

Patient Guide for the Zilver[®] PTX[®] Drug-Eluting Peripheral Stent



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Glossary

Angiography - A way of taking x-rays of blood vessels after a special dye is injected.

Angioplasty - A way to open narrowed or blocked arteries by using a small balloon catheter.

Antiplatelets - Blood thinners.

Atherosclerosis - Hardening of the arteries.

Balloon catheter - A balloon that is attached to, and inflated through, a hollow, flexible tube.

Catheter - A hollow, flexible tube that is used to access parts of the body, such as arteries.

Drug-eluting stent - A stent that is coated with a drug.

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

Paclitaxel - A drug made from the Pacific yew tree that prevents cell division.

Peripheral arterial disease - When fatty deposits restrict blood flow in arteries.

Restenosis - When an artery narrows again after treatment.

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

Ultrasound - A way for doctors to see inside of a body by using sound waves.



Peripheral arterial disease

What is peripheral arterial disease?

Peripheral arterial disease (PAD) happens when fatty deposits form in arteries that are outside of your heart. These fatty deposits can restrict the flow of blood. PAD often occurs in the legs. In severe cases it can lead to amputation. People who have PAD are at greater risk of suffering a heart attack or stroke. PAD is a serious condition that affects 8-12 million Americans each year.¹

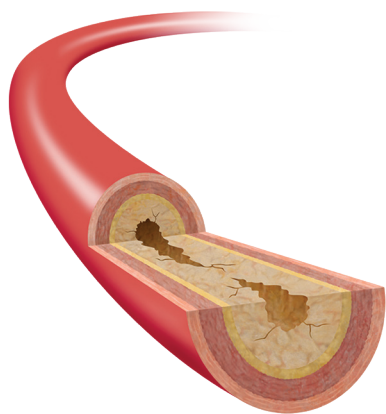
Who is at risk?

PAD can strike anyone, but it is most common in older people. PAD affects up to 20% of people over the age of 70.²

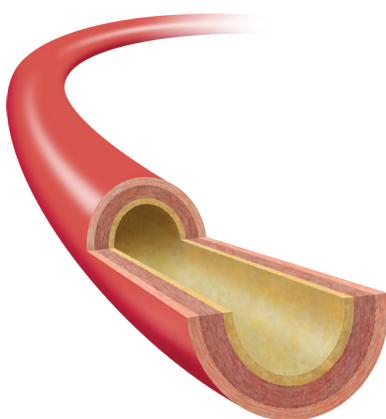
Smoking increases the risk of PAD. Heavy smokers are four times more likely than nonsmokers to develop PAD.² On average, smokers are diagnosed with PAD 10 years earlier than nonsmokers.²

Diabetes is another leading risk factor for PAD. People with type 2 diabetes are three to nearly four times as likely to develop PAD.² Other risk factors include the following:

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



This artery has a fatty deposit that can restrict or completely block the flow of blood.



This artery is healthy.

What are the symptoms of PAD?

Most people with PAD don't show any warning signs. Only one quarter to one third of people who are diagnosed with PAD have any symptoms at all.² People who do have symptoms often mistake them for signs of aging.

The most common symptom of PAD is leg pain that occurs when walking but goes away during rest. Other symptoms include the following:

- 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



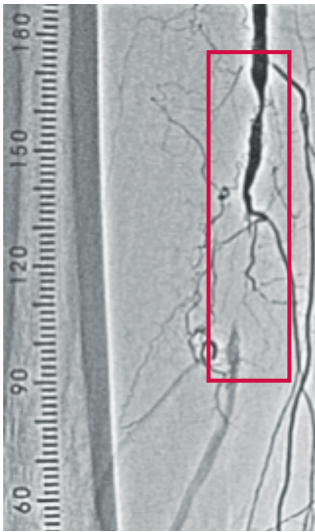
The most common symptom of PAD is leg pain while walking.



A symptom of advanced PAD is an ulcer or sore on the leg or foot that doesn't heal.

1. National Institutes of Health. Facts about peripheral arterial disease (P.A.D.). National Heart, Lung and Blood Institute Web site. http://www.nhlbi.nih.gov/health/public/heart/pad/docs/pad_extfctsht_general_508.pdf. Published August 2006. Accessed September 20, 2012.

2. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). *Eur J Vasc Endovasc Surg*. 2007;33(suppl 1):S1-S75.



This angiogram shows the largest artery in the thigh of a PAD patient. Fatty deposits are restricting the flow of blood. An angiogram of a healthy artery would show a thick, dark line from the top of the image to the bottom.

How is PAD diagnosed?

The simplest way to diagnose PAD is to measure someone's blood pressure both at the ankle and at the arm. Blood pressure that is lower in the ankle than in the arm indicates a problem in an artery between the heart and the ankle. This test is called the ankle-brachial index (ABI).

Other tests used to diagnose PAD are more complicated. One kind of test involves sound waves (**ultrasound**). In another kind of test, a doctor injects a special dye into the bloodstream and takes x-rays of blood vessels (**angiography**).

Angiograms are the pictures that doctors take during **angiography**.

The treatment of PAD

If you have PAD, your doctor will ask you to exercise more. If you are a smoker, your doctor will also ask you to stop smoking. Your doctor may also prescribe drugs to thin your blood and to lower your cholesterol and blood pressure. All of these actions can help to slow the progression of PAD. They can also decrease your chances of having a heart attack or stroke.

However, drugs and lifestyle changes don't help some PAD patients. For these patients, **angioplasty**, **stenting**, or bypass surgery may be necessary.

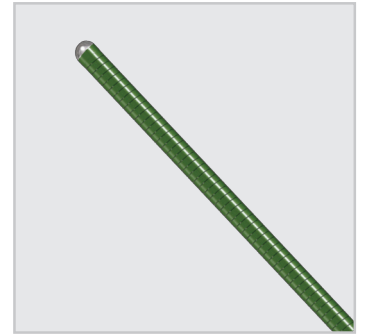
Angioplasty

A doctor can use a very small balloon to open up fatty deposits. This procedure is called **angioplasty**. The doctor uses a needle through the skin to access the artery and then inserts long, thin tools to reach the fatty deposits. The tools usually include the following:

- Wire guides
- Flexible tubes called **catheters**
- Special **catheters** that have a balloon on the tip. Some of these balloons are coated with a drug called **paclitaxel** to prevent the artery from renarrowing.

The doctor threads the deflated balloon through the fatty deposit and then inflates the balloon. After the fatty deposit is spread open, the doctor deflates and withdraws the balloon.

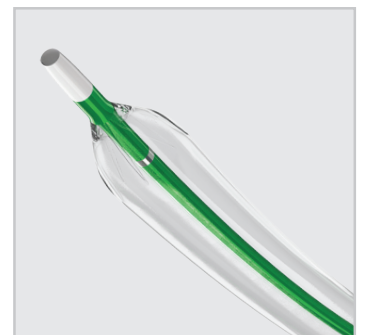
Go to www.zilverptx.com/video to see how these products work.



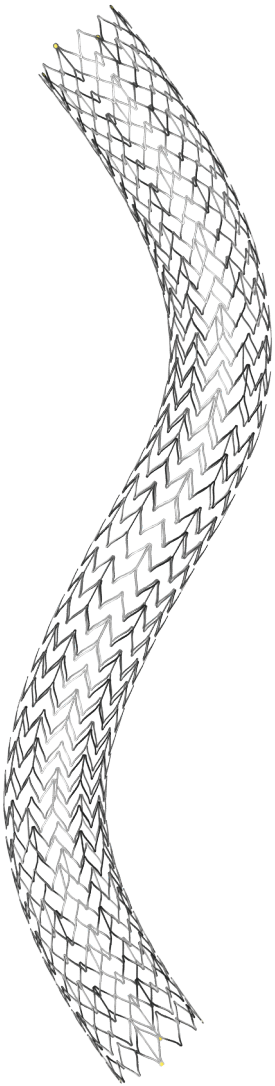
The wire guides that doctors use are complex tools.



Some **catheters** have a slippery coating so they can move through the body easier.



Small balloons are used to open fatty deposits.



Stents are flexible metal tubes that can hold open an artery.

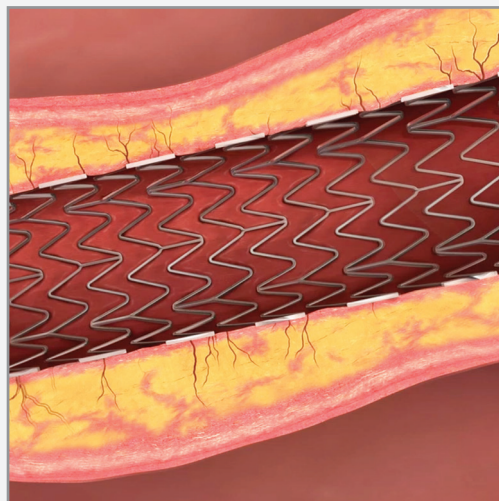
Stenting

If an artery is still too narrow after angioplasty, or your doctor thinks that the balloon treatment alone won't keep your artery open, he may use another tool called a **stent**. A **stent** is a small, metal tube that lines the inside of a fatty deposit and keeps the artery propped open. Like balloons, **stents** are delivered through blood vessels. Once a **stent** is placed, it remains there forever.

How does a stent work?

Many **stents** are made of nitinol, which is a combination of nickel and titanium. This blend of metals was discovered in 1965. Nitinol has an unusual property. It can remember its original shape, even after being squeezed or bent many times.

Nitinol **stents** are squeezed inside catheters that can reach fatty deposits. When the doctor deploys the **stent**, it expands by itself to its original shape and holds the artery open.



This image shows a **stent** inside a fatty deposit.

Bypass surgery

Angioplasty and **stenting** won't work with some patients. In these patients, doctors may do bypass surgery. Bypass surgery involves cutting open the leg and sewing a new vessel above and below the fatty deposit. The new vessel can either be artificial or a vein that is transplanted from another part of the body.

Which way is the best?

Whether treated with a balloon or with a **stent**, the arteries of some patients may narrow again. This process is called **restenosis**. **Restenosis** can happen when your body tries to heal a small injury to your artery. Excess tissue may grow over the **stent**, and another procedure may be necessary.

In comparison to **angioplasty** and **stenting**, bypass surgery may carry more risks, especially for patients who have heart disease, high blood pressure, or diabetes. Bypass surgery may also require a longer recovery time than **angioplasty** or **stent** placement. Your doctor will work with you to decide which treatment is the best for you.



Stents are available in a variety of lengths and widths. The picture above shows a common size of stent that is used in the thigh. The **stent** is about a quarter of an inch wide and about three inches long.

Go to www.zilverptx.com/video
to see a stenting animation.



This image shows the Zilver PTX drug-coated **stent**.

The Zilver PTX drug-coated stent

What is Zilver PTX?

Zilver PTX is a drug-coated (**drug-eluting**) **stent**. The **stent** is used to treat the fatty deposits that can restrict blood flow in the largest artery of the thigh. This vessel is called the superficial femoral artery, or "SFA" for short.

The Zilver PTX **stent** is made of nitinol. Nitinol is a mixture of two metals: nickel and titanium. Things that are made of nitinol return to their original shape after they are squeezed or bent.

Nitinol makes the Zilver PTX **stent** open up by itself when your doctor puts it in your artery. **Stents** like Zilver PTX that open up by themselves are called self-expanding **stents**.

Zilver PTX is the first **stent** with a drug coating that the FDA approved for use outside of the heart.

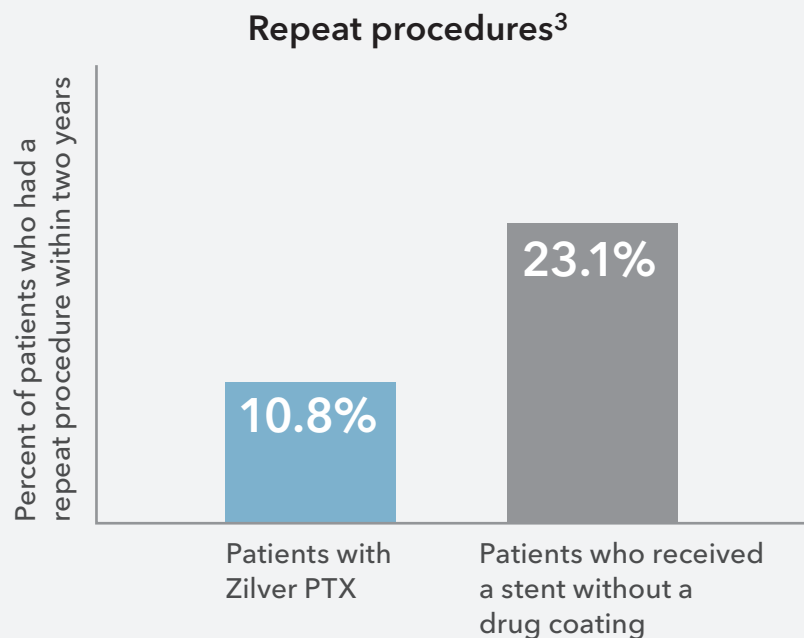
What are the benefits of Zilver PTX?

Zilver PTX holds open the SFA and delivers the paclitaxel. This drug helps stop tissue growth that could close an artery. If an artery closes again, then another procedure may be necessary.

In a clinical trial, doctors compared Zilver PTX both with balloons and with **stents** that are not coated with a drug. Zilver PTX did better than both.

This treatment is highly valued by patients because it improves their quality of life and decreases their need for repeat procedures. While this treatment can be very helpful for people suffering from PAD, it might cause problems for some patients. For more on what can go wrong, see page 18.

Compared with **stents** that are not coated with a drug, Zilver PTX reduced the number of patients who needed to have a repeat procedure by 53% at two years.³



For a list of potential risks and things that could go wrong, see page 18.

Two years after treatment, 74.8% of patients who received Zilver PTX and 26.5% of patients who were treated initially with balloons still had open arteries without additional treatment.⁴

3. Ansel G. Zilver PTX randomized trial of paclitaxel-eluting stents for femoropopliteal disease: 24-month update. Presented at: the Society for Cardiovascular Angiography and Interventions (SCAI) 2011; May 4-7, 2011; Baltimore, Maryland.

4. Ask your doctor about the Zilver PTX Instructions for Use (IFU). This document contains full prescribing information, including indications, contraindications, warnings, precautions, and clinical data.

What is paclitaxel?

Paclitaxel was discovered in 1967 in the bark of the Pacific yew tree. The drug blocks a cell's ability to divide and is often used to treat cancer. For cancer patients, the **paclitaxel** dose is large and goes throughout the body.

The Zilver PTX **stent** carries a much smaller **paclitaxel** dose that is applied directly to the artery wall. Your blood may wash away a small amount of the drug.

How does paclitaxel work?

The **paclitaxel** on Zilver PTX starts to go into your artery wall as soon as your doctor places the **stent**.

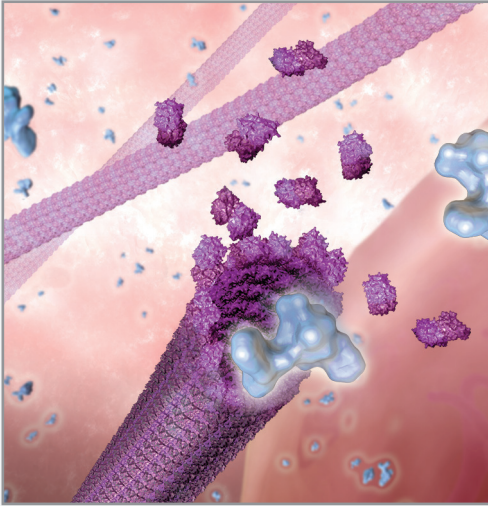
Once inside a cell, **paclitaxel** blocks parts of cells that are involved in cell division. When the cells can't divide, the excess growth that can close your artery again is prevented.

Over time, a kind of cell growth that is good takes place. The inner lining of the artery grows over the **stent** and reduces the risk of blood-clot formation.

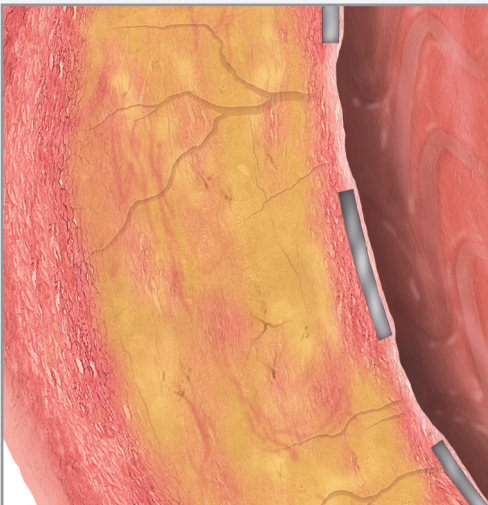
Who should not get a Zilver PTX stent?

The following people should not get Zilver PTX:

- Women who are pregnant, are breast-feeding, or plan to become pregnant in the next five years. It is unknown if **paclitaxel** can get into a mother's milk. If it does, it could hurt a nursing baby.
- Patients who cannot take blood thinners (**antiplatelet** drugs).
- Patients in whom **stents** cannot be properly placed.



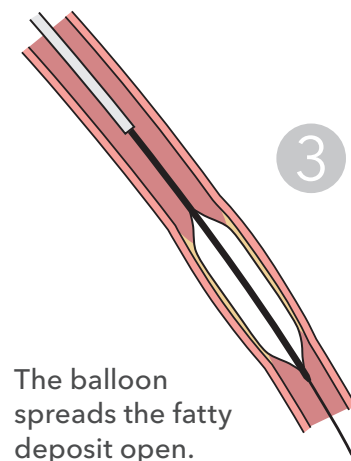
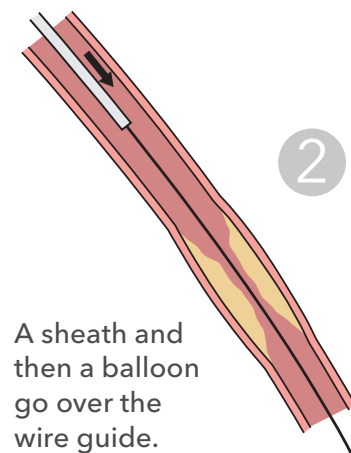
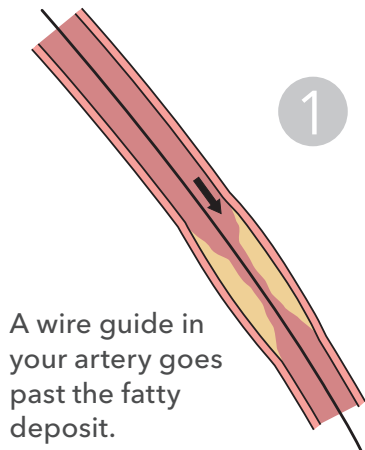
This image shows **paclitaxel** molecules blocking parts of cells that are involved in cell division.



This image is a cross-section that shows how the inner lining of an artery grows over a Zilver PTX **stent**.

Your angioplasty and stenting procedure

Angioplasty



Before your procedure

Your doctor will tell you how to prepare for your **angioplasty** and **stenting** procedure. You may have to take drugs such as aspirin for a few days to prevent blood clots. You may also have to stop eating or drinking on the night before you go to the hospital.

During your procedure

You will be awake during the procedure so that you can move, cough, or breathe when your doctor asks. Your doctor might give you a sedative to help you relax.

Most **angioplasty** procedures begin at the groin. A nurse will shave the area, swab it with a chemical that kills germs, and numb it with a drug.

You doctor may then perform the following steps:

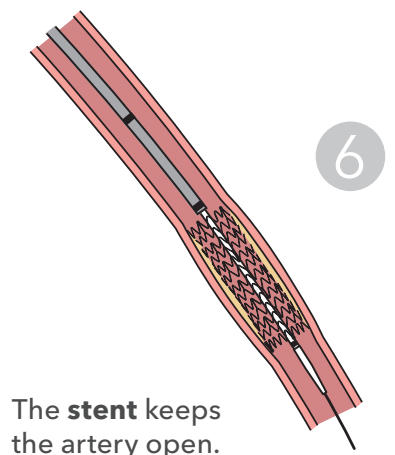
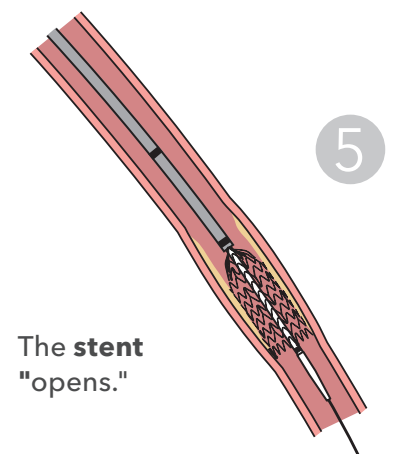
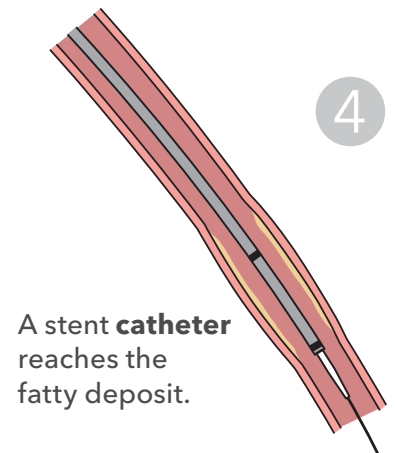
- Insert a needle into your artery.
- Insert a short and flexible wire guide through the needle so that the wire guide is partly inside your artery and partly outside your body.
- Slide the needle off the wire guide while keeping the wire guide in place.
- Slide a short tube called an **introducer** over the wire guide and into your body. An **introducer** has a valve that allows devices to enter your arteries but keeps your blood from coming out.
- Take out the first wire guide and insert a longer wire guide.

- Push the wire guide deeper into your arteries until it goes past your fatty deposit. Your doctor will inject a special dye into your arteries. The dye is visible under x-rays and lets your doctor see inside your body.
- Advance a special **catheter** called a sheath over the wire guide. The sheath will guide and support the devices that will come next.
- Insert a **catheter** that has a deflated balloon at its tip into the sheath and through the fatty deposit.
- Inflate the balloon for about a minute so that the fatty deposit widens.
- Deflate and remove the **balloon catheter**.
- Insert and carefully position another catheter that has the Silver PTX **stent** inside it.
- Pull back the outer covering of the **catheter** that contains the **stent** so that the **stent** can expand.
- Check that the **stent** is properly placed and is holding your artery open.
- Remove the wire guide, **catheters**, and **introducer** from your body.
- Compress and bandage the spot where the needle first went in.

After your procedure

When your procedure is finished, you will go to a recovery area. You may feel some discomfort, which pain medicine can relieve. Nurses will closely monitor your blood pressure and heart rate. Your doctor will decide when you can go home.

Stenting



What could go wrong?

The angioplasty and stenting procedure

No medical procedure is perfectly safe. Your **angioplasty** and **stenting** procedure involves serious risks. The following could happen to you during or after your procedure:

- You could get an infection.
- Your kidneys could fail.
- You could have to get a leg amputated.
- You could die.

The following is an incomplete list of other things that could go wrong:

Your skin where your doctor gained access to your artery

- You could bleed or develop a large, thick clot outside the blood vessel.
- You could get an infection or abscess.

Your artery

- The wall of your artery could weaken and bulge outward.
- The wall of your artery could break.
- Blood could collect outside of your artery through a small hole.
- A passage could develop between an artery and a vein.

The stent

- The **stent** could be positioned incorrectly.
- The **stent** could move.
- The **stent** could break.

Your blood circulation

- Blood clots could form.
- Small fatty deposits that move toward your feet could block your blood flow and turn your toes blue.
- Blood clots, air bubbles, or foreign objects could move and block the flow of blood in other vessels.
- Blocked blood flow might make your legs hurt while you walk or while you rest.
- Blocked blood flow could result in bypass surgery or the amputation of your toe, foot, or leg.

Your body's response

- You could have an allergic reaction to blood thinners or the special dye that lets your doctor see inside your body.
- You could have an allergic reaction to the material that the stent is made from.
- Your immune system could become overly sensitive.
- The stented artery could narrow again (**restenosis**).

Talk to your doctor about any concerns you may have.

The drug paclitaxel

Paclitaxel also has risks. The following could happen to you when you get a drug-coated stent:

- You could have an allergic reaction to **paclitaxel**.
- You could experience unwanted hair loss.
- Your number of red blood cells could decrease.
- Your bone marrow could produce fewer blood cells.
- You could need a blood transfusion.
- You could experience symptoms in your stomach and intestines.
- Your number of white blood cells or platelets could decrease.
- Your liver function could change.
- The wall of your artery could die or become damaged or inflamed.
- You could experience joint pain or muscle pain.
- Your nerves could become damaged.

Talk to your
doctor about
any concerns
you may have.

What problems have people had with Zilver PTX?

Doctors around the world are taking part in a clinical trial of the Zilver PTX drug-coated **stent**. The doctors are comparing Zilver PTX both with balloons and with **stents** that are not coated with a drug. The doctors are examining patients closely for five years after being treated. Before the trial started, doctors listed the following as the worst things (major adverse events) that could happen to patients:

- Amputation
- Necessity of a repeat procedure
- Surgery on the treated artery
- Surgery on the treated limb
- Significant worsening of PAD
- Death

During the trial, an independent panel of experts examined all of the major adverse events that happened. The panel found that 13.4% of patients who received the Zilver PTX **stent** experienced a major adverse event within two years, and 22.1% of the patients who did not receive a Zilver PTX stent experienced a major adverse event within two years.³ In almost all of the cases, the major adverse event was a repeat procedure.³

No patients in the trial died because they received the Zilver PTX **stent**.³

3. Ask your doctor about the Zilver PTX Instructions for Use (IFU). This document contains full prescribing information, including indications, contraindications, warnings, precautions, and clinical data.

After you get Zilver PTX

Take blood thinners

Your doctor will prescribe blood thinners (**antiplatelets**) after you receive your **stent**. These drugs prevent blood clots from forming. Blood thinners include the following drugs:

- Aspirin
- Cilostazol
- Clopidogrel
- Ticlopidine

In the Zilver PTX clinical trial, patients took clopidogrel or ticlopidine for at least 60 days and aspirin for an unlimited time. Your doctor may prescribe other kinds of drugs and for different amounts of time. You may have to get blood tests when you take these drugs. Your doctor will order tests as needed. You must follow your doctor's instructions when you take these drugs. Don't stop taking these drugs without your doctor's permission.

Change your lifestyle

Stents do not cure PAD. To help prevent both restenosis and the progression of PAD, you should do the following:

- Quit smoking
- Control your diabetes
- Control your high blood pressure
- Control your high cholesterol
- Eat healthy foods
- Exercise more

Keep your patient card

After your procedure, your doctor will give you a patient card. Keep it with you and show it when you go to a hospital again. Other doctors will want to know that you have a metal **stent** inside your body before they give you an MRI (magnetic resonance imaging) scan.

This patient has received a


Zilver® PTX®
 DRUG ELUTING PERIPHERAL STENT

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MRI information on backside.

Patient Name		Implant Date	
Implanting Facility Name			
Implanting Physician			
Implanting Physician Phone #			
Follow-up Physician			
Follow-up Physician Phone Number			
Product Catalog #			

Because unforeseen variations in patient anatomy or scanners may increase risk, the MRI facility should allow prompt intervention if necessary.

Your doctor will give you this patient card after your procedure. Keep this card with you.



Customer Service

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