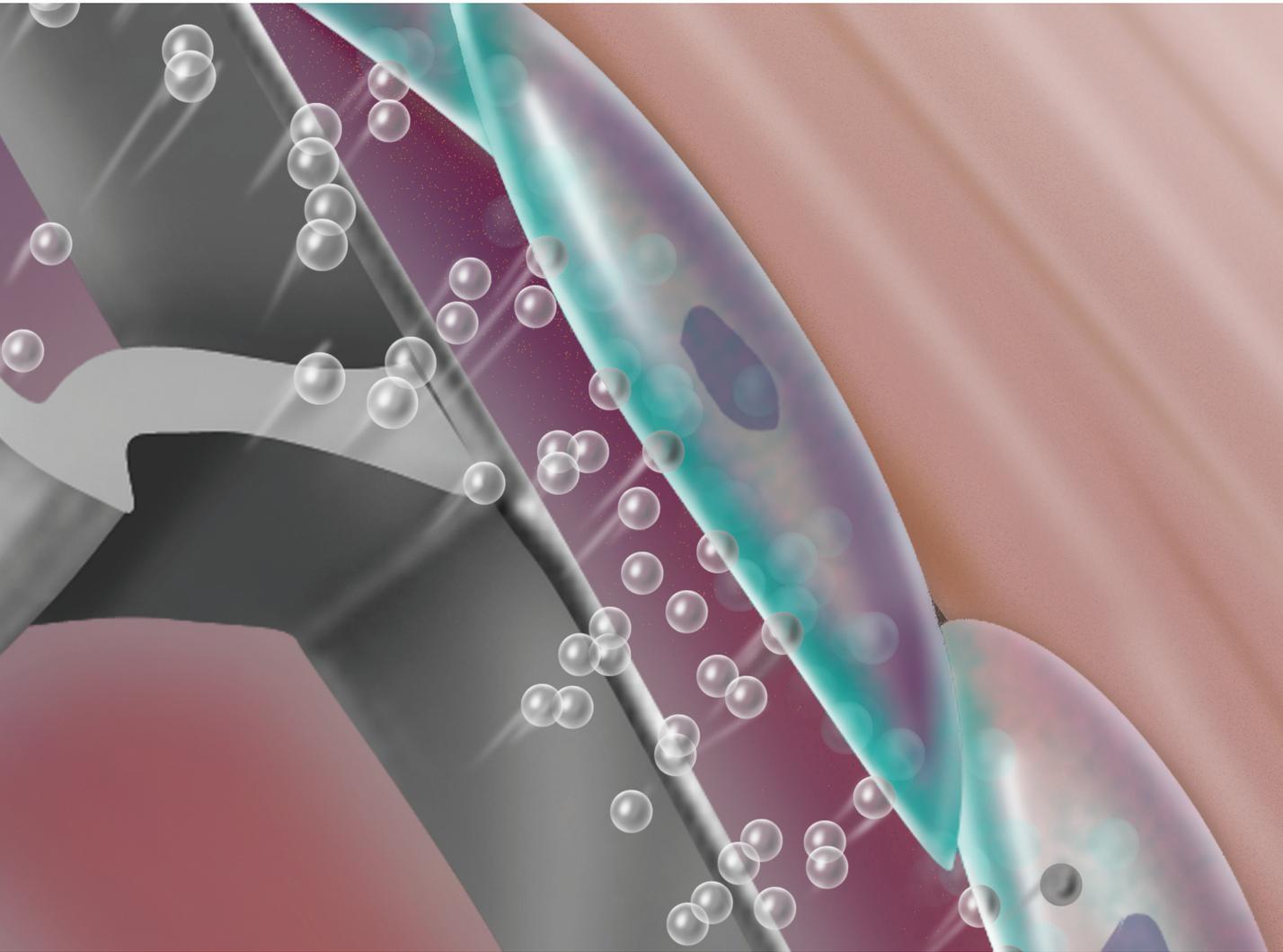




Zilver[®] PTX[®]

DRUG-ELUTING STENT



PATIENT GUIDE



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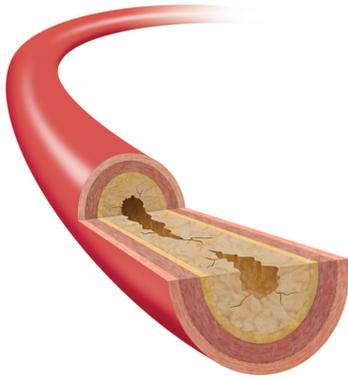
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Peripheral arterial disease

Peripheral Arterial Disease

What is peripheral arterial disease?

Peripheral arterial disease, known as PAD, affects more than 30 million people worldwide every year. This serious, under-diagnosed disease is similar to coronary artery disease in that it develops when cholesterol levels and scar tissue build up, causing the arteries to narrow and restrict blood flow. The difference is that PAD affects arteries outside the heart.

Untreated, PAD can lead to difficulty in walking and, in its most severe stage, gangrene leading to leg amputation. Also, people who have PAD often have arterial blockages in other parts of the body and are therefore at greater risk of suffering a heart attack or stroke.

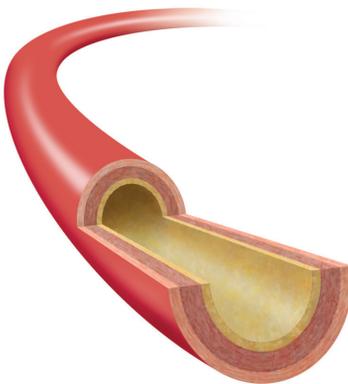
Who is at risk?

While **peripheral arterial disease** can strike anyone, it is most common in people over the age of 65. Up to 20 percent of all adults over the age 65 are affected by PAD.

The most common risk factor for PAD is smoking. According to the University of Maryland, smoking increases the risk of PAD by two to five times. The American Heart Association says that on average smokers are diagnosed with PAD 10 years earlier than nonsmokers.

Diabetes is also a leading risk factor for PAD. People with Type 2 diabetes have three to four times the normal risk of PAD. Other risk factors include:

- Obesity
- High blood pressure
- Lack of exercise
- Family history of atherosclerosis (hardening of the arteries)
- High cholesterol



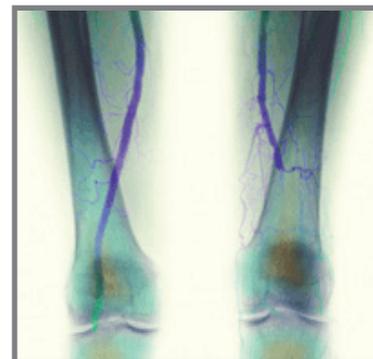
Artery during normal function

What are the symptoms of PAD?

Many people with PAD do not exhibit any warning signs. In fact, only 33 percent of those diagnosed with PAD have any symptoms at all. Those who do have severe symptoms often mistake them for signs of aging.

The most common symptom of PAD is leg pain that occurs when walking, but disappears during rest. Other symptoms include:

- Numbness or weakness in the legs
- Aching pain in the feet or toes while at rest
- Ulcers or sores in the leg or foot that don't heal
- Cold legs or feet
- Skin-color changes in the legs or feet



How is PAD diagnosed?

Unfortunately, many cases of PAD go undiagnosed because the symptoms are often mistaken for signs of aging. One way to determine whether someone could be suffering from PAD is an ankle-brachial index (ABI) test. The ABI test measures the blood pressure at the ankle and at the arm. A comparison of the two blood pressure readings can point to problems. Specifically, a blood pressure that is lower in the ankle than in the arm implies a blockage in the artery between the heart and the leg. Other tests used to diagnose PAD include ultrasound, X-ray, **angiography** and magnetic resonance imaging **angiography** (MRA).



Treatment of PAD

The first-line treatment for PAD consists of lifestyle changes, such as smoking cessation, exercise and lowering blood pressure and cholesterol. These changes can help to slow the progression of PAD and decrease the likelihood of a heart attack or stroke. Lifestyle changes are often made in combination with the use of certain drugs—such as antiplatelet therapy to inhibit blood clotting, statins to reduce cholesterol, and ACE inhibitors to lower blood pressure. In a minority of patients, however, lifestyle changes and drug therapy are not enough to prevent PAD progression. For these patients, **angioplasty**, stenting or surgery may be necessary.

Angioplasty

Angioplasty is a nonsurgical procedure that widens narrowed or blocked peripheral arteries. In an **angioplasty** procedure, a **catheter** with a deflated balloon is inserted into the narrowed segment of the artery. The balloon is inflated to open the artery; the balloon is then deflated and the **catheter** is withdrawn.

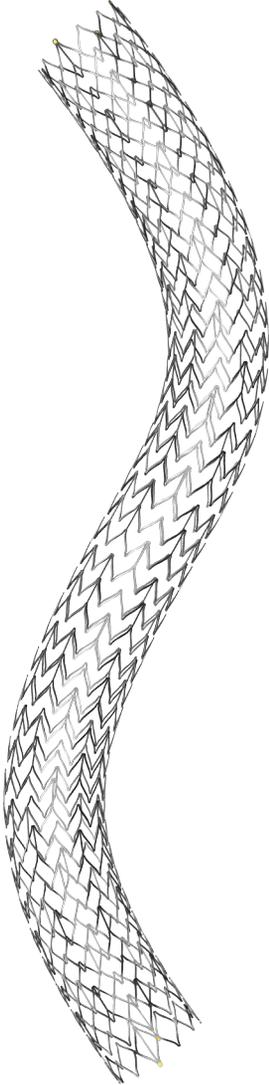
In other cases, a **stent**—a tubular metal device that acts as a scaffold—is placed in the narrowed segment of the artery. The **stent**, in an unexpanded form, is delivered via a **catheter** to the correct place. The **stent** expands and stays in place to keep the artery open after the **catheter** is withdrawn.

Restenosis

In many cases, patients who have been treated with balloon **angioplasty** and stenting experience a re-narrowing, or **restenosis**, of the artery over time. This is partly because the body tries to heal the injury to the vessel that occurs when the balloon is inserted and inflated. During the healing process, excess tissue may grow over the **stent** causing the vessel to narrow again. Statistics show that 30 to 60 percent of patients will suffer from a re-narrowing of arteries over time, making a repeat intervention necessary.

Bypass surgery

Bypass surgery is typically reserved for patients whose anatomy is not appropriate for less invasive catheter-based treatment and for whom lifestyle changes don't work. Surgery involves sewing a vein from another part of the body or an artificial blood vessel above and below the blocked area to detour blood flow around the blockage. Surgery has additional risks, however, particularly for patients who suffer from other disorders such as heart disease, high blood pressure or diabetes.



Your Zilver PTX Stent

Drug-coated stents

A **drug-coated stent** is a metal **stent** that has been coated with a medicinal substance intended to prevent re-narrowing of the artery. Clinical data demonstrate that the Zilver PTX stent is effective in preventing re-narrowing of the artery and can help patients who suffer from PAD.

The Zilver PTX paclitaxel-eluting stent

The Zilver PTX paclitaxel-eluting stent is a nitinol **stent** coated with the drug **paclitaxel**.

What is paclitaxel?

Paclitaxel is the active component of Taxol,* a drug that is used as an anti-cancer agent. **Paclitaxel** is also used on **stents** used in the heart to reduce the risk of re-narrowing of the artery. It is intended to limit the response of the blood vessel so excess tissue growth that could cause re-narrowing of the vessel does not occur.

The Zilver PTX **stent** uses a very small amount of **paclitaxel**, which is applied directly to the vessel wall.

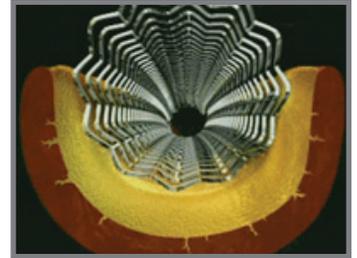
Who should not receive a Zilver PTX stent?

- Patients with blockages of their artery that will not allow the physician to properly inflate the **angioplasty** balloon or place the **stent**.
- Patients with bleeding disorders.
- Women who are pregnant, breast-feeding or plan to become pregnant in the next five years should not receive a Zilver PTX **stent**. There is the possibility that **paclitaxel** will be excreted in human milk, which could result in an adverse reaction in the nursing infant.

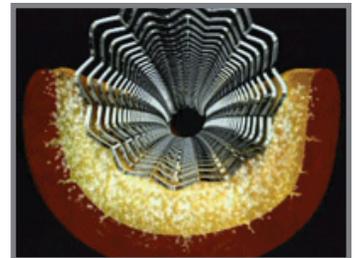
* Taxol is a registered trademark of Bristol Myers Squibb Company.

What are the potential adverse events that may be associated with a Zilver PTX stent?

- Allergic reaction to anticoagulant and/or antithrombotic therapy or contrast medium
- Allergic reaction to nitinol
- Atheroembolization (Blue Toe Syndrome)
- Arterial **aneurysm**
- Arterial rupture
- Arterial thrombosis
- **Arteriovenous fistula**
- Death
- **Embolism**
- **Hematoma**/hemorrhage
- Hypersensitivity reactions
- Infection
- Infection/abscess formation at access site
- **Ischemia** requiring intervention (bypass or amputation of toe, foot, or leg)
- **Pseudoaneurysm** formation
- Renal failure
- **Restenosis** of the stented artery
- **Stent** embolization
- Stent malapposition
- Stent migration
- Stent strut fracture
- Vessel perforation or rupture
- Worsened **claudication**/rest pain



PTX **paclitaxel**-eluting stent placed in affected vessel



The drug **paclitaxel** is intended to keep the blood vessel from re-narrowing

Potential adverse events, not described previously, may be unique to the **paclitaxel** drug coating, and include:

- Allergic/immunologic reaction to the drug coating
- **Alopecia**
- Anemia
- Blood product transfusion
- Gastrointestinal symptoms
- **Hematologic dyscrasia** (including leukopenia, neutropenia, thrombocytopenia)
- **Hepatic enzyme** changes
- Histologic changes in vessel wall, including inflammation, cellular damage or **necrosis**
- **Myalgia/Arthralgia**
- **Myelosuppression**
- Peripheral **neuropathy**

You may want to ask your physician about the potential for each of these risks in your specific situation.

The Angioplasty and Stenting Procedure

Before the procedure

Your doctor will explain how to prepare for your **angioplasty** and **stenting** procedure before you are admitted to the hospital. You may be asked to avoid eating or drinking anything after midnight on the night before the procedure. You may also be asked to take aspirin or other medication for a few days prior to the procedure to thin your blood and prevent clots from forming.

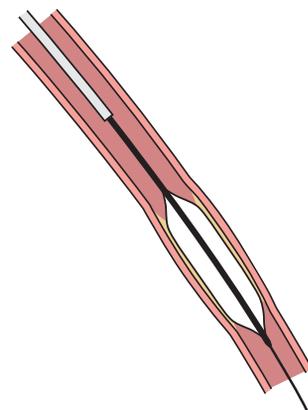
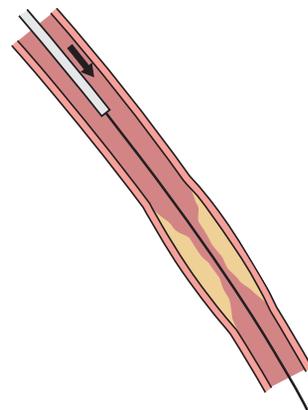
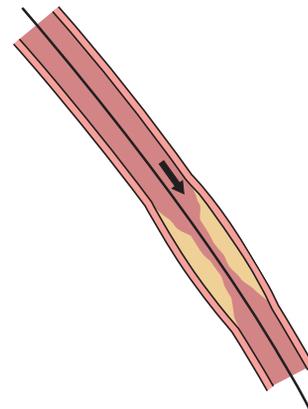
During the procedure

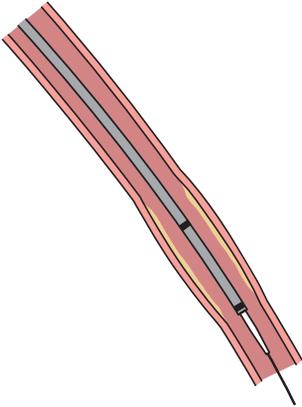
Your **angioplasty** and **stenting** procedure will take place in the hospital, in a catheterization lab. Although you may be given a sedative to help you relax, you will be awake during the procedure. This will allow you to follow your doctor's instructions to move, cough or breathe as needed.

Your doctor will be accessing your artery through your groin. The access area will first be shaved, swabbed with antiseptic and numbed with a local anesthetic. Your doctor will then make a small incision in your skin and gain access to your artery with a needle.

A wire guide will be inserted through the needle and advanced to the part of your artery that contains the blockage. The doctor will then insert an **introducer sheath** over the wire guide into your artery, and a **balloon catheter** will be advanced through the **introducer sheath** to the site of the blockage. The balloon will be inflated briefly, widening the blocked artery.

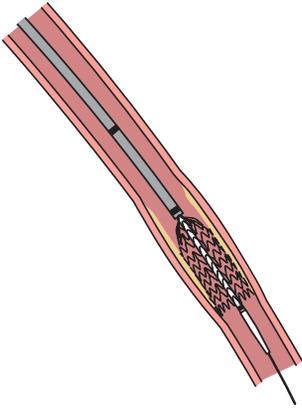
After the artery has been widened, the doctor will deflate the balloon and remove the **balloon catheter**. He or she will then advance a **delivery catheter** containing the **PTX stent** to the area of the artery where the balloon previously was. When the **stent** is positioned in the right spot, the doctor will unsheath it, allowing it to expand against the walls of your artery. The doctor will then remove the **catheter** and wire guide, leaving the **stent** in place. The **introducer sheath** may also be left in place for a few hours while you are monitored.





After the procedure

When your procedure is finished, you will be moved to a recovery area. You may feel some discomfort, which can be relieved with pain medicine. Your blood pressure and heart rate will be monitored closely. Your doctor and the standard protocol of the hospital where your procedure was performed will determine when you are allowed to go home.



Frequently Asked Questions

1. What is a stent?

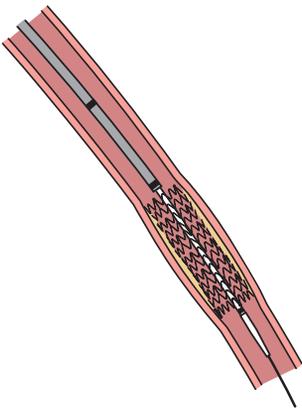
A **stent** is a metal tube used to keep the artery open. The Zilver **stent** is made of nitinol, an alloy of nickel and titanium. This blend of metals was discovered in 1965. It has super-elastic properties that help it maintain its shape, even after it is crushed many times. The **stent** is compressed into a plastic tube so that it can be passed into your artery. The **stent** is placed across the blockage, where it is released and expands to the size of your artery.

2. What is a drug-coated stent?

A **drug-coated stent** is simply a **stent** with drug on it. **Drug-coated stents** have recently become widely used for the arteries of the heart. The **drug-coated stents** used in the heart have reduced the occurrence of blockages after the **stents** are in place. Zilver PTX clinical trials confirmed that **drug-coated stents** help to keep the leg arteries from becoming blocked again.

3. What is paclitaxel?

Paclitaxel (păk'li-tăk'səl) is a natural product that was discovered in 1967. It originally came from the bark of the Pacific yew tree. **Paclitaxel** reacts with cells in several ways. One is that it keeps cells from dividing. The cells cannot divide because **paclitaxel** keeps the microtubules (which are like muscles in your cells) from pulling the cell apart to form two new cells. Too much cell division is known to happen often after your artery has been treated, sometimes causing it to become blocked again. Thus, by preventing cell division, **paclitaxel** may keep your artery from becoming blocked again.



Since cancer cells divide rapidly and since **paclitaxel** keeps cells from dividing, it is sometimes given to treat cancer (e.g., ovarian or breast cancer). The drug to treat cancer is called Taxol. Taxol includes **paclitaxel** and an oil to make the drug easy to inject. When Taxol is given to treat cancer, the dose is large and the drug goes throughout the entire body, which may cause side effects. The PTX **stent** was designed to reduce the chances of such side effects because the **paclitaxel** amount on the **stent** is small, does not contain the oil found in Taxol and is given locally from the **stent** to your artery.

4. How much paclitaxel is on the stent?

The **stent** carries only 1/1300 to 1/200 the amount of **paclitaxel** given in a single cancer treatment.

5. Where do the stent and the drug go after the doctor puts them in my body?

The doctor puts the **stent** across the blockage in the artery. The **stent** remains in that place in your artery for the rest of your life. The wall of your artery absorbs the drug from the **stent**. A small portion of the drug may get carried away by the blood flowing through your artery.

Glossary

Alopecia - Baldness; absence of hair from the skin areas where it is normally present.

Aneurysm - A sac formed by localized dilation of the wall of an artery, a vein or the heart.

Angiography - A method of taking X-rays after injection of contrast dye.

Angioplasty - A catheter-based treatment to open narrowed or blocked arterial vessels.

Arteriovenous fistula - An abnormal or artificial connection between an artery and vein.

Arthralgia - Pain in a joint.

Catheter - A hollow, flexible tube used to access parts of the body, such as arterial vessels.

Claudication - Condition marked by pain, tension and weakness of legs induced by walking, and the disappearance of all discomfort when at rest. This condition is caused by a narrowing of the arteries in the legs.

Drug-coated stent - A stent with a drug coating that is intended to prevent the vessel from re-narrowing.

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.

Hematologic Dyscrasia - An abnormal condition in the composition of blood.

Hematoma - A localized collection of extravasated blood, usually clotted, in an organ, space or tissue.

Hepatic Enzyme - A protein secreted by the liver that promotes or accelerates a chemical change in other substances.

Introducer sheath - A tube that is inserted into the body to provide access and allow delivery of other devices.

Ischemia - Lack of blood in an area of the body due to an obstruction or constriction of a blood vessel.

Myalgia - Muscular pain.

Myelosuppression - Bone marrow suppression.

Necrosis - The morphological changes indicative of cell death caused by progressive enzymatic degradation; it may affect groups of cells or part of a structure or an organ.

Neuropathy - A functional disturbance or pathological change in the peripheral nervous system; sometimes limited to noninflammatory lesions as opposed to those of neuritis.

Paclitaxel - A drug derived from the Pacific yew tree which prevents cell division.

Peripheral arterial disease - A condition that develops when cholesterol levels and scar tissue build up, causing arteries to narrow and restrict blood flow.

Pseudoaneurysm - False aneurysm; dilation or tortuosity of a vessel, giving the appearance of an aneurysm.

Restenosis - The re-narrowing of a vessel.

Stent - An expandable metal tube that is used to keep a vessel open.



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