Figure 1*) is a network of tube-like blood vessels that carry blood and other nutrients to and from the cells in your body.

Arteries are blood vessels that carry oxygen-rich blood from your heart to the organs and tissues throughout your body. **Veins** are blood vessels that return oxygen-poor blood from your organs and tissues to the lungs and then back to your heart.

Healthy arteries are like rubber tubes. They have smooth, flexible inner walls so that blood can flow through them easily. When arteries become diseased they are more like clogged pipes that limit or restrict the flow of blood to organs and tissues. When this happens, the arteries need to be treated so that blood flows easily again.

Peripheral vascular disease (PVD) refers to any disease of the **circulatory system** outside the brain and heart.

This brochure talks about one type of **peripheral vascular disease** called **peripheral arterial disease (PAD)**. **PAD** happens when arteries become narrowed, which reduces the blood flow to your body.



Because your arteries are the main “highway” for transporting oxygen-rich blood throughout your body, health problems can develop when blood flow is decreased or restricted.

- artery
- vein

Figure 1. **Circulatory System**

► PERIPHERAL ARTERIAL DISEASE

What Causes PAD?

Peripheral arterial disease (PAD) happens when there is a build-up of fatty material, called **plaque**, inside your arteries. Another name for this condition is **atherosclerosis**, or hardening of the arteries.

The **plaque** deposits can cause your arteries to stiffen and become narrowed or blocked, limiting the supply of oxygen-rich blood throughout your body (*see Figure 2*).

This can cause different health problems, depending on which arteries are blocked. In less severe cases of **PAD**, patients may have symptoms such as **claudication** (pain) when walking due to less oxygen-rich blood traveling to their muscles than is needed. Severe **PAD** can cause a less common condition known as **critical limb ischemia (CLI)**. Patients with **CLI** have reduced blood flow due to blockages in the arteries that leads to pain in the legs even while resting. Patients with **CLI** can also have wounds in the feet and lower legs that have trouble healing because of poor blood flow.

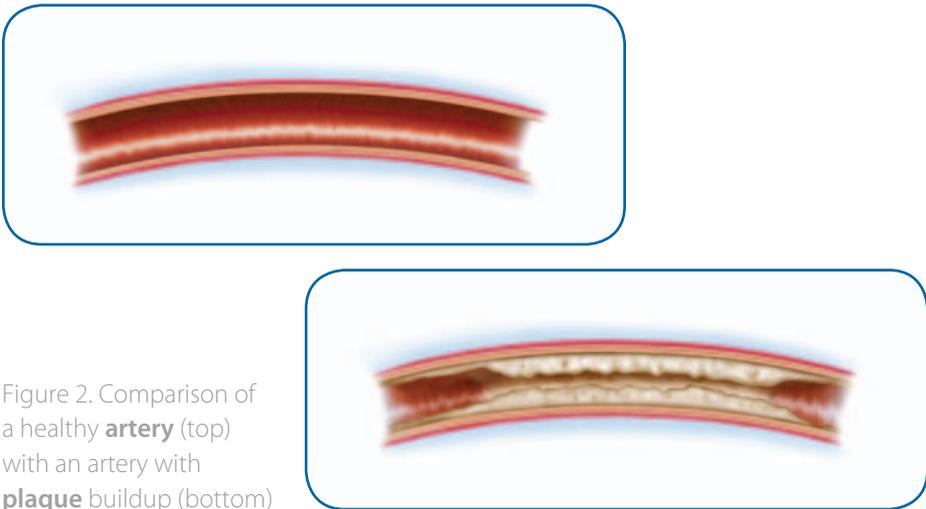


Figure 2. Comparison of a healthy **artery** (top) with an artery with **plaque** buildup (bottom)

Who is at Risk?

According to the US Department of Health and Human Services, one in every 20 Americans over the age of 50 has **PAD**.^{*} Many who suffer from the disease are never diagnosed or treated. Symptoms of **PAD** are often mistaken for general signs of aging.

While some hardening of the arteries and **plaque** build-up in the arteries is normal as you grow older, certain risk factors, including behaviors, conditions, or habits, can lead to developing **PAD** sooner. The more risk factors you have, the higher your chances of developing **PAD**.

Some of the risk factors for **PAD** are:

- > Smoking
- > High blood pressure (also called hypertension)
- > High levels of cholesterol and triglycerides in your blood
- > African-American
- > Diabetes
- > Family history of heart or vascular disease
- > Obesity (overweight)
- > Lack of exercise or physical activity
- > Stress
- > Age over 50 years old

Although you cannot control risk factors like age, gender, race, and family history, you can control or manage some risk factors to lower your risk. These include smoking, **diabetes**, high blood pressure, high cholesterol, obesity, stress, and leading an inactive lifestyle. Your doctor can advise you in making healthier choices about your diet, tobacco use, activity level, and stress management.

If you are at risk of developing **PAD**, it is important to talk with your doctor about ways to lower your risk factors. In addition to having **atherosclerosis** (hardening of the arteries), people with **PAD** are also at high risk for suffering a heart attack or stroke. For more steps you can take to help prevent or slow the process of **PAD** see - Living with **Peripheral Arterial Disease**.

What are the Symptoms of PAD?

- > Pain or tiredness in the lower extremities
- > Buttock pain

^{*} NIH Publication No. 06-5837, August 2006.

- > Burning or tingling in the feet
- > Sores or breaks in the skin of the legs and feet
- > Loss of hair on the feet or toes
- > Aching in the feet or toes when at rest
- > Changes in skin color (reddish, bluish, or pale discoloration)
- > Decrease in skin temperature
- > Impotence (inability to get or maintain an erection)

How is PAD Diagnosed?

When making a diagnosis, your doctor will review your medical and family history, risk factors and symptoms. If your doctor suspects that you have **PAD**, he or she may give you a series of tests and examinations before deciding on a treatment plan. These tests are designed to measure how well your blood is flowing through your arteries and identify areas of concern, and they may include one or more of the following:

- > **Ankle-brachial index (ABI):** Used to diagnose **PAD** in the lower extremities (legs). It compares the blood pressure measured at your ankle with the blood pressure measured at your arm. If the blood pressure measured at your ankle is much lower than the blood pressure measured at your arm, this can show that there are blockages in the vessels in your leg that slow the flow of blood to your foot. A regular blood pressure cuff and special ultrasound device are used in this test.
- > **Exercise stress test:** Involves walking on a treadmill for a period of time (usually about five minutes) or until you must stop walking because of tiredness or discomfort in your legs. These symptoms can show that reduced blood flow is reaching your muscles and may mean that there are blockages in your vessels.
- > **Ultrasound:** Uses high-frequency sound waves to create an image that can help your doctor evaluate blood flow and narrowing or blockages in your blood vessels.
- > **Magnetic resonance imaging (MRI):** Uses magnetic fields and radio waves to create an image that shows blockages inside your arteries.
- > **Angiography:** Uses an imaging technique called fluoroscopy, which uses X-ray technology and a fluid called contrast dye to “film” the blood flow in your arteries. These images can show the exact location of any narrowing in the blood vessel. This test is done in a **catheterization** laboratory, or “cath” lab.
- > **Computed tomography (CT):** Uses specialized X-ray scans to make detailed pictures of your arteries to detect blockages.

► TREATMENT OPTIONS FOR PAD

PAD can be managed in several ways. Your doctor will recommend a treatment plan for you based on your symptoms, test results, medical history, and future potential risks. This plan may include lifestyle changes and medications to relieve your pain and symptoms, and interventional procedures to increase blood flow through your arteries.

Lifestyle Changes

PAD is common among smokers, people with **diabetes**, and people who are overweight or obese. Changes in lifestyle are one of the first things you can do to manage your **PAD**. If you are a smoker, it is important to quit. You should talk to your doctor if you would like support to make a plan to quit smoking. If you have **diabetes**, take steps to lower your blood sugar. It is critical for those with **diabetes** and **PAD** to monitor and protect their feet from injury. If you are overweight or obese, talk to your doctor about starting a low-fat, low-cholesterol diet and also exercising as ways to achieve a healthy weight and to lower your blood pressure.

Benefits to lifestyle change to help control **PAD** include:

Benefits:

- > May help to slow the progression of **PAD** and decrease the likelihood of a heart attack or stroke.
- > May be able to avoid surgery or other procedures that involve additional health risks and can be costly.

Lifestyle changes alone may not improve the condition of your arteries; you may need more treatment.

Medications

Along with recommending lifestyle changes, your doctor may prescribe medications (pills) to slow the progress of the disease or to ease some symptoms. Some medications may be used to help control cholesterol, blood sugar, or blood pressure, while others may help prevent clots from forming within narrowed blood vessels. Sometimes, medication alone does not clear blocked arteries, and you may need more treatment.

Benefits and risks to medications to help control **PAD** include:

Benefits:

- > May be able to avoid surgery or other procedures that involve additional health risks and can be costly.

Risks:

- > Some medications cause side effects you may not be able to manage, along with other health-related risks.
- > Medication alone may not clear your arteries; you may need more treatment.

Endovascular Procedures:

An **endovascular procedure** is a non-surgical procedure performed inside your **artery** using a thin, long tube called a **catheter**. Examples of different types of **endovascular procedures** are listed below:

Balloon Angioplasty

Balloon **angioplasty** is a non-surgical procedure done in the **catheterization** laboratory. The doctor injects a special dye through a small, thin tube called a **catheter** into the patient's bloodstream. The dye allows the doctor to view the arteries on an X-ray monitor. A device with a small balloon on its tip is then inserted through an **artery** in the leg and threaded through the arteries until it reaches the narrowed area. The balloon is inflated to flatten the **plaque** against the wall of the **artery**, opening the **artery** and restoring blood flow. The balloon is deflated and removed from the patient's body.

Benefits and risks to balloon **angioplasty** are:

Benefits:

- > The narrowing in the **artery** may be reduced resulting in improved blood flow
- > The patient is awake for the procedure (local anesthesia)
- > The hospital stay is usually brief
- > Patients may be able to return to normal activities quickly
- > Major complications are uncommon

Risks:

- > The insertion site may bleed or become infected
- > The balloon could tear the **artery** wall (**Artery Dissection**)
- > The balloon could puncture the **artery** (**Artery Perforation**)
- > The **artery** may become blocked again (**Restenosis**)

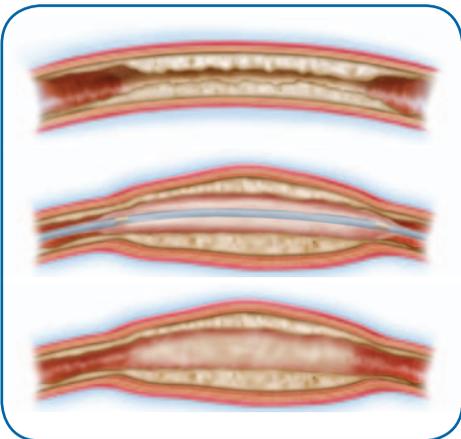


Figure 3. In balloon **angiography**, a special balloon is temporarily inserted into an **artery** narrowed by **plaque** buildup and inflated slightly to flatten the **plaque** against the **artery** wall, opening the **artery** and restoring blood flow.

Stent Therapy

Your doctor may recommend placing a **stent** to reopen your blocked **artery**. A **stent** is a small, expandable, metal, mesh-like tube that supports the **artery** and helps to keep it open.

Implanting a **stent** does not require open surgery. The doctor inserts a **catheter** into an **artery** in the leg, similar to the balloon **angiography** procedure. A specially designed **catheter** delivers the **stent** to the narrow area in the **artery**. The **stent** is expanded, flattening the **plaque** against the **artery** wall and holding the **artery** open with a mesh-like tube. The **catheter** used to deliver the **stent** is then removed, but the **stent** stays in the **artery** permanently to maintain healthy blood flow.

Benefits and risks of **Stent** Therapy include:

Benefits:

- > The **stent** keeps the **artery** open improving blood flow
- > The patient is awake for the procedure (local anesthesia)
- > The hospital stay is usually brief
- > Patients may be able to return to normal activities quickly
- > Major complications are uncommon

Risks:

- > The insertion site may bleed or become infected
- > The **stent** can clog up (occlude) causing reduced and/or no blood flow to the area
- > The **stent** delivery system could tear the **artery** wall (**Artery Dissection**)
- > The **stent** delivery system could puncture the **artery** (**Artery Perforation**)
- > The **artery** may become blocked again
- > The **stent** can break or fracture

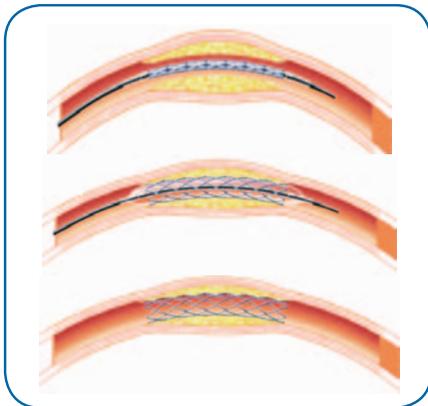


Figure 4. A **stent** is a tiny, expandable, metal, mesh-like tube that helps support the **artery**, increasing blood flow.

Open Surgery

There are several types of surgery that may also be used to treat **PAD**. Two of the most common types of surgery are **endarterectomy** and **bypass**.

Endarterectomy

An **endarterectomy** is a procedure that removes **plaque** directly from the inside of the **artery** wall. This treatment is for patients with serious **PAD**.

During this procedure, the doctor makes a small incision (cut) along the blocked or narrowed **artery** and physically removes the **plaque**. In some cases, the blocked portion of the blood vessel is also removed. After the **plaque** has been removed, the **artery** is closed with stitches or by a patch made from the patient's own **vein** or synthetic (man-made) material. Blood flow is then restored through the **artery** and the outer incision is closed. Patients usually stay in the hospital for one to two days and then continue their recovery at home.

Benefits and risks of **endarterectomy** include:

Benefits:

- > Effective at restoring blood flow and relieving **PAD** symptoms
- > Improved blood flow usually lasts many years

Risks:

- > Pain around incision site
- > Requires conscious sedation or general anesthesia, (you are not conscious during surgery) which increases health risks
- > Patients may experience temporary skin numbness and swelling around the incision site
- > Infection
- > **Arterial thrombosis**
- > The **artery** may become blocked again

Bypass

Your doctor may choose to do a **bypass** in more serious cases of **PAD** where blockages are very long or very hard (calcified). This procedure uses a graft (either a healthy blood vessel from another part of the body, or a synthetic tube) to reroute the blood flow around a blocked **artery** and create a new, permanent pathway for blood to flow.

The procedure is done in a hospital under general anesthesia. The doctor makes a small opening near the blockage in the diseased **artery**. The graft is then attached (grafted) above and below the blockage, creating a new passageway for blood to flow (**bypass**) around the blocked **artery**. During the procedure, the doctor may do an **angiography** or ultrasound to check the **bypass** for any problems and to make sure it is working properly. Patients typically stay in the hospital for several days and then continue their recovery at home for two to three months.

Benefits and risks of **bypass** include:

Benefits:

- > Effective at restoring blood flow and relieving **PAD** symptoms
- > Improved blood flow usually lasts many years

Risks:

- > Requires general anesthesia (you are not conscious during surgery), which increases health risks.
- > The affected blood vessel could be injured
- > Long recovery time
- > Infection
- > The **artery** may become blocked again (occlude)
- > The **bypass** can clog up (occlude) causing reduced and/or no blood flow to the area

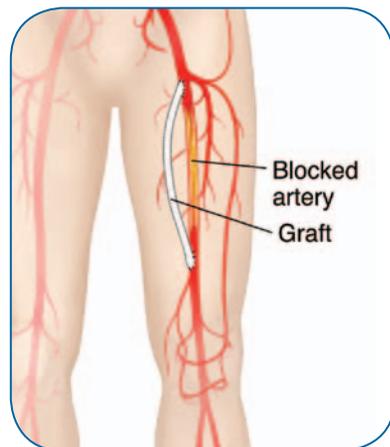


Figure 5. **Bypass** procedure

► MEDTRONIC IN.PACT™ ADMIRAL™ DRUG-COATED BALLOON (DCB)

The IN.PACT Admiral is a drug-coated **angioplasty** balloon designed for percutaneous transluminal **angioplasty** (PTA) in patients with **PAD** of the peripheral arteries. The balloon is coated with a combination of two substances:

- > **Paclitaxel:** is a drug that helps limit the growth of scar tissue. Historically, in much larger doses, it has been used to treat various types of cancer.
- > **Urea:** a natural substance that aids in the transfer of **paclitaxel** from the balloon to the **artery** wall.

The IN.PACT Admiral Drug-Coated Balloon is intended to prevent the re-narrowing of the **artery** due to **plaque** build up.

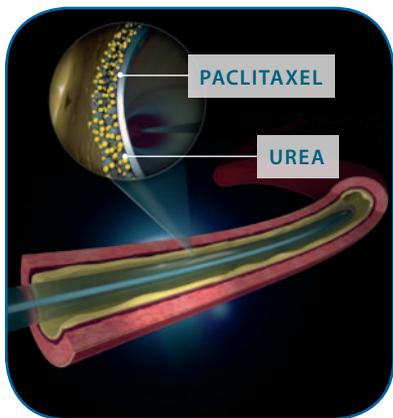


Figure 6. The IN.PACT Admiral Drug-Coated Balloon is coated with
-Paclitaxel
-Urea

Where IN.PACT Admiral is Not Recommended for Use:

Contraindications:

- > coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- > patients who cannot receive recommended anti-platelet and/or anticoagulant therapy
- > lesions that cannot be crossed with a guidewire
 - patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- > patients with known allergies or sensitivities to paclitaxel
- > women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and there is a potential for adverse reaction in nursing infants from paclitaxel exposure

► POTENTIAL ADVERSE EVENTS

Complications associated with the use of the IN.PACT Admiral Balloon **catheter** are similar to the ones associated with standard PTA procedures. Possible complications may include, but are not limited to:

- > **Abrupt vessel closure**
- > **Access site pain**
- > Allergic reaction to contrast medium, **antiplatelet medications**, or **catheter** system components
- > **Amputation/loss of limb**
- > **Arrhythmias**
- > Arterial aneurysm (balloon-like bulge in the arterial wall)
- > **Arterial thrombosis** (blood clot)
- > **Arteriovenous (AV) fistula**
- > Death
- > **Dissection**
- > **Embolism**
- > Fever
- > **Hematoma (bruise)**
- > **Hemorrhage (bleeding)**
- > **Hypotension**
- > **Hypertension**
- > Inflammation
- > Ischemia or infarction of tissue/organ (restricted blood supply/tissue death)
- > Local infection at puncture site
- > Local or distal **embolic events**
- > Perforation or rupture of the **artery**
- > **Pseudoaneurysm**
- > Renal insufficiency or failure
- > **Restenosis** of the dilated **artery**
- > **Sepsis or systemic infection**
- > **Shock**
- > **Stroke**
- > **Systemic embolization**
- > **Vessel spasms or recoil**
- > **Vessel trauma which requires surgical repair**

Although systemic effects are not anticipated, potential adverse events not captured above that may be unique to the paclitaxel drug coating include, but are not limited to:

- > Allergic/immunologic reaction
- > Alopecia (hair loss)
- > Anemia (low red blood cell count)
- > Gastrointestinal symptoms
- > Hematologic dyscrasia -including leucopenia, neutropenia, thrombocytopenia (abnormal white blood cell count)
- > Hepatic enzyme changes (liver enzymes)
- > Histologic changes in vessel wall, including inflammation, cellular damage (also known as necrosis)
- > Myalgia/arthralgia (muscular and joint pain)
- > Myelosuppression (bone marrow abnormality)
- > Peripheral neuropathy (nerve damage)

Refer to the Physician's Desk Reference for more information on the potential adverse events observed with paclitaxel. There may be other potential adverse events that are unforeseen at this time.

► WHAT TO EXPECT AFTER YOUR DCB PROCEDURE

Immediately after your procedure

- > You will be moved to a recovery area within the hospital and will be monitored for several hours or overnight.
- > The puncture site may be sore or bruised after the procedure but typically will resolve in a few days. Watch for bleeding, swelling, pain or discomfort at the puncture site. If you experience any of these, notify your physician.
- > You may be prescribed medication to take following the procedure.
- > If you feel any of the following: faintness, weakness, fever, or redness or swelling in your leg, notify your physician.

Follow-up care

- > Take medications as directed.
- > Avoid strenuous activity for at least 48 hours.
- > Follow-up with your physician as directed.

► LIVING WITH PERIPHERAL ARTERIAL DISEASE

Although **PAD** can be treated effectively, it has no permanent cure. Along with learning more about living with **PAD**, you can help to prevent or slow the disease by making some healthy lifestyle changes.

Consider maintaining a healthy lifestyle by regularly exercising, maintaining a healthy diet and avoiding tobacco use.

Ask your doctor how you can learn to:

- > Stop smoking
- > Control diabetes
- > Maintain a healthy weight
- > Manage stress
- > Manage your blood pressure
- > Control high cholesterol
- > Exercise
- > Eat healthy food

► GLOSSARY

Abrupt vessel closure: Blockage of a blood vessel that greatly limits the flow of blood to areas of the body.

Access site pain: The physical feeling of hurt at the area where the catheter had entered the body

Amputation/loss of limb: The surgical removal of part of the body

Angioplasty: A procedure used to open narrow arteries using a small balloon-tipped **catheter**.

Angiography: Medical imaging technique used to visualize the inside of blood vessels and organs of the body, particularly the arteries, **veins**, and heart chambers.

Ankle-brachial index (ABI): Compares the blood pressure measured at your ankle with the blood pressure measured at your arm.

Antiplatelet medications: Drugs that inhibit the function of platelets, the blood cells that clump together to begin the process of blood clot formation. Examples include Plavix, also known as clopidogrel, Ticlid, also known as ticlopidine and Effient, also known as prasugrel.

Arrhythmias: Irregular or abnormal heart beat rhythm

Artery: A blood vessel that carries blood away from the heart to the rest of the body.

Artery perforation: Vessel damage that ranges from a small puncture in the vessel wall, to vessel rupture.

Arterial thrombosis: A blood clot that develops in an **artery** that can obstruct the flow of blood

Arteriovenous (AV) fistula: Is an abnormal connection or passageway between an **artery** and a **vein**

Atherosclerosis: A disease process involving the buildup of a waxy substance called **plaque** on the inside of the arteries.

Bypass: A surgical operation that uses either a synthetic tube or a blood vessel taken from another part of the body to redirect blood around a narrowed or blocked **artery** to restore blood flow.

Calcifications: Hardened deposits that form on the inside of a blood vessel.

Catheterization: Procedure in which a thin, hollow tube (**catheter**) is inserted into an **artery** to allow the physician to see the blood vessels and diagnose and treat **PAD**.

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

Circulatory system: A network of tube-like blood vessels that carry blood and other nutrients to and from the cells in your body.

► GLOSSARY

Claudication: Impairment in walking or pain, and/or tiredness in the legs that occurs during walking.

Computed tomography (x-ray CT): Used to visualize the arterial and venous vessels through the body.

Critical Limb Ischemia (CLI): Severe form of **peripheral arterial disease** caused by reduced blood flow to the legs and feet.

Dissection: A tear or damage to the inner wall or lining of an **artery**.

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 balloon catheter** that delivers **paclitaxel** to the arterial wall.

Embolic events: Also known as an embolism, is a block to the blood vessel due to a blood clot or other foreign matter that gets stuck while traveling in the blood stream.

Embolism: The sudden obstruction of an artery by a clot or any foreign material formed or introduced elsewhere in the circulatory system and carried to the site of blockage by the bloodstream (Embolization and Systemic Embolization).

Endarterectomy: A surgical procedure to clean out the **plaque** in an **artery**.

Endovascular: Within or inside the blood vessels.

Endovascular procedure: A form of minimally invasive surgery designed to access many regions of the body with a **catheter** via major blood vessels.

Exercise stress test: Also called a treadmill test, helps a doctor find out how well your heart handles work.

Histologic: Microscopic changes to the tissue.

Hypotension: Blood pressure that is below normal.

Hypertension: Blood pressure that is higher than normal.

Magnetic resonance imaging (MRI): An imaging technique that uses electromagnetic radiation to take images of the body's internal organs for diagnosing certain diseases.

Paclitaxel: A drug which inhibits cell growth. It prevents cellular division and replication. Historically, in larger doses, it has been used to treat various types of cancer.

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

Peripheral vascular disease (PVD): Any disease of the **circulatory system** outside the brain and heart.

► GLOSSARY

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

Pseudoaneurysm: A collection of blood from a ruptured vessel that gives the appearance of an aneurysm; also known as a false aneurysm.

Restenosis: Re-narrowing of an **artery** at the site of a previously treated blockage.

Sepsis or systemic infection: Presence of bacteria, other infectious organisms, or toxins created by infectious organisms in the bloodstream that spread through the body.

Shock: Life-threatening condition when the body is not getting enough blood flow.

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

Stroke: When blood flow to the brain is interrupted or severely reduced depriving brain tissue of oxygen and nutrients.

Systemic embolization: When a vessel is blocked or obstructed anywhere in the circulatory system in the body.

Thrombosis: Formation of a blood clot inside a blood vessel, obstructing the flow of blood through the **circulatory system**.

Ultrasound imaging: A tool used to diagnose certain medical conditions by taking an image using high-frequency sound waves.

Urea: an organic substance found in the human body.

Vein: A blood vessel that returns blood from the body's extremities (arms and legs) and smaller **veins** to the heart.

Vessel spasms or recoil: Sudden constriction of a blood vessel.

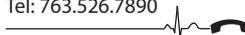
Vessel trauma which requires surgical repair: Injury to the vessel which requires surgery to repair.

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