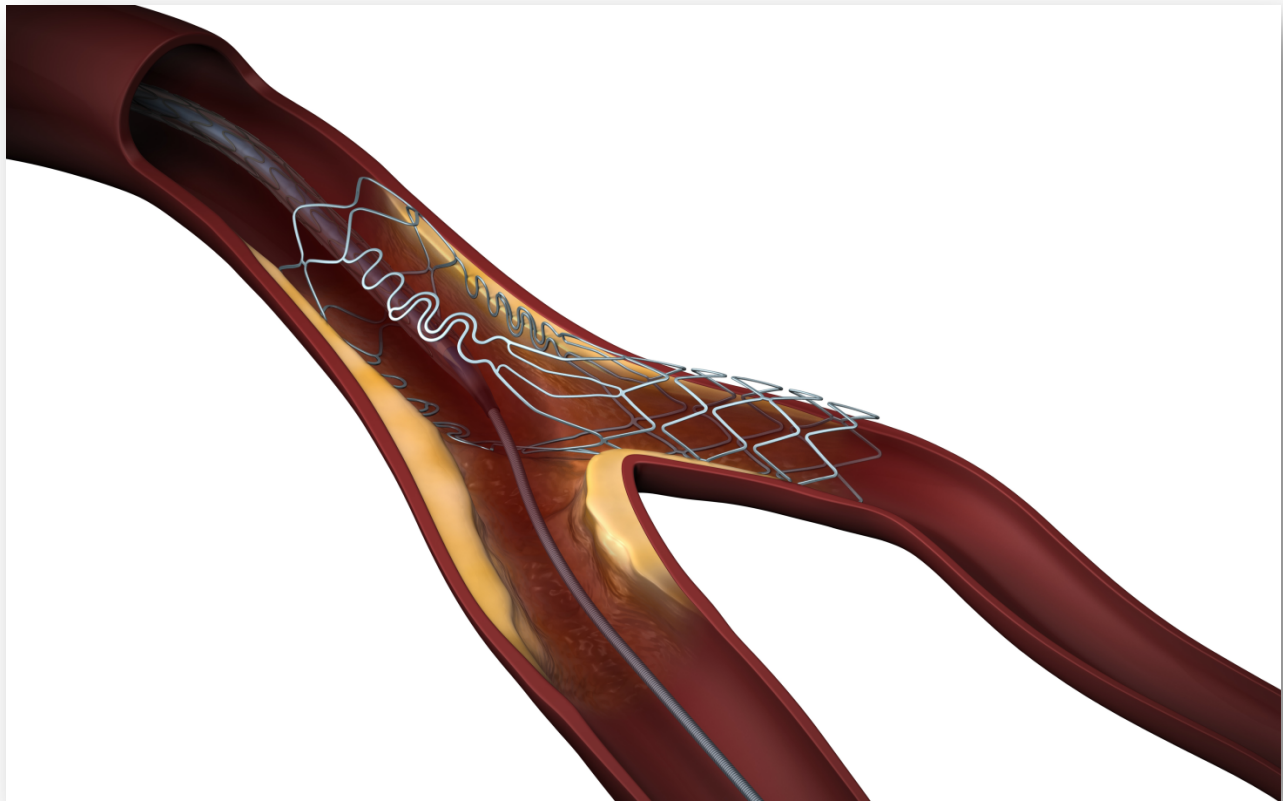


# **PATIENT GUIDE FOR TRYTON SIDE BRANCH STENT<sup>®</sup>**



Indications, contraindications, warnings and instructions for use can be found in the labeling supplied with each product. CAUTION: Federal (U.S.A.) law restricts these products to sale by or on the order of a physician.

TRYTON Side Branch Stent<sup>®</sup> is a product of TRYTON Medical Inc.

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## **PATIENT INFORMATION GUIDE**

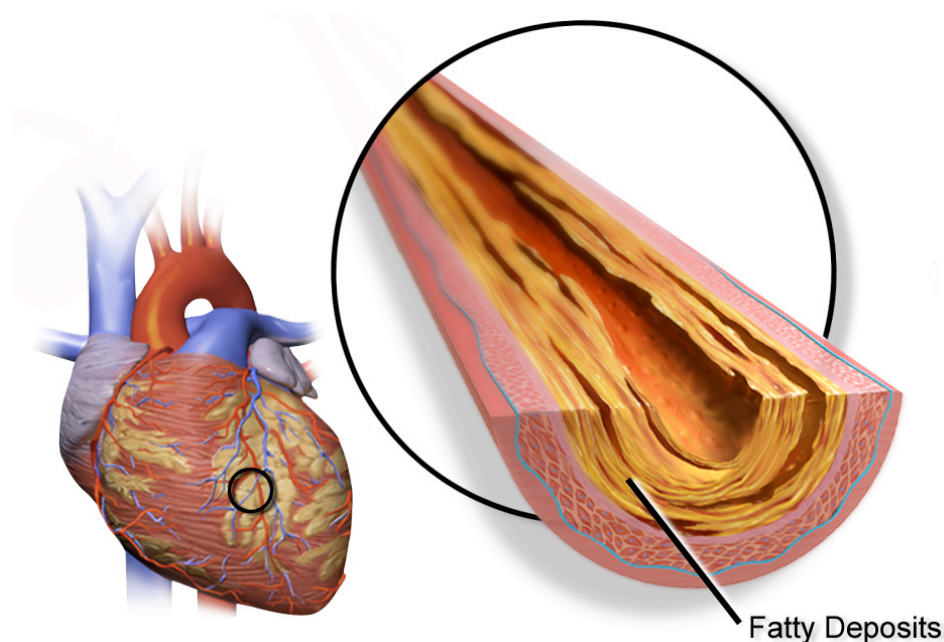
You have recently had a TRYTON Side Branch **stent** implanted in the **coronary arteries** of your heart, or you have coronary artery disease that may be treated with a TRYTON Side Branch Stent. The following information is important for you to know, including the possible risks associated with having a stent implant along with medication recommendations and questions you may have about your stent.

If you have any questions about the TRYTON Side Branch Stent or the stenting procedure after you read this booklet, be sure to ask your physician.

## CORONARY ARTERY DISEASE (CAD)

### What is CAD?

**CAD** is the most common form of heart disease. It is a condition that occurs when the arteries that supply oxygen-rich blood and nutrients to the heart muscle become narrowed or blocked by a gradual build-up of **plaque**. Plaque is made up of fatty deposits (cholesterol), white blood cells, calcium, and other substances that collect over time in the wall of a coronary artery. This process is called **atherosclerosis**. As the plaque narrows the opening (**lumen**) of a coronary artery, it can limit blood flow to the heart muscle.



Source:

[https://commons.wikimedia.org/wiki/File:Blausen\\_0257\\_CoronaryArtery\\_Plaque.png](https://commons.wikimedia.org/wiki/File:Blausen_0257_CoronaryArtery_Plaque.png)

### What are the Symptoms of CAD?

Two common symptoms of CAD are chest pain (also known as angina) and shortness of breath, which are caused by the reduction of blood flow to the heart muscle. If plaque build-up does not reduce blood flow excessively, there may be no symptoms at rest, but symptoms such as chest heaviness or pressure may occur with exercise or stress. A heart attack (**myocardial infarction**) can occur if the artery suddenly becomes completely blocked, usually by a blood clot that forms over ruptured (broken) plaque. Heart attacks cause permanent damage to the heart muscle and can also lead to sudden death.

**CAD symptoms that patients may experience are:**

- Pain in the jaw or neck
- Pain radiating to the arms or back
- Heartburn
- Nausea
- Vomiting
- Heavy sweating

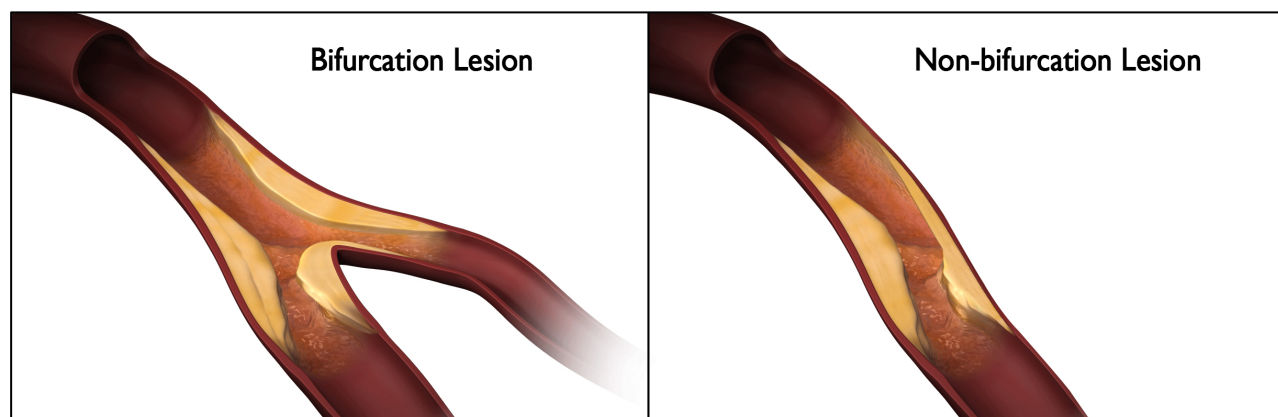
When blood flow is significantly reduced, and the heart muscle does not receive enough blood to meet its needs, severe symptoms such as chest pain (**angina**), heart attack (myocardial infarction), or heart rhythm disturbances (arrhythmias) may occur. There are some patients who report no symptoms of CAD. It is possible to have a heart attack without experiencing any symptoms.

Recent research has shown that some women experience different CAD symptoms from men and are less likely than men to report chest pain, heaviness in the chest, or chest discomfort during a heart attack. Women may notice other early symptoms, such as unusual tiredness or sleep disturbances up to one month prior to a heart attack. These differences in symptoms may cause some women to delay seeking treatment.

**Treatment of CAD**

CAD can be managed by a combination of changes in lifestyle (eating a healthy diet that is low in saturated fat, regular exercise, and quitting smoking) and medical treatment. Your treatment may include medications to relieve your chest pain and/or to expand the coronary arteries, increasing blood flow to your heart. However, because medicine alone may not adequately relieve your symptoms, you may need further treatments, which may include bypass surgery, balloon **angioplasty**, and stenting. Your physician has determined that use of a coronary stent is the best treatment for you.

In about 15% of patients, the blockage in a major heart artery also involves a blockage within a side branch that come off of that major heart artery. This is referred to as a **bifurcation lesion**. Bifurcation lesions are more complex than non-bifurcation lesions, and their treatment with angioplasty and stents is associated with higher risks of heart attack and the need for a repeat procedure to treat a re-narrowed heart vessel.



### Coronary Artery Stents

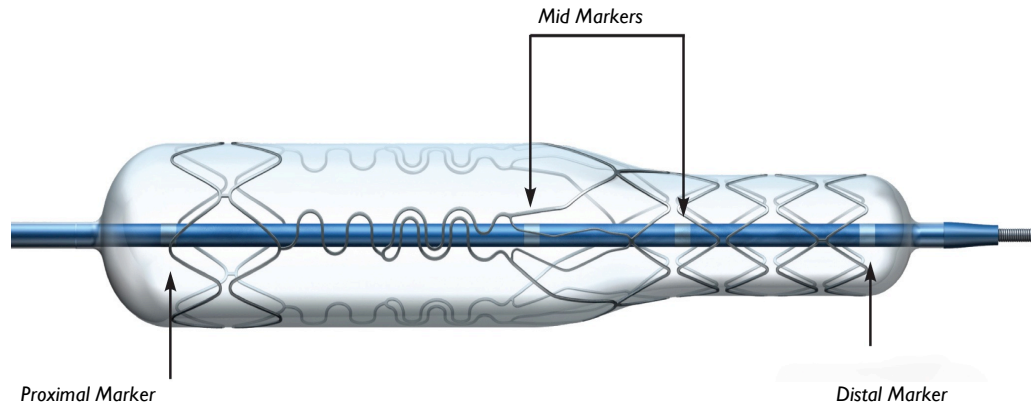
Coronary artery stents are devices (small metallic mesh tubes) that are placed over a balloon catheter and delivered to the narrowed portion of a coronary artery. The balloon is used to expand the stent. The stent presses against the narrowed vessel wall, holding the vessel open. This makes a wider channel to improve blood flow to the heart muscle. This may be followed by repeat balloon inflations within the stent to achieve the result desired by your doctor. Once the balloon has been deflated and withdrawn, the stent stays in place permanently, holding the coronary artery open. The inner lining of the artery grows over the surface of the stent, making the stent a permanent part of your artery.

Coronary artery stents are less invasive than bypass surgery. Stenting involves a shorter hospital stay – usually one to three days – and faster recovery than surgery. However, the coronary artery may re-narrow (called **restenosis**) in some patients who receive stents (**in-stent restenosis**), due to the build-up of scar tissue within the stent leading to narrowing of the stent lumen. This may require further treatments, such as repeat angioplasty and/or bypass surgery, to reopen the artery and increase blood flow to the heart.

### TRYTON SIDE BRANCH STENT<sup>®</sup>

The TRYTON Side Branch Stent is a stent made from cobalt chromium alloy. Cobalt chromium is a biocompatible metal specifically developed for coronary stents. The stent is flexible and was specially designed to allow it to fit the shape of a blocked major heart artery that also has a blockage in a side branch (bifurcation lesion). The TRYTON Side Branch Stent is delivered to the artery on a balloon delivery catheter and will be used with another company's drug-eluting stent (DES) that your doctor will implant in one of your main heart arteries.

*Diagram of the TRYTON Side Branch Stent mounted on Delivery Balloon*



### **WHEN THE TRYTON STENT SHOULD NOT BE USED (CONTRAINDICATIONS)**

- If your artery is completely blocked
- If your physician sees moderate to severe calcium deposits in the artery
- If your artery is severely curved making it difficult to get to the blockage
- If your physician sees blood clots/thrombus blocking the artery
- If your physician feels he/she cannot completely inflate the angioplasty balloon
- Not inflating the angioplasty balloon in the main branch and side branch prior to TRYTON stent placement
- Placement of TRYTON stent alone, without a main branch stent
- Poor flow beyond the stent implantation site due to severe CAD
- An untreated significant (> 50%) blockage before or after the main branch or side branch target lesion
- If your heart's pumping strength is very poor
- If you have impaired kidney function
- If you have abnormal blood tests indicating bleeding disorders, increased risk of infections, or known or suspected liver disease
- If you are a recipient of heart transplant
- If you have an allergy or hypersensitivity to cobalt-chromium or structurally-related compounds, cobalt, chromium, nickel, or tungsten
- If your physician plans to perform rotational atherectomy (use of a device to break up plaque inside the artery)
- If your physician decides you should not receive a drug-eluting stent because you cannot take the recommended blood thinning anti-platelet medications

## POTENTIAL ADVERSE EVENTS ASSOCIATED WITH THE TRYTON SIDE BRANCH STENT

The risks of using the TRYTON Side Branch Stent are similar to those that are associated with other standard heart stent procedures. A stent that becomes blocked by a blood clot may lead to a heart attack, the need for urgent bypass surgery, death or the need for another angioplasty procedure. Even with successful stent implants, there is a chance of re-narrowing (restenosis) of your coronary artery. This may require further treatments, such as repeat angioplasty and/or bypass surgery, to increase blood flow to the heart. The risks from using balloon catheters to implant stents may be serious enough to require surgery or cause death.

Other risks associated with balloon angioplasty and heart stent implantation procedures include, but are not limited to:

- Abrupt vessel closure (sudden closure of the vessel)
- Acute myocardial infarction (heart attack)
- Aneurysm (weakening of a portion of the wall of the blood vessel)
- Arrhythmia, including ventricular fibrillation (irregular heart beat)
- Arteriovenous fistulas (abnormal connection between two vessels that normally do not connect)
- Coronary artery spasm
- Coronary vessel dissection (tear within the blood vessel wall), perforation, or injury
- Death
- Drug reactions or allergic reactions to contrast medium
- **Emboli** (air, pieces of devices, fragments of clot, or fragments of plaque that can block blood vessels causing tissue injury)
- Fever
- Hematoma (tissue swelling caused by a blood clot) or hemorrhage (bleeding)
- Hypotension or Hypertension (decreased or increased blood pressure)
- Hypersensitivity (allergic) reactions
- Infection
- Myocardial ischemia/Angina, (chest pain due to decreased oxygen supply to the heart)
- Non-heart-related chest pain
- Pseudoaneurysm (enlargement of a blood vessel due to an injury to the blood vessel wall)
- Restenosis of the treated vessel (re-blockage of the blood vessel following the procedure)
- Stent misplacement or migration (movement of the stent from where it was placed)



- Stroke
- Thrombosis (blood clot within a blood vessel)
- Occlusion (blockage) of a **coronary artery** or heart **bypass graft**
- Angina pectoris (chest pain caused by inadequate blood flow to the heart)

## THE TRYTON CLINICAL TRIALS

The safety and effectiveness of the TRYTON Side Branch Stent was established in two research studies: the TRYTON Pivotal Randomized Clinical Trial (RCT) and the Extended Access (EA) Confirmatory Study.

In the TRYTON Pivotal RCT Study, 704 patients with CAD involving bifurcation lesions were randomly divided into two groups for treatment. One group of 355 patients was assigned to receive the TRYTON Stent to treat the blocked side branch, and the other group of 349 patients was to be treated with balloon angioplasty of the blocked side branch. Both patient groups also received an approved drug-eluting stent to treat the blockage in the major vessel. At 9 months after the procedure, patients in the TRYTON group had a higher rate of heart-related complications (16.7%) compared to the balloon angioplasty group (12.6%), but most of the difference in the complication rate between the two groups was due to very small heart attacks occurring at the time of the procedure. Importantly, when doctors used the TRYTON stent in side branch heart vessels that were suited to the size requirements of the TRYTON Stent, the rate of heart-related complications at 9 months was lower in the TRYTON group (10.5%) versus the balloon angioplasty group (14.8%). Overall, implantation of the TRYTON Stent appears to be comparable to angioplasty with regard to heart-related complications. Implantation of the TRYTON Stent was also associated with a reduction in the severity of side branch blockage at 9 months compared to balloon angioplasty.

The TRYTON Extended Access (EA) Confirmatory Study included 133 patients with heart vessel bifurcation lesions implanted with the TRYTON Side Branch Stent to treat the blocked side branch along with implantation of an approved drug-eluting stent to treat the blockage in the major vessel. The focus of the EA Study was on the rate of heart attacks associated with implantation of the TRYTON Stent in patients with heart vessel side branches that were of the appropriate size for treatment with the TRYTON Stent. The EA study showed that doctors could identify side branch heart vessels that were suited to the size requirements of the TRYTON Stent in over 99% of the enrolled patients. The rate of heart attacks (most of which were very small) associated with implantation of the TRYTON Stent met the goal established for the EA study.

## YOUR CORONARY STENT PROCEDURE

### How Do I Prepare for My Procedure?

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

- Tell your doctor about all of your medications
- Take all of your prescribed medicines
- Tell your doctor if, for any reason, you cannot take aspirin or other blood thinning drugs such as Plavix, Effient, or Brilinta
- Make sure your doctor knows about any allergies you may have
- Refrain from eating and drinking after midnight on the night before your procedure
- Follow all instructions given to you by your doctor or nurse

## YOUR TRYTON SIDE BRANCH STENT PLACEMENT PROCEDURE

You may be given a mild sedative to help you relax, but you will not be put to sleep. There are two reasons for this. Firstly, most people find they experience little to no discomfort from the procedure. Secondly, your doctor may need to ask you to take a deep breath while X-rays are being taken, to improve the quality of the pictures.

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

The blood vessel at the top of your thigh is the most common site for catheter insertion and requires a very small skin incision. The area will be shaved and cleaned with an antiseptic, and you will be given a **local anesthetic** to numb the area. This incision will allow an introducer sheath (short tube) to be inserted into your **femoral artery** (the main artery of the thigh, supplying blood to the leg). Your doctor will then insert a guiding catheter (a long flexible tube) into the introducer sheath and advance it to where the coronary arteries branch off to the heart. A flexible guide wire is then advanced through the guiding catheter to the narrowing in the coronary artery. This helps carry all the necessary devices required during the stenting procedure.

Additional options for catheter insertion include an arm artery (brachial artery) on the inside of your elbow and the wrist (radial artery).

After the catheters are advanced to your heart, your doctor will inject fluid (contrast dye) through the guiding catheter 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 take a deep breath and hold it for a few seconds. You may

also be asked to cough after the X-ray picture is completed, to help speed the removal of the contrast dye from the arteries.

Using the guiding catheter, a balloon catheter will be positioned in the narrowing in the coronary artery and the balloon is then inflated. This compresses the plaque and widens the coronary artery opening. This procedure is called pre-dilatation. The placement of the TRYTON stent is described in the following steps:

**Step 1:** The stent mounted on a balloon catheter is delivered to the narrowing in the Side Branch of the coronary artery by a delivery catheter.

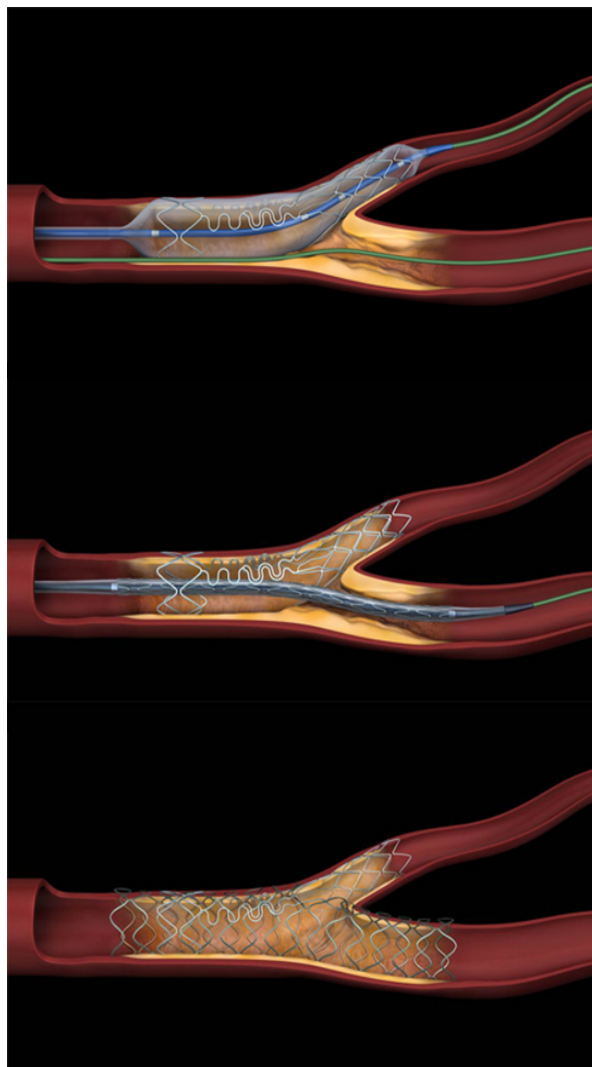
The balloon is then inflated and this expands the stent, pressing it against the coronary artery wall. Your doctor may choose to expand the stent further, by using another balloon so that the stent can make better contact with the artery wall. This is known as post-dilatation.

**Step 2:**

Once the TRYTON Side Branch Stent is in place, a drug-eluting stent will be placed into the Main Branch of the artery following the same procedure.

**Step 3:** When both stents are in their positions your physician will expand both stents further by using a balloon in the Side branch and another balloon in the Main branch. Both stents remain as a permanent implant in your coronary artery.

Selecting the size of the TRYTON Side Branch Stent that correctly matches the artery size is very important to obtain the best results from the stenting procedure. Your doctor may choose to perform additional measurements of the artery size using an ultrasound catheter before or after placing the stents. The implantation procedure of the stents usually lasts about 90 minutes, during which time your doctor will ask you to remain very still. For the most part, you will be comfortable, but you may feel some pressure or chest pain whenever a balloon is inflated. This is normal and will quickly fade when the balloon is deflated.



### **Immediately after Procedure**

You will be asked to lie flat for four to six hours following the procedure and to not bend your leg or arm, depending on which area your doctor used to insert the catheters. Pressure will also be placed on the area.

A vascular closure device may be used to seal the incision site in your groin or arm. You will be allowed to get up and walk around sooner if this type of device is used.

### **Take All Medications as Instructed**

After you leave the hospital, your cardiologist will instruct you to take a daily dose of aspirin and another blood thinning **antiplatelet** drug such as Plavix, Effient, or Brilinta. 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 instructs you:

- Follow your medication schedule exactly to avoid possible complications after you receive your stent. 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 stent procedure.

**CAUTION:** Notify your doctor if you are scheduled to see the dentist while on 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 or any other health care provider to stop your prescribed medications.

If surgery or dental work that would require you to stop taking antiplatelet medications is recommended after you have received the stent, 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.

**CAUTION:** Before undergoing implantation of a drug-eluting stent, speak with your doctor if you plan to have any type of surgery that may require you to stop taking antiplatelet medications.

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

### **Follow-up Care**

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

Your doctor will ask you to return for follow-up visits. The first visit is usually two to four weeks after your stents are implanted, with follow-up visits every six months for the first year. Be sure to keep all appointments for follow-up care, including blood tests.

**CAUTION:** Notify your doctor immediately if you experience chest pain (angina), or notice any changes such as more severe or frequent chest discomfort, especially in the first month after a procedure. These symptoms may indicate a re-narrowing in your coronary arteries.

**CAUTION:** Show your Patient Implant Card if you report to an emergency room. This card identifies you as a patient who has had a stent implanted.

### **Keep Your Patient Implant Card Handy**

#### **MRI Information**

If you require a **magnetic resonance imaging (MRI)** scan, tell your doctor or MRI technician that you have a stent implant. MRI may be performed immediately following the implantation of the TRYTON stent(s). Your Patient Implant Card has detailed information regarding the safest MRI conditions to be used after implantation of the TRYTON Side Branch Stent.

## FREQUENTLY ASKED QUESTIONS

**How long will the stent stay in my body?** Stents are designed to stay in your body permanently.

**Will I be able to feel the stent inside me?** No, you will not be able to feel the stent once it has been implanted in your artery.

**Can the stent move or rust?** Once the stent is pressed against the inside wall of your coronary artery, it will remain in place permanently and will not move on its own. Tissue will grow around the stent and hold it in place. It will not rust because it is made of non-corroding metal.

**Will my stent set off the metal detector at airport security checkpoints?** No, your stent implant will not trigger alarms at security checkpoints.

**How long should I take my medications?** The most important thing that you can do to minimize the risk of blood clots within stents (stent thrombosis is) to take the blood thinning antiplatelet medications your doctor prescribes. Do not stop taking these medicines until your cardiologist tells you to, even if you are feeling better.

**What if I still get pains?** If you experience pain, inform your cardiologist or the center where the procedure was performed immediately.

**What are the restrictions or cautions after I've received a stent?** If you require magnetic resonance imaging (MRI), tell your doctor or MRI technician that you have an implanted stent.

**When can I resume my regular activities?** Your doctor will advise you. Many patients can return to work and follow their normal routine about a week after their stent procedure.

**What should I change in my diet?** Your doctor may prescribe a cardiac diet to help reduce the levels of fat in your blood and reduce your risk.

**Could I have recurring symptoms?** Yes, it is possible that you will experience symptoms again, either due to a new blockage in the region treated with the stent or due to a blockage at another place in your coronary arteries. Your doctor will monitor your progress.

**How can I help prevent a recurrence of symptoms?** While there is no sure way to prevent a recurrence of symptoms, you can reduce the risk through exercise, not smoking, eating a healthy diet, and taking recommended heart medications. Your doctor can advise you about lifestyle changes.

## GLOSSARY

**Angina:** Chest pain caused by an inadequate supply of blood to the heart.

**Angioplasty (also referred to as PTCA):** A minimally invasive procedure in which a balloon catheter is passed through to the blocked area of an artery. Once inflated, the balloon compresses the plaque against the blood vessel wall and enlarges the vessel opening. An angioplasty can also be performed with placement of a stent.

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

**Antiplatelet:** A substance to reduce clumping of platelets in the blood. An antiplatelet medicine helps thin the blood to prevent clot formation.

**Atherosclerosis:** A disease that causes narrowing or blockage of arteries caused by a build-up of fat (cholesterol) within the artery wall. The build-up is referred to as plaque.

**Bifurcation lesion:** A major coronary artery with blockage that also has a blockage in a side branch.

**Cardiac Catheterization Laboratory (Cath Lab):** A sterile X-ray theater in which heart catheterization is performed.

**Catheter:** A thin, hollow, flexible tube used to access the coronary arteries during an angiogram or during an **angioplasty** procedure. This catheter can be used to inject medication, fluids, or contrast dye during the procedure. A catheter can also refer to the device used to deliver the balloon or stent during an **angioplasty** procedure.

**Coronary Angiography (or Heart Catheterization or Cardiac Cath):** A test in which contrast dye is injected to create images of the coronary arteries. This allows the doctor to see the extent of the disease in the coronary arteries and make a decision on how to best treat the blockages.

**Coronary Arteries:** The blood vessels that carry blood containing oxygen to the heart muscle. There are four major coronary arteries: the left main, the right coronary artery, the left anterior descending, and the left circumflex.



**Coronary Artery Bypass Graft Surgery (CABG):** Open-heart surgery to treat CAD.

**Coronary Artery Disease (CAD):** The formation of blockages or atherosclerotic plaques within coronary arteries that result in restricted blood flow to the heart muscle.

**Emboli or Embolism:** Air, pieces of devices, or fragments of blood clots that travel in the bloodstream and block the blood vessel

**Electrocardiogram (ECG/EKG):** A test that records the electrical activity of the heart. An ECG/EKG may indicate that parts of the heart muscle are damaged due to decreased blood flow.

**Femoral Artery:** The main artery of the thigh that supplies blood to the leg and is often used to insert catheters to perform coronary angiography procedures.

**In-stent Restenosis:** Recurrent blockage or narrowing of a previously stented vessel.

**Local Anesthetic:** A substance used to numb the area to which it is applied.

**Lumen:** The inner channel or cavity of a vessel or tube. In a blood vessel, it is the opening through which blood flows.

**Myocardial Infarction (MI):** A heart attack, which is due to interruption in the blood flow to the heart muscle and results in damage of an area of heart tissue.

**Magnetic Resonance Imaging (MRI):** A non-invasive procedure used to obtain images of internal body structures through the use of magnets and radio waves.

**Percutaneous:** Performed through the skin.

**Plaque:** An accumulation or build-up of fatty deposits, calcium, white blood cells, and scar tissue in the wall of an artery that results in narrowing of the vessel lumen.

**Restenosis:** A recurring blockage caused by the excessive growth of scar tissue inside the artery or stent that may occur following an **angioplasty** procedure.



**Stent:** A metallic mesh tube that is implanted into an artery during an **angioplasty**, providing a scaffold to help hold the artery open and increasing blood flow to the heart muscle.

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